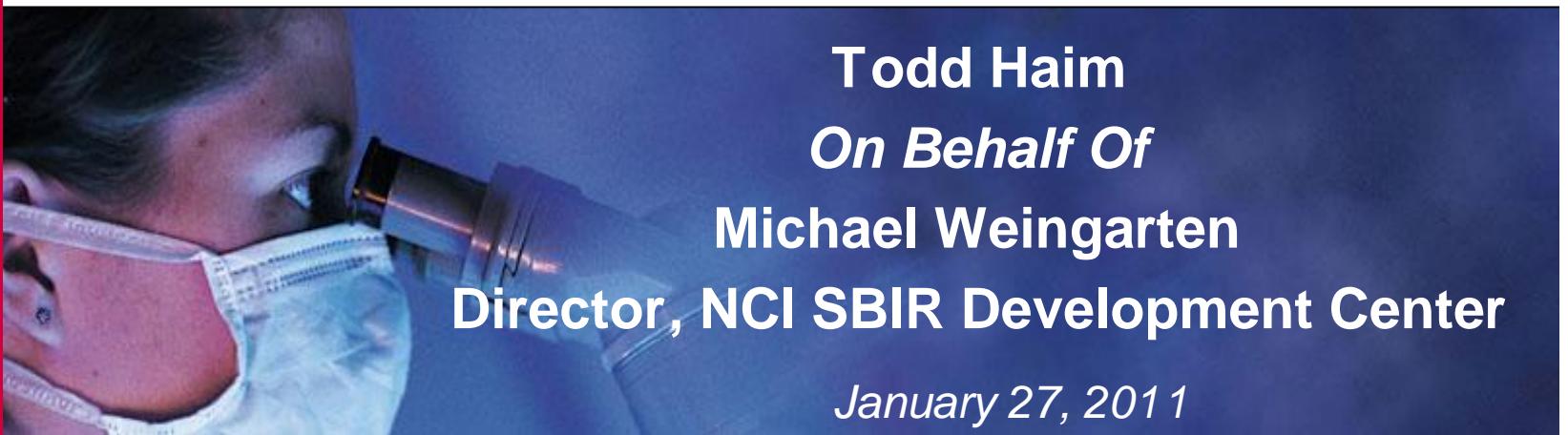




The NCI SBIR Program

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

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

SBIR's Role at the NCI



- 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



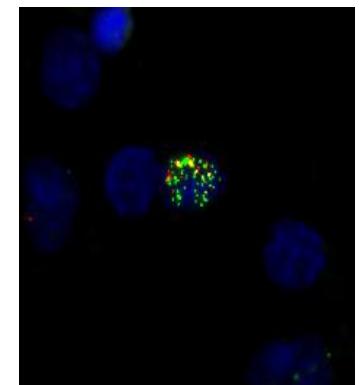
Julianne Willis (*Program Specialist*)

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

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



*A CTC detected using
ACD's RNAscope™*

Companion Diagnostics

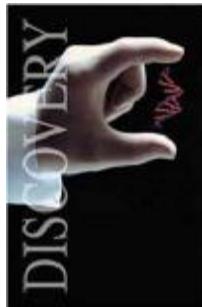
Ø Project Goals

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

Focused solicitations = ~24% of SBIR Budget

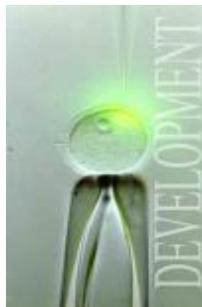
Helping Companies Bridge the “Valley of Death”





PHASE I – R41, R43

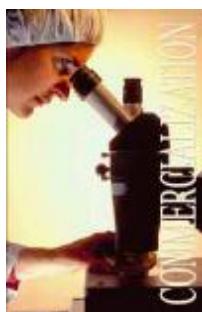
- Feasibility Study
- \$150K, 6-months (SBIR)
- \$100K, 12-months (STTR)



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

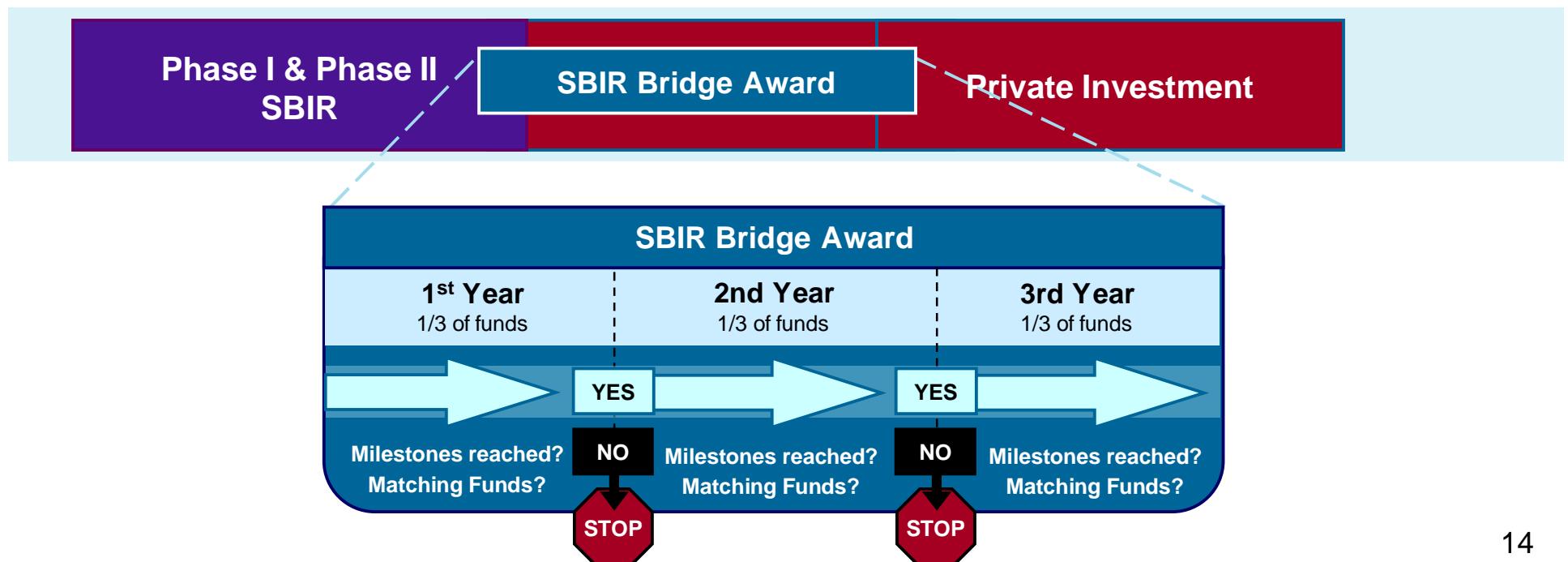
Example: How the Bridge Award Would Apply in the Area of Drug Development



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



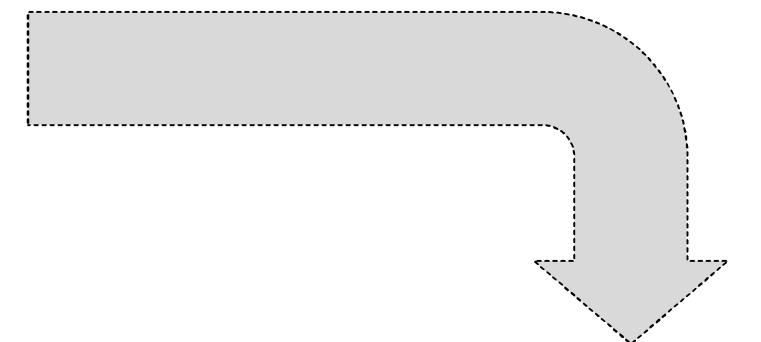
Company	Title	All-Year Total Cost Estimate
Altor Biosciences	Bifunctional T Cell Receptor Based Immunotherapeutics	\$2,969,291
Gamma Medica-Ideas	Molecular Breast Imaging to Guide Early-Stage Patient Care	\$3,000,000
Guided Therapeutics	Economic Spectroscopic Evaluation of Cervical Cancer	\$2,517,125
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
Total		\$27,395,816

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

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. The Nexus 128 system is also quantitative off-the-rack, non-invasive, color-coded software for medical agents and helps pre-clinical researchers gain deeper insights into active research drug design, trial efficacy and

AACR American Association for Cancer Research

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AACR 101st ANNUAL MEETING 2010

April 17-21, 2010 • Walter E. Washington Convention Center • Washington, DC

Endra, Inc.

Booth 1848

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

Phone: 734-274-2258; 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



A banner for the National Cancer Institute SBIR Investor Forum. It features the NCI logo, the text "SBIR Investor Forum", and a collage of images including a scientist, chemical structures, and two people shaking hands. The event details are: NOVEMBER 9, 2010, 9:00 AM – 6:00 PM PST, at STANFORD UNIVERSITY, FRANCES C. ARRILLAGA ALUMNI CENTER, 326 Galvez Street, Stanford, CA, USA 94305 – 6105. The San Jose BioCenter logo is also present.

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