

Developing a Competitive Phase II Small Business Grant Application



OSBR: SBIR & Extramural Career Development



Todd Haim

Chief



M-D Kerns

HSA



Maria Carranza

HSA



Saroj Regmi

HSA



Armineh Ghazarian

Program Analyst



Joy Toliver

Program Analyst



Don Rose

EIR



NIA Office of Small Business Research: Core Activities

Central Coordination



Administer all SBIR/STTR awards at NIA

Guidance



Help applicants prepare for application/resubmission, and discuss funding options

Outreach



Attend conference/workshops and visit regional organizations to raise awareness of the program

Funding



Seed emerging technology areas by developing targeted funding opportunities and Omnibus interest topics

Networking



Facilitate connections between awardees and potential strategic partners (NIA programs/external partners)

Entrepreneurship

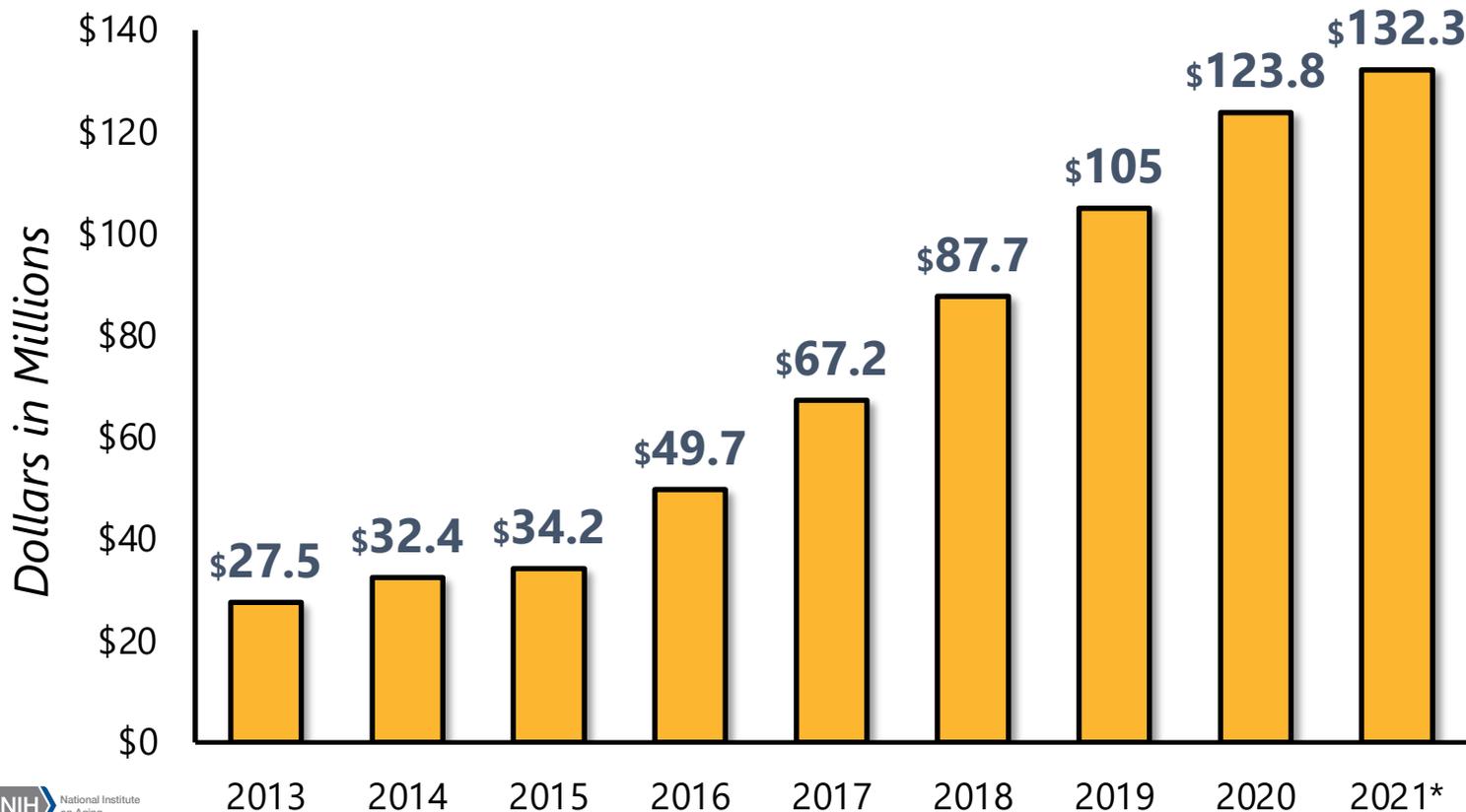


Provide entrepreneurship training as well as webinars on key commercialization-related topics

**Stakeholder
Engagement for
Cross- Leverage:
ADDF SBIR Bridge
Funding and
Longevity Innovation
Summits**



Budget Obligations for 2021



SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	<ul style="list-style-type: none"> • Up to 1 year • Awards up to \$300,000, or up to \$500,000 for AD/ADRD • Establish technical merit, feasibility, and potential for commercialization
Phase II	Development & Full R&D	<ul style="list-style-type: none"> • 2 years • Awards up to \$2 million, or up to \$2.5 million for AD/ADRD • Continues Phase I R&D efforts • Requires a commercialization plan
Fast Track		<ul style="list-style-type: none"> • One combined application for Phases I and II
Direct-to-Phase II (SBIR only)		<ul style="list-style-type: none"> • Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		<ul style="list-style-type: none"> • Funding for late-stage R&D and technical assistance for commercialization
Phase IIB	Competing Renewal	<ul style="list-style-type: none"> • 3 years • Awards up to \$3 million



NIA Funding Opportunities

	Omnibus FOAs	AD/ADRD-Focused FOAs
SBIR	<p><u>PA-20-260</u> (clinical trial not allowed) <u>PA-20-262</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p><u>PAS-19-316</u> (Advancing Research on AD/ADRD) <i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p> <p><u>PAR-18-512</u> (Lifespan/healthspan-extending Interventions for AD/ADRD patients) <i>Budget limits: Phase I \$350,000; Phase II \$2 million</i></p>
STTR	<p><u>PA-20-265</u> (clinical trial not allowed) <u>PA-20-261</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p><u>PAS-19-317</u> (Advancing Research on AD/ADRD) <i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p> <p><u>PAR-18-514</u> (Lifespan/Healthspan Extending Interventions for AD/ADRD Patients) <i>Budget limits: Phase I \$350,000; Phase II \$2 million</i></p>



Already have a Phase II? Consider the Commercialization Readiness Pilot (CRP) Program

- Can be simultaneous or follow-on to Phase II and Phase IIB (both SBIR and STTR).
- SB1 mechanism enables an absence of subcontracting restriction. The subcontracting plan must still be justified in the application.
- Special review criteria include a focus on “innovation” of the product.
- Provides funding for activities that are not typically supported by research grants.



NIA Funding Opportunities (Continued)

Commercial Readiness Pilot (CRP) Program	Budget Limits
<u>PAR-20-128</u> (CRP Technical Assistance; clinical trial not allowed)	\$300,000
<u>PAR-20-129</u> (CRP Technical Assistance and Late Stage Development; clinical trial not allowed)	\$1.75 million/year for 2 years (\$3.3 million total)
<u>PAR-20-130</u> (CRP Technical Assistance and Late Stage Development; clinical trial required)	\$1.75 million/year for 2 years (\$3.3 million total)
Supplements & NIA Participating Initiatives	Budget Limits
<u>PA-18-837</u> (Administrative Supplements to Promote Diversity in Research and Development Small Business; clinical trial not allowed)	\$250,000 in direct costs
<u>PA-18-705</u> (SBIR Technology Transfer; clinical trial not allowed)	Phase I \$300,000; Phase II \$2 million

We also participate in additional funding opportunities that can be found here: www.nia.nih.gov/research/osbr/nia-small-business-funding-opportunities



Budget Specifics

TOTAL COST BUDGETS

- SBIR budgets are defined by **total cost**, and subcontracting is limited. Know the rules and the criteria.
- Check budget allowance in each funding opportunity.

- **Can request a 7% fee:**
 - Company profit.
 - Part of total budget.

- **Fee for service: CRO-type activities can count as small business costs, providing that:**
 - 1) It is a commercially available service.
 - 2) All analysis is done by the small business.
 - 3) It is a fee per basis (no indirect costs by fee for service providers).



Technical Assistance

- **Purpose:** Help small businesses make better technical decisions, solve technical problems, minimize technical risks, and develop and commercialize new products and processes
- **Examples:**
 - Technology expertise
 - Product sales expertise
 - IP protections expertise
 - Market research and validation
 - Development of regulatory plans
 - Development of manufacturing plans
 - Technical and business literature
- **If requested,** business cannot participate in NIH Technical Assistance Programs (Commercialization Accelerator Program, Niche Assessment Program)

Request within the Application:

- F. Other Direct Costs, lines 8–10
- Label as “Technical Assistance”

Budget Allowance:

- Phase I up to \$6,500 per year
- Phase II cap of \$50,000





Developing the Commercialization Plan

Commercialization Plan: *nuts and bolts*



- Required for all Phase II proposals
- Phase I follow-on, Direct to Phase II and Fast Track
- Maximum of 12 pages
- Instructions in SF424 Application Guide (p. B-108)
(<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/sbir-sttr-forms-f.pdf>)
- Read the Funding Opportunity Announcement for the program for additional requirements



Developing the Commercialization Plan

- SBIR grants are meant to support research projects on commercially viable Products
- The Commercialization Plan (CP) should be based on a company's Business Plan
- Goal of the CP is to convince reviewers that:
 - Product meets a compelling need
 - You know how to develop and commercialize the Product
 - You have, or can access, the requisite expertise and resources



Think about the 5 Cs (HBS)

1. Customer Needs: What needs do we seek to satisfy?
2. Company Skills: What special competence do we possess to meet those needs?
3. Competition: Who competes with us in meeting those needs?
4. Collaborators: Who should we enlist to help us and how do we motivate them?
5. Context: What cultural, tech and legal factors limit what is possible?



Impact on the Overall Application

- Commercialization Plan contributes primarily to “Significance” score of proposal
- Potential to lead to marketable product that will have beneficial impact in field of use: **Changing the _____ paradigm**
- Scoring criteria may change with funding opportunity
- Talk to program officers
- Does **NOT** Replace the Research Strategy
- Commercialization Plan can also impact the four other review criterion scores: Innovation, Team, Approach, and Environment



7 components of the Commercialization Plan

- I. Value of Project, Expected Outcomes & Impact
- II. Company
- III. Market, Customer & Competition
- IV. Intellectual Property (IP) Protection
- V. Finance Plan
- VI. Production & Marketing Plan
- VII. Revenue Stream



I. Value of Project, Expected Outcomes & Impact

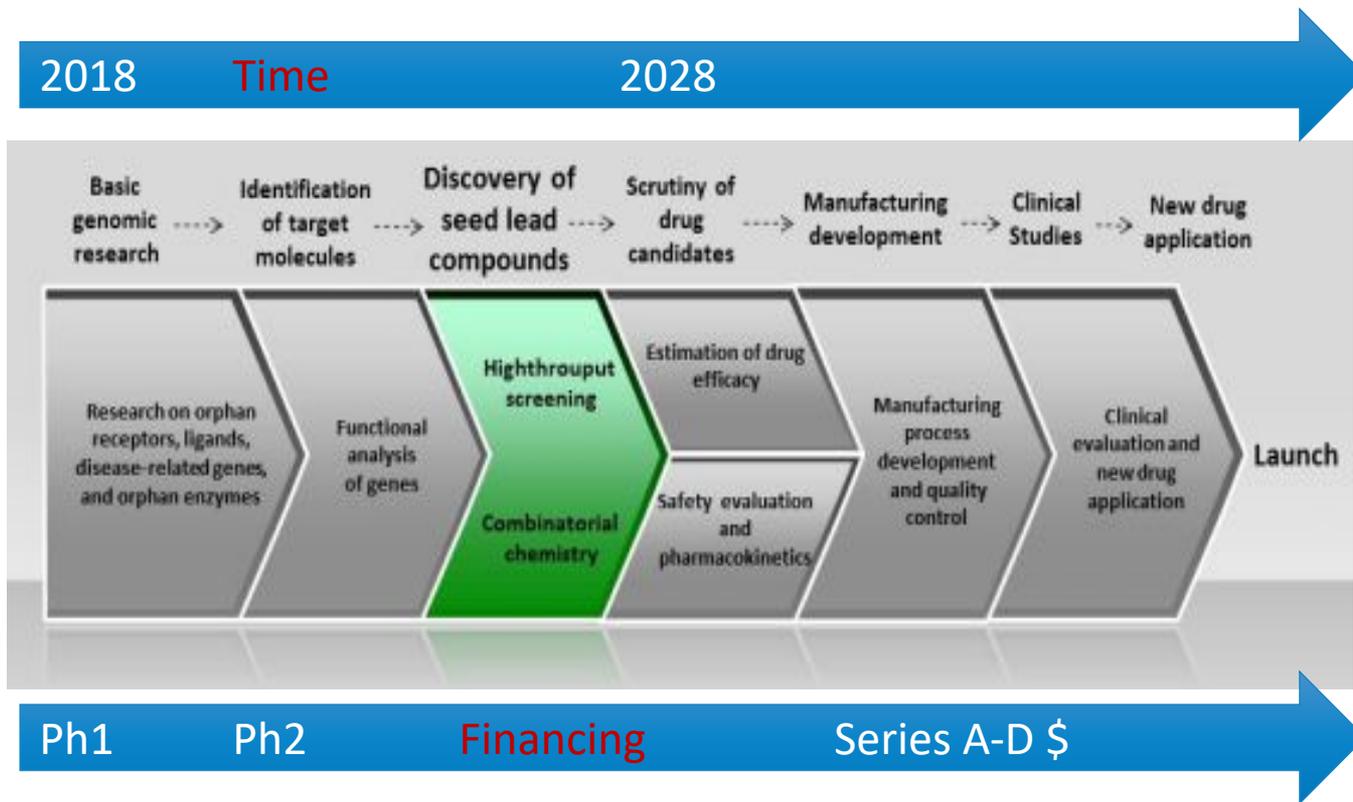
Describe the relative value of the Product (the value proposition) and how you intend to bring it to market

- What need are you trying to address? Quantitative ways your product uniquely addresses such need?
- How does the Product fit with your overall business goal(s)?
- What hurdles will you encounter?
- How do you plan to address hurdles and achieve your goals?



I. Value of Project, Expected Outcomes & Impact

Outline the Product development plan, including key milestones and a timeline – Gantt Chart



I. Value of Project, Expected Outcomes & Impact

- How will you advance the Product to the **market**?
- Describe the **regulatory** pathway
 - Device, pharmaceutical, diagnostic

Demonstrate an understanding of development pathway even if you don't plan to take it all the way to market



II. Company

- Core Competencies
 - What are your (unique) capabilities?
- Team (Beyond the project team)
 - Leadership, Boards & staff
 - Advisers & consultants
- Corporate Objectives
 - What do you want to be when you grow up?
 - Transition from R&D company to commercial entity
 - Describe funds received to date and what you've done with them

Articulate a clear vision for your company



III. Market, Customers and Competition

Expected Benefits Vary with Product Type

Does product:

- **Supplement** or augment existing Dx or Tx approach?
- **Replace** an existing Dx or Tx approach?
- Diagnose or treat a **previously undiagnosed or untreated** condition?



III. Market, Customers and Competition

Estimating Sales Revenues:

Calculate forward:

- Number of patients with specific Dx or Tx need
- Does product address entire segment or a subset? (the “Addressable Market”)
- Assume a “reasonable” time-dependent rate of market penetration (the “Accessible Market”)
- Estimate price: Use current cost per year to diagnose or treat patients as a basis

Revenues = Accessible Market x Price



III. Market, Customers and Competition

Illustrative Example

- ~540K knee & 230K hip replacements in US per yr
- Estimate cost of perioperative Tx with Factor Xa inhibitor (e.g., rivaroxaban) to be \$500
- Addressable U.S. Market = 770K x \$500 = \$385M
- Assume initial market share of 5% - 25%
 - Accessible U.S. Market \approx \$20 – \$100M



III. Market, Customers and Competition

Estimating Product Sales Revenues:

Calculate backward:

- What products are on the market **and** in development for the targeted indication?
- What are sales for the marketed products?
- Which products, if any, will new product displace?
 - Relative benefits & drawbacks
- Use empirical data to make case for anticipated price & market penetration of new product



III. Market, Customers and Competition

Customers: Patients, Physicians, Payers

Patients ↔ Disease Indication

- What are the **stages** of disease & how are they diagnosed and treated?
 - **Standard-of-care**
- How **many** patients have the disease? (% in each stage)
- Do patients have special **characteristics** (e.g., age; co-morbidities)?
- What are the diagnostic (Dx) & treatment (Tx) **needs**?



III. Market, Customers and Competition

Customers: Patients, Physicians, Payers

- What **specialists** diagnose & treat the disease?
 - How do they make money?
- **Where** is disease diagnosed, monitored & treated?
 - Office, hospital, clinic, home
- Who **buys** the product?
 - Patient, clinic, physician
- Is product covered by **insurance**?
 - CMS, private insurers



III. Market, Customers and Competition

Proper market evaluation requires a solid understanding of competitive landscape

- Strengths & weaknesses of **marketed, investigational, and preclinical** compounds/technologies
 - Publications; databases; conversations; surveys
- Clinical development or regulatory hurdles for investigational products
- Patent expiries for marketed & investigational products. Launch date & patent expiry of new product.

What value are competitors not capturing?



III. Market, Customers and Competition

Competitive Advantage

	Important Benefit V	Important Benefit X	Important Benefit Y	Important Benefit Z
Our Product	++++	+	+++	++++
Current Competitors	*		**	**
Upcoming Competitors	**	*	***	***



III. Market, Customers and Competition

Research Tools – Primary

- Conversations/interviews with physicians, especially key opinion leaders
 - What is the current clinical management paradigm?
 - What are the greatest Dx & Tx needs?
- Conversations with patients
 - 1-on-1
 - Blogs
- Customized market research studies
 - **Needs Assessment Program** Reports
 - Patient and/or physician panels



III. Market, Customers and Competition

Research Tools – Secondary

- Company press releases
- Patent databases
- www.uspto.gov; www.wipo.int
- Market research databases & consultancies (\$)
- Clinical trials databases and FDA approvals
- Trade Journals
- Scientific and Medical Literature
- Disease Advocacy Groups



IV. Intellectual Property Protection

- Patents for most biomedical products but trade secrets and copyrights may be more relevant for some products
- List patents covering Product and describe the claims
- Who owns the patents?
 - If not Company, describe rights to practice the patents
- How will you protect Project-related inventions?
- How will you expand patent coverage after Project period?
- Other options for commercial exclusivity? e.g.,
 - Regulatory exclusivity
 - Exclusive supply agreements

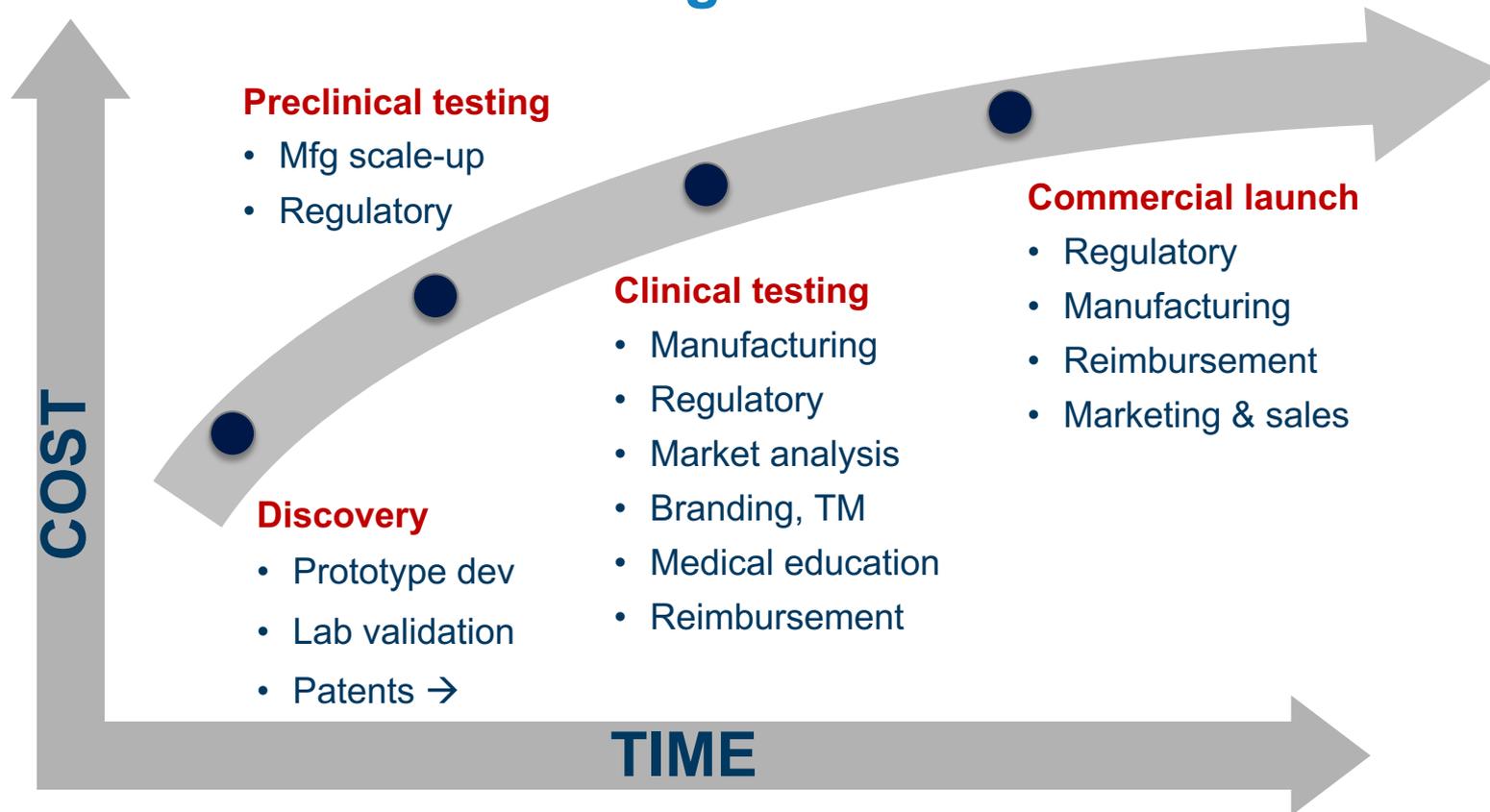


V. Finance Plan

- How much funding will be needed to develop the Product?
 - Key development milestones – tie to Gantt chart
 - Cost to achieve milestones
- How do you plan to secure the required funding?
 - Be as specific as possible
 - Describe discussions with potential investors and partners
- **Include letters of support, where appropriate**



VI. Production and Marketing Plan



VI. Production and Marketing Plan

Resources: Consider and describe

- In-house talent
- Academic collaborators
- Consultants
- Contract research, development & manufacturing
- Strategic partners
- Promotional partners

Include letters of support from key collaborators and partners



VI. Production and Marketing Plan

External Path: Licensing & Partnering

- Grant another party rights to develop/make/sell Product in return for payments
- Gain access to partner expertise
- Partnerships run the gamut:
 - Hand off to partner and collect check
 - Co-development
 - Co-promotion



VI. Production and Marketing Plan

Internal Path: In-house development, marketing & sales

- Higher revenues but costs also high
 - What will net profit be?
- Where will you get money to do all the development and other pre-launch work?
- Will still need to outsource some activities (e.g., manufacturing)
- Need to recruit commercial talent
 - Consider core competencies



VII. Revenue Stream

- How will you (or licensor) generate revenues if the project is successful?
 - Includes direct sales, contracting revenues, licensing revenues, and joint ventures
- Revenue stream projections should correlate closely with all other commercialization plan sections
- Demonstrate that you understand staffing requirements and expansion needed to obtain projected revenues



If You Weren't Funded on the First Try

Rejection is painful, but feedback provides a roadmap for next steps.

- **Carefully review the Summary Statement (written critiques).**
 - Discuss the Summary Statement with your NIH Program Officer.
 - Use reviewer comments to improve your application.
- **Revise and resubmit the application.**
 - Introduction Page: Respond to reviewer critiques.
 - Be constructive, NOT defensive.
 - Success rate for resubmissions is **26.3%** compared to **12.5%** for non-resubmissions in FY20 thus far*
- **Learn more about SBIR/STTR grants.**
 - Talk to successful applicants.
 - Understand the review process and dynamics: <http://csr.nih.gov>



Application Resources

- Small Business Resources:
 - NIA [Sample Application](#) and [Summary Statement](#) (More coming soon)
 - [Sample SBIR Grant Applications from NIAID](#)
 - [Office of Small Business Research, National Institute on Aging](#)
 - [Commercialization Plan Outline](#)
- Database of NIH-Supported Research: [NIH RePORTER](#)
- NIA-Supported Animal Model Resources:
 - [Alzheimer's Disease Preclinical Efficacy Database](#) (models, agents, and markers)
 - [MODEL-AD Consortium](#) focused on developing next-generation animal models for Alzheimer's



Connect with NIA

 Visit nia.nih.gov/sbir

 Follow us on Twitter: [@NIA_SBIR](https://twitter.com/NIA_SBIR)

 View [upcoming events](#) and [funding opportunities](#)

 Join our [mailing list](#)

 Questions? Email: NIAsmallbusiness@mail.nih.gov



A woman with short white hair is riding a bicycle away from the camera on a gravel path. She is wearing a red dress with white polka dots. The background shows a large body of water, possibly a lake or bay, with some buildings and hills in the distance. The entire image has a blue color overlay.

Thank you

