

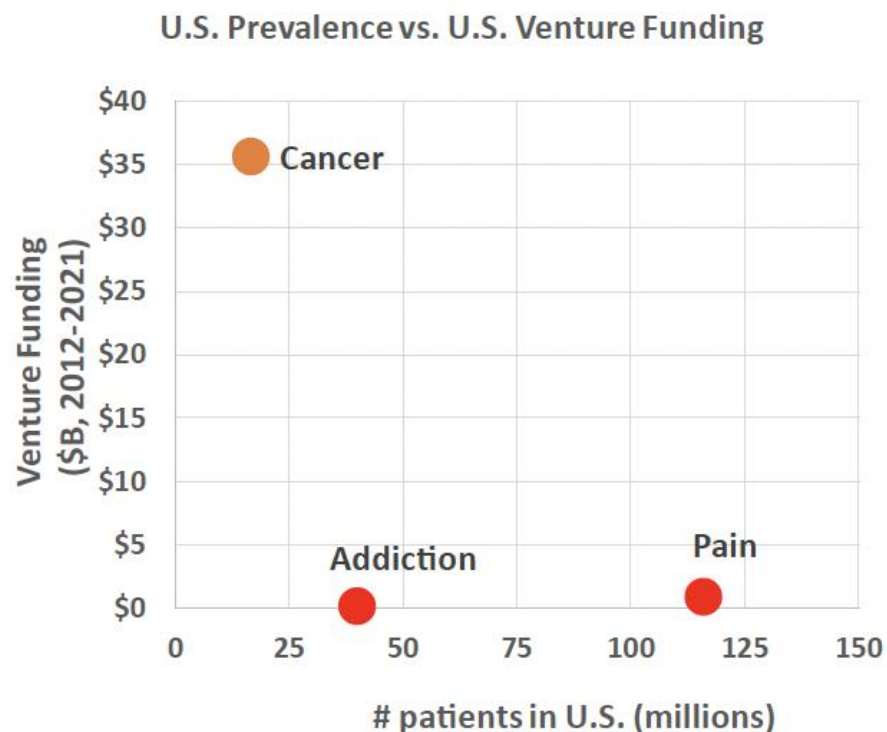
SMALL BUSINESS INNOVATION FOR PAIN

Ana Moreno, PhD

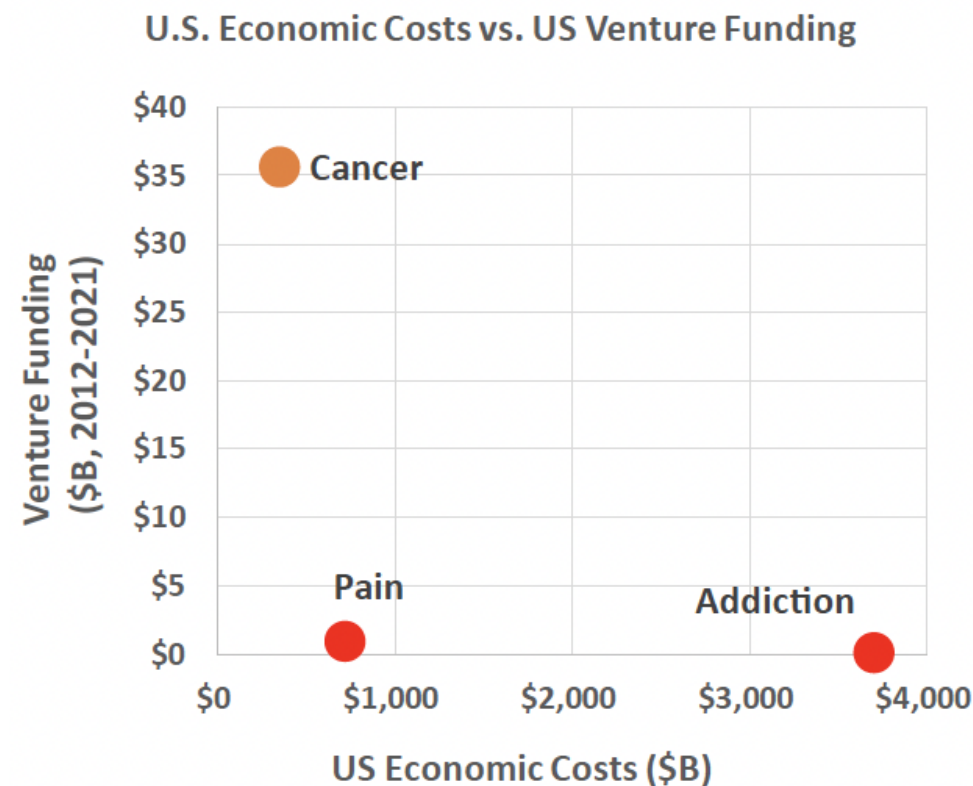
Founder and CEO, Navega Therapeutics

The Current State of Private Investment in Pain

Investment is Lagging in Pain Research



Pain Management Needs Outpace Investment

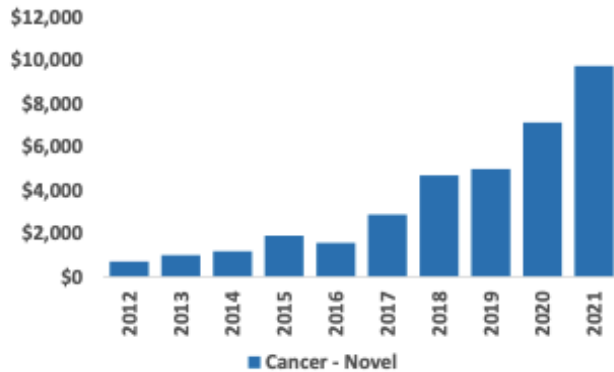


David Thomas and Chad Wessel, "State of Innovation in Pain and Addiction", 2023 BIO

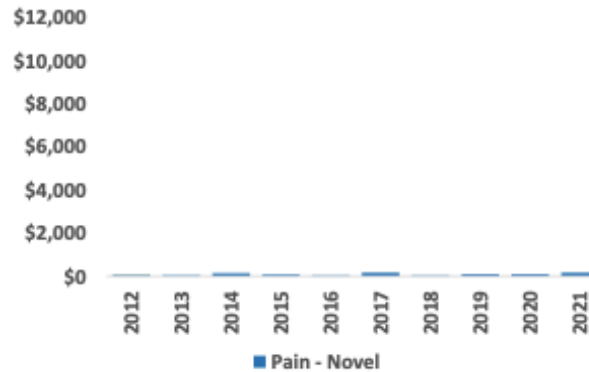
Investment Disparity: 41 times more funding for oncology

Venture Investment into US Companies 2012-2021 With Lead Programs in Pain vs. Oncology

Venture Investment into US Companies
with Lead Program in Cancer



Venture Investment into US Companies
with Lead Program in Pain

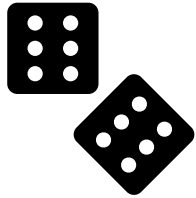


Lack of Growth Trend in Pain vs. Oncology: investment in novel pain drugs showed no clear growth trend, with most years below \$200 million, while investment in novel oncology drug development rose steadily from below \$1 billion in 2012 to approximately \$10 billion in 2021.

Focus on Reformulation: 48% funding directed toward reformulated or repurposed pain drugs, limiting innovation in new pain therapies.

Fewer Financed Pain Companies: On average, only 11 companies with lead pain drugs were financed each year, compared to 109 oncology companies.

Challenges for Finding Private Funding in Pain



High
Development
Risk

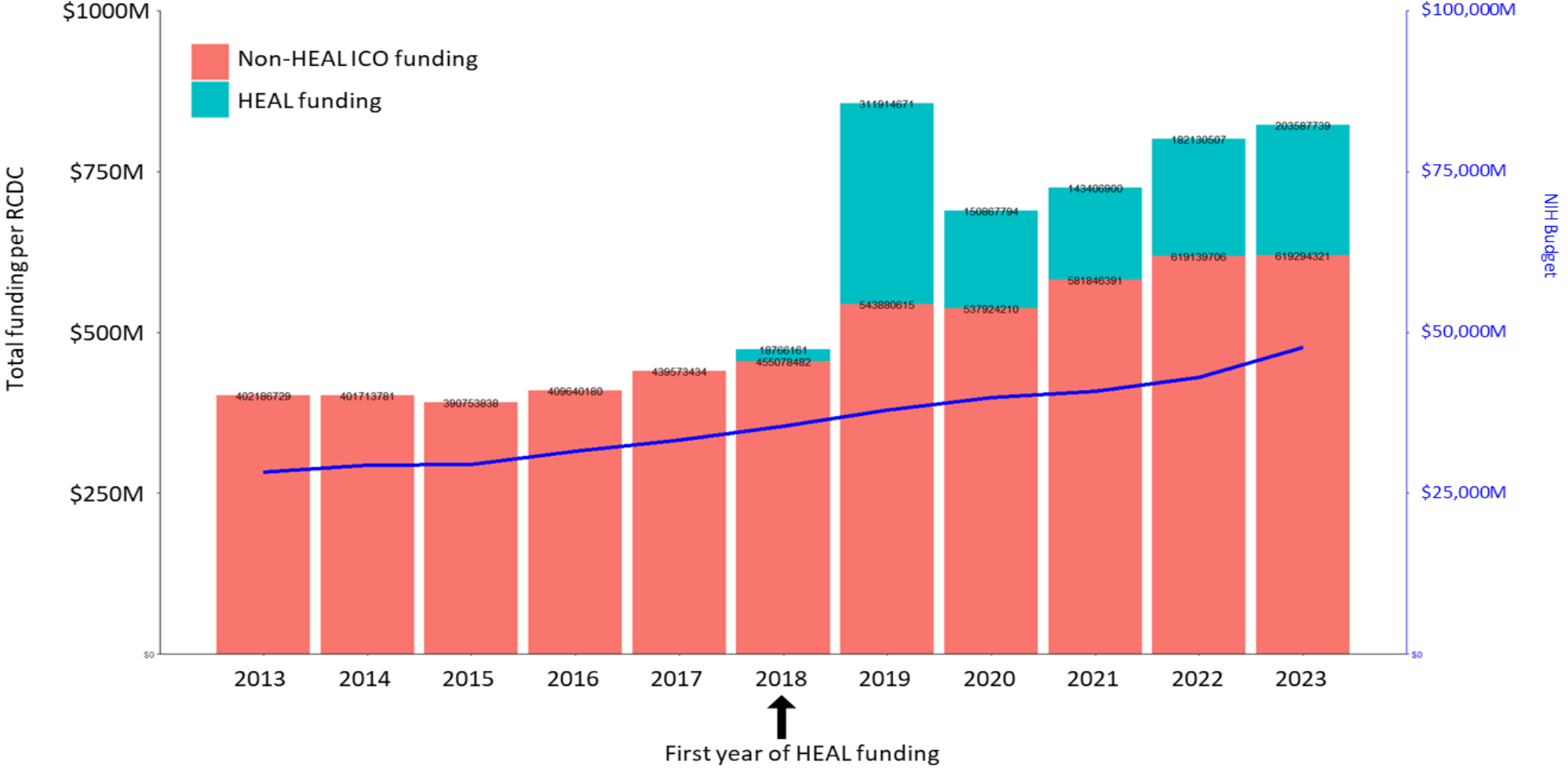


Regulatory
Barriers



Market
Uncertainty

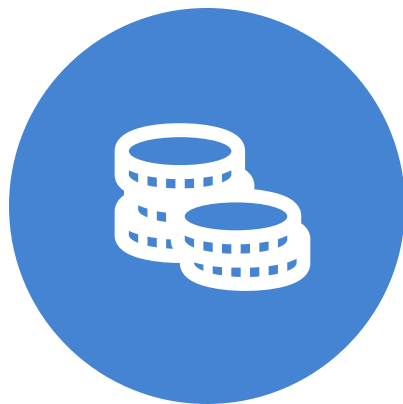
HEAL has helped increase funding in pain



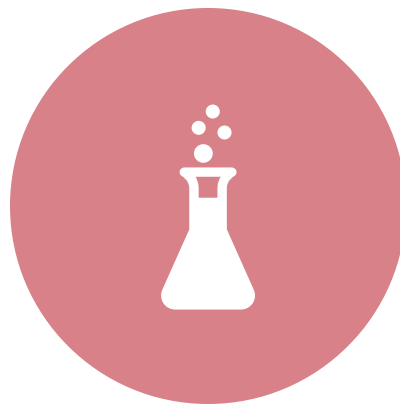
A person in a red jacket is walking across a suspension bridge that spans a deep, forested valley. The bridge has a wooden deck and metal railings. The surrounding landscape is filled with dense evergreen trees, and the scene is shrouded in a light mist or fog. The perspective is from the bridge, looking down the length of it towards the person in the distance.

HOW DO WE BRIDGE THE GAP?

Challenges for Small Businesses



**LIMITED IN-HOUSE EXPERTISE IN
KEY DEVELOPMENT AREAS**



**TRANSLATIONAL SCIENCE
SUPPORT**



**DIFFICULTY IN ATTRACTING
INVESTMENT AND PARTNERSHIPS
WITH EARLY-STAGE PAIN ASSETS**

Area 1: Limited in-house expertise

Rationale:

- Small biotech and pharma startups often operate with limited staff and budget, making it challenging to manage all aspects of drug development.
- **NIH Consultant Network:** Establish a network of consultants with expertise in CMC, regulatory strategy, clinical trial design, and preclinical data analysis. Small businesses could apply for a set number of consulting hours based on project needs.
- **On-Demand Access to Regulatory and CMC Experts:** NIH could offer “office hours” with experts in CMC and regulatory pathways, where companies can ask questions, review materials, and get real-time guidance tailored to their program.
- **Guidance for IND and Clinical Protocol Development:** Provide specialized NIH consulting support to help small businesses with IND filings, clinical protocol design, and statistical analysis plans, ensuring alignment with FDA expectations.
- **Dedicated Supplements for Key Hires:** NIH could provide supplemental funding through SBIR/STTR programs to support key hires in business development, finance, and commercialization, essential for attracting investment and advancing commercialization.

Area 2: Translational Science Support

Rationale:

- Translational science support helps small businesses bridge the gap from early research to clinical trials, overcoming resource limitations, regulatory complexities, and challenges related to investor risk tolerance.
- **Funding for Large Animal Pharmacology and Toxicology Studies:** Support preclinical studies in large animal models to help small businesses generate the safety and efficacy data required for regulatory submissions, which are often prohibitively expensive.
- **CMC (Chemistry, Manufacturing, and Controls) Development Assistance:** Provide resources or grants to support CMC development, ensuring that small businesses can establish scalable and regulatory-compliant manufacturing processes early in the development cycle.
- **NIH Core Services:** Fund research using iPSC-derived models, primary tissue, or other innovative preclinical models to validate targets and mechanisms in human-relevant systems, reducing the risk of clinical trial failures.

Area 3: Clinical Trial Support for Novel Pain Targets or Modalities

Rationale:

- Investors and pharma partners often reluctant to fund clinical trials for new or less-established targets or modalities due to perceived risks and uncertainties in regulatory and commercial outcomes.
- **Trial Design and Regulatory Support:** Offer NIH resources to help small businesses design clinical trials that meet regulatory standards and include endpoints aligned with FDA guidance.
- **Dedicated Phase 2 Funding Mechanisms:** Establish funding streams specifically for Phase 2 trials on novel pain targets or modalities.
- **Public-Private Co-Funding Partnerships:** NIH could create co-funding programs in collaboration with private investors or larger companies, where early positive data could unlock additional funding from private sources.

THANK YOU

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