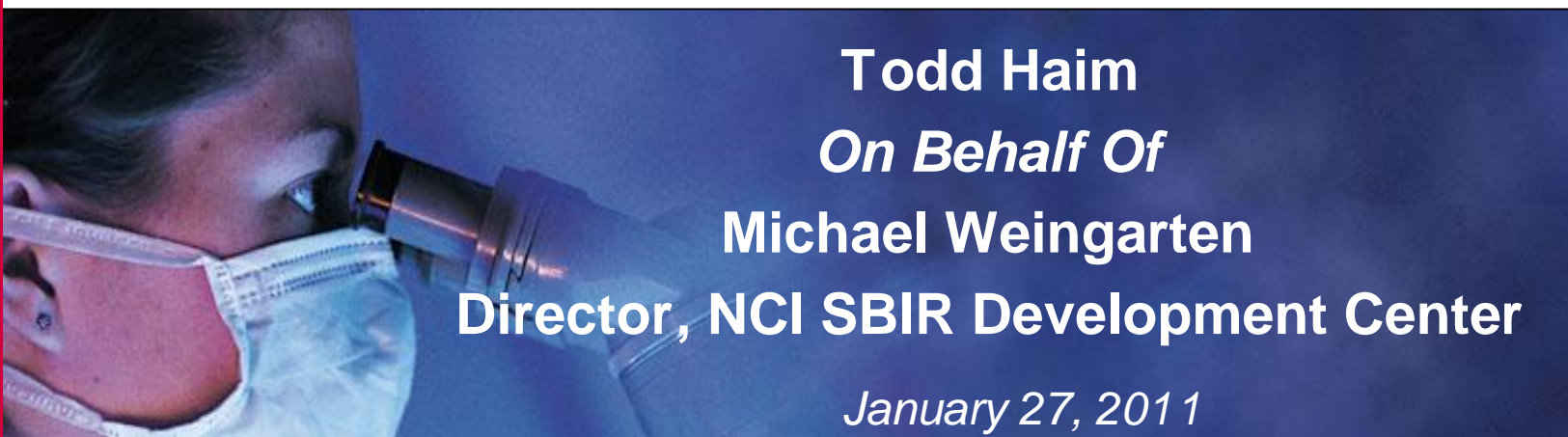




# **The NCI SBIR Program**

## **Presentation at the National Academies Symposium on Early-Stage Capital for Innovation**



**Todd Haim**  
*On Behalf Of*  
**Michael Weingarten**  
**Director, NCI SBIR Development Center**

*January 27, 2011*

# Today's Presentation



- § New Paradigm for Managing SBIR at NIH
- § Strategic Shift Toward Focused Solicitations
- § Helping Companies Bridge the "Valley of Death"
- § Connecting SBIR companies with Investors
- § Regulatory Assistance Program

## Slide 2

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s1

I would take this out, you already have slides that introduce each section. You could say this aloud on your first slide if you would like.

sawyers, 7/30/2008

- **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**

## New Paradigm for Managing SBIR at NCI



## **Old SBIR Management Model at NCI**

- Awards were managed by 50 people who each spent a small amount of their time on SBIR
- Few of these NCI program managers had significant industry experience or commercialization expertise

## **New Development Center at NCI**

- Team of 9 program managers and one Director, entirely funded by NCI
- Exclusively focused on the management of NCI's SBIR/STTR portfolio
- Managers have previous industry experience and professional networks to help mentor awardees in commercialization strategy and process
- Center staff continues interactions with NCI program staff concerning cancer research



# 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



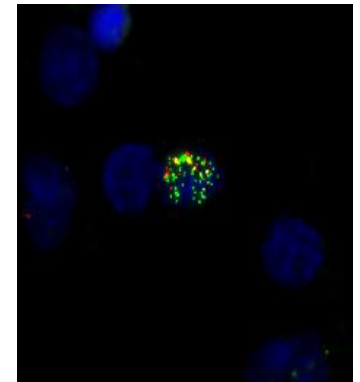
**Julienne Willis** (*Program Specialist*)

**In FY 2007, NCI made a strategic shift toward funding more SBIR contracts in areas with greatest commercial potential**

## Point of Care Analysis for Circulating Tumor Cells (CTCs)

### Ø Project Goals

- ❑ To develop Point of Care devices and methods of CTC detection, enumeration, isolation, removal and molecular analysis
- ❑ To provide tools with cost and/or performance advantages over current technologies



*A CTC detected using  
ACD's RNAscope™*

## Companion Diagnostics

### Ø Project Goals

- ❑ To provide noninvasive tests to evaluate molecular profiles of patients
- ❑ To develop companion diagnostics to select patients for whom a particular therapeutic regimen will be safe and effective

**Focused solicitations = ~24% of SBIR Budget**



## Helping Companies Bridge the “Valley of Death”

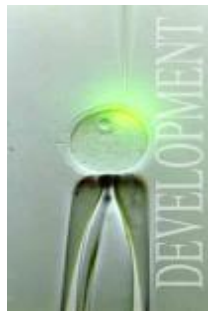


# SBIR & STTR: Three-Phase Program



## PHASE I – R41, R43

- Feasibility Study
- \$150K, 6-months (SBIR)
- \$100K, 12-months (STTR)



## PHASE II – R42, R44

- Full Research/R&D
- \$1M (SBIR) / \$750K (STTR), 2-years
- 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
- Ø 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

## Benefits to Investors/Strategic Partners



- **Affords investors/strategic partners the opportunity to leverage up to \$3 million in NCI funding.**
- **NCI takes no equity position in the companies**
- **All companies applying for the program have been vetted through the NIH peer review twice (Phase I and Phase II)**
- **NCI will be a partner in helping move these companies into the clinic and towards commercialization**

## **Technical Scope: Cancer Therapies & Imaging Technologies**

- 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

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

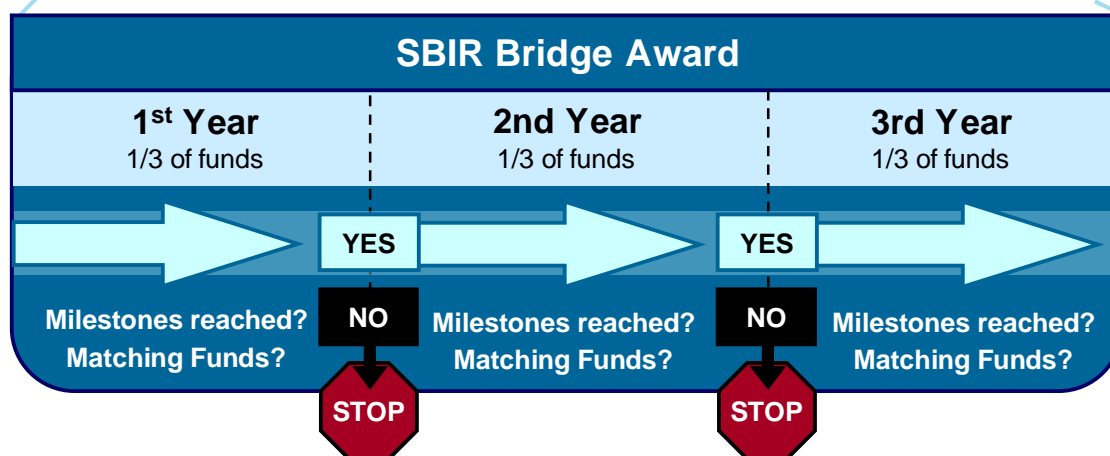


SBIR Bridge Award addresses the problem by bridging the “**Valley of Death**”

**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 in FY2009 & FY2010



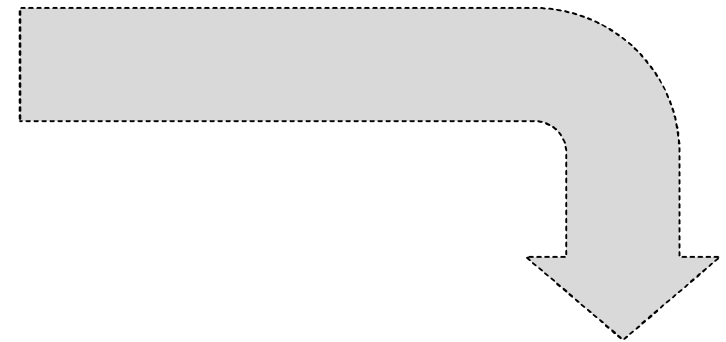
Company	Title	All-Year Total Cost Estimate
Altor Biosciences	Bifunctional T Cell Receptor Based Immunotherapeutics	\$2,969,291
Gamma Medica-Ideas	Molecular Breast Imaging to Guide Early-Stage Patient Care	\$3,000,000
Guided Therapeutics	Economic Spectroscopic Evaluation of Cervical Cancer	\$2,517,125
Koning Corporation	Koning Cone Beam Breast CT	\$2,986,453
Optosonics	Photoacoustic CT for Preclinical Molecular Imaging	\$2,997,247
Lpath Therapeutics	Commercialization of ASONEP for the Treatment of Cancer	\$3,000,000
20/20 Gene Systems	Predicting patient response to mTOR pathway inhibitors prior to treatment	\$2,750,000
Advanced Cell Diagnostics, Inc	Automated systems for detection and molecular characterization of circulating tumor cells	\$2,996,450
Ambergen, Inc.	Expression-based multi-gene signatures for CRC recurrence and chemo-selection	\$2,998,830
Praevium Research, Inc.	Ultrahigh speed and resolution OCT/OCM using broadband swept VCSEL technology	\$1,180,420
<b>Total</b>		<b>\$27,395,816</b>

## Third-party Investment

*Cumulative for 10 Bridge Awards Made in FY2009 & FY2010*



Traditional Venture Capital	\$21,500,000
Strategic Partners	\$24,200,000
Other Investment Firms	\$5,500,000
Individuals/Other	\$11,750,000



**Investor Total (3 yrs) \$62,950,000**

**NCI Total (3 yrs) \$27,395,816**

**Leverage >2.3 to 1**

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# Endra Announces Product Launch



## News

April 16 PRNewswire

### Endra Life Sciences Launches First Ever Commercial Photoacoustic 3-D Tomographic Imaging System

Endra Life Sciences today announced the launch of the Nexus 128, a preclinical photoacoustic computed tomography (CT) scanner for small animal imaging. The system is used for simple, fast, non-invasive quantification of tumor vasculature and other physiological parameters for preclinical research.



Endra, Inc.

Booth 1848

35 Research Drive, Suite 100, Ann Arbor, MI 48103

Phone: 734-274-2258; [www.endrainc.com](http://www.endrainc.com)

Endra develops non-invasive imaging systems combining optical laser illumination and ultrasound. Endra's preclinical photoacoustic device is specifically designed for *in vivo* imaging of mouse models of cancer. The system acquires 3D images of vessels in order to quantify tumor development and response to therapy.

## Highlights



- New program just launched this month
- Designed to assist companies working on therapeutics, devices, diagnostics, and other technologies requiring regulatory approval
- Program will be available for up to 40 Phase II awardees per year
- Provides up to 30 hours of consulting time to assist companies in developing a regulatory approval strategy and plan

# 2010 NCI SBIR Investor Forum hosted by San Jose BioCenter



National Cancer Institute  
**SBIR Investor Forum**

**NOVEMBER 9, 2010**  
9:00 AM – 6:00 PM PST

**STANFORD UNIVERSITY**  
**FRANCES C. ARRILLAGA**  
**ALUMNI CENTER**  
326 Galvez Street  
Stanford, CA, USA 94305 – 6105

**bio center** SAN JOSE

MagArray



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presage  
BIOSCIENCES

zacharon  
pharmaceuticals

NOVARTIS

**MDV**  
MOHR DAVIDOW VENTURES

Pfizer

USVP  
U.S. VENTURE PARTNERS

DFJ in cube  
ventures

MERCK  
Be well

*"The Forum was a great opportunity to get exposed to new companies in oncology."*  
Ankit Mahadevia, M.D., MBA, Life Sciences Associate, Atlas Venture

*"I was very impressed with your choice of companies. The mix of stages was ideal."*  
Sarah Bodary, Ph.D., Venture Partner, SV Life Sciences



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

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**NCI SBIR Development Center**

**Phone: 301-594-7709**

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**Register on web site for funding  
opportunity updates**