Developing the Business of Technology
Phase II Proposal Development

To be covered:
- Assumptions (since we only have 110 minutes…)
- Phase II Planning
- Review of Key Proposal Components
- Elements of a Commercialization Plan

Introduction to SBIR/STTR

Assumptions
- You meet the Phase II eligibility requirements
  - Eligible small business
  - The small business has company controlled research facilities
  - The small business has research personnel
  - You have received an NIH Phase I award
- You have or will have achieved your Phase I aims
- Funding Cycles match your commercialization goals
The Project: What Does SBIR/STTR Fund?

- **PRODUCT Development**
- Based on “technological innovation”
  - “high risk”
- Credible Commercialization Strategy

Phase II SBIR/STTR: Where Does it Fit?

3+ Years, ~$1,150,000+

Phase I:
- 6 Months, $150K+

Phase II:
- 2 Years, ~$1,000 K+

Phase III: Commercialization (no federal SBIR/STTR $$)
SBIR/STTR: Planning 3 Phases

**Goals**
- Phase I Goal = **FEASIBILITY**
  - Feasibility of what? Whatever you hope to accomplish in Phase II!
- Phase II Goal = Further R&D
  - How far? You decide based on…
- **ULTIMATE GOAL = COMMERCIALIZATION!**

---

**Phase II Proposal Development**

**Planning**
- Update scientific literature search and market research
- Update/Write Commercialization Plan
- Acquire and Analyze Phase I data
  - Demonstrate FEASIBILITY
- Plan experiments/R&D activities
- Convene the technical team
  - For Phase II and beyond…
- Secure facilities and other resources
NIH Review Criteria

- **Significance**
  - Significant Science
  - Significant Product
  - Significant Commercial Opportunity

- **Investigators**
- **Innovation**
- **Approach**
- **Environment**

**IMPACT**

---

Writing the Proposal

**Primary Questions to be Answered**

- What you are going to do?
- Why is it worth doing?
- Who is going to do the work?
- Where are you going to do the work?
- How much will it cost?
Components of an NIH SBIR/STTR

- Introduction to Application (1pg)
- Specific Aims (1 pg)
- Research Strategy (6 or 12 pg)
  - Significance
  - Innovation
  - Approach
- Inclusion Enrollment Report
- Progress report/Publication List (Phase II proposals only)
- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract (30 lines)
- Public Health Relevance
- Statement/Narrative
- Biographical Sketches (5 pg ea.)
- Facilities & Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms

Specific Aims Page

- Single and most important page of application
- An Executive Summary of the Proposal
- One page sets the tone for the reviewer
  - Is the project compelling?
  - Are the outcomes significant?
  - Will the project have impact?
  - Is it well written?
  - Do I want to read more?
Specific Aims -- Outline

- The Company
- Significance
  - Problem to be solved
  - Gap in knowledge
- The Product
  - Technological Innovation
  - Impact
- Long Term Goal
  - Rationale for the goal
  - Phase I Results ("feasibility")

- Phase II Project:
  - Phase II Hypothesis
  - Specific Aim 1...
    - Criteria for acceptance
  - Specific Aim 2...
    - Criteria for acceptance
  - Expected Outcomes
    - Proof of Feasibility
  - Commercial Application

PAGE LIMIT: One PAGE

Aims vs. Activities

- **Specific Aims = Objectives/Outcomes**
  - Either achieved or not
  - Have measurable, desired end points
  - Do not yield results/data

- **Tasks = Activities**
  - Steps to achieve your aims/objectives
  - Make up your work plan
  - They are performed or carried out
  - Yield results &/or data
The Specific Aims

- Support a significant, testable hypotheses appropriate for the Phase of development
- Should be stated succinctly in one sentence each
  - Aims test the hypothesis
  - Experiments (as described in the research strategy section) support aims
- Should be independent
- Should be achievable within the budget and time frame
- Should have “criteria for acceptance” so that you will know when you’ve achieved them and the reviewers therefore know that you will know!

Components of an NIH SBIR/STTR

- Introduction to Application (1pg)
- Specific Aims (1 pg)
- Research Strategy (12 pg)
  - Significance
  - Innovation
  - Approach
- Inclusion Enrollment Report
- Progress report/Publication List (Phase II proposals only)
- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography and Refs Cited
- Project Summary/Abstract (30 lines)
- Public Health Relevance Statement/Narrative
- Biographical Sketches (5 pg ea.)
- Facilities & Other Resources
- Equipment
- Project Budget
- Subaward Budget
- Cover Letter
- Commercialization Plan (12 pg; Ph II & Fast Track only)
- Forms
Research Strategy

- Significance
  - Significant **product**
  - Significant **science/technological innovation**
  - Significant **commercial opportunity**

- Innovation
  - Clearly state the **technological innovation**
  - Will success improve the “State-of-the-art”, establish new research directions, change clinical practice?

- Approach
  - Do experiments relate to the Specific Aims?
  - Are the end-points/milestones clearly defined?

---

Research Strategy – BBC Outline

**Significance – Make the Reviewer Care!**

- Problem to be solved
- Product to be developed
  - Impact of proposed product to provide a solution
  - Impact of product/innovation on state of the science/technology
- Value of the solution to the problem
- Commercial Potential (summarize…. Detail in commercialization plan)
  - Market analysis
  - Competition (competing technologies and competitors)
  - Commercialization strategy
- Other applications of the technology
Research Strategy – BBC Outline

Innovation
- The technological innovation (describe)
- Relevance to current state of the science
  - Why is it innovative?
  - How does it move the field forward?
  - What future advancements will this innovation enable?

Approach - Phase II
- Phase I Progress Report
  - Beginning and ending dates of Phase I
  - Summarize Phase I Aims
  - Results and conclusions (achievement of aims)
  - Describe any significant changes to aims/new directions
- Summary
  - Demonstration of Feasibility
  - How the outcomes support the Phase II
  - Technology developed, intended use, status of product development
Approach – Phase II (cont.)

For Each Specific Aim:
- [Restate the Aim]
- Rationale
  - Give the reasoning behind the aim
- Experimental Design & Methods
  - Lay out what experiments (in detail) will be conducted to complete the aim and methods to be employed in each experiment
- Data Analysis & Interpretation
  - How will you analyze the data?
- Potential Pitfalls / Alternative Approaches
  - What could go wrong and how will you compensate if it does?
- Expected Outcomes
  - What do you expect to happen?

Summary
- Tell the reviewers:
  - What (Specific Aims)
  - Why (Significance, Innovation, Prior Work)
  - How (Research Strategy)
- Summarize who, when and where:
  - Gantt Chart
    - Detailed timeline for project
    - Details who will be responsible for completion of each aims
    - Where the work will be done (company, subcontractor etc.)
## Gantt Chart (who, when, where?)

<table>
<thead>
<tr>
<th>Specific Aims</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Specific Aim 1</td>
<td></td>
</tr>
<tr>
<td>Experiment 1</td>
<td></td>
</tr>
<tr>
<td>A. Scientist, Ph.D.</td>
<td></td>
</tr>
<tr>
<td>NewCo. Labs</td>
<td></td>
</tr>
<tr>
<td>Specific Aim 2</td>
<td></td>
</tr>
<tr>
<td>Experiment 1</td>
<td></td>
</tr>
<tr>
<td>A.N. Scientist, Ph.D.</td>
<td></td>
</tr>
<tr>
<td>NewCo. Labs</td>
<td></td>
</tr>
<tr>
<td>Specific Aim 3</td>
<td></td>
</tr>
<tr>
<td>Experiment 1</td>
<td></td>
</tr>
<tr>
<td>A. Engineer, M.S.</td>
<td></td>
</tr>
<tr>
<td>MidWest University</td>
<td></td>
</tr>
</tbody>
</table>

## Which sections?

- Who is going to do the work?
- Where will the work be done?
- How much will it cost?

- Biographical Sketches
- Facilities and Resources
- Letters of Support
- Budget and Budget Justification
Key Personnel: Build a Strong TEAM!

- Your (the SBC’s) employees
  - Includes the PI if SBIR
  - If STTR should have at least 1 (may include PI)
- Subcontractor’s employees
- Consultants
- Other Significant Contributors
  - e.g. “advisors”; 0% effort on project (think ahead to Phase II and commercialization)

Biographical Sketches

NEW FORMAT November 2014: Every Biosketch MUST use this format!

Biosketch – Personal Statement

- Personal Statement – why experience and qualifications make the applicant particularly well-suited for role in the project
  - how you are qualified for your assigned role on study
  - how your formal education, training & experience contribute to feasibility of work
  - your access to resources/collaborations

Position where you will be doing the work

Include up to 4 relevant publications or research products
Personal Statement

***Make it easy for the reviewer!

Used to establish why
- this person is qualified to have
- this specific role
- on this project.

Therefore start this paragraph out with 1-2 sentences as follows:
- “In my role as {------------} I will be responsible for {-------- -----}. I am qualified because.....”

- Make sure to list the small business for all personnel that will be working there at the time of award
- If not already employed add not "to be implemented at time of award"
All key persons should include
- You may cite up to 5 contributions
- Up to 4 relevant publications or research products

Facilities and Resources – include:

- **Company’s Research Facility(s)**
  - Make sure to indicate that the facilities are “company-controlled”

- **Subcontractors’ Research Facilities**

- **Other R&D Resources**
  - Other Significant Contributors (e.g., Scientific Advisory Board)

- **Commercialization Resources**
  - Management
  - Strategic Partners
  - Funding
  - Regulatory/Reimbursement

Critical for Phase II!
(briefly summarize here; details in commercialization plan)
Letters of Support

Validate your resources and opportunity

- Consultants (required); must include:
  - Role, Rate, Time
- Subcontractors
- Other Significant Contributors
- Research Resources, e.g.
  - Facilities, equipment not on budget or owned by company
- Commercialization Resources (critical for Phase II), e.g.:
  - Strategic Partners
  - Investors
  - Key Customers

Budget limitations

- Guidelines:
  - $150,000 Phase I, $1,000,000 Phase II
- “Limits” – max 150% of guidelines, therefore:
  - $225,000 Phase I, $1,500,000 Phase II
- Appendix A
REMINDER: “Outsourcing” Limits

- SBC (applicant organization) must do required minimum (% of direct + indirect)
  - SBIR - Phase I - ≥ 67%
  - SBIR - Phase II - ≥ 50%
  - STTR - Phase I & II - ≥ 40%
- Therefore total of Consultants + Subcontractor Costs must be:
  - SBIR - Phase I - <33.3%
  - SBIR - Phase II - <50%
  - STTR - Phase I & II - ≥ 30% for primary subcontractor; <30% for all other consultants + subcontractors

Budgets

- Direct Costs
  - E.g., Salaries, supplies, equipment, travel, consultants fees, subcontract costs
- Indirect Costs (F&A)
  - ≤ 40% of TOTAL direct costs for Phase I (includes fringe benefits)
  - Request higher rate IF you can support it through a negotiation with DFAS
- Fee
  - 7% of total costs (direct and indirect)
- Unallowable Costs
  - Make sure to justify your direct costs extremely well.
Budget approach

When a cap or restriction is enforced...
Work backwards to determine the direct dollars

<table>
<thead>
<tr>
<th>IF Budget Cap = $1,500,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct costs = $1,000,000</td>
</tr>
<tr>
<td>Indirect costs = $1,000,000 x ~40%</td>
</tr>
<tr>
<td>Fee = ($1,000,000 + $400,000) x 6.99%</td>
</tr>
<tr>
<td>TOTAL: Direct + Indirect + Fee</td>
</tr>
</tbody>
</table>

Therefore – design your project to fit ≤$1m directs

Commercialization

There is no such thing as the “Build it and they will come” Business Model
The Philosophy of Commercialization

Life is sales!

Know thy customer

Commercialization

This is NOT a feasible business model:

Technology
What is Commercialization?

Ability to provide a solution to a problem in exchange for money

- Targeted and Differentiated Solution
- Important Problem
- Viable Business Model

Commercialization Plan Elements

a. Value of the SBIR/STTR Project, Expected Outcomes and Impact
a. Value of the SBIR/STTR Project, Expected Outcomes and Impact

- Lay description of proposed project and key technology objectives
  - (Don’t forget to clearly define the product and the innovation)
- Need addressed
  - Specify weakness in current approaches to meet the need
- What are the potential commercial applications of the research and the innovation?
  - Be sure to specify: 1) potential societal, educational, and scientific benefits; 2) Non-commercial impacts to the overall significance of the project
- Advantages compared to competing products, technologies or services
- How does project integrate into Company business plan?

---

Story

ReceptorPro: Part I

easier faster better cheaper
b. Company

- Brief description of the company, including:
  - Corporate objectives
  - Core competencies
  - Present Size
    - Annual sales
    - Number, type of employees
  - History of previous Federal and non-Federal funding
    - Regulatory experience
    - Subsequent commercialization
  - Current products/services with significant sales
- Succinct history of the company
- Vision for future
  - How will you grow/maintain a sustainable business entity
  - How will you meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity
The Company

- Brief History
- Mission
- What will you look like in 5 years?

Entrepreneurial Opportunities

**Critical Success Factors**

- Combination of technical & business expertise
- Customer focus with a well-defined target segment
- Proven business model
Business Models

- License
- Joint development
- Contract Manufacturing
- Fully integrated manufacturing, marketing, distribution
- OEM
- Distribution

Management Team

- Executive Officers
- Scientific Advisory Board
- Board of Directors
- Business Advisors
- Regulatory Experience
- Recruiting Plans
Track Record

- Applicant organization’s record of successfully commercializing SBIR or other research, if applicable
- Existence of Phase III funding commitments from private sector $
- Description of products/services with significant sales
- Presence of other indicators of the commercial potential of the subject research

Company Vision

- How will you grow your business?
- How will you maintain that growth?
- Where will you go to attract management talent?
- Describe hurdles you foresee as the company becomes a commercial entity
  - Propose solutions!
c. Market, Customer, and Competition

- Describe the target market and market segments
- Customer profile
- Positioning (ie – product advantages)
- Hurdles to overcome to gain acceptance (ie – barriers to entry)
- Strategic alliances, partnerships, licensing agreements
  - To get FDA approval
  - To market and sell
- Marketing and sales strategy
- Competitive analysis
  - Current landscape
  - Future potential competitors
Why a Marketing Plan?

- Foundation of Your Business
- Primary Communication Tool …inside & outside the company
- Source of company goals, milestones, and measures of progress

Do your homework

(a.k.a. – MARKET RESEARCH)

For the computer savvy

For the socially adept
What you need to know...

**The Market**
- Market size and growth
- Customer profile
- Sales and market share projections
- Pricing and margin analysis
- Competitors
- Market trends

Story

**XYZ Technologies: “Beseech Them…..”**
Product Positioning

1: No need
   Unique Product

2: Big Need
   Many Products

3: No Need
   Many Products

Put your product description through the “so what” test

“So what?”
Competitive Analysis

Competitive Products

- What are the alternatives?
- How are these products sold now?
- What is their price?
- How big is their market share?
- What is their intellectual property position?
Competitive Companies

- Who are they?
- How large are they?
- Are they developing something new?
- Are they a potential partner?
- How do you intend to compete?

Commercialization Plan Elements

d. Intellectual Property Protection
d. Intellectual Property Protection

- How will you protect IP that results from this innovation
- What actions might you consider that will constitute at least a temporal barrier to others aiming to provide a similar solution

_not from NIH outline:_

- Existing IP
  - List and describe importance to THIS project
  - Clearly explain the company’s right to use the intellectual property
  - Discuss how the IP fits into the broader base of IP in the competitive landscape

- HOW DOES YOUR IP ENABLE YOUR BUSINESS STRATEGY??

“Rights” to Commercialize

- If you are an academic or employed elsewhere:
  - READ and KNOW your institution’s Intellectual Property Rights Policy
  - Assume the institution owns the IP unless proven otherwise
  - Beware of public disclosure
  - Beware of conflict of interest issues

- Transfer is based on negotiation and a viable business opportunity
“Rights” to Commercialize

Two other pieces of good advice:

- Hire a good attorney
- Read the Bayh-Dole Act
  - The Bayh-Dole Act requires a grantee institution to disclose an invention to the granting agency (NIH)
  - Read NOT-95-003: A "20-20" VIEW OF INVENTION REPORTING TO THE NATIONAL INSTITUTES OF HEALTH

Story

ReceptorPro: Part 2
Commercialization Plan Elements

e. Finance Plan

"I call my invention "The Wheel," but so far I've been unable to attract any venture capital."
e. Finance Plan

** page B-97:
Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product or service resulting from the SBIR/STTR grant.

---

** e. Finance Plan

- Describe necessary fundraising to commercialize the product, process or service
  - Plans to raise requisite financing to launch into Phase II and begin revenue stream
  - Fundraising timeline
- Demonstrate through:
  - Letters of commitment of funding
  - Letters of intent or evidence of negotiations
  - Letter of support and/or in-kind commitment
  - Specific steps to secure Phase II funding
Commercialization Plan Elements

f. Revenue Stream

How will you bring in $$ to the company upon successful completion of project?
Examples include (but are not limited to):

- Manufacture and direct sell
- Sales through resellers or distributors
- Joint venture
- Licensing
- Service

How will your staffing change to meet revenue projections?
Sales Financials

Product sales and margin projections, to include:
- **Income:**
  - Revenue from sale of product
  - Related licensing revenue
- **Expenses:**
  - Cost of Goods
  - Other sales expenses
- **Bottom line in gross margin dollars and percent**

Commercialization Plan Elements

**NIH Proposed Layout**

a. Value of SBIR/STTR project
b. Company information
c. Market, Customer, Competition
d. Intellectual Property Protection
e. Finance Plan
f. Revenue Stream

No more than 12 pages
What is Commercialization?

- Ability to provide a solution to a problem in exchange for money
  - Targeted and Differentiated Solution
  - Important Problem
  - Viable Business Model

Why focus on commercialization?

Entrepreneur as a “risk-taker”
Rather than a “risk-manager”
Final Words….

- Remember why the SBIR/STTR is funding your company!
- Develop your Commercialization Plan with the same scrutiny you give your Research Plan
  - Identify reasonable assumptions
  - Provide external validation
- Go for the IMPACT!

But more importantly….

Remember that you are running a company!
For more assistance:

- SBIR/STTR Assessment Form at www.bbcetc.com

BBC’s Grant Assistance

- Assessment of competencies and capabilities
- Strategic planning
- Training on all aspects of the process including in-depth proposal preparation
- Proposal development tools
- Pre-submission review and editing
- Assistance with revision and resubmission
- Post-award administrative assistance and grant management
Phase II Proposal Development

19th Annual NIH SBIR/STTR Conference
November 9, 2017
Milwaukee, WI

Presenter:
Lisa M. Kurek
Partner Emerita
734.930.9741
lisa@bbcetc.com
bbcetc.com / @BBC_etc

Copyright © BBC Entrepreneurial Training & Consulting, LLC