# Building an SBIR program for a niche market

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National Institutes of Health U.S. Department of Health and Human Services

# NIDA's SBIR Program Positioning

\$25.3m in total funding
Statutory authority: To
conduct and support research
.... with respect to the
prevention of drug abuse and
the treatment of drug abuser
Limited market opportunities
for small business (\$3.1bn –
substance use treatment and
diagnosis; \$47.7bn – cancer;
\$11bn - antidepressant )

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Limited number of quality applications

Absence of dedicated FTEs, SBIR/STTR grants managed by many POs



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## NIDA SBIR Team



- Elena Koustova, DBNBR
   Augusto Diana, DESPR
- 3. Kristopher Bough, DPMC
- 4. Scott Chen, OEA
- 5. Quandra Scudder, CTN
- 6. Will Aklin, DCNBR
- 7. Cecelia McNamara Spitznas, *DCNBR*
- 8. Dale Weiss, NIDA International Program
- 9. Brian H. O'Laughlin, NIDA R&D Contracts Management Branch, Office of Acquisitions

# Envisioning Early Strategy

- Findings and recommendations of National Research Council to improve the operations of an already effective SBIR Program at NIH (An Assessment of the Small Business Innovation Research Program at the National Institutes of Health, National Research Council, ISBN: 0-309-10952-3, (2009))
  - Low relative scores
  - Modest management and leadership engagement
  - Limited commercial review
  - Burden on staff/Staff reluctance to engage



Lack of assessment

## Address Modest Management/Senior Leadership Engagement

	diction			C0	
Drugs of Abuse	Related Topics	Publications	Funding	News & E	
ep Two - Fundi	ng Options				
nding nding Opportunities		Small Business Fund	ing		
NDA Requests for Contract * Proposals (RFPs)		1	1		
Small Business Funding 🔹 🔻	GRANT ?		CONTRAC	77	
Step One - Collaboration Step Two - Funding Options		1			
Step Three - SBIR/STTR Funding Areas	SBIR S	TTR	SBIR o	nly	
Step Four - Grant Application				_	
Step Five - Other Funding Sources	Understand yo	our funding options:			
Step Six - Contact Us	• What is the diffe	rence between the grant and	contract?		
Science Education Grants	What is the difference of	rence between the SBIR and	STTR?		
end Contracts NIH Extramural Loan Repayment Program Repayment Chical Researchers	<ul> <li>What is a "fast track" application option?</li> </ul>				
	Finite State Grant Opportunities (PDF, 1.7MB) (NIH)				
	Contract Opportunities (PDF, 1.0MB) (NIH)				
WH Common Fund		Or, please contact Mr. Brian O'Laughin to for specific information			
nical Research	Non-SBIR/STTR fi	unding opportunities for small	businesses		
st Award Concerns	• Phase II competi	ing Renewal Rewards			
neral Information					
ant & Contract Application	Grants vs. Cor	ntracts: What's the	difference?		

- SBIR Webpage on NIDA website created
  - Allocated time for regular presentations at the NIDA Senior Staff Meetings
  - "Tea with NIDA Director" celebratory ceremony for the winners of the best SBIR contract topics contest established
  - Separate and transparent funding meetings instituted by the Senior Leadership
- NIDA SBIR Idea Board is established
- Visibility of the program raised





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# Improve relative scores and number of applications

- Promote the program through meetings (Yellow T-shirt Campaign)
- Listserves (LinkedIn ThomsonBanker- iBridge)
- Assist SBCs with alternative path development (LAE)
  - Scout





# Scouting and Outreach



 17 databases
 searched in Science and Business
 Reading Room in
 Adams Building of
 the Library of
 Congress

- NAICS of all potential SBCs which can conduct research in NIDA's area of interest determined
  - Outreach lists created





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910 Clopper Road, South Building, Suite 210 Gaithen			thersburg, MD 20878 UNITED STATES Quick Filling Lin				
Phone :240-683-2450   Fax : 240-683-2451		683-2451	w.introno.com REGDEX 06/23/				
VE Industry Code: Other Medical Diagn		Diagnostic F	echnology (4119) REGDEX 06/11				
			REGDEX 10/19				
SIC Code: Diagnostic substances		stances (20	View Full Film				
application allows for therapeuti	ns including gene repro the effective turning or ic effect. It can also be in rovel therapeutics to t	gramming, F or off of a used to iden	genes. The Company uses a technology, known as SMuRT which has brow regar, real-time molecular imaging, and genomics. Interont schnology e, as well as the ability to change the output of a gene to achieve a desire which proteins are involved in the pathology of a specific disease, as well e.				
# of Employees		12	12				
Last Available Sales Figure			0.0 USD MI (2005)				
Company Founded Date			01-Jan-2001				
Company Status		Ac	Acquisition				
Legal Counsel		Hu	Hutchison & Mason PLLC				
Banking Relationships		St	State Street Bank				
Accountant		Pri	PricewaterhouseCoopers				
Total Funding to Date		11	11.5 USD MI				
Histori	ical Sales						
Period	Sales (USD Mil)	Source	Based on latest 5-year period available				
2005	0.0	n/a	Sales Chart - Last 5 Years				
2005	n/a	n/a	1.20				
2004	1it a		Sales				
	0.8	n/a	0.60 Dates				
2004		n/a n/a	0.60 2001 2002 2003 2004* 2005*				



## Results of implementing new SBIR Contract practices



# Majority of NIDA SBIR grant applications not discussed



- NIDA grants with one due date reviewed by 14 study sections
- Applicants complain about the lack of appropriate expertise in study sections
- □ SBIR/STTR Study Sections:
  - ZRG1 MOSS-K 11 SPECIAL EMPHASIS PANEL Small Business: Oral, Dental and Craniofacial Sciences (NIDCR)
    - MOSS-Q and –S Muscle, Orthopedic and Skeletal Biology (NIAMS)
    - OTC-H, -R, -T Cancer DD, Diagnostics, Radiation Therapy

# Working on decreasing the burden on staff

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DEPARTMENT OF HEALTH & HUMAN SERVICES

CES Public Health Service National Institutes of Health National Institute on Drug Abuse 6001 Executive Bivd.

Bethesda, Maryland 20892

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DA SE

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#### Memorandum

Guidelines for SBIR Contract Topic Preparation, Submission and Approval, National Institute on Drug Abuse

3 March, 2011

1. Preparation. Each Divisional SBIR Coordinator is responsible for soliciting the SE contract topics, as well as advising and assisting in their preparations. Topics are prep b/Division staff by filling out the SBIR Contract Topic template with the aid of the S Manual, which is maintained and updated by the NIDA SBIR Coordinator. 2. submission. An unlimited number of topics from NIDA ADD Divisions will be accepted consideration by the NIDA SBIR Coordinating Committee (SBIR CC). Divisional SB Coordinators will present those topics to the SBIR CC. Coordinators may also elect to invite the submitting Program Official (PO) for a topic presentation.

3. Selection. Up to ten topics selected by the NIDA SBIR CC will be submitted for exterview. After external review, SBIR CC will reduce (if needed) the number of remain topics to 7, so that the most efficient dissemination and oversight of NIDA contract to can be provided. Each member of the SBIR CC will accept responsibility for one spec topic. Efforts will be made to combine topics where overlap exists. Each Division (DBNBR, DCNBR, OD, DPMC, CCTN, DESPR) will have at least one topic in the SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH AND THE CENTERS FOR DISE.

#### Creating a Topic for an SBIR Contract



Multiple templates, manuals and materials designed to assist NIDA POs were created

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service National Institutes of Health National Institute on Drug Abuse 6001 Executive Blvd. Bethesda, Maryland 20892

Date:

SBIR Contract Topic (no page limit)

Division, Name, Phone

Contract Topic Title\_

#### I. What are the need and the scientific opportunity to address this need? Provide the Summary of scientific opportunity

Provide the description of Project Goals. This topic addresses the need for.

Provide the description of Phase I Activities and Expected Deliverables
 Provide the description of Phase II Activities and Deliverables (If the topic solicits proposals for Phase I only, include the following: Phase II information is provided for informational purposes to assist Phase I offerors with their long-term strategic planning even when only Phase I applications are requested).

#### Is it a Fast Track? If yes, justify Fast Track.

(Consult NIDA SBIR Contract Manual for Fast Track guidance) The NIH Fast-Track application process expectices award decisions and funding of SBIR and STTR Phase II applications for scientifically menicorious projects that have a **high optential for commercialization**. The Fast-Track process allows Phase I and Phase II grant applications to be submitted and reviewed together. This concept is appropriate for Fast Track whent is conguent with the stage of technological readiness (e.g. technologies necessary to resolve the need NIDA seeks to resolve are available and are at the appropriate development stage).

#### II. Potential for commercialization

 Market size: How many people would purchase the product developed in response to your contract concept? Who are the customers?

2. Urgency: How badly do people need this right now?

3. Uniqueness: How unique is this versus what's available? And what is available?

### For small IC, how to find the balance?



# Educating Staff on Commercialization Issues

- Commercialization Assessment Index (CAI)
- Market Opportunity Analysis (MOA)

Office of

**Grants Policy** 

Policy & Guidance

Compliance & Oversight

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About Grants

Extramural Research

Funding Forms & Deadlines

Grants Policy & Guidance

On This Page: • Grants Policy Statements

Strategic Technology Evaluation Program (STEP) Model



NIH is required by statute to reserve a portion of its annual extramural budget for projects under the SBIR and STTR programs. These programs primarily are intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the following three phases:

- <u>Phase I.</u> The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II.
- <u>Phase II.</u> The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding
  will be based on the results of Phase I and the scientific and technical merit and commercial potential of the
  Phase II application. Only Phase I grantees are eligible to receive Phase II funding. Unless submitted as a
  Fast-Track application (<u>see below</u>), Phase II applications may be submitted only after the Phase I award is
  made. NIH expects non Fast-Track Phase II applications to be submitted within the first six receipt dates
  following expiration of the Phase I budget period, i.e., normally 2 years beyond the expiration date of the
  Phase I award.
- <u>Phase III.</u> The objective of this phase, where appropriate, is for the SBC to pursue, with non-SBIR/STTR funds, the commercialization of the results of the research or R&D funded in Phases I and II.

# Evaluating internal ideas for SBIR RFPs and RFAs

### **Rating Scale**

- 1. Market size: How many people would purchase the product developed in response to your contract concept? Who are the customers?
- 2. Urgency: How badly do people need this right now?
- **3. Uniqueness:** How unique is this versus what's available? And what is available?
- 4. Speed to Market: How quickly can it be created and sold?
- 5. **Cost of Value Delivery:** What would it take for a small business to create and deliver the value you envisioned in your contract concept?
- 6. **Pricing Potential:** What's the highest price people would be willing to pay?
- 7. Cost of Customer Acquisition: How easy is it to acquire a new customer?
- 8. **Up-Front Investment:** How much is needed to invest before having an offer ready?
- 9. Up-Sell Potential: What related offers could the company, which executes your contract concept, present to purchasing customers?
- 10. Evergreen Potential: Once the value you envisioned in your contract concept is created, how much work does the small business have to put into it to continue selling?

### **Final Score**

- Rate each of the 10 factors on a scale of 0 to 10, where 0 is extremely unattractive and 10 is extremely attractive. When in doubt, be conservative in your estimate.
- Add up your score. If it is 50 or below, move on to another ideas

   there are better places to invest your energy and recourses. If 75 and above – you have a very promising idea, anything between 50 an 75 has a potential.

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# NIDA SBIR/STTR Issues and Challenges

Staff engagement (finding balance?)
 Peer review (establishing special emphasis panel for niche ICs?)
 Limited number of quality grant applications