

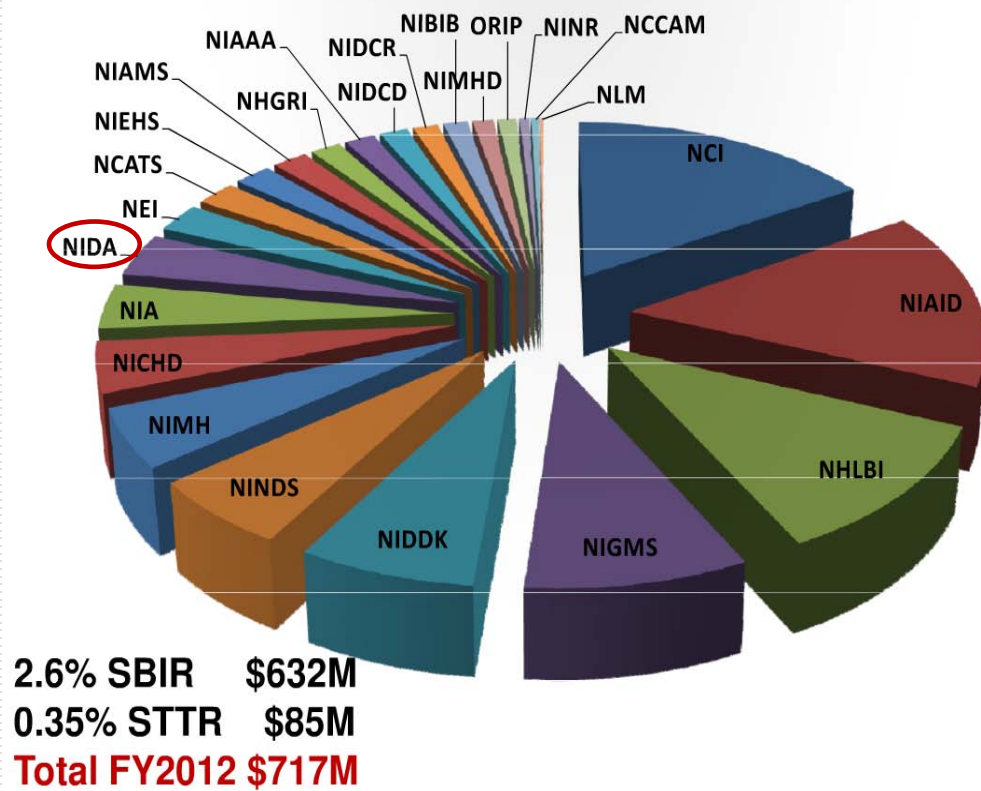
Building an SBIR program for a niche market

Elena Koustova, PhD, MBA
SBIR/STTR Coordinator

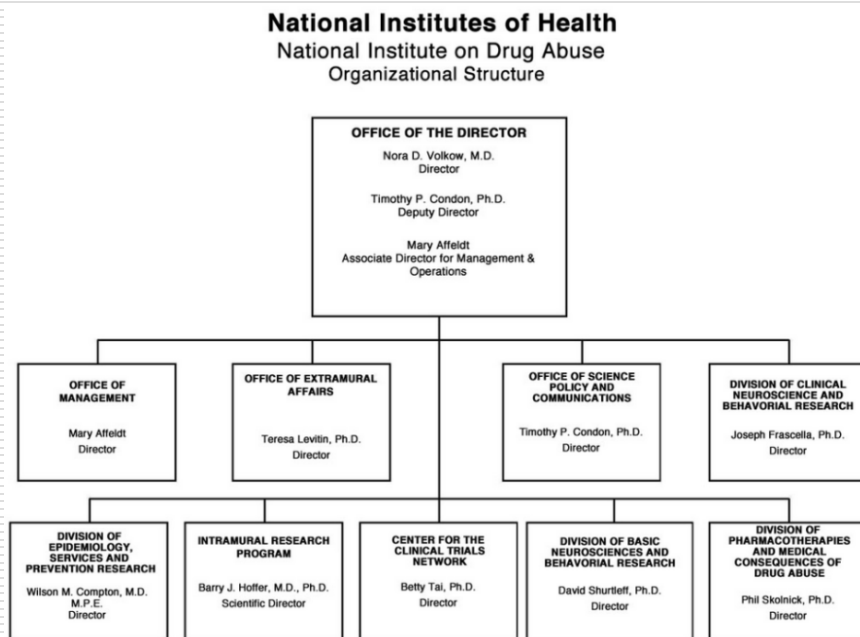


NIDA's SBIR Program Positioning

- \$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)
- Limited number of quality applications
- Absence of dedicated FTEs, SBIR/STTR grants managed by many POs



NIDA SBIR Team



1. Elena Koustova, *DBNBR*
2. 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

- ❖ 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



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

Company Overview
 Symbol: TWI-O (C000075424)

Third Wave Technologies Inc
 Third Wave Technologies -NASNM - TWI-O
 502 South Rosa Road
 Madison, WISCONSIN 53719 USA
<http://www.twi.com>

Exchange: NASNM
 Sector: Health Care
 Industry: Biotechnology

CUSIP: 88428W108
 SEDOL: 2724698

S&P GICS: 35201010
 Biotechnology
 Company Status: Active

Quote
 Last: 11.90
 Change: 0.010
 % Change: 0.089%
 High/Low: 11.210/11.190
 Open: 11.190
 Volume: 406.697
 Currency: USD
 As Of: 1:00:04 PM
 Source: Thomson Financial delayed at least 15 minutes.

View Detailed Quote

Business Description
 Third Wave Technologies, Inc. The Group's principal activities are to develop and market molecular diagnostics for a variety of DNA and RNA analysis applications, providing its clinical, research and agricultural customers with superior molecular solutions. Our products are based on our proprietary Invader chemistry. The Group converts its proprietary Invader(R) molecular chemistry into valuable molecular diagnostic products. These products have applications in genetics and pharmacogenetics, women's health, infectious disease and oncology etc and it has been extended to research, agricultural and other applications also. The Group markets and sells products through a combination of direct sales personnel and through collaborative relationships. Its registered trademarks are Third Wave(R), Cleavase(R), Invader(R), InvaderCreator(R) and Invader Plus(R). The Group has operations in the United States, Japan, Germany, France and the United Kingdom.
 Source: Worldscope

Key Financials

	Y07	Y06	Y05
Sales	31.12	28.03	23.91
Operating Income	-25.96	-18.71	-16.15
Net Income	-16.85	-18.89	-22.35
Total Assets	69.00	64.23	58.40
Total Liabilities	39.20	33.10	18.33
EBITDA	-12.05	-14.45	-18.28

Source: Worldscope - Millions USD

Price Chart
 Third Wave Technologies -NASNM (1.0/2008-7/0/0)
 Interactive Chart
 130.0%
 120.0%
 110.0%
 100.0%
 90.0%
 80.0%
 70.0%
 TWI-O
 Feb Mar Apr May Jun Jul
 USD Source: Datatream

Analyst Rating
 Sell Strong Buy
 Source: First Call

Estimate Revisions
 Estimates Up/Down (Total 7)
 Change in Estimate 0.00%
 Last -0.589
 Current -0.599

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



Company Profile INTRON INC
 Profile Last Updated: 11/21/2007

910 Chopper Road, South Building, Suite 210 Gaithersburg, MD 20878 UNITED STATES
 Phone: 240-683-2450 | Fax: 240-683-2451 | www.intron.com

VL Industry Code: Other Medical Diagnostic Biotechnology (4119)
 SIC Code: Diagnostic substances (2835)

Business Description
 Develops RNA splicing technology to re-program genes. The Company uses a technology, known as SmartIT which has broad applications including gene reprogramming, RNA repair, real-time molecular imaging, and genomics. Intron's technology allows for the effective turning on or off of a gene, as well as the ability to change the output of a gene to achieve a desired therapeutic effect. It can also be used to identify which proteins are involved in the pathology of a specific disease, as well as to develop novel therapeutics to treat that disease.

Key Facts

# of Employees	12
Last Available Sales Figure	0.0 USD Mil (2005)
Company Founded Date	01-Jan-2001
Company Status	Acquisition
Legal Counsel	Hatchison & Mason PLLC
Banking Relationships	State Street Bank
Accountant	PricewaterhouseCoopers
Total Funding to Date	11.5 USD Mil

Historical Sales

Period	Sales (USD Mil)	Source
2005	0.0	n/a
2004	n/a	n/a
2003	0.8	n/a
2002	1.3	n/a
2001	1.6	n/a

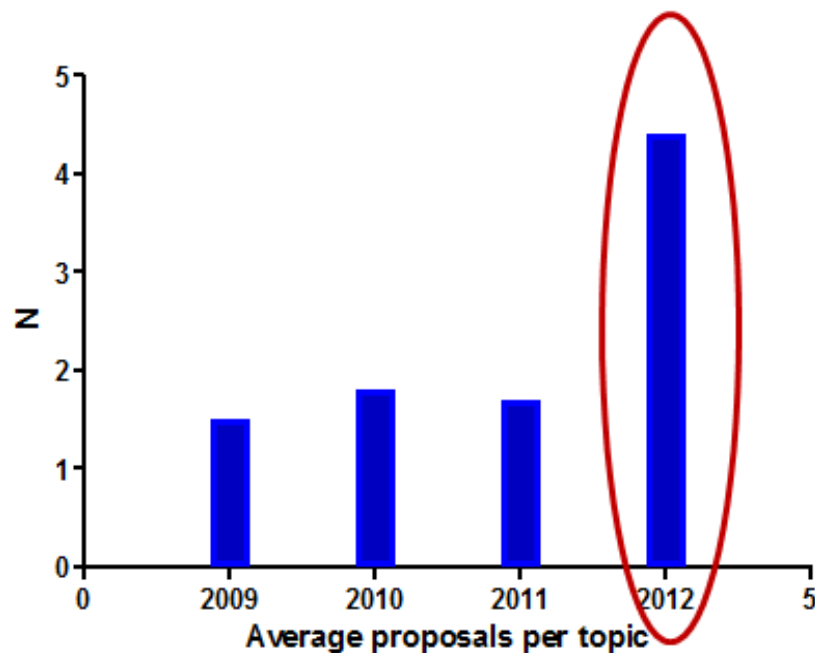
Based on latest 5-year period available

Sales Chart - Last 5 Years

* indicates no data available



Results of implementing new SBIR Contract practices

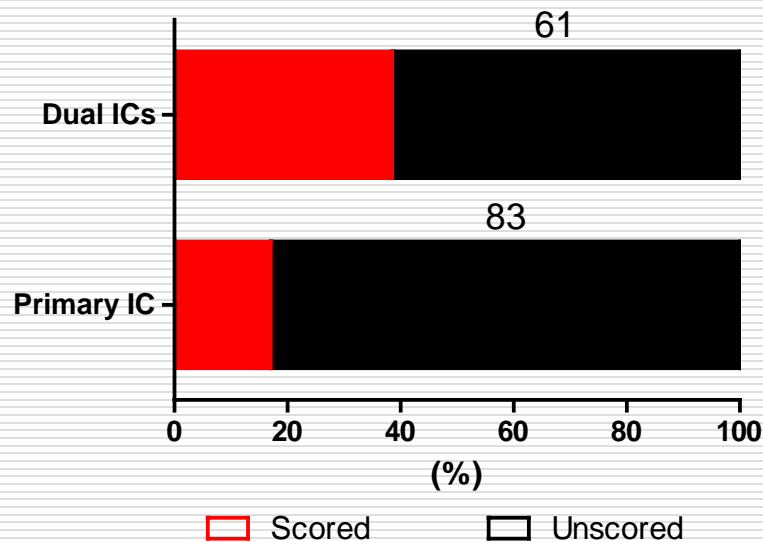


↑
New processes
implemented



“Products for at-home
Deactivation of
Psychoactive
Prescription Medicines”

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum:

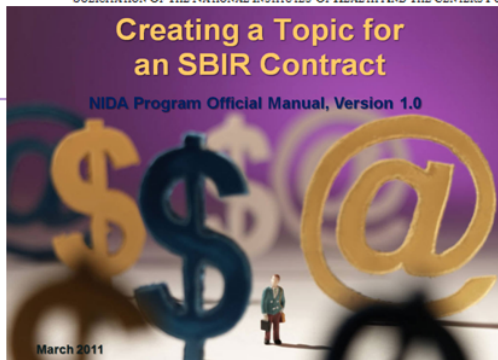
Guidelines for SBIR Contract Topic Preparation, Submission and Approval, National Institute on Drug Abuse

3 March, 2011

1. **Preparation.** Each Divisional SBIR Coordinator is responsible for soliciting the SBIR contract topics, as well as advising and assisting in their preparations. Topics are prepared by Division staff by filling out the SBIR Contract Topic template with the aid of the SBIR Manual, which is maintained and updated by the NIDA SBIR Coordinator.

2. **Submission.** An unlimited number of topics from NIDA Divisions will be accepted for consideration by the NIDA SBIR Coordinating Committee (SBIR CC). Divisional SBIR 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 external review. After external review, SBIR CC will reduce (if needed) the number of remaining topics to 7, so that the most efficient dissemination and oversight of NIDA contract topics can be provided. Each member of the SBIR CC will accept responsibility for one specific 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 Disease Control and Prevention.



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 expedites award decisions and funding of SBIR and STTR. Phase II applications for scientifically meritorious projects that have a **high potential 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 when it is congruent 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

- On scale from 0 to 100, how attractive is the market for your idea? _____
(Consult NIDA SBIR Contract Manual for additional assistance)

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?

For small IC,
how to find the
balance?



Educating Staff on Commercialization Issues

- ❑ Commercialization Assessment Index (CAI)
- ❑ Market Opportunity Analysis (MOA)
- ❑ Strategic Technology Evaluation Program (STEP) Model

18.5 SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS

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:

- **Phase I.** 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.
- **Phase II.** 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 ([see below](#)), 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.
- **Phase III.** 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.



Office of Extramural Research
National Institutes of Health

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Research Teaching Issues

Grants Policy & Guidance

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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.



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