NIH SBIR/STTR Program
Transforming Medicine Through Innovation

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SBIR/STTR Program Coordinator
Office of Extramural Research, NIH
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Topics to Discuss Today

• Transitioning SBIR/STTR Medical Innovations to the Marketplace

• Innovative Approaches to Helping SBIR Firms Overcome Commercialization Challenges
“We in government must work in partnership with small businesses to ensure that technologies and processes are readily transferred to commercial applications.”

• Stimulate technological innovation
• Use small business to meet Federal R&D needs
• Foster and encourage participation by minorities and disadvantaged persons in technological innovation
• Increase private-sector commercialization innovations derived from Federal R&D

Small Business Innovation Development Act of 1982
P.L. 106-554 (Signed 12/21/2000 extends program through 09/30/2008)
The largest, most accessible source of seed capital for the nation’s innovative small businesses

$2.3 Billion in 2008

NIH: $650M

SBIR/STTR PROGRAMS

$2.3B (11 agencies)
This capital is in the form of grants and contracts:

- no repayment
- no debt service
- no equity forfeiture
- no IP forfeiture
SBIR/STTR: COMPETITIVE 3-PHASE PROGRAM

• PHASE I
  • Feasibility Study - idea with commercial potential
  • $100K and 6-month (SBIR) or 12-month (STTR) Award

• PHASE II
  • Full Research/R&D
  • $750K and 2-year Award (SBIR & STTR)
  • Pre-requisite: Phase I award

• PHASE III
  • Commercialization Stage
  • Use of non-SBIR/STTR Funds

NIH permits deviations where scientifically justified
Challenges for Biotech Firms: Navigating the Peaks and Valleys

- Unusually long development times (5-12 yrs)
- High & intense capital needs (>1B)
- Exceptionally high burn rate for investment funds
- Multiple rounds of financing required

Phase I  →  Phase II  →  Phase III

Early-Stage Technology

Market-Ready Technology
Transitioning Medical Innovations to the Marketplace

Phase II
Competing Renewal

Commercialization Assistance Program

Manufacturing Assistance Program

Phase III

Early-Stage Technology

Valley of Death

Market-Ready Technology

Phase II

Phase III
In-NIH-vative Approaches to Commercialization Challenges
• Competing Renewal Phase II awards
• Commercialization Assistance
• Pipeline to Partnerships (P2P)

“From the Test Tube to the Medicine Cabinet”
Phase II Competing Renewal Award

Purpose

• To take existing, promising compounds or devices developed under a Phase II through the next step of drug discovery / medical device refinement and development.
• Provide additional Phase II research support to continue assessing and improving devices or conducting preclinical studies of drugs or devices that ultimately require:
  ❖ clinical evaluation
  ❖ approval of a Federal regulatory agency
  ❖ refinements to medical equipment (DME) designs
Purpose (cont.)

OR....

To support:
• Complex Instrumentation
• Clinical research tools
• Behavior Interventions/treatments
(see http://grants.nih.gov/grants/guide/pa-files/PA-08-115.html)
Eligibility

• SBIR Phase II awardee
• Promising pharmacologic agent identified or device developed
• Generally, some preclinical pharmacology conducted.
• Clinical research tools that require extensive development to demonstrate validity
• Complex instrumentation comprising distinct parts that must work together
• Response to an NIH Funding Opportunity
• Generally, $750k-$1M/year for up to 3 years
In-NIH-vative Approaches to Commercialization Challenges

• Competing Renewal Phase II awards
• Commercialization Assistance
• Pipeline to Partnerships (P2P)
<table>
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<th>Technical Assistance Programs</th>
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| Niche Assessment          | Identify other uses of technology |
| (Phase I awardees)        | Determines competitive advantages |
|                           | Develops market entry strategy    |

| Commercialization Assistance | Business & strategic planning |
| (Phase II awardees)          | Builds alliances and investor partnerships |

| Manufacturing Assistance | Partnership with NIST MEP Centers |
| (Phase II awardees)      | Help make better manufacturing and operational decisions |
The NIH-CAP

- National Institutes of Health Commercialization Assistance Program (NIH-CAP)
  - funded by NIH SBIR set-aside
  - developed and executed by Larta Institute
  - assists SBIR Phase II NIH awardees with commercialization
    - Currently in its fourth year
- 10 month program with fresh crop of companies each year
- >100 life science companies each year for past 3 years
The NIH-CAP

- **Key program components**
  - Workshops with real-time advisors
    - Training appropriate to level of company: both seasoned companies and start-ups
    - Real-world training customized to needs
  - Mentoring by experienced “Principal Advisors”
  - Investment/Partnering event
  - Networking and matchmaking
  - Tracking post-program

- **Impact**
  - Partnership and deal-related activities
  - Growth in equity investment
  - Impact on company revenue
  - Strategic thinking, roadmap and plan!
Vivo Biosciences Inc.

Company Mission
Vivo Biosciences Inc. (VBI) is an early stage biotechnology company engaged in research and development of new preclinical bioassay platforms for accelerating drug discovery, diagnostics and therapeutics. VBI is jointly formed in 2004 by the technology developer Dr. Raj Singh, Diversified Scientific Inc. and UAB Research Foundation.
The company relies on its proprietary HuBiogel™ technology. A new series of 3-D or tissue-like human bioassay systems are established via NIH and NASA SBIR programs. Current R&D and business operations are dedicated to cancer drug screening, biomarker profiling and toxicity prediction, the critical bottlenecks of drug development.

News
- New Preclinical Bioassay Technology: FDA Critical Pathway Initiative, DC, 2006

12-Month Progress
- $2 Million investment by Toucan Capital
- Met the first milestone
- Joint venture
- Doubled staff to 4
- Would not have happened without CAP

- Academic spinoff
  - Raj Singh, Ph.D., President
- Innovative science
  - The first 3-D human bioassay platform
- Very large preclinical testing market
  - Fast and human physiology-based drug testing
• Competing Renewal Phase II awards
• Commercialization Assistance
• Pipeline to Partnerships (P2P)
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Potential partner identifies technology of interest and contacts company's Web site.
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SBIR/STTR SUCCESS ABOUNDS!
How Can You Qualify for and Compete Successfully for NIH Funding?

- Understand our mission.
- Review Funding Opportunity Announcements (FOAs).
- Propose innovative ideas with significance as well as scientific and technical merit.
- Give yourself ample time to prepare application.
- Contact NIH Staff to discuss
  - your research idea.
  - outcome of your review.
  - challenges and opportunities.
STAY INFORMED…

- NIH SBIR/STTR Web site
  
  http://grants.nih.gov/grants/funding/sbir.htm

- NIH Guide for Grants and Contracts (weekly notification)
  
  http://grants.nih.gov/grants/guide/listserv.htm

- NIH SBIR/STTR Notification
  
  LISTSERV@LIST.NIH.GOV: Subscribe SBIR-STTR your name

- Contact NIH Program Staff:
  
  Listed in Solicitations under each IC
www.nih.gov

http://grants.nih.gov/grants/oer.htm

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