Overview of the NCI SBIR Program

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Michael Weingarten
Director, NCI SBIR Development Center
Why we’re here today

• **Increase awareness about:**
  • Funding and resources to support your company
  • Regulatory approval processes
  • Policies on coverage for new medical technologies
  • Special intellectual property resources

• **Understand and leverage NCI SBIR initiatives**
  • SBIR Development Center
  • Targeted Solicitations
  • SBIR Phase IIB Bridge Award
  • SBIR Investor Forum

• **Accelerate technology development and commercialization**
NCI SBIR Development Center
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

A $110M Program at the NCI
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

We’re here to help you!
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Specialties/Programs</th>
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<tbody>
<tr>
<td>Greg Evans, PhD</td>
<td>Lead Program Director</td>
<td>Cancer Biology, E-Health, Epidemiology</td>
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<tr>
<td>Patti Weber, DrPH</td>
<td>Program Director</td>
<td>Digital Health, Therapeutics, Biologics, SBIR Investor Forum, FRAC Workshop</td>
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<tr>
<td>Deepa Narayanan, MS</td>
<td>Program Director</td>
<td>Cancer Imaging, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop</td>
</tr>
<tr>
<td>Diana Connolly, PhD</td>
<td>Program Analyst</td>
<td>Success Stories, Awardees in the News, Scientific Communications, FRAC Workshop</td>
</tr>
<tr>
<td>Tamar Boghosian</td>
<td>Program Analyst</td>
<td>Portfolio Analysis, Budget Tracking, FRAC Workshop</td>
</tr>
<tr>
<td>Julienne Willis</td>
<td>Program Specialist</td>
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<tr>
<td>Andrew J. Kurtz, PhD</td>
<td>Lead Program Director</td>
<td>Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award</td>
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<tr>
<td>Jian Lou, PhD</td>
<td>Program Director</td>
<td>In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, FRAC Workshop</td>
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<tr>
<td>Todd Haim, PhD</td>
<td>Program Director</td>
<td>Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop</td>
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<tr>
<td>Amir Rahbar, PhD, MBA</td>
<td>Program Director</td>
<td>In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics, SBIR Investor Forum</td>
</tr>
<tr>
<td>Ming Zhao, PhD</td>
<td>Program Director</td>
<td>Cancer Diagnostics &amp; Therapeutics, Cancer Control &amp; Prevention, Molecular Imaging, Bioinformatics, Stem Cells</td>
</tr>
<tr>
<td>Jennifer Shieh, PhD</td>
<td>AAAS Science &amp; Technology Policy Fellow</td>
<td>Evaluation, SBIR Investor Forum, Success Stories, FRAC Workshop</td>
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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 oversight and active management of projects
- Mentoring and guiding companies throughout the award period
- Facilitating matchmaking with potential third-party investors and strategic partners
Exploring new initiatives:

- Providing access to other resources at NCI and NIH
- Phase IB Bridge Program
- Collaborating with foundations
- Active engagement with venture capital, strategic partners, and angel investors
Targeted Solicitations
Benefits of this Approach

• **Targeted solicitations afford several benefits:**
  
  • Provides an additional funding mechanism to catalyze the community to perform R&D in emerging areas with strong commercial interest
  
  • **Examples:** *Companion diagnostics and novel cancer imaging agents*
  
  • Reviews are conducted by NCI, 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
SBIR Phase IIB Bridge Award
NCI SBIR Phase IIB Bridge Award
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)
## 13 Bridge Awards (to date)

<table>
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<tr>
<th>FY</th>
<th>Company</th>
<th>Technology/Product</th>
<th>Award Size</th>
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<tbody>
<tr>
<td>2009</td>
<td>Lpath Therapeutics</td>
<td>Commercialization of ASONEP for the Treatment of Cancer</td>
<td>$3,000,000</td>
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<td>2009</td>
<td>Optosonics</td>
<td>Photoacoustic CT for preclinical molecular imaging</td>
<td>$2,997,247</td>
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<tr>
<td>2009</td>
<td>Guided Therapeutics</td>
<td>Fluorescence/reflectance spectroscopy for detection of cervical cancer</td>
<td>$2,517,125</td>
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<tr>
<td>2009</td>
<td>Koning Corporation</td>
<td>High-performance breast CT as diagnostic adjunct to mammography</td>
<td>$2,986,453</td>
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<tr>
<td>2009</td>
<td>Gamma Medica-Ideas</td>
<td>Molecular imaging to detect metabolic activity of breast lesions</td>
<td>$3,000,000</td>
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<tr>
<td>2010</td>
<td>20/20 GeneSystems</td>
<td>mTOR companion diagnostic assay</td>
<td>$2,750,000</td>
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<td>2010</td>
<td>Advanced Cell Diagnostics</td>
<td><em>In situ</em> RNA detection assay for analyzing circulating tumor cells</td>
<td>$2,996,450</td>
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<tr>
<td>2010</td>
<td>Ambergen</td>
<td>Expression-based prognostic assay for recurrence of colorectal cancer</td>
<td>$2,998,830</td>
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<td>2010</td>
<td>Praevium Research</td>
<td>High-performance imaging engine for optical coherence tomography</td>
<td>$1,180,420</td>
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<tr>
<td>2011</td>
<td>Wilson Wolf Manufacturing</td>
<td>Moving TIL therapy past the Valley of Death</td>
<td>$1,006,256</td>
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<td>2011</td>
<td>Oncoscope</td>
<td>Validation &amp; commercialization of a/LCI for detection of esophageal neoplasia</td>
<td>$2,999,084</td>
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<td>2012</td>
<td>Omniox</td>
<td>Tumor radiosensitization using a tunable oxygen-binding protein</td>
<td>$1,000,000</td>
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- **4 therapeutics**
- **6 imaging technologies**
- **3 molecular diagnostics**

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<th>Bridge Awards (to date)</th>
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<tr>
<td><strong>NCI Total</strong></td>
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<tr>
<td>Third-Party Investments</td>
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<tr>
<td>Leverage</td>
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- **Venture Capital**: ~1/3
- **Strategic Partners**: ~1/3
- **Individuals & Other**: ~1/3
SBIR Investor Forum
18 top SBIR-funded companies presented
Over 200 life science investors & leaders
150+ one-on-one meetings in 2012
8 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.
Measuring Success

### 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**
Call to Action

• **Explore** the resources and information from the speakers and Federal Partners here today

• **Engage** in one-on-one meetings and follow-up

• **Share** updates on technical progress, investments/third-party partnerships with your Program Directors so we can track successes; discuss new project ideas