

# Overview of the NCI SBIR Program

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



- **Increase awareness about:**
  - Funding and resources to support your company
  - Regulatory approval processes
  - Policies on coverage for new medical technologies
  - Special intellectual property resources
- **Understand and leverage NCI SBIR initiatives**
  - SBIR Development Center
  - Targeted Solicitations
  - SBIR Phase IIB Bridge Award
  - SBIR Investor Forum
- **Accelerate technology development and commercialization**

# **NCI SBIR Development Center**



**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**

**A \$110M Program at the NCI**

## **New Model: SBIR Development Center**

- 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 NCI's scientific priorities

**We're here to help you!**

# NCI SBIR Development Center Staff



**Michael Weingarten, MA**  
*Director*



**Greg Evans, PhD**  
*Lead Program Director*  
Cancer Biology, E-Health, Epidemiology



**Andrew J. Kurtz, PhD**  
*Lead Program Director*  
Biologics, Small Molecules, Nanotherapeutics,  
Molecular Diagnostics, Bridge Award



**Patti Weber, DrPH**  
*Program Director*  
Digital Health, Therapeutics, Biologics, SBIR  
Investor Forum, FRAC Workshop



**Jian Lou, PhD**  
*Program Director*  
In-Vitro Diagnostics, Theranostics, early-stage  
drug development, Bioinformatics, FRAC  
Workshop



**Deepa Narayanan, MS**  
*Program Director*  
Cancer Imaging, Clinical Trials, Radiation Therapy,  
SBIR Investor Forum, FRAC Workshop



**Todd Haim, PhD**  
*Program Director*  
Small Molecules, Biologics, Immunotherapeutics,  
Theranostics, SBIR Investor Forum, FRAC Workshop



**Diana Connolly, PhD**  
*Program Analyst*  
Success Stories, Awardees in the News, Scientific  
Communications, FRAC Workshop



**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics, Therapeutics,  
Proteomics, SBIR Investor Forum



**Tamar Boghosian**  
*Program Analyst*  
Portfolio Analysis, Budget Tracking, FRAC Workshop



**Ming Zhao, PhD**  
*Program Director*  
Cancer Diagnostics & Therapeutics, Cancer Control &  
Prevention, Molecular Imaging, Bioinformatics,  
Stem Cells



**Julienne Willis**  
*Program Specialist*



**Jennifer Shieh, PhD**  
*AAAS Science & Technology Policy Fellow*  
Evaluation, SBIR Investor Forum, Success Stories,  
FRAC Workshop

## **Development Center staff are responsible for:**

- Conducting regular outreach events to help recruit more focused, commercially-minded SBIR applicants
- Coaching applicants on developing stronger applications
- Providing oversight and active management of projects
- Mentoring and guiding companies throughout the award period
- Facilitating matchmaking with potential third-party investors and strategic partners

## **Exploring new initiatives:**

- Providing access to other resources at NCI and NIH
- Phase IB Bridge Program
- Collaborating with foundations
- Active engagement with venture capital, strategic partners, and angel investors

# Targeted Solicitations



- **Targeted solicitations afford several benefits:**
  - Provides an additional funding mechanism to catalyze the community to perform R&D in emerging areas with strong commercial interest
  - ***Examples:*** *Companion diagnostics and novel cancer imaging agents*
  - Reviews are conducted by NCI, with a balanced consideration of the scientific and commercial merits of the proposals.
    - Industry representatives make up about 50% of the review panel
  - NCI actively utilizes the contracts mechanism.
    - Awards are milestone-based with defined activities and deliverables

# SBIR Phase IIB Bridge Award





## Follow on to SBIR Phase II Awards

- Provides up to \$1 M per year for up to 3 years to extend selected projects
- Involves another peer-review cycle to evaluate progress & future plans
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners earlier in the development process

A thick, brown, curved arrow pointing from the third bullet point of the previous list down to the question below.

### *How does NCI accomplish this goal?*

- NCI gives competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e.,  $\geq 1:1$  match)

# 13 Bridge Awards (to date)

FY	Company	Technology/Product	Award Size
2009	Lpath Therapeutics	Commercialization of ASONEP for the Treatment of Cancer	\$3,000,000
2009	Optosonics	Photoacoustic CT for preclinical molecular imaging	\$2,997,247
2009	Guided Therapeutics	Fluorescence/reflectance spectroscopy for detection of cervical cancer	\$2,517,125
2009	Koning Corporation	High-performance breast CT as diagnostic adjunct to mammography	\$2,986,453
2009	Gamma Medica-Ideas	Molecular imaging to detect metabolic activity of breast lesions	\$3,000,000
2009	Altor BioScience	Tumor-targeted immunotherapy for treatment of p53-positive cancers	\$2,969,291
2010	20/20 GeneSystems	mTOR companion diagnostic assay	\$2,750,000
2010	Advanced Cell Diagnostics	<i>In situ</i> RNA detection assay for analyzing circulating tumor cells	\$2,996,450
2010	Ambergen	Expression-based prognostic assay for recurrence of colorectal cancer	\$2,998,830
2010	Praevium Research	High-performance imaging engine for optical coherence tomography	\$1,180,420
2011	Wilson Wolf Manufacturing	Moving TIL therapy past the Valley of Death	\$1,006,256
2011	Oncoscope	Validation & commercialization of a/LCI for detection of esophageal neoplasia	\$2,999,084
2012	OmniOX	Tumor radiosensitization using a tunable oxygen-binding protein	\$1,000,000



**4 therapeutics**

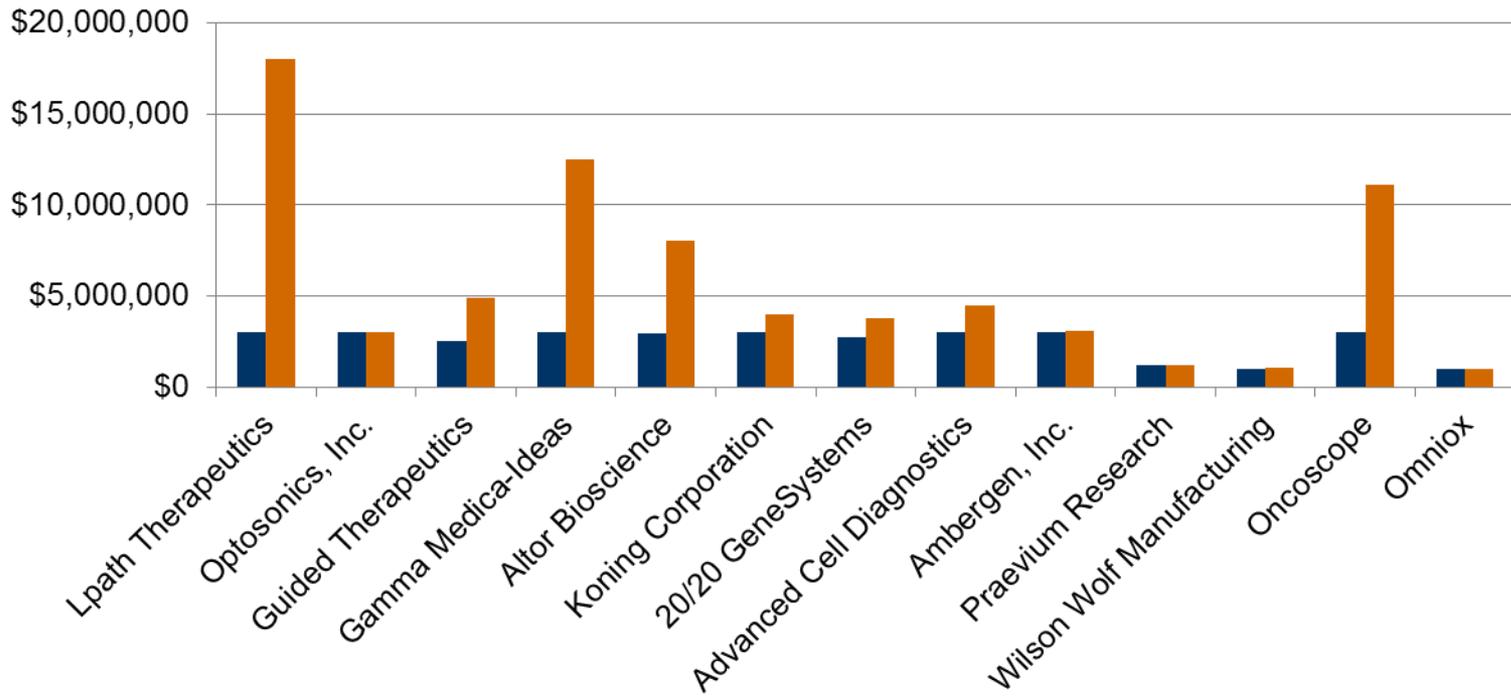
**6 imaging technologies**

**3 molecular diagnostics**



<http://projectreporter.nih.gov/reporter.cfm>

# Bridge Awards (to date)



<b>NCI Total</b>	<b>\$32,401,156</b>
<b>Third-Party Investments</b>	<b>\$76,100,756</b>
<b>Leverage</b>	<b>&gt; 2 to 1</b>



# SBIR Investor Forum



A promotional banner for the 2012 NCI SBIR Investor Forum. It features a photograph of four diverse professionals (three women and one man) smiling, with one woman holding a magnifying glass over a molecular structure. The background is a blue grid with a molecular structure overlay.

National Cancer Institute

2012 NCI SBIR  
**Investor  
Forum**

APRIL 18, 2012  
Agilent Technologies,  
Aristotle Room  
5301 Stevens Creek Blvd  
Santa Clara, CA 95051

 **FNIH**  
Foundation for the  
National Institutes of Health

**PRE** SCIENCE  
INTERNATIONAL

- 18 top SBIR-funded companies presented
- Over 200 life science investors & leaders
- 150+ one-on-one meetings in 2012

- **8 out of the 14 presenting companies have closed deals valued at over \$230M**
  - **Zacharon, a company focused on developing therapeutics for rare diseases and cancer, finalized a major partnership with Pfizer worth up to \$200M**
  - **Lpath** closed a \$4.9 Million Equity Financing round to fund continued development of two drug candidates
  - **MagArray** closed a strategic partnership deal with IMRA America for \$10M to continue development of its cancer diagnostic platform
  - **ImaginAb** raised \$12.5M in a Series A round to engineer antibodies into *in vivo* PET imaging agents for targeted molecular diagnostics.

## Metrics (short term)

- **Pre-Award**
  - ✓ Number and quality of proposals received
- **During Award (0-2 Years)**
  - ✓ Achievement of technical milestones & deliverables
  - ✓ Regulatory Applications/Approvals
  - ✓ Funding Leverage
    - 3<sup>rd</sup>-party match for Bridge Awards
- **Post -Award (1-3 Years)**
  - ✓ Follow-on Funding beyond Phase II
    - Other non-Federal funding (VC, pharma, state, other)
  - ✓ Job creation & company growth

## Metrics (long term)

- **Innovation Metrics**
  - ✓ Invention disclosures, patents, publications
- **Commercialization Metrics**
  - ✓ Regulatory approval rates (e.g., IND, 510K)
  - ✓ FDA approvals for marketing
  - ✓ Licensing agreements and revenues
  - ✓ Company sold or merged, acquisition of outside capital
  - ✓ Number of products yielding sales, cumulative sales
- **Job creation and company growth**

- **Explore** the resources and information from the speakers and Federal Partners here today
- **Engage** in one-on-one meetings and follow-up
- **Share** updates on technical progress, investments/ third-party partnerships with your Program Directors so we can track successes; discuss new project ideas