Writing Your Phase II SBIR Commercialization Plan

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Objectives

- Outline of Phase II SBIR Commercialization Plan
- Communicating the Value Proposition of the product or service ("Product")
- Analyzing the market & competition
- Estimating Product revenues
- Describing Product development & fundraising plans
- Explaining the “go-to-market” strategy
Overview

- SBIR grants are meant to support research projects on commercially viable Products
- The Commercialization Plan 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

Phase II SBIR Commercialization Plan

- Required for all Phase II proposals
  - Phase I follow-on
  - Fast Track
- Maximum of 12 pages
- Read the Funding Opportunity Announcement for the program for additional requirements
Commercialization Plan contributes to “Significance” score of proposal
  - Potential to lead to marketable product that will have beneficial impact in field of use
  - Scoring criteria may change with funding opportunity
  - Talk to program officers

Describe the value of the Product and how you intend to bring it to market

- What need are you trying to address?
- How does the Product fit with your overall business goal(s)?
- What hurdles will you encounter?
- How do you plan to achieve your goals?
Phase II SBIR 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

- How does project Research Strategy relate to Product development plan?
- How do project & Product relate to overall business strategy of company?
I. Value of Project, Expected Outcomes & Impact

- Outline the Product development plan, including key milestones and a timeline
- Describe the regulatory pathway
- How will you advance the Product to the market?
- Reference current standard-of-care & comparable or competing products

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

II. Company

- Core Competencies
- Team
- Corporate Objectives
II. Company

- Core Competencies
  - What are your (unique) capabilities?
- Team
  - Leadership & staff
  - Advisers & consultants
- Corporate Objectives
  - What do you want to be when you grow up?
  - Transition from R&D company to commercial entity

Articulate a clear vision for your company

III. Market, Customer & Competition

Customers: Patients, Physicians, Payers

- Patients ↔ Disease Indication
  - What are the stages of disease & how are they diagnosed and treated?
  - How many patients have the disease? (% in each stage)
  - Do patients have special characteristics (e.g., age; co-morbidities)?
  - What are the major diagnostic (Dx) & treatment (Tx) needs?
**Chronic Obstructive Pulmonary Disease Stages**

**Dx Criteria**
- FEV/FVC < 0.70
- FEV, ≥ 80% predicted

**Tx**
- Aminosalicylates
- Corticosteroids (oral; local)
- Add short-acting bronchodilator (when needed)
- Add regular treatment with one or more long-acting bronchodilators (when needed): Add rehabilitation
- Add inhaled glucocorticosteroids if repeated exacerbations
- Add long-term oxygen if chronic respiratory failure. Consider surgical treatments

**Int J Clin Pract, August 2009, 63, 8, 1136–1149**

**Figure 1** Therapy at each stage of chronic obstructive pulmonary disease (COPD), as recommended by Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines (1)
III. Market, Customer & Competition

- What **specialists** diagnose & treat the disease?
  - How do they make money?
    - Office visits
    - Procedures

- **Where** is disease diagnosed & treated?
  - Hospital procedures
  - Oral medication
  - Biologic infused in clinic

- Who **buys** the actual Dx or Tx product?

- Is product cost covered by **insurance**? Who is paid?

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III. Market Analysis: MadLibs Version

More than ___________ people in the U.S. suffer

**BIG NUMBER**

from _________. Current treatments for _________

**DISEASE**

are _______________. _________’s product

**NEGATIVE ADJECTIVE(S)** **COMPANY**

will be _______________.

**POSITIVE ADJECTIVE(S)**
Product Profile

- **Benefits** of product vs. standard-of-care
  - Potential product benefits:
    - Tx: Improved efficacy; safety; ease of administration; reduced dosing frequency
    - Dx: Shorter time to decision; better accuracy; reduced complexity; non-invasiveness

III. Market, Customer & Competition

Constraints

- Regulatory Requirements
- Physician Habits
- Clinical Guidelines
- Benefits vs Costs

Product

National Heart, Lung, and Blood Institute
III. Market, Customer & 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?

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**III. Market, Customer & Competition**

**Supplement an existing Dx approach:**

ColoGuard DNA test for colon cancer

- Non-invasive *in vitro* diagnostic test to screen low-risk patients >50 yrs for colon cancer
- Avoids need for routine colonoscopy
  - Will information enable a Dx or Tx decision by physician?
  - Who buys the product?
  - Will test be reimbursed? If so, how?
  - Does the test save money for the healthcare system?
**III. Market, Customer & Competition**

*Replace an existing Tx approach:*

Factor Xa inhibitors vs. heparin for preventing blood clots (VTE) in patients undergoing hip or knee replacement surgery

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Clot Prevention</th>
<th>Bleeding Risk</th>
<th>Route of Administration</th>
<th>Predictability of Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low MW Heparin</td>
<td>+</td>
<td>+</td>
<td>Injected</td>
<td>+</td>
</tr>
<tr>
<td>Factor Xa inhibitors</td>
<td>+++</td>
<td>++</td>
<td>Oral</td>
<td>+++</td>
</tr>
</tbody>
</table>

**III. Market, Customer & Competition**

*Treat a previously untreated condition:*

PCSK9 inhibitors for high LDL cholesterol in patients who: (1) can’t tolerate statins; (2) have hereditary high cholesterol

- Do clinical benefits outweigh safety concerns?
- Do benefits justify the treatment cost?
### III. Market, Customer & Competition

**Competition**

- Proper market evaluation requires a solid understanding of competitive landscape
  - Strengths & weaknesses of marketed & investigational products
    - Publications; conversations with stakeholders; 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?**

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<table>
<thead>
<tr>
<th>Drug</th>
<th>Developers</th>
<th>Class</th>
<th>Formulation</th>
<th>Indication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vorapar</td>
<td>Merck &amp; Co.</td>
<td>PAR1 inhibitor</td>
<td>Oral</td>
<td>Post-ACS</td>
<td>Approved May 2014</td>
</tr>
<tr>
<td>Casagrelor</td>
<td>The Medicines Company</td>
<td>P2Y12 inhibitor</td>
<td>Injectable</td>
<td>ACS/PCI</td>
<td>Filmed</td>
</tr>
<tr>
<td>Daseplatope</td>
<td>Lundbeck</td>
<td>tPA</td>
<td>Injectable</td>
<td>Ischaemic stroke</td>
<td>Filmed</td>
</tr>
<tr>
<td>Betrixaban</td>
<td>Portola Pharmaceuticals</td>
<td>FXa inhibitor</td>
<td>Oral</td>
<td>VTE</td>
<td>Phase III</td>
</tr>
<tr>
<td>Tecfararin</td>
<td>Amneien</td>
<td>VKOR</td>
<td>Oral</td>
<td>Prosthetic heart valves</td>
<td>Phase III</td>
</tr>
<tr>
<td>REG1</td>
<td>Regado</td>
<td>FXa inhibitor</td>
<td>Injectable</td>
<td>PCI</td>
<td>Phase III</td>
</tr>
<tr>
<td>EP1769</td>
<td>Erolitis</td>
<td>FXa/FIIa inhibitor</td>
<td>Injectable</td>
<td>ACS/cardiac surgery</td>
<td>Phase II</td>
</tr>
<tr>
<td>THR-18</td>
<td>D-Pharm</td>
<td>tPA</td>
<td>Injectable</td>
<td>Ischaemic stroke</td>
<td>Phase II</td>
</tr>
<tr>
<td>Te Giruban</td>
<td>TeRo/Roche</td>
<td>FXa inhibitor</td>
<td>Oral</td>
<td>VTE</td>
<td>Phase II</td>
</tr>
<tr>
<td>Andexanet</td>
<td>Portola Pharmaceuticals</td>
<td>FXa-antidote</td>
<td>Injectable</td>
<td>Major bleeding</td>
<td>Phase III</td>
</tr>
</tbody>
</table>

ACS, acute coronary syndrome; FIIa/FIIa, factor IIa/Xa/Xa; P2Y12, P2Y purinergic receptor 12; PAR1, platelet-activating receptor 1; FXa, factor Xa/IXa; FXII, factor XII/IIA; VKOR, vitamin K epoxide reductase; VTE, venous thromboembolism.

III. Market Analysis: MadLibs Version

The global market for ________ is $__________.

_______ will capture ___________% of the

resulting in revenues of $ ___________.

III. Market, Customer & Competition

Estimating Product 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
Market for Factor Xa Inhibitor for VTE Prophylaxis

**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 ≈ $20 – $100M

III. Market, Customer & 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
Antithrombotic Drug Market


III. Market, Customer & Competition

Research Tools – Secondary

- Company press releases
  - Fierce Biotech, Pharma, Medical Devices, Diagnostics…
  - BioSpace
- Patent databases
  - www.uspto.gov; www.wipo.int
- Market research databases & consultancies ($)
  - Datamonitor
  - Thomson Reuters Cortellis
  - GlobalData
  - EvaluatePharma
  - PharmaProjects
III. Market, Customer & Competition

**Research Tools – Secondary**

- For public companies: U.S. SEC filings (e.g., 10-K; S-4)
- Reports by stock market analysts
- Clinical trial designs & FDA approvals
  - [www.clinicaltrials.gov](http://www.clinicaltrials.gov); [www.FDA.gov](http://www.FDA.gov)
- Trade journals
  - Drug Discovery News; CAP Today (Dx)
- Scientific & medical literature
  - Medscape
  - Nature Reviews
  - Conference proceedings

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**III. Market, Customer & Competition**

**Research Tools – Secondary**

- Epidemiology databases
  - WHO; CDC; Institute for Health Metrics & Evaluation ([www.healthdata.org](http://www.healthdata.org))
- Disease advocacy groups, e.g.,
  - American Heart Association
  - American Cancer Society
- Clinical management guidelines
  - [www.guidelines.gov](http://www.guidelines.gov)
  - National Comprehensive Cancer Network ([www.nccn.org](http://www.nccn.org))
  - Medical specialty societies
III. Market, Customer & 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
  - Patient and/or physician panels
  - Surveys

IV. Intellectual Property Protection

- 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
  - Cost to achieve milestones
  - Equity: Large % of Small $ vs. Small % of Large $
- How do you plan to secure the required funding?
  - Be as specific as possible
  - Describe discussions with potential investors/funders
    Include letters of support, where appropriate

VI. Production & Marketing Plan

Getting product into the hands of end-users

“Go-to-Market Strategy”

- After the SBIR project is completed:
  - How will you Develop & Manufacture the Product?
  - How will you Market & Sell the Product?
VI. Production & Marketing Plan

Discovery
- Prototype dev
- Lab validation
- Patents

Preclinical testing
- Mfg scale-up
- Regulatory

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

Commercial launch
- Regulatory
- Manufacturing
- Reimbursement
- Marketing & sales

Resources
- 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 & Marketing Plan

- 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 & Marketing Plan

- Licensing & Partnering
  - Define the Product application & understand the customer
  - Formulate your own Product development plan, with milestones and costs
  - Don’t rely on prospective partner to figure out the value of your technology – do the calculations yourself
VI. Production & Marketing Plan

- Licensing & Partnering
  - Earlier hand-off → lower payments
    - How far do you plan to advance Product on your own?
    - How involved do you want to be in later stage development? Commercialization?

*Consider corporate *strategy; existing & desired competencies; funding requirements*

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VI. Production & Marketing Plan

- “In-house” development, marketing & sales
VI. Production & Marketing Plan

**Discovery**
- Prototype dev
- Lab validation
- Patents

**Preclinical testing**
- Mfg scale-up
- Regulatory

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

**Commercial launch**
- Regulatory
- Manufacturing
- Reimbursement
- Marketing & sales

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**VI. Production & Marketing Plan**

- “In-house” development, marketing & sales
  - What do you want to be when you grow up?
  - 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
VI. Production & Marketing Plan

- “In-house” development, marketing & sales
  - The patient population studied in your clinical trials will be your initial target market
  - Manufacturing is part of development process
  - Clinical development, manufacturing, marketing & sales are all regulated by the FDA
  - When products are reimbursed, end-users don’t usually buy from you
  - Marketing is more than just advertising

VI. Production & Marketing Plan

- Marketing (an iterative process)
  - Learn about product through R&D
  - Refine Product Profile
  - Conduct primary market research
  - Develop & refine product message
  - Create brand awareness & educate customers

*May want to retain some of this function even if you license to strategic partner*
VII. Revenue Stream

- Sales revenue projections for Product (3-5 yr)
- Gross profit
- Net profit

- If licensing, sales royalties + milestone payments from partner (minus payments to licensor)
- Subtract manufacturing costs
- Subtract Sales & Marketing and General & Administrative expenses; Taxes
### Summary

- SBIR grants are meant to support *research* projects on commercially viable *products*.
- The **Commercialization Plan** 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.
- Do your homework… it will pay off!

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