

# Go for the Gold: Path to a Fundable Fast-Track Or Direct-to-Phase II



National Institute  
on Aging

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# Panelists



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# 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
- Maximum of 12 pages
- Required for Fast-track, Phase II Competing Continuations, Direct-to-Phase II and Phase IIB applications
- 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>)

# 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

# Seven 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

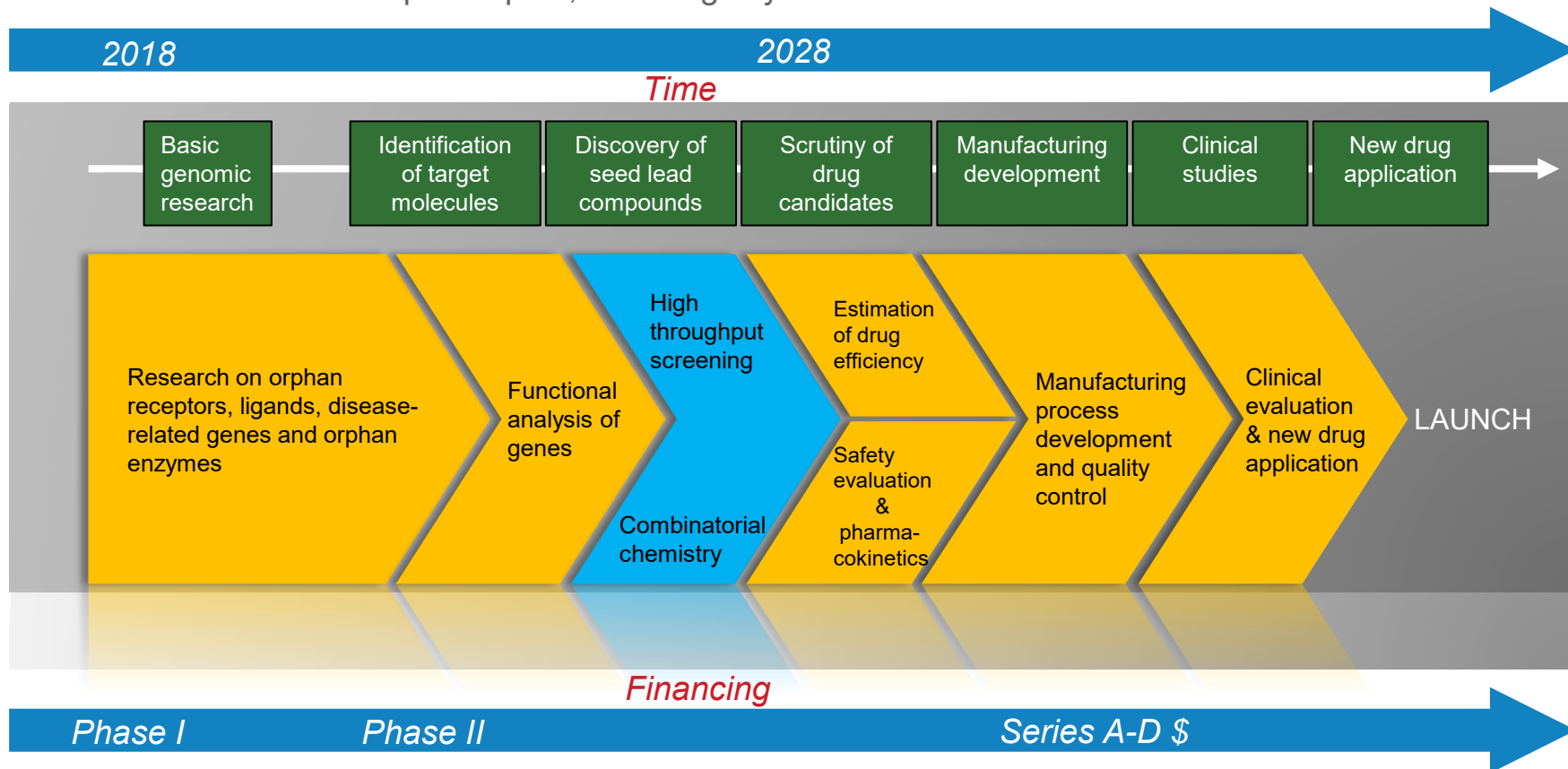
# I. Value of Project, Expected Outcomes & Impact

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: Plan

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



## 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: Revenues

#### 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: Questions

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: Benefits

#### Competitive Advantage

	Important Benefit 1	Important Benefit 2	Important Benefit 3	Important Benefit 4
Our Product	++++	+	+++	++++
Current Competitors	*		**	**
Upcoming Competitors	**	*	***	***

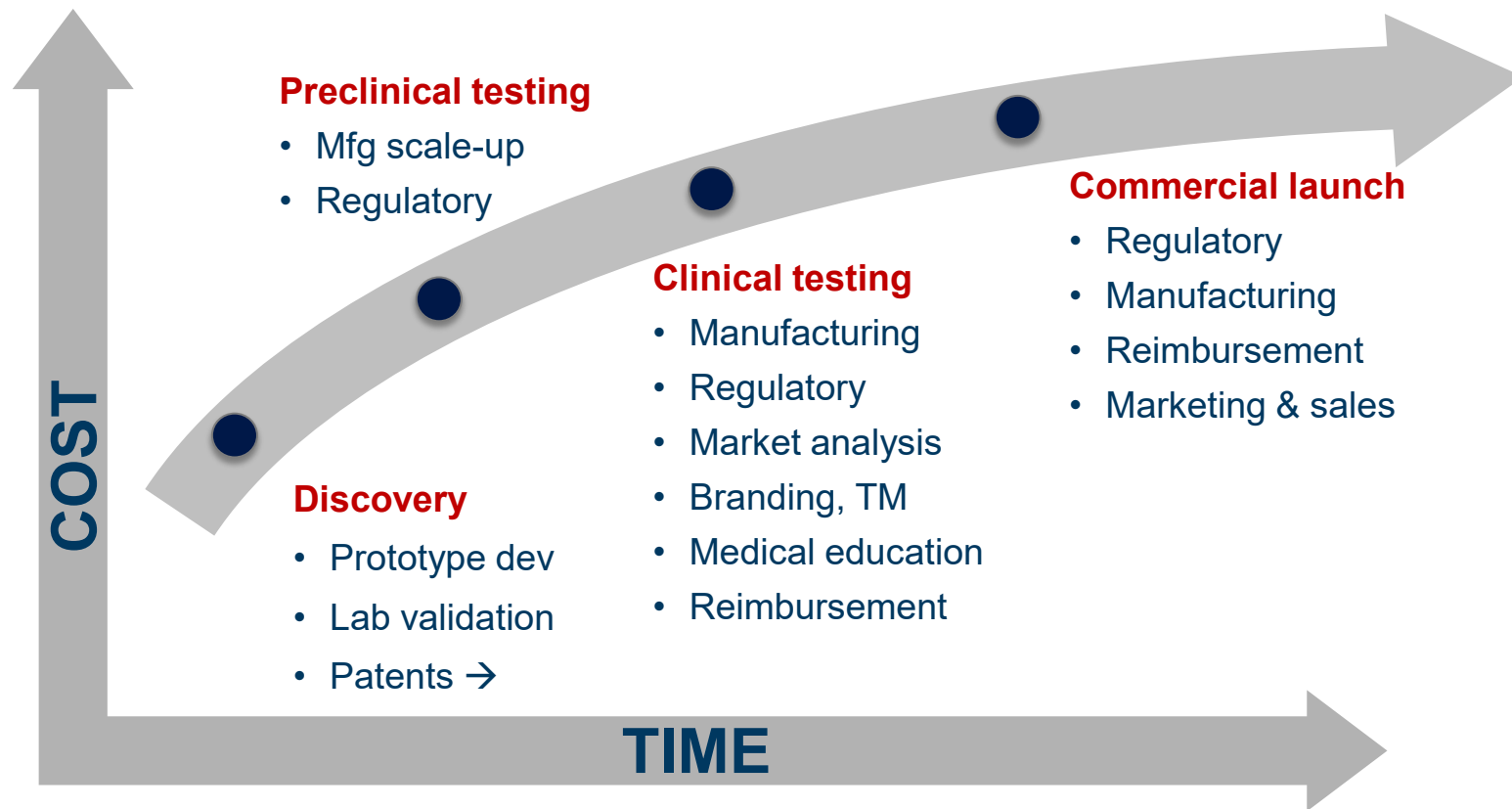
## IV. Intellectual Property Protection

- 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



## 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>



\*As of 4/23/20



# Application Resources

- Small Business Resources:
  - Sample Applications:
    - [NIA](#)    [NCI](#)    [NIAID](#)
    - [Commercialization Plan Outline \(NIDA\)](#)
    - [Application Infographic](#)
    - [SBIR/STTR Application Guide & Annotated Forms](#)
- [NIH RePORTER](#): Database of NIH-Supported Research
- [NIH Success Stories](#)
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# Questions & Discussions



# Commercialization Plan – Business Model Canvas

<p>Key Partners</p> 	<p>Key Activities</p> 	<p>Value Propositions</p> 	<p>Customer Relationships</p> 	<p>Customer Segments</p> 
	<p>Key Resources</p> 		<p>Channels</p> 	
<p>Cost Structure</p> 			<p>Revenue Streams</p> 