
SMALL BUSINESS PROGRAMS AT THE NATIONAL INSTITUTE ON DRUG ABUSE

Office of Translational Initiatives and
Program Innovation (OTIPI),
Office of Director,
National Institute on Drug Abuse (NIDA)



Elena Koustova, PhD, MBA

DISCLOSURE STATEMENT

- I have no real or apparent relevant financial relationships to disclose
- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to or any organization with which the presenter is employed or affiliated

AN INVESTOR OF FIRST RESORT: THE STATE

3.2%

(FY22)

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D - with potential for commercialization

0.45%

(FY22)

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions - with potential for commercialization

SBIR/STTR FEDERAL AGENCIES



genzyme

CHIRON

affymetrix

biogen idec



COMPAQ

illumina®



23andMe®

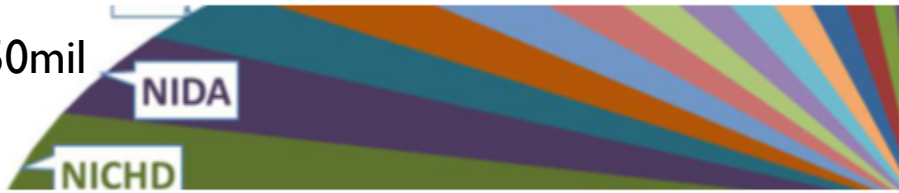
Robot

intel®

QUALCOMM®



>\$50mil



Over \$1.2 bil

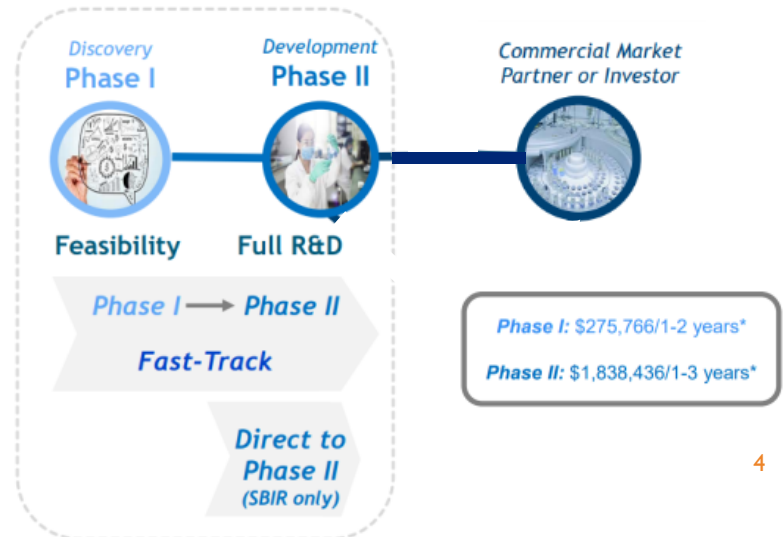
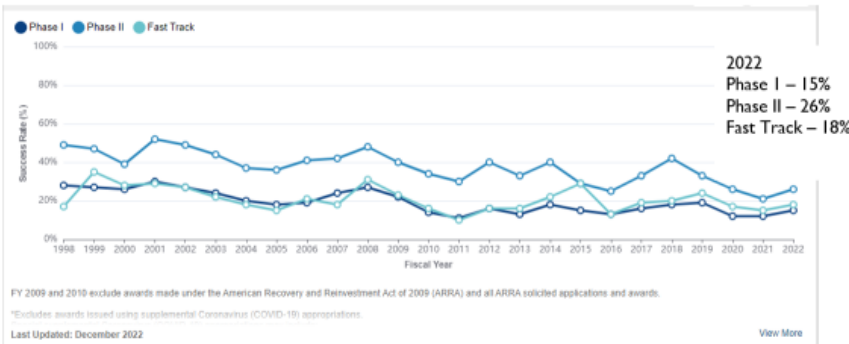


To seek **fundamental knowledge** about the nature and behavior of living systems

The only present way to bring scientific discoveries to the patients is to subject them to business practices and market forces

The **application** of that **knowledge** to enhance health, lengthen life, and reduce illness and disability

SBIR Grants: Success Rates of Competing Applications, by Phase





Award is always made to the small business

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by <u>either</u> the research institution partner or small business

General Grant Omnibus Solicitations

Clinical Trial Not Allowed:

SBIR (PA-22-176) and STTR (PA-22-178)

Clinical Trials Required:

SBIR (PA-22-177) and STTR (PA-22-179)

Targeted Solicitations

- Developing Regulated Therapeutic and Diagnostic Solutions for Patients Affected by Opioid and/or Stimulants use Disorders (OUD/StUD)

SBIR (RFA-DA-23-021) (Clinical trial optional)

Due date: August 25, 2023; February 14, 2024; August 13, 2024; February 14, 2025

Award Budget: Up to \$320,000 for Phase I, and \$2.5 million for Phase II

- Blueprint MedTech: Small Business Translator

SBIR (PAR-21-282) (Clinical trial optional)

Due date: June 20, 2023; October 18, 2023; February 20, 2024; and June 20, 2024 Award Budget: Up to \$320,000 for Phase I, and \$2.5 million for Phase II

- Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System

SBIR (PAR-20-111) (Clinical trial optional)

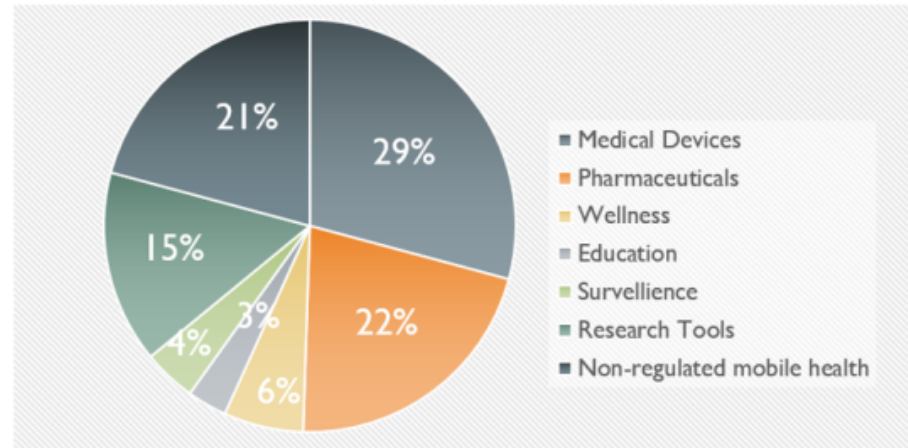
Due date: February 9, 2023.

Award Budget: Up to \$320,000 for Phase I, and \$2.5 million for Phase II

Portfolio Companies - 164

SBIR grants - 156

STTR grants - 36



1R43DA050360-03

Transcutaneous auricular neuro-stimulation for neonatal abstinence syndrome



5R44DA049300-03

Prapela™ SVS: A cost-effective stochastic vibrotactile stimulation device to improve the clinical course of infants with neonatal abstinence syndrome.



Overdose Prevention Strategy

Strategic Priorities



Primary Prevention

focuses on root causes and key predictors of substance use and substance use disorder, and how to safely and effectively manage pain.



Harm Reduction

focuses on reducing risks associated with substance use, including overdose and infectious disease transmission.



Evidence-Based Treatment

focuses on providing the most effective, evidence-based treatments without delay, stigma, or other barriers.



Recovery Support

focuses on funding, reimbursing, training workforces for, and developing protocols around peer, employment, and housing supports.

invistics

S:3 Research

appliedVR

 SOUND
life sciences

BIOBOT Biobot Analytics

Workit Health

SG Sober Grid

Woebot

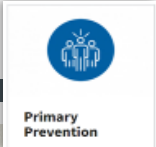
village

emocha
MOBILE HEALTH INC.

 prapela

we the Village

Marigold
HEALTH



Discover RelieVRx

Immersive Therapeutics | About RelieVRx | Clinical Results | Register



RelieVRx—first in a new class of non-pharmacological pain treatment¹⁻⁷

RelieVRx is the first comprehensive, immersive adjunctive VR treatment for chronic pain to ever be FDA-authorized.

RelieVRx promotes neuroplasticity and enables patients to build long-term skills to respond to pain.



Rooted in biopsychosocial pain education¹

RelieVRx is a novel adjunctive pain management program rooted in evidence-based principles for the treatment of patients living with CLBP.



A therapeutic option with fewer trade-offs¹

In clinical studies, RelieVRx use did not trigger any serious AEs, with a manageable side effect profile.



Patient-empowered pain management¹

RelieVRx empowers patients to be active in their own pain management simply and non-pharmacologically. VR treatment is self-administered over **8 weeks** in the comfort of a patient's home with an **average daily session of 7 minutes** duration.

RelieVRx offers a simple user experience at every step of the journey



1. At prescribing

After prescribing RelieVRx and sending the Rx to the Hub, the Hub will ship the device directly to the patient's home with easy-to-follow instructions.



2. Ready to Use

RelieVRx comes ready to use out of the box with preloaded content.



3. Returning the device

Patients will then return the device in the original packaging using the provided prepaid return shipping label.

2019: R44 DA049640-02 Virtual Reality as an Opioid Sparing Intervention for Acute Postoperative Pain Management

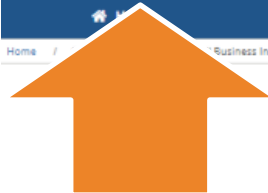
- October 2020: Receives FDA **Breakthrough Device Designation** to Treat Pain with Digital Therapeutic
- November 2021: Receives FDA **De Novo clearance** for treating chronic lower back pain

Indication for Use

RelieVRx is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back-pain (defined as moderate to severe pain lasting longer than three months). The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.

Contraindications

There are no known contraindications.



- Grants and Funding
 - NIDA Funding Opportunities
 - FY22 Priority Research Areas
 - Small Business Innovation Research (SBIR) and Technology Transfer (STTR) Programs
 - About the SBIR/STTR Programs
 - Resources for SBIR/STTR Applicants
 - SBIR/STTR Portfolio
 - Entrepreneurship & Business Programs
 - Contact SBIR/STTR Staff
 - Special Considerations for NIDA Funding Opportunities and Awards
 - NIDA Funding Strategy
 - Trans-NIH Funding Opportunities
 - NIDA Office of Acquisitions Contracting
 - Technology Transfer

Small Business Innovation Research (SBIR) and Technology Transfer (STTR) Programs



The National Institute on Drug Abuse (NIDA) is the lead federal agency for advancing the science on drug use and addiction with the goal of improving public health. Each year, NIDA provides more than \$50 million in awards to small businesses through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

NIDA invites aspiring entrepreneurs, startups, and small businesses to explore the funding opportunities and resources within this website and begin the application process.

<https://nida.nih.gov/funding/small-business-innovation-research-sbir-technology-transfer-sttr-programs>



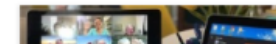
About the SBIR/STTR Programs
Gain an overview of NIDA SBIR/STTR programs and learn about current funding opportunities



Resources for SBIR/STTR Applicants
Access a suite of resources to successfully submit a grant application



SBIR/STTR Funding
Access current small business opportunities from NIDA



nidasbir@mail.nih.gov