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

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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

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

<table>
<thead>
<tr>
<th>2018</th>
<th>2028</th>
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<tbody>
<tr>
<td><strong>Time</strong></td>
<td></td>
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<tr>
<td>Basic genomic research</td>
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<td>Identification of target molecules</td>
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<td>Discovery of seed lead compounds</td>
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<td>Scrutiny of drug candidates</td>
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<td>Manufacturing development</td>
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<td>Clinical studies</td>
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<td>New drug application</td>
<td>LAUNCH</td>
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- Research on orphan receptors, ligands, disease-related genes and orphan enzymes
- Functional analysis of genes
- Combinatorial chemistry
- High throughput screening
- Estimation of drug efficiency
- Safety evaluation & pharmacokinetics
- Manufacturing process development and quality control
- Clinical evaluation & new drug application

**Financing**

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Series A-D $</th>
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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

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<thead>
<tr>
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<th>Important Benefit 1</th>
<th>Important Benefit 2</th>
<th>Important Benefit 3</th>
<th>Important Benefit 4</th>
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<tbody>
<tr>
<td><strong>Our Product</strong></td>
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<td><strong>Current Competitors</strong></td>
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<tr>
<td><strong>Upcoming Competitors</strong></td>
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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

Preclinical testing
- Mfg scale-up
- Regulatory

Clinical testing
- Manufacturing
- Regulatory
- Market analysis
- Branding, TM
- Medical education
- Reimbursement

Discovery
- Prototype dev
- Lab validation
- Patents →

Commercial launch
- Regulatory
- Manufacturing
- Reimbursement
- Marketing & sales
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](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
- IC SBIR/STTR Contacts
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Questions & Discussions

NIH National Institute on Aging
NIH NATIONAL CANCER INSTITUTE
NIH National Heart, Lung, and Blood Institute
<table>
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<th>Key Partners</th>
<th>Key Activities</th>
<th>Value Propositions</th>
<th>Customer Relationships</th>
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<td>Key Resources</td>
<td>Channels</td>
<td>Cost Structure</td>
<td>Revenue Streams</td>
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**Commercialization Plan – Business Model Canvas**