Understanding SBIRs for Researchers

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Session 4 – Commercialization Plan
Outline

- SBIR vs. STTR
- SBIR vs. RO1
- What is commercialization?
- Commercialization strategy
- Components of the Phase II Commercialization Plan
- Review criteria
- Tips and mistakes to avoid
SBIR vs. STTR

- More agencies, more solicitations, more topics
- PI must be primarily employed by small business (>51%)
- Can subcontract up to 30% to university
- Six month Phase I

- Fewer agencies, fewer solicitations, fewer topics
- PI employment requirement stipulated by agency
- Can subcontract up to 60% to university
- One year Phase I
SBIR vs. STTR

- No IP allocation of rights agreement
- Funding is always awarded to the small business
- Same application mechanics

- If awarded, need IP allocation of rights agreement
- Funding is always awarded to small business
- Same application mechanics

SBIR

STTR
**SBIR vs. RO1**

- Investigator-initiated
- Goal is commercial product or service ($$)
- PI must be primarily employed by small business
- Career stage not considered
- Higher award rate

- Investigator-initiated
- Goal is to advance medical science (Pubs.)
- PI employment percentage not stipulated
- “New Investigator/ESI” designations
- Lower award rate
SBIR vs. RO1, con’t

- Applicant is small business (must meet eligibility requirements)
- Phased (I, II, competing continuations)
- Funding limitations
- Apply electronically
- Standard submission dates

- Applicant is generally (but not limited to) an academic or non-profit research org.
- Types (1,2,3,4,7,9)
- Not limited in dollars
- Apply electronically
- Standard submission dates
What is commercialization?

- Transitioning an innovation from research and development to the marketplace
- In the SBIR/STTR programs, the marketplace can be the government or the private sector
- Definition of successful commercialization depends on the sponsoring agency
- Your definition of successful commercialization may depend on your ability to make a profit in Phase III
What is commercialization?

Commercialization or commercial potential has received increased emphasis since the SBIR program’s last reauthorization in 2000:
- All Phase II applications are required to have a commercialization plan.
- Companies with numerous Phase II awards may be penalized for failure to get products or services into the market.
Commercialization strategy

- How will you make money?
- Who will buy your product or service?
- Who will make or deliver it?
- Who will market it?
- Who will sell it?
Commercialization strategy

Should you

- License your service, product or technology to someone else to sell?
- Do it yourself?
Commercialization strategy

- If you license
  - Need intellectual property protection
    - Patents
    - Copyrights
    - Other legal protection
  - Need to identify potential licensees
    - Start early
    - Negotiations may be difficult
  - Need a fairly well-developed product, service or technology
  - Need some credible marketing and cost data
Advantages of licensing

- Licensee may have more resources available for commercialization
- Licensee may have access to or knowledge of additional potential markets
- May realize revenues more quickly
- Frees you/your company to pursue additional projects
Commercialization strategy

- Disadvantages of licensing
  - Loss of control over technology
  - Risk that the technology is “shelved”
  - Your involvement is minimized
  - Finding the “right” licensee and protecting your interests is difficult and can be time consuming
Commercialization strategy

If you do it yourself
  ◦ How will you manufacture it?
  ◦ How will you market it?
  ◦ How will you distribute it?
  ◦ How will you finance it?
Advantages of doing it yourself

- Potentially higher returns
- Excitement and pride in creating, developing and selling your product
- Potentially retain more control of or financial interest in company
Commercialization strategy

Disadvantages of doing it yourself

- Increased risk
- Increased responsibilities, new roles, will take even more of your time
- Requires $$$$
  - May require outside investment
Commercialization strategy

Where will additional financing come from?

- Private sources
- Small business loans
- Angel investors
- Venture capital
- Strategic partners
- Revenues from existing products/licensing agreements
- Very important for Phase II
Commercialization strategy

- Developing your commercialization strategy starts *before* you submit Phase I!
What is a commercialization plan?

A plan for bringing a particular product or technology to the market that includes:

- The path to commercialization
- Barriers to commercialization and competitive analysis
- Financial projections for the product or technology
Common components of commercialization plans

- Introduction of the SBIR/STTR project and expected outcomes
- Company information
- Market, customer and competition
- Intellectual property protection
- Financing
- Revenue generation
- (Production and marketing plan)
Commercialization Plan Components: Introduction to the SBIR Project and Expected Outcomes

- Not so technical description of the proposed project’s benefits and features
- What need it addresses (what is the problem, and what is wrong with the state of the art)
- What is the commercial potential?
- What about the technology is innovative?
- Why would it be used over competing technologies, products or services?
- What are the impacts: commercial and non-commercial (educational, societal and scientific)?
- How does the project fit with the company’s overall strategy?
Commercialization Plan Components: The Company

- Describes company’s mission and objectives
- Provides a brief history of the company
- Gives a company overview
  - Number of employees
  - Sales/revenues
  - Current products or services
  - Previous funding and commercialization success
- Profiles the management and/or how management roles will be filled
- Describes the company’s vision for the future and how it will become successful
Commercialization Plan Components: The Market, Customers and Competition

- The market
  - Describe the market: make sure it is really the market for your product
  - Give size of the overall market and your specific market segment
  - Is it growing? How fast?
  - How will you access this market?
Commercialization Plan Components: The Market, Customers and Competition

- Market research
  - If possible in Phase I, take advantage of market assessments made available through the funding agency, such as Foresight’s Technology Niche Assessment
  - Trade publications
  - Purchase a research report
  - Google
  - Local resources (SBDC, etc.)
Diagnostics Market Research Reports

MarketLooks: The Market for Rapid Diagnostic Tests for Cardiovascular Diseases
MarketLooks are concise, graphic-rich summaries of full-length market ...
www.kalorainformation.com/browse.asp?CategoryID=1125&Sort=D&DocType=all&View=full&Page=2 - 52k - Cached - Similar pages

NanoLogix Unveils Advanced DNA Extraction System for Molecular ...
The molecular diagnostics market will expand to $12 billion by 2010 and $35 billion by 2015. A major portion of it can be attributed to advances in genomics ...

The Molecular Diagnostics Market Will Expand to $12 Billion by ...
Currently, there has been a considerable interest in developing rapid diagnostic ... In the year 2005, the global market for molecular diagnostics will be ...

HIV and H.Pylori testing kits by Saliva Diagnostic Systems
Sells rapid diagnostic tests for infectious diseases.
www.salv.com/ - 23k - Cached - Similar pages

Stratagene deal enters molecular diagnostics market
"The molecular diagnostics testing market represent a large and growing revenue ...
Currently, there has been a considerable interest in developing rapid ..."
NanoLogix Unveils Advanced DNA Extraction System for Molecular Diagnostics Market

NanoLogix, Inc., a Nano-biotechnology company engaged in the research, development and commercialization of technologies for the production of bacteria and disease testing kits, alternative sources of fuel, and remediation of toxic materials, announced today that its DNA extraction system and protocol is both easier -- due to less steps, and quicker -- taking significantly less time than standard spin column extraction methods according to Paul Hyman, Ph.D. at Ohio State University.

According to Jain PharmaBiotech, in the year 2005, the global market for molecular diagnostics will be worth $6.5 billion, representing approximately 3.3% of the total diagnostics market and approximately 14% of the in vitro diagnostic market. The molecular diagnostics market will expand to $12 billion by 2010 and $35 billion by 2015. A major portion of it can be attributed to advances in genomics and proteomics. Biochip and nanobiotechnology are expected to make a significant contribution to the growth of molecular diagnostics.

Paul Hyman, Ph.D. stated, "The NanoLogix buffer allowed the DNA extraction from different strains of mycobacteria, requiring a single buffer, one incubation and one post-lysis centrifugation compared to other products, like Qiagen's QIAamp procedure, which utilizes six buffers, three incubations and four post-lysis centrifugations."
MarketLooks: The Market for Rapid Diagnostic Tests for Cardiovascular Diseases

January 1, 1999
15 Pages - Pub ID: ML0819

Countries covered: United States

Now 40% off the original sale price of $499.
MarketLooks are concise, graphic-rich summaries of full-length market research reports. Reports that cover more than one market segment are split into corresponding MarketLooks to allow you to purchase only what you need. All MarketLooks are created in PowerPoint(R) for easy extraction of text, charts and tables for use in presentations and internal company reports.

Compiled From: The Market for Rapid In Vitro Diagnostic Tests
Abstract from full report:

This completely updated FIND/SVP report assesses the fast-growing global market for rapid in vitro diagnostic (IVD) testing products. After analyzing the current business environment for rapid IVD testing, the report presents market analysis, product descriptions, market shares and growth forecasts through 2003. Covers tests for infectious diseases (including HIV, H. pylon, streptococcus and sexually transmitted diseases), drugs of abuse, therapeutic drug monitoring, cancer, cardiac disease, pregnancy...
Gives information about the market, state of the art, competing technologies, and customers, as well as your competitors (or potential partners)
Commercialization Plan Components: The Market, Customers and Competition

- Customers
  - Who is really the customer?
    - Funding agency or private sector?
  - Does your product really address their needs?
  - Do you have a letter of customer interest?
Commercialization Plan Components: The Market, Customers and Competition

- Competition: be aware of your barriers to entry:
  - Acceptance of new technology?
  - Large number and/or well established competitors?
  - Governmental regulations?
  - Potentially dominating patents?
  - Switching costs?
  - Are you seduced by your own technology?
Competition: how will you create barriers to entry for your competitors?
  ◦ What are the current products/services/technologies used?
  ◦ Who provides these? How much do they sell for?
  ◦ Is your product/service/technology
    • Faster?
    • Cheaper?
    • Simpler?
    • More sensitive?
    • More reliable?
  ◦ Does your intellectual property position give you an advantage?
Commercialization Plan Components: The Market, Customers and Competition

- Do you have a sales and promotion plan?
  - Existing sales network
  - Through partnerships
  - Use of product described in current scientific literature
  - Exhibit at scientific meetings and conferences
  - Advertise in trade journals or scientific magazines
  - Four P’s
4Ps (Marketing Mix)

- Product: emphasize benefits and competitive advantages
- Price: how much will you charge for your product or service
- Placement: what channels you will use to distribute your product or service
- Promotion: how you will promote your product or service
Commercialization Plan Components: Intellectual Property Protection

- Describe intellectual property relevant to the project
- Indicate what the company’s rights to the IP are
- How does the IP confer a competitive advantage?
- Describe how any new IP will be protected—how will this help you build a sustainable business?
Commercialization Plan Components: Financing

- You *will* need more financing to commercialize your product/service/technology
  - How much will you need?
  - When will you need it?
  - Where will you get it?
Commercialization Plan Components: Financing

- Sources of financing
  - Revenues from existing products or services
  - Equity: self, family, friends, angels, VCs
  - Loans
  - Strategic partnerships
  - State funding programs
Commercialization Plan Components: Financing

- Be prepared to show commitments for financing
  - Internal co-funding
  - Private investment
  - In-kind contributions from strategic partners
- Summarize financing needs and resources in a table
  - Need to be reasonable and appropriate
- Start identifying resources early
Sample table for describing financing needs and resources

<table>
<thead>
<tr>
<th>Source</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales of existing products</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corporate Partners</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticipated need</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

May need additional resources early
Commercialization Plan
Components: Revenue Generation

- Need to demonstrate that you can make a profit on your innovation
- Should show anticipated costs and selling price
- Make reasonable sales projections
  - Market size
  - Market trends
  - How much can you capture?
  - Utilize annual reports from public companies
- Summarize in a table
Sample table for revenue projections

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct Labor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production Overhead</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total COGS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales</td>
<td></td>
<td></td>
<td></td>
<td>Sales should increase at a reasonable rate</td>
<td></td>
</tr>
<tr>
<td>Gross Profit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Expenses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net Income</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>May be negative early</td>
</tr>
</tbody>
</table>
Commercialization plan review criteria

- Introduction to the SBIR Project and Expected Outcomes
  - Is there a compelling *value proposition* for the project?
  - Is market pull demonstrated?
  - Is there a compelling case that there are educational, scientific, and societal impacts?
Commercialization plan review criteria

- **Value proposition:**
  - A clear and concise statement of the tangible benefits a customer gets from using your products or services
  - “Elevator speech”
    - Trigger words: For, Who, The, Is A, That, Unlike, Our
For water quality testing laboratories whose *Cryptoporidium parvum* detection methods require awkward sample manipulation and several days to obtain results, the BioDetective *Cryptosporidium parvum* detection kit offers rapid testing in a simple format. Unlike currently used methods that require a variety of laboratory equipment and a highly trained microscopist to interpret results, our assay can be completed by a technician within four hours using only a water bath.
Commercialization plan review criteria

- **Market pull**: Identifying a marketplace need and then developing a new product to meet that need

- **Technology Push**: Identifying an interesting technology, making a product and then searching for a marketplace

Do you meet the agency’s needs?
What are the other benefits of performing the research and development?
  ◦ Societal
  ◦ Educational
  ◦ Scientific
Commercialization plan review criteria

- The company
  - Is the company focused?
  - Does the company have the appropriate core competencies?
  - Does the company have the appropriate resources to do the project?
  - Does the company have the necessary business network or a plan to develop the network needed for commercialization?
  - Does the company have the necessary expertise to successfully commercialize the product/service?
Commercialization plan review criteria

Market, customer and competition
- Is there a market need for the product/service?
- Does the company understand the market?
- Does the company accurately describe the customer?
- Does the company understand the competition?
- Can the company execute a sales and marketing strategy to bring the innovation to the market?
Commercialization plan review criteria

- Intellectual property protection
  - Is intellectual property addressed and are there plans for sufficient protection to gain a competitive advantage in time-to-market?
  - What is the company’s history/intellectual property portfolio?
  - Can the company’s intellectual property protection strategy help it build a sustainable business?
  - Reviewers may also consider whether there are potentially blocking or dominating patents
Commercialization plan review criteria

- Financing
  - Does the company have a reasonable estimate of the amount of necessary financing needed in Phase III?
  - Is there evidence of a plan to obtain the necessary financing?
  - Is there a high probability of obtaining this financing?
  - Are there letters to document “hard” commitments?
Commercialization plan review criteria

- Revenue generation
  - Are plans for revenue generation adequately described?
  - Are the revenue projections and assumptions behind them reasonable?
  - Is the revenue stream sustainable?
  - Will the revenue generation help the company grow/sustain itself?
Commercialization Plan Tips

- Consider having a business advisory board
  - Can bring in experienced managers without having to pay hefty salaries (but expect to compensate them somehow)
  - Can bring industry connections

- Consider having a scientific advisory board
  - Can help fill scientific roles within the company (but expect to compensate advisors somehow)
  - May also bring industry or other connections
Commercialization Plan Tips

- Identify all sections of the commercialization plan using the same language as the solicitation instructions
- Follow the order indicated in the solicitation instructions
- Attach letters of support/commitment for follow-on funding, strategic partnership, beta testing, customer interest, etc.
- Do not exceed page limitations
- Maintain contact with your grant/contract manager throughout Phase I and learn what is wanted in Phase II
  - Take advantage of Phase I opportunities for market assessments, partnering, etc.
Commercialization Plan Tips

- Include financial and revenue projections
- Make projections realistic and avoid hyperbole: do not invite skepticism
- Start identifying partners early
- Do not rely solely on grant funding for financing
- Do not rely solely on “passive” marketing: depending only on testimonials and referrals creates a “trust me” proposal
- Know your pathway to commercialization
Commercialization Plan Mistakes to Avoid

- Mistake #1: Say you’ll capture 5% of a multi-billion dollar market
  - Reviewers will immediately become skeptical
  - Need credible market and sales projections
  - Can provide sensitivity analysis (high and low estimates)
Commercialization Plan Mistakes to Avoid

- Mistake #2: Trying to go it alone
  - “Virtual” and “stealth” companies not perceived favorably by many reviewers
  - “Weaknesses include a lack of business experience among the key personnel…”
  - “The company has limited financial resources and no clear plan for obtaining additional financing …”
Commercialization Plan Mistakes to Avoid

- Mistake #3: Pretending there’s no competition
  - Everyone has some competition
  - How will you compete? Price, performance or other?
  - Provide a table highlighting your advantages over competing products or approaches
Commercialization Plan Mistakes to Avoid

- Mistake #4: Fudging costs and pricing information
- “Weaknesses of the proposal are that the rationale for instrument pricing is vague and that the company underestimates additional development costs…”
Questions?