Catalyzing the Next Generation of Cancer Technologies

Presentation to the IOM Workshop on the Cures Acceleration Network

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Today's Presentation

- Program Overview
- Helping Companies Bridge the "Valley of Death"

Congressionally Mandated Programs

SBIR & STTR

Set-Aside (FY12)

- **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization — **2.6%**

- **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization — **0.35%**

A $115M Program at the NCI

SBIR & STTR: Three-Phase Program

SBIR & STTR

- Feasibility study
- $150,000 over
  6 months (SBIR)
  or 1 year (STTR)

- Commercialization stage
- Use of non-SBIR/STTR funds

- Research & Development
- Commercialization plan required
- $1 million over 2 years

Why are SBIR and STTR Important to 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**

Benefits of the SBIR & STTR Programs

- **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**
- **Funding is non-dilutive capital**
- **Can be a leveraging tool to attract other funding**
- **Projects undergo NIH's rigorous scientific peer review**

NCI SBIR
Phase II Bridge Award

SBIR & STTR: Three-Phase Program

Strategy

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., ≥ 1:1 match)

Partnership Benefits

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**

Technical Scope

Cancer Therapeutics

- Small molecule anticancer agents
- Anticancer biologics, including therapeutic vaccines
- Multifunctional cancer [illegible] hnology
- Anticancer drug deliv [illegible]

Opportunity to impact >75% of the Phase II projects in NCI's SBIR portfolio

Cancer Imaging Techn [illegible] & *In Vivo* Diagnostics

- Medical devices for i [illegible] guided interventions
- Radiation therapy de [illegible] es
- Imaging agents, inclu [illegible] als
- Devices and technol [illegible] s

In Vitro and *Ex Vivo* Cancer Diagnostics and Prognostics

- Molecular diagnostics and prognostics, including *in vitro* diagnostic multivariate index assays (IVDMIA)
- Image analysis tools for diagnosis
- Spectroscopic techniques for *in vivo* and *ex vivo* tissue analysis

Program Funding Solicitation

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

"Valley of Death"

SBIR & STTR

How are we sure that they need more money from the NCI?

Applicants must provide a concise "Statement of Need" that includes answers to the following questions:

- **What is the perceived "Valley of Death" for the product/technology?**
- **Why is additional government funding critically needed to accelerate the development of the product or technology toward commercialization?**
- **What activities are being proposed that would not otherwise be possible through independent third-party investments OR would be significantly delayed without additional NIH support?**
- **To what extent would a possible award advance the product or technology far enough to attract sufficient, independent third-party financing and/or strategic partnerships to carry out full commercialization?**

12 Bridge Awards (to date)

SBIR & STTR

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**	*In situ* 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

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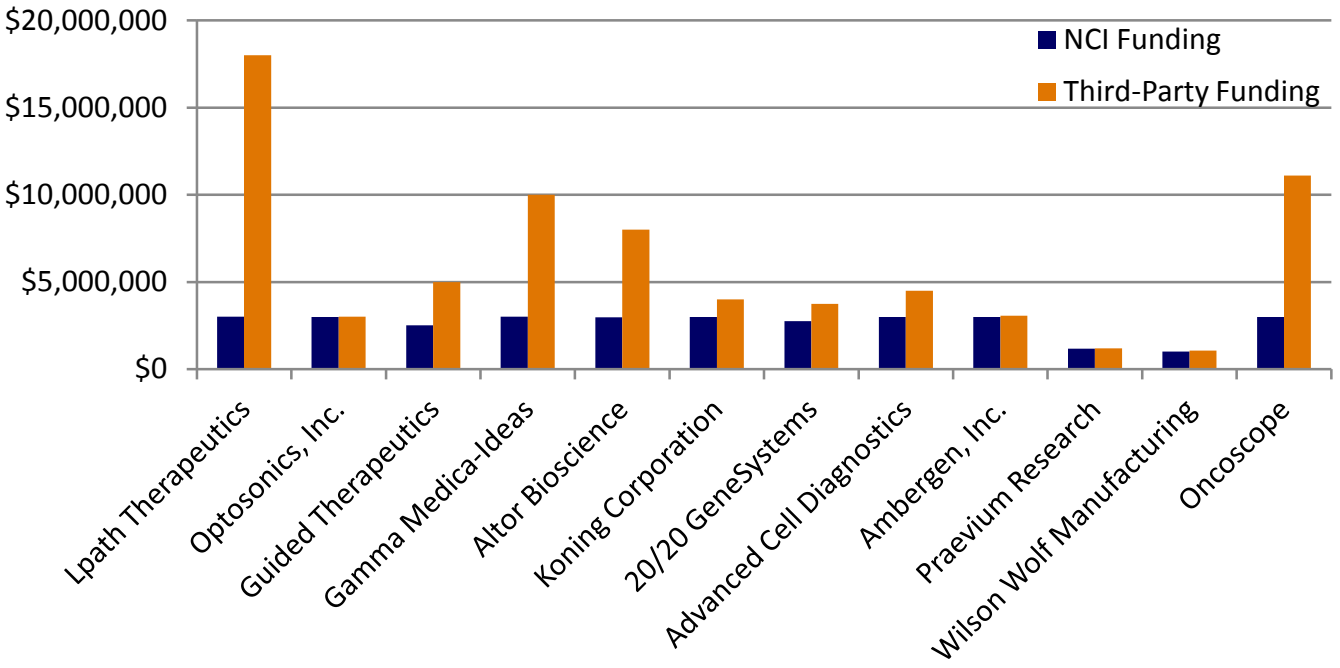
3 therapeutics
6 imaging technologies
3 molecular diagnostics

NIH RePORTER
http://projectreporter.nih.gov/reporter.cfm

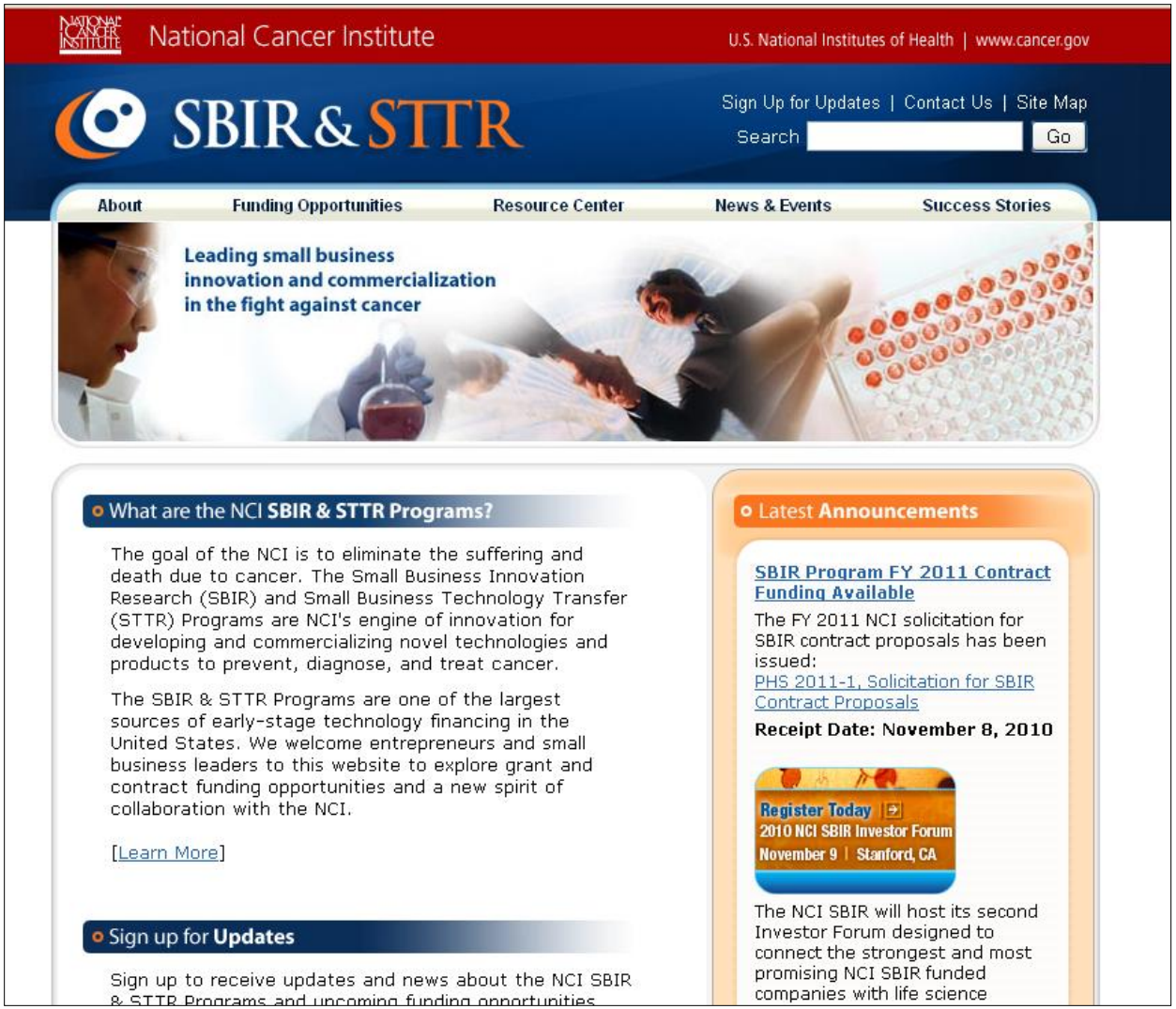
12 Bridge Awards (to date)



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

Venture Capital: ~1/3
Strategic Partners: ~1/3
Individuals & Other: ~1/3

http://sbir.cancer.gov



http://sbir.cancer.gov

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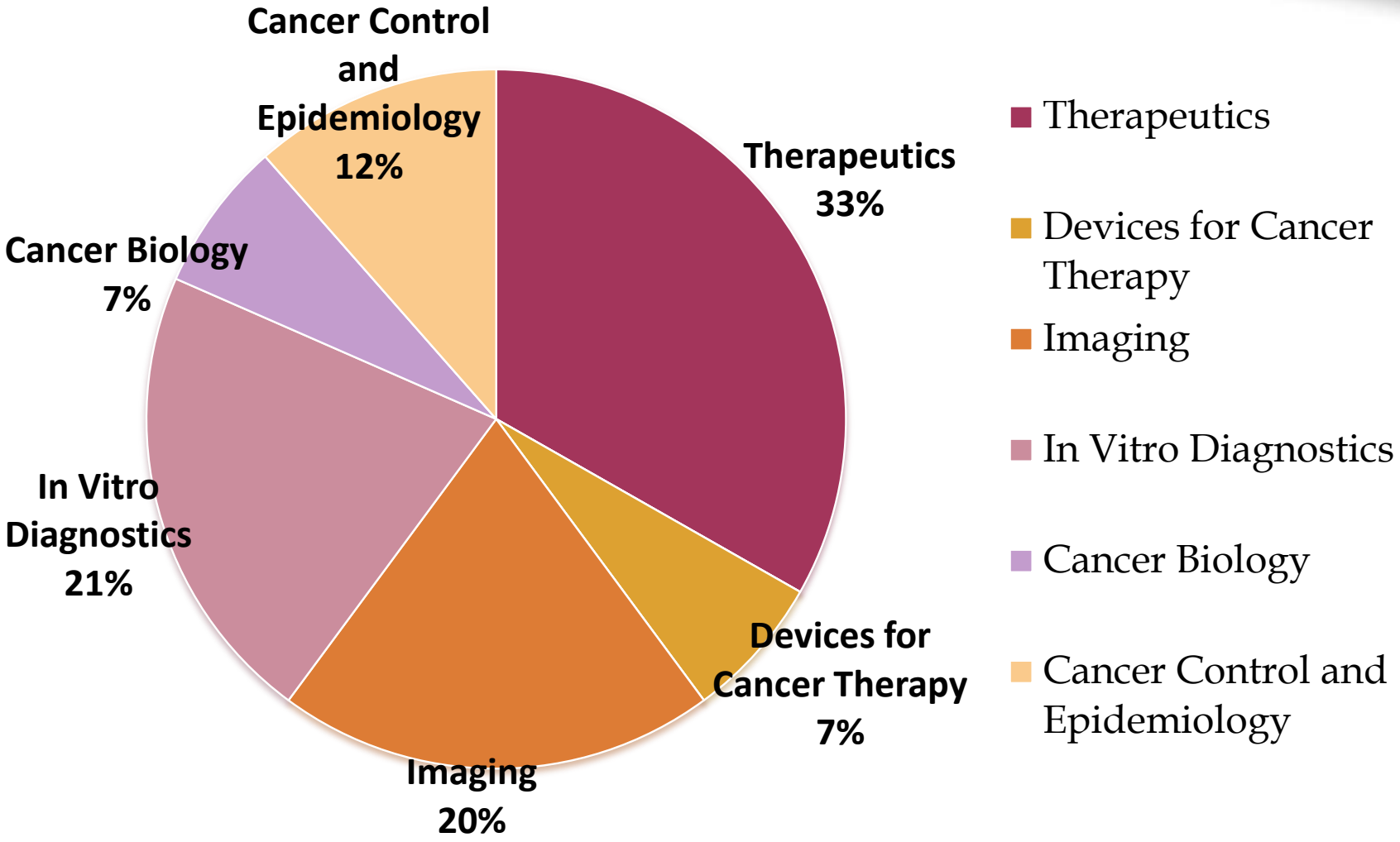
Register on web site for funding opportunity updates

Pipeline of 400+ vetted projects



SBIR Reauthorized through FY 2017

Venture Capital Participation

NIH will be allowed to spend up to 25% of SBIR funds to small businesses majority owned by multiple VCs, hedge funds, or private equity firms. (Previously not allowed)

SBA plans to release draft of new eligibility guidelines by April 30th for public comment.

Investor Forum attendees will be notified when released.