Catalyzing the Next Generation of Cancer Technologies

Presentation to the
Council of State Bioscience Associations (CSBA)

Michael Weingarten
Director, NCI SBIR Development Center

Agenda

- **SBIR/STTR Overview**
- **SBIR/STTR Reauthorization Changes**
- **NCI SBIR Development Center**
- **NCI Phase IIB Bridge Award**
- **NCI SBIR Investor Forum**
- **Funding Opportunities**

Congressionally-Mandated Programs

SBIR & STTR

	Set Aside (FY13)
➢ **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization	**2.7%**
➢ **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization	**0.35%**

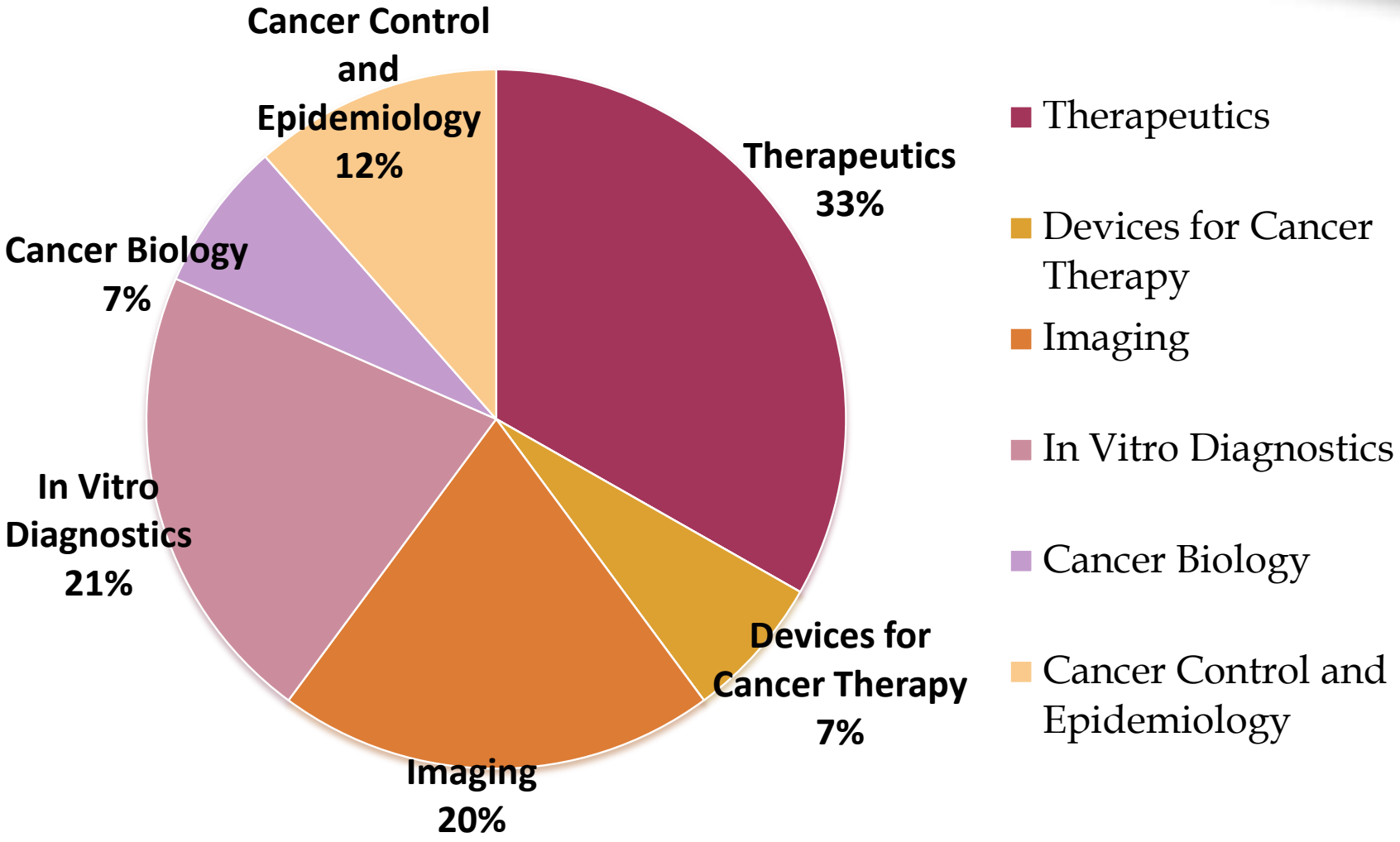
~$115 million annually at the NCI

~$717 million annually at the NIH

Reasons to Seek SBIR/STTR Funding

- **One of the largest sources of early stage 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**

Pipeline of 400+ vetted projects



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**
- ✓ **≥ 51% U.S.- owned by individuals and independently operated***

OR

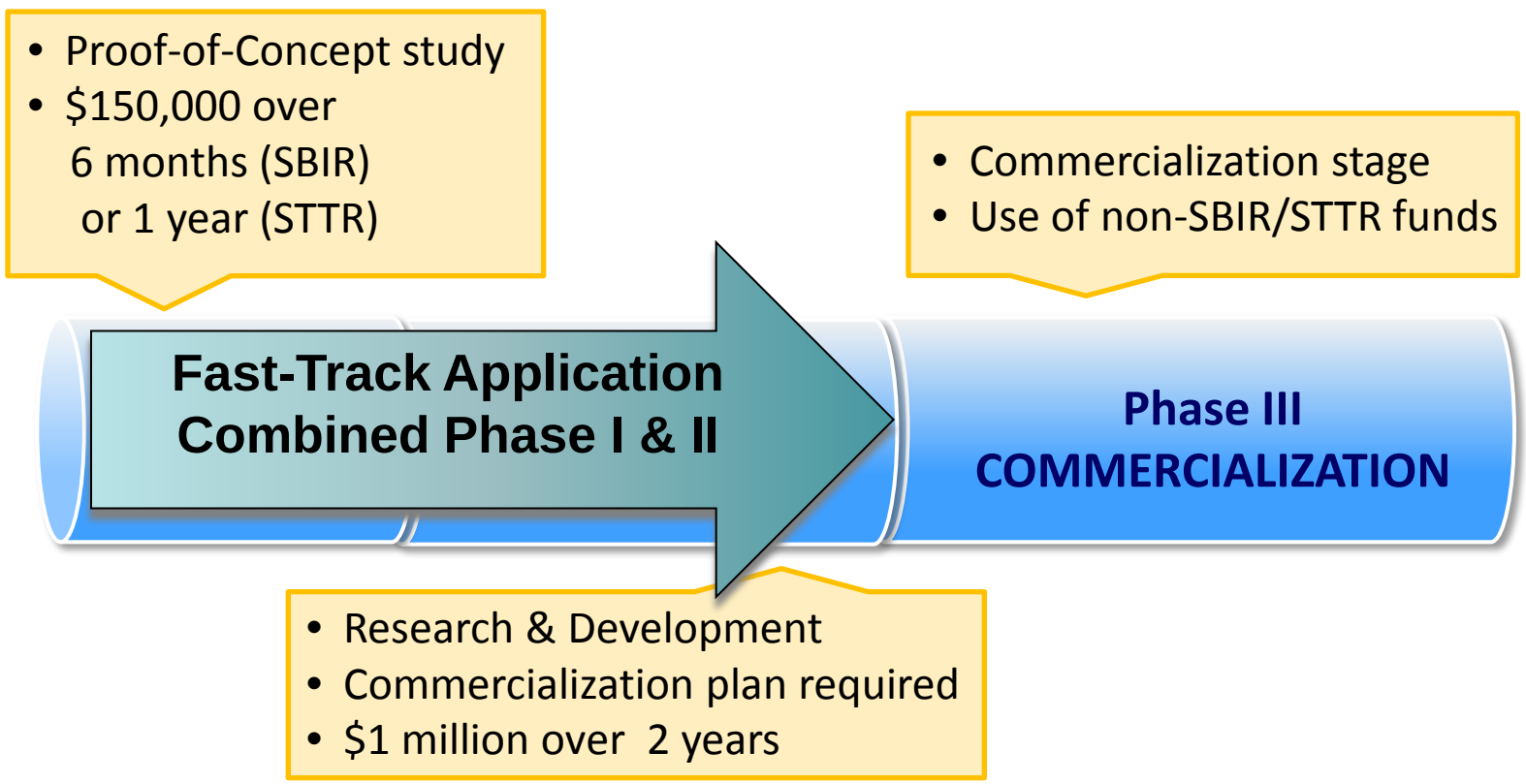
≥ 51% owned and controlled by another (one) business concern that is ≥ 51% owned and controlled by one or more individuals*

*** Recent reauthorization includes some exceptions to this rule**

STTR Eligibility

- ✓ **Applicant is a Small Business Concern**
- ✓ **Formal Cooperative R&D Effort**
  - Minimum 40% by small business concern
  - Minimum 30% by U.S. research institution
- ✓ **U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)**
- ✓ **Intellectual Property Agreement**
  - Should provide the necessary IP rights (to the SBC) in order to carry out follow-on R&D and commercialization
- ✓ **Principal Investigator's primary employment may be with either the Small Business Concern or the research institution**

SBIR & STTR: Three-Phase Program



SBIR/STTR Reauthorization: Key Changes

Congressional Reauthorization

- **SBIR/STTR programs were re-authorized through FY2017 by the 2012 Defense Authorization Act (P.L.112-81)**
  - New law includes a range of important changes to the programs
  - US Small Business Administration (SBA) is responsible for providing policy guidance on how to implement changes
  - Increases SBIR set-aside (incrementally) from 2.5% to 3.2% by 2017.
  - Increases STTR set-aside from 0.30% to 0.45% by 2017
  - Establishes hard caps on funding levels for Phase I & II awards
    - $225K for Phase I
    - $1,500K for Phase II

Changes to Eligibility

SBIR & STTR

New "Size Regulations"

- NIH will be permitted to spend up to 25% of SBIR funds on small businesses majority owned by *multiple* VCs, hedge funds, or private equity firms (previously not allowed)
- Effective after new rules are finalized (expected 1/1/13)

Cross-Program Awards

- STTR Phase I awardees can receive SBIR Phase II awards, and vice versa (previously done rarely, and with prior SBA approval)

Cross-Agency Awards

- Phase I awardee may receive a Phase II from a different agency

…and other proposed eligibility changes

Focus on Commercialization

SBIR & STTR

Expanded Technical Assistance

- Increased funding for technical assistance ($5000 per award)
- This can be provided through NIH technical assistance programs, i.e. Niche Assessment Program (Phase I), or Commercialization Assistance Program (Phase II), or requested by the awardee
- STTR awardees now eligible (previously not allowed)

Commercialization Readiness Program

- Allows NIH up to 10% of SBIR/STTR funds to support commercialization and Phase III efforts

Company Commercialization Record

- Applicants will be required to provide information on commercialization of prior SBIR/STTR awards

…and other proposed commercialization initiatives

Implementation Timeline

Effective	New Program Element
Now	• Set-aside increases (FY13) o SBIR = 2.7% o STTR = 0.35%
With the next issued solicitation	• 150% award caps • SBIR to STTR & STTR to SBIR • Cross-agency awards
January 1, 2013 (expected)	• New Size Regulations (i.e., eligibility requirements re: ownership)

NCI SBIR Development Center

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**

NCI SBIR Development Center Program Staff

Michael Weingarten, MA *(Director)*

Previous

- **NASA** – Program Manager, NASA Technology Commercialization Program

Greg Evans, PhD *(Lead Program Director)*

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)

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

Previous

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

Andrew J. Kurtz, PhD *(Lead 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 Director)*

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

Ming Zhao, PhD *(Program Director)*

Previous

- **NCI**– Program Director, Center to Reduce Cancer Health Disparities
- **GE Global Research** – Senior Scientist
- **Pfizer** – Scientist

NCI SBIR
Phase IIB 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

13 Bridge Awards (to date)

SBIR & STTR

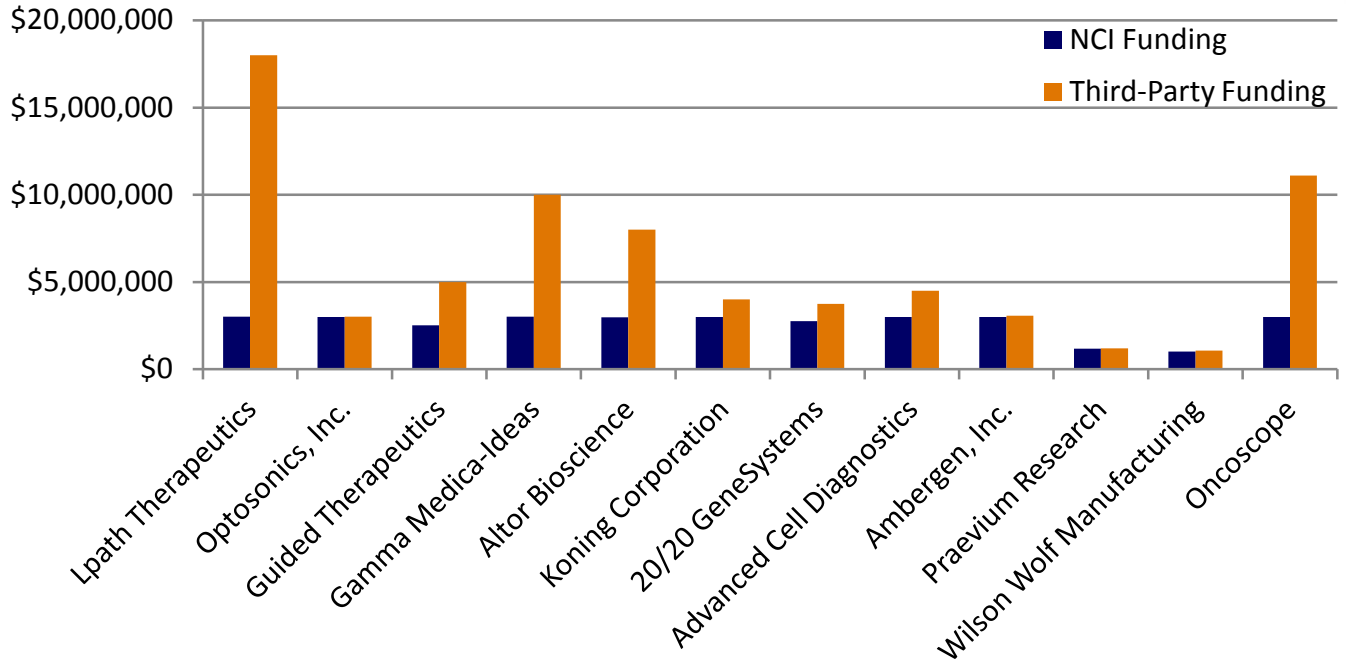
FY	Company	Technology/Product	Award Size
2009	**Lpath Therapeutics**	Humanized monoclonal antibody for treatment of prostate cancer	$3,000,000
2009	**Optosonics**	Photoacoustic CT for preclinical molecular imaging	$2,997,247
2009	**Guided Therapeutics**	Fluorescence/reflectance spectroscopy for detection 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
2012	**Omniox**	Tumor radiosensitization using a tunable oxygen-binding protein	$1,000,000

↓

4 therapeutics
6 imaging technologies
3 molecular diagnostics

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

13 Bridge Awards (to date)



Omniox (FY12)

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

SBIR & STTR

NATIONAL CANCER INSTITUTE

NCI SBIR
Investor Forum

NCI SBIR Investor Forum

Exclusive opportunity for some of the most promising NCI-funded companies to showcase their technologies

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

- **Opportunity to pitch and network with >150 investors and potential strategic partners**
- **Features NCI's top portfolio companies with innovative technologies**
- **Exclusive one-on-one meetings**

Previous Presenters

- *Zacharon Pharmaceuticals, Inc.*
- *Omniox, Inc.*
- *ImaginAb, Inc.*
- *Fluxion Biosciences*

Results from 2010 Investor Forum

- **7 out of the 14 presenting companies have closed deals valued at approximately $230M**
  - **Zacharon,** a company focused on developing therapeutics for rare diseases and cancer, finalized a major partnership with Pfizer worth up to $210M
  - **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

SBIR & STTR

NATIONAL CANCER INSTITUTE

NCI SBIR Funding Opportunities

http://sbir.cancer.gov/funding/

http://sbir.cancer.gov

Multiple Funding Solicitations

Know the Application Deadlines

SBIR & STTR

- **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 the NIH Guide for other Program Announcements (PA's) and Requests for Application (RFA's), i.e. grants**

  Release: Weekly

  Receipt Dates: Various

http://grants.nih.gov/grants/guide

SBIR & STTR

NATIONAL CANCER INSTITUTE

NCI SBIR
Grant Funding Opportunities

http://sbir.cancer.gov/funding/grants

Cancer Diagnostic & Therapeutic Agents Enabled by Nanotechnology (PAR-10-286)

SBIR & STTR

Goal: Accelerate translation & commercialization of nanotechnology-derived cancer therapeutics & *in vivo* diagnostics from advanced discovery phase to end of preclinical characterization.

- For development of new, or improvement of existing applications of, nanotechnology-based therapeutics and/or *in vivo* diagnostics.
- Supports pre-clinical optimization & testing leading to IND or IDE
- Cooperative Agreement – U43/U44
- Support through the NCI Nanotechnology Characterization Laboratory

Contact Dr. Andrew Kurtz: kurtza@mail.nih.gov

Image-Guided Cancer Interventions (SBIR & STTR, PA-10-079/PA-10-080)

Goal: Support the development & clinical validation of systems for image-guided interventions (IGIs) for cancer, such as:

- The development & optimization of fully integrated cancer imaging, monitoring, and therapy systems;
- Validation of integrated IGI systems through clinical evaluations;
- The development of multiple prototype integrated IGI systems as required for multisite clinical evaluations; and
- Image-guided-diagnosis, image-guided-surgery, and image-guided-therapy.

Contact Deepa Narayanan: narayanand@mail.nih.gov

Innovative Health IT for Broad Adoption by Healthcare Systems & Consumers (PA-12-196)

SBIR & STTR

Goal: Accelerate development & commercialization of evidence-based consumer health IT to:

- Prevent or reduce the risk of cancer
- Facilitate patient-provider communication
- Improve disease outcomes in consumer & clinical settings

- Phase II or Fast-Track applications only
- Strong applicants will have a **partnership with large business** (e.g. commercial IT firm, EMR vendor, healthcare systems, etc.)

Contact Dr. Patricia Weber: weberpa@mail.nih.gov

http://sbir.cancer.gov/resource/hit/

SBIR & STTR

NATIONAL CANCER INSTITUTE

SBIR Contract Solicitation

http://sbir.cancer.gov/funding/contracts

SBIR Contracts vs. Grants

	Funding Solicitations for SBIR Grants	Funding Solicitation for SBIR Contracts
Scope of the proposal	Investigator-defined within the mission of NIH	**Defined by the NIH (focused)**
Questions during solicitation period?	May speak with any Program Officer	**MUST** contact the contracting officer
Receipt Dates	3 times/year for Omnibus	**Only ONCE per year**
Basis for Award	Based on score during peer review	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
Reporting	One final report (Phase I); Annual reports (Phase II)	Monthly or quarterly progress reports
Set-aside of funds for particular areas?	NO	YES

http://sbir.cancer.gov

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Register on web site for funding opportunity updates