

Catalyzing the Next Generation of Cancer Technologies

Presentation to the SMRB

July 11, 2012

Michael Weingarten
Director, NCI SBIR Development Center



- **Major Initiatives for Enhancing NCI SBIR**
 - SBIR Development Center
 - Targeted Solicitations
 - SBIR Phase II Bridge Award
 - SBIR Investor Forum
- **Issues for the SMRB to consider**

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 \$115M Program at the NCI

SBIR Development Center



Old Management Model

- Awards were managed by 40-50 NCI program directors who spent 5 - 10% of their time on SBIR
- Few of these NCI program directors had significant commercialization expertise or industry experience

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
- Center is developing a range of new initiatives to help small businesses

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



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)



Catherine Langston, MA (*Program Analyst*)



Julienne Willis (*Program Specialist*)



Andrew J. Kurtz, PhD (*Branch Chief*)

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



Amir Rahbar, PhD, MBA (*Program Director*)

Previous

- **NCI**– Program Director, Center for Strategic Scientific Initiatives
- **BioInformatics, LLC** – Senior Science Market Analyst
- **Naval Research Laboratory** – Research Scientist



Jennifer Shieh, PhD (*AAAS Science & Technology Policy Fellow*)

Previous

- **National Academy of Sciences** – Christine Mirzayan Science and Technology Policy Fellow
- **Syapse, Inc.** – Biology Associate

Development Center staff are responsible for:

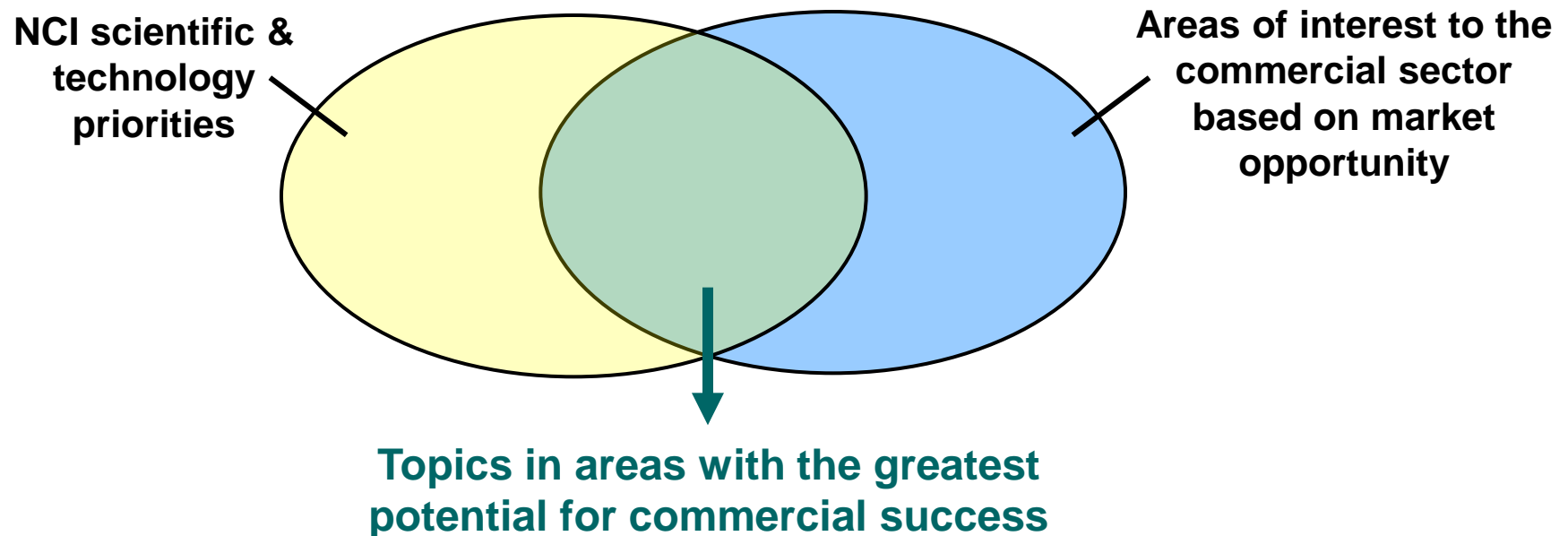
- Conducting regular outreach events to help recruit more focused, commercially-minded SBIR applicants
- Coaching applicants on developing stronger applications
- Providing rigorous oversight and active management of projects
- Mentoring and guiding companies throughout the award period
- Facilitating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

Targeted Solicitations



- **Targeted solicitations afford several benefits:**
 - This strategy helps catalyze the small business community to perform critically-needed R&D in emerging areas with strong commercial interest
 - ***Examples:*** *Companion diagnostics and novel cancer imaging agents*
 - Reviews are conducted by NCI DEA, 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

The SBIR Development Center convenes an ad hoc Technology Advisory Group (TAG) to evaluate NCI priorities and select topics for solicitation



SBIR Phase II Bridge Award





The Truly Staggering Cost Of Inventing New Drugs



80 comments, 64 called-out

[+ Comment now](#)

During the Super Bowl, a representative of the pharmaceutical company Eli Lilly [posted the on the company's corporate blog](#) that the average cost of bringing a new drug to market is \$1.3 billion, a price that would buy 371 Super Bowl ads, 16 million official NFL footballs, two pro football stadiums, pay of almost all NFL football players, and every seat in every NFL stadium for six weeks in a row. This is, of course, ludicrous.



Image by AFP/Getty Images via @daylife

The average drug developed by a major pharmaceutical company costs at least \$4 billion, and it can be as much as \$11 billion.

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



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)

Benefits to the NCI

- Opportunity to leverage millions of dollars in external resources
- Valuable input from third-party investors:
 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 third-party investors

- Opportunity to partner with small businesses to develop & commercialize:
 1. Technologies that have been vetted by NIH peer-review, **AND**
 2. Projects for which substantial proof-of-concept data already exists

➤ **Opportunity to share in the early-stage investment risk with the NCI**

Eligibility

- Current Phase II awards & and those that ended within the last 2 years
- Cancer-related Phase II projects initially funded by other NIH institutes

Special Review to Evaluate Technical and Commercial Merits

- Reviewers are academics, clinicians, industry professionals, venture capitalists
- Emphasizes important commercialization considerations such as intellectual property (e.g., patents) and strategy for gaining FDA approval

➤ Third-Party Fundraising plan

- **Preferred Types of 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

12 Bridge Awards (to date)

FY	Company	Technology/Product	Award Size
2009	Lpath Therapeutics	Humanized monoclonal antibody for treatment of prostate 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

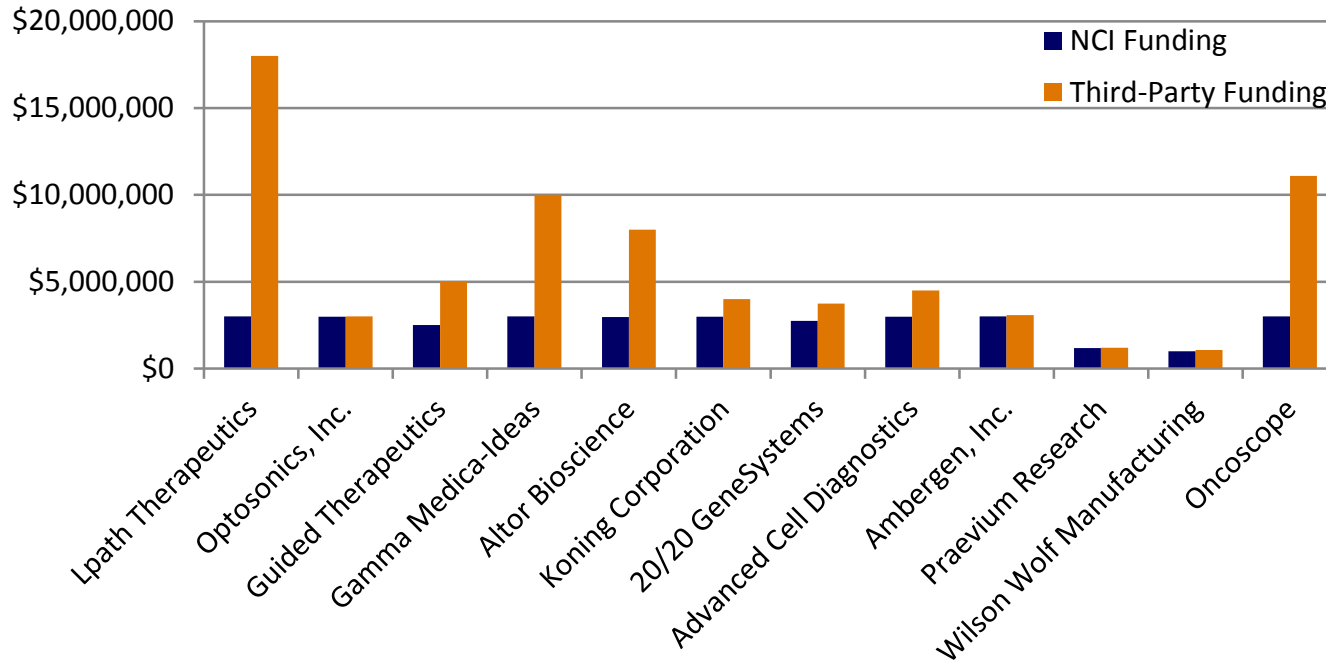


3 therapeutics
6 imaging technologies
3 molecular diagnostics

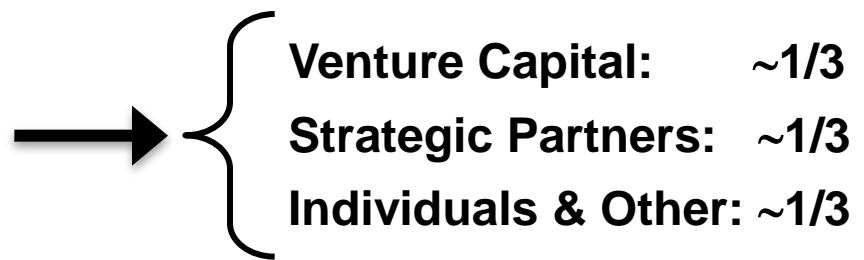


<http://projectreporter.nih.gov/reporter.cfm>

12 Bridge Awards (to date)



NCI Total	\$31,401,156
Third-Party Investments	\$72,695,374
Leverage	> 2 to 1



SBIR Investor Forum



A promotional banner for the 2012 NCI SBIR Investor Forum. It features a photograph of four people (three women and one man) smiling, with one woman holding a magnifying glass over a DNA helix graphic. The text includes the National Cancer Institute name, the event title, date, location, and logos for FNIH and PRE SCIENCE INTERNATIONAL.

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

- **6 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.

- **Tailor the peer-review process to the needs of small business**
 - Ensuring that SBIR review criteria are uniquely suited for small business applicants
 - Increasing participation by industry professionals on study sections
 - Exploring strategies for shortening the time between application and selection
- **Establishing a comprehensive program for metrics collection & analysis**
 - Tracking companies for 5-10 years post-award.
 - Standardized sets of metrics-oriented questions
 - Ability for the Institutes to access and analyze the raw data on individual awardees across the NIH.
- **The need to maintain program flexibility on award sizes.**
 - Proposed caps would severely constrain NIH's ability to mature technologies to key inflection points.
 - ~ 50% of NCI awards currently exceed the caps

Thank you!

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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
 - 3rd-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**