Bringing Science to the Market: The NCI SBIR Program

Presentation to the NCAB

September 13, 2011

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Today's Presentation

- **General SBIR/STTR Program Overview**
- **Discuss our major initiatives for enhancing SBIR at NCI**
  - SBIR Development Center
  - Targeted solicitations that are milestone based
  - SBIR Investor Forum
  - SBIR "Bridge Award"

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

Percent of NCI and NIH Budget

SBIR & STTR

	Set Aside
➢ **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization	**2.5%**
➢ **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization	**0.3%**

~$110 million annually at the NCI

~$680 million annually at the NIH

Why are SBIR and STTR Important to NCI?

- **One of NCI's primary resources for enabling commercialization of high impact technologies that can benefit patients, such as:**
  - **Small Molecules and Biologics**
  - **Cancer Diagnostics**
  - **Cancer Imaging**
  - **Health Communication Tools**
  - **Research Tools**

Reasons to Seek SBIR & STTR Funding

- **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**
- **Doesn't impact stock or shares in any way (no dilution of capital)**
- **Provides recognition, verification and visibility**
- **Can be a leveraging tool to attract other funding (VC, strategic partners, etc.)**

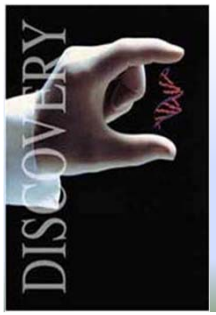
SBIR Eligibility

- ✓ **Applicant must be a Small Business Concern (SBC)**
- ✓ **Organized for-profit U.S. business**
- ✓ **500 or fewer employees, including affiliates**
- ✓ **PD/PI's primary employment (i.e., >50%) must be with SBC at the time of award and for duration of the project period**
- ✓ **At least 51% U.S.- owned by individuals and independently operated**

OR

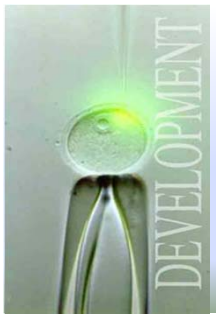
At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals

SBIR & STTR: Three-Phase Programs



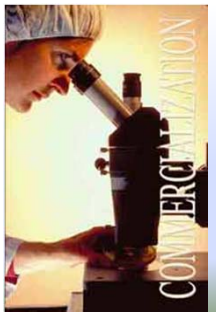
PHASE I – R41, R43

- **Feasibility Study**
- **$150-250K, 6-12 months**



PHASE II – R42, R44

- **Full Research/R&D**
- **$1-2M, 2-3 years**
- **Commercialization plan required**

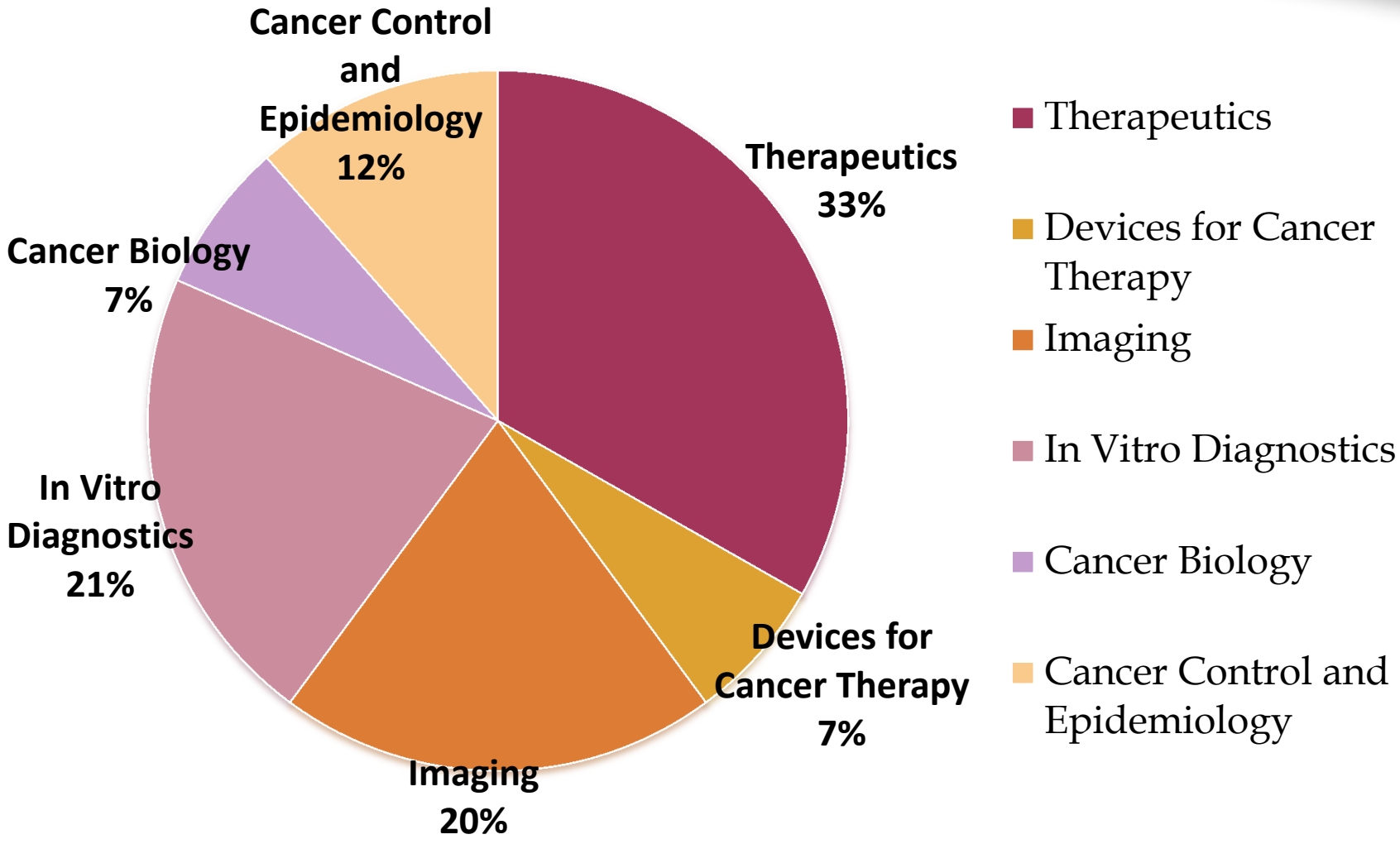


PHASE III

- **Commercialization Stage**
- **Use of non-SBIR/STTR Funds**

** These funding levels are guidelines. Companies should request the budget appropriate to accomplish the goals of the project.*

NCI SBIR Portfolio Summary

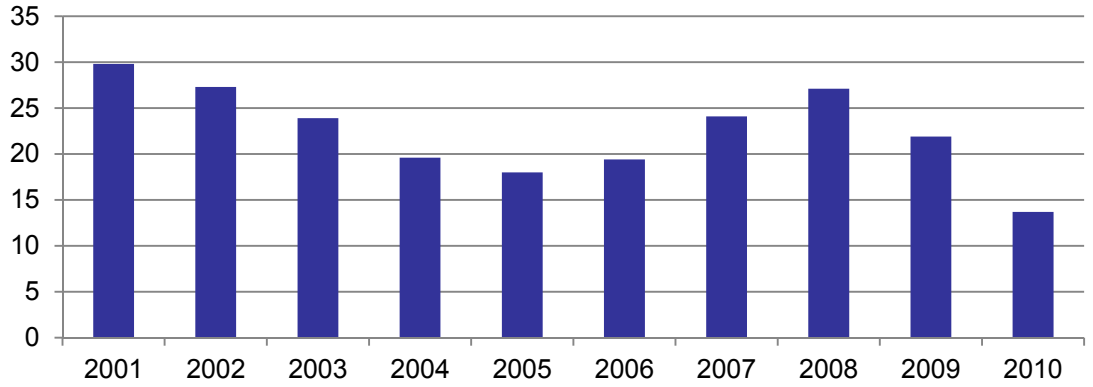


As of 9/1/2011

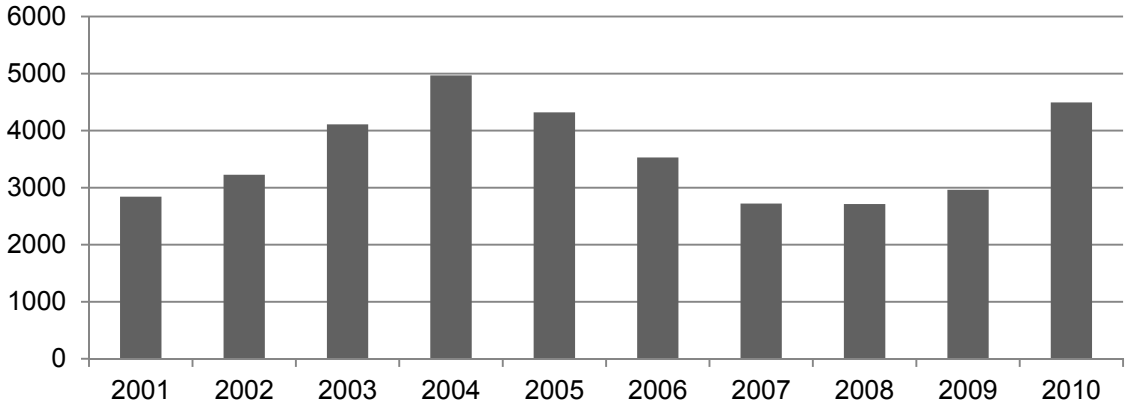
NIH SBIR Success Rates
(1998 – 2010)

SBIR & STTR

Phase 1 Success Rates (%)



Phase 1 Applications Received



Multiple Funding Solicitations

- **NIH SBIR/STTR Omnibus Solicitations for Grant Applications**

  Release: January

  Receipt Dates: April 5, August 5, and December 5

- **Solicitation of the NIH & CDC for SBIR Contract Proposals**

  Release: August

  Receipt Date: Early November

- **See NIH Guide for various other Program Announcements (PAs) and Requests for Application (RFAs), i.e. other grants**

  Release: Weekly

  Receipt Dates: Various

SBIR & STTR

NATIONAL CANCER INSTITUTE

New Enhancements to SBIR at NCI

New SBIR Development Center

Goal: Enhance commercialization success of SBIR-funded projects

- 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 Institute's 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

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)*

New Activities of Center

- **Active outreach to bring in a new class of commercially viable applicants**
- **Coaching companies on developing stronger applications**
- **Active management of projects and better oversight**
- **Mentor and guide companies throughout the award period**
- **Matchmaking with investors**

Move towards more targeted solicitations

- **Targeted solicitations afford a number of benefits including:**
  - Catalyzing the community to apply in emerging areas where there is strong commercial interest
    - Examples-- Companion diagnostics and novel imaging agents
  - Reviews conducted by NCI DEA focus not only on the scientific strength, but also the commercial viability of proposals.
  - These are milestone based awards
- **Since FY 2008, targeted solicitations have been increased from ~10% to ~25% of the SBIR budget**

Move towards more targeted solicitations

- **Program Directors from across NCI submit potential topic ideas.**
  - Many topics are derived from scientific and industry meetings and workshops.
    - Example – NCI SBIR Industry Forum
    - Goal-- to gain external input on technology areas in which NCI SBIR can have the greatest impact on cancer R & D
    - Participants from big pharma, medical device firms, and VCs.
- **NCI divisional representatives help determine which topics meet both NCI priorities & are ripe for commercialization.**

NCI SBIR Investor Forum

Exclusive opportunity for 14 NCI awardees to showcase their companies to investors

http://sbir.cancer.gov/investorforum/

Featured Small Businesses

- **Present to and network with close to 200 top investors and strategic partners**
- **Participate in panel discussion with successful Bridge awardees and their investors**

ACD ADVANCED CELL DIAGNOSTICS, INC
MagArray
zacharon pharmaceuticals

Investors

- **Opportunity to evaluate NCI's top companies with innovative technologies**
- **Exclusive one-on-one meetings**
- ***Next Forum scheduled on March 8th in Silicon Valley***

SV Life Sciences
atlasventure
Pfizer
biogen idec
FLAGSHIP VENTURES
genzyme

Results from Investor Forum

- **4 out of the 14 presenting companies have closed deals with investors or strategic partners**
  - **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.**
  - **Acoustic Medsystems signed an agreement with a strategic partner for further development of its high-intensity ultrasound ablation technology.**

Success Story

SBIR & STTR

Guided Therapeutics, Inc

The company's first product, the LuViva Advanced Cervical Scan, is a non-invasive device used to detect cervical disease instantly, and at the point-of-care.

2009 ➢ NCI Bridge Award
$2.5 M NCI + $2.5 M 3rd Party

LuViva
Advanced Cervical Scan

2010
➢ Submitted PMA to FDA

2011
➢ Raised additional $5.5M
➢increased market cap from $10-45M
➢ increased employees from 15 – 40

Regulatory Assistance

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Goal

- Provide awardees access to regulatory consultants to accelerate the FDA approval process for drugs, biologics and devices

Path

- Provide selected awardees (51) ≥30 hours of consulting time and activities, including:
  1. A preliminary conversation with the company regarding the writing of a regulatory plan
  2. Review and editing of the regulatory plan
  3. Post review discussion

Thank you!

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Register for updates at http://sbir.cancer.gov

Evaluation Phase -- Initiating Collection of Results Focused Metrics

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**

NCI Contract Funding Topics

- 255 Development of Anticancer Agents
- (*) 277 Development of Companion Diagnostics
- (*) 291 Development of Radiation Modulators For Use During Radiotherapy
- 300 Reformulation of Cancer Therapeutics using Nanotechnology
- 301 Probing Tumor Microenvironment Using In-vivo Nanotechnology-based Sensors
- 306 Development of Innovative Algorithms for Processing & Analysis of *In Vivo* Images
- (*) 307 Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging, and Treatment
- 308 Automated Collection, Storage, Analysis, and Reporting Systems for Dietary Images
- 309 Development of Low Cost, Small Sample Multi-Analyte Technologies for Cancer Diagnosis, Prognosis and Early Detection
- 310 Simplified Tissue Microarray Instrument For Clinical and Research Settings (NIH Technology Transfer)
- 311 High Throughput Isolation of Antigen Specific T-cells for Cancer Therapy (NIH Technology Transfer)
- 312 Generation and Qualification of Site-specific Post-translationally Modified Proteins for Use as Calibrators in Pharmacodynamic (PD) Assays

Example 2:
Topic 307 Imaging Agents

- **Budget:** Phase I $250,000 ; Phase II $1,500,000
- **Number of Anticipated Awards:** 3-5
- **Project Goal:** Novel imaging agents for:
  - early detection of cancer
  - stratification of patients for selecting cancer therapy,
  - surgical planning
  - evaluation of tumor response to chemotherapy, radiation therapy,
  - detection of cancer recurrence, etc.
- **The work scope may include** animal testing, formulation, GMP production, pharmacokinetic, pharmacodynamic, toxicological studies, etc.

Example 3:
Topic 277 Companion Diagnostics

- **Budget:** Phase I $200,000 ; Phase II $1,500,000
- **Number of Anticipated Awards:** 4
- **Project Goal:**
  - Companion diagnostics for selecting patients for which a particular therapeutic regimen, including existing drugs and those in clinical development and radiation, will be safe and effective
- **Phase I Work Scope:**
  - Test development and analytical validation
  - If the drug is not commercially available – establish partnership w/ the source
- **Phase II Work Scope:**
  - Full clinical validation