Writing a Good Commercialization Plan: Suggestions for SBIR/STTR Applicants

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Phase II Fast-Track and Phase II Competing Renewal applications must include a succinct Commercialization Plan within the <u>SBIR/STTR</u> <u>Application (https://grants.nih.gov/grants/how-to-apply-applicationguide/forms-h/sbir-sttr-forms-h.pdf)</u>. During Phase III, the small business concern (SBC) is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal).

Overview

The commercialization plan should offer a clear and concise description of the proposed work's market potential and the planned path to commercialization.

It describes the strategy that your organization will use to generate revenue and business opportunities, maps out a strategy to move forward, and describes the current and anticipated landscape/resources required to address the opportunity enabled by your innovation.

Objectives

As it is specified in the <u>SBIR/STTR Application Guide</u> (SF424 (R&R) SBIR/STTR Application Guide for NIH and Other PHS Agencies), potential applicants are to create a document entitled "Commercialization Plan", no longer than 12 pages, and to provide a description of each of the following areas:

- A. Value of the SBIR/STTR Project, Expected Outcomes, and Impacts
- B. Company Overview
- C. Market, Customer, and Competition Analysis (TPP or equivalent)
- D. Intellectual Property (IP) Protection
- E. Regulatory Strategy
- F. Finance Plan
- G. Production and Marketing Plan
- H. Revenue Stream
- I. Risk Analysis/Mitigation Strategy



Key Ideas

The Commercialization Plan should illustrate your vision for the enterprise and how the proposed innovation fits into the future market.

This goal could be achieved by clearly articulating a compelling value proposition for your intended customer.

Keep in mind:

- 1. Reviewers see the Commercialization Plan first
- Clear Value Proposition is Key (Educate/Few Business Experts on Review Panel Despite Strong Effort)
- Don't Worry, It Doesn't Have to Be Perfect, Plus Everyone Gets It Wrong

A) Value of the SBIR/STTR Project, Expected Outcomes, and Impact

A good starting point for writing a commercialization plan is a clearly written statement that identifies the overall commercial goal of the project. This is your vision of what the product will do to meet a need and whom the project will affect.

Define the specific problem or opportunity addressed and its importance. The project and key technological objective(s) should describe enough of the technical aspects of the project for experts to appreciate the technical merit without going too deep into detail. Also, remember that failure to give sufficient detail may cause knowledgeable readers to question credibility.

Give a brief background/history that suggests there is a real problem that your project is addressing. The background should only be detailed enough to outline why there is a need for action to be taken. If applicable, state the advancements that have happened which have allowed your project to address the issue/problem. Expand on how your project creates a better solution to the previously addressed concern, specifying weaknesses in the current approaches (the advantages compared to competing products or services).

Describe the commercial applications of the research. List the potential impact a successful project could have. Identify key technical objectives and general expectations in terms of market opportunities, potential future products, or new areas of research. This is a brief overview of the market; a more detailed look into the market will follow in section C.

Be sure to highlight the non-commercial impacts on the overall significance of your project (specify the potential societal, educational, and scientific benefits of this work). Then finally, touch on how the SBIR/STTR project integrates with the overall business plan of the company.

Points of Emphasis

- Commercial and societal benefits
- Competitive advantage over existing technology

Outline of Part A

- Overall goal/objective
- The product, the problem it solves, and the benefits
- History/past data suggesting a problem
- The advantages compared to competing products or services
- Recent advancements
- Commercial application
- Market potential, future markets, new research
- Non-commercial impact
- SBIR/STTR integration with the business plan

B) Company Overview

The company overview asks for a brief description of the company to give the reviewers a better understanding of the company as a whole. They are looking for basic information such as when the organization was created, current number of employees, corporate objectives, core competencies, and a short description of the company's origins. If the company consists of only a few employees, then you should describe the team's capabilities specifically as they relate to the commercialization of your technology (example below).

Organizer: Christopher C. King, Founder & CEO, We Are Marcus - He is a social entrepreneur, activist, and educator. He earned his MBA from Howard University School of Business in 2018, MPA from Baruch College, Austin Marxe School of Public Affairs. He recently joined DC's premier Accelerator at 1776. The beta-launch of his product spans across several states in the US-including NYC, DC, Charlotte, and abroad in London, Dubai, Capetown, Ghana, and Jamaica. He has been featured in Black Enterprise and recently moderated at National Public Radio. Beyond these achievements, he brings with him a decade of diverse experiences from higher learning, consulting at Intel Corporation, to working on the operations staff for President Barack Obama in 2012.

Go into detail when listing previous history of Federal and non-Federal funding, regulatory experience, subsequent commercialization, and any current products/services that have significant sales. These past funding experiences, if applicable, should show that the funding awarded for the project was adequately used and provided a favorable outcome for the company.

Include your vision for the future in the short and long run. How will you grow/maintain a sustainable business entity? Will you meet critical management functions as your company evolves?

C) Market, Customer, and Competition

Market size is defined by the total annual sales of products that address a market's particular need. But one has to be specific about what the market's needs are. If applicable, when considering the market you are targeting, break it into primary, secondary, and tertiary customerbases. This will help you describe the target market segments and size while providing a brief profile of the potential customers.

When identifying these markets, it is helpful to ask the questions of why to target these markets, what the benefits are, and what data and studies would support this conclusion. Statistical data that shows the potential market size, market trends in the area, and potential profits from capturing a percentage of the market may be useful.

• For Example, 10% penetration into a \$2B market results in annual sales of \$200M. If a \$2B market is growing at 10% a year and your product can capture 50% of new patients, then first-year sales would be \$100M, followed by \$210M in the second year, \$330M in the third, and so on.

Points of Emphasis

- Relevant commercialization capabilities of your team [Short Bios – Business Experts First]
- Tap into your Board of Directors or Scientific Advisory Board
- Product lines that show successful market implementation [e.g., Services that the company provides]

Outline of Part B

Company information including:

- Corporate objectives
- Core competencies
- Present size, products/services with significant sales
- History of previous Federal and non-Federal funding
- Regulatory experience
- How the company plans to develop from a small technology R&D business to a successful commercial entity

Points of Emphasis

- Know your market and market needs
- Identify main customer bases
- Know your competition
- Look into what similar competition has done and amount of the total market they are attracting
- Reiterate the need for the product and address your competitive advantage
- Consider if collaboration/ partnering is strategically smart for you and if so, explain why
- Describe your market and sales strategy

Overestimating market penetration is a common mistake. Consider whether or not it is easy to gain market shares in a mature, slowgrowing market. Look at how other competitors penetrated the same or similar markets.



Clearly explain the Target Market [Will Later be Expanded Upon in the Customer Section of the Commercialization Plan - Personas]

Market characteristics to consider would be the motivation of customers to buy the product, the number of people that could potentially utilize the product and selling characteristics that make your project appealing. Keep in mind and reiterate the need for the product on the market and be proactive in identifying, characterizing, and marketing for the future. In cases where no comparable products exist to estimate a market's size, look at comparable markets and analogous products.

Make clear the advantages your product will bring to the market. How is it better than your competitors or previous way of meeting the need being addressed? For example, better performance, lower cost, faster, more efficient, or effective, or new capabilities. Explain the hurdles you will have to overcome to gain market/customer acceptance of your innovation. [Leads into next section, Competitors]

Each customer actually consists of an **end user** and a **decision-making unit (DMU)**. The end user is very likely an integral part of DMU but may not be the most important person in it. More specifically:

End User: The individual (a real person) who will use your product. The end user is usually a member of the household or organization that purchases your product.

DMU: the individual(s) who decides whether the customer will buy your product, consisting of:

- Champion: the person who wants the customer to purchase the product; often the end user.
- Primary economic buyer: the person with authority to spend money; sometimes, this is the end user.
- Influencers, Saboteurs, Purchasing departments: people who have sway to direct control over the decisions of the Primary economic buyer.

You will find much variety among the end target users. But as a startup, you will have to exclude many potential customers in order to stay focused on a key group of relatively homogeneous end users, who

Notes on Part C

Company analysis

 Corporate strengths and weakness need to be understood. Assessing product/company fit requires an understanding of the finances, R&D capacity, manufacturing capacity, and other assets of the firm.

Competitive Analysis:

- Identify both current and potential competitors. Competitor's strengths and weaknesses must be understood to seek differentiating possibilities.
- It is very important that you understand and know the competition.

Collaborator Analysis:

• Two key collaborators are the retailers and suppliers. With respect to the trade, the firm must understand their cost structure; expectations about margins and allocations of task; support and training requirements; and the nature of their relationship with the firm's competitors.

Context Analysis:

 Politics, regulation, law, and social norms are not fixed features of the marketing landscape, but factors to consider and monitor for signs of disruption will provide much needed initial cash flow. In biotech, the end users (customer who will use your product) is not the same person who makes the purchase decision (the buyer). The buyer often has distinctive needs from the end user that need to be addresses to achieve PMF, and you should define your target buyer in addition to your target end user when warranted.

D) Intellectual Property (IP) Protection

This section should summarize how the company will protect the intellectual property that enables the commercialization of its products while keeping competitors at bay. Should take note if the company plans to issue additional patents throughout the process.

• What patents protect the project or idea, and to whom do they belong?

If the company does not already have the IP it needs to discuss the licensing/filing strategy to make sure that no one else gets it first. If applicable, note other actions that the company may consider to constitute a temporal barrier to others aiming to provide a similar solution.

E) Regulatory Strategy

Describe the regulatory strategy that you are going to be undertaking to move your product towards the market. Outline how you plan to address data compliance and security (as this has become a very sensitive and large problem in the space).

F) Finance Plan

Start off with estimations of raised financing broken out by the different phases. The assumptions in phase II/III should identify the timing of the financial event(s) and milestones the company hopes to achieve in the forecasted time period. These should clearly describe the timing and financial needs to commercialize the product, process, or service.



Points of Emphasis

 List current patents or describe how the company plans to protect the IP

Sources of Funding for Commercialization

SBIR/STTR firm itself; private investors or "angels"; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a federal agency with the intention that the results will be used by the United States government; or other industrial firms.



Plans for financing may be demonstrated through one or more of the following ways:

- Letter of commitment of funding
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exists
- Letter of support for the project and or some in-kind commitment, e.g., to test or evaluate the innovation
- Specific steps you are going to take to secure Phase III funding

Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for the commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Phase III funding may be from any of several different sources.

G)Production and Marketing Plan

Describe how the production of your product/process/service will occur. Describe each step involved with taking your product to the market to sell which may include plans for licensing or internet sales.

Think about the 4 P's:

- 1. Product
- 2. Place (Channels of Distribution)
- 3. Promotion (Communications Strategy)
- 4. Pricing

Product: It should not be the thing itself but rather the total package of benefits obtained by the customer. After introducing a new product to the market, there should be a process of Product Life Cycle Management where the company continually tries to learn more about consumers from their reactions to the introduced product.

Place: The marketing channel is the set of mechanisms or networks from which a company takes its product to market with its customers for various tasks.

Promotion: Determining the appropriate ways to communicate with customers to foster awareness, knowledge about its features, interest in purchasing, likelihood of trying the product, and/or repeat purchasing.

Pricing: The value of the product can come from the customers' perception or from the actual product.

H)Revenue Stream

This section describes exactly how you plan to make money selling your product that is developed as the result of NIDA SBIR/STTR funding. A clearly laid-out explanation of how you plan to generate a revenue stream may incorporate many tools, such as revenue model estimations, charts, and graphs to display timeline goals. If a market is large and fragmented enough, a potential option would be to partner with other companies with a proven history of generating revenue. Also, take note of whether the company is a well-diversified company that has multiple products with few shared risk factors or if the company is developing a single product where the risks may be more centralized.

Examples of revenue stream generation include but are not limited to:

- Manufacture and direct sales
- Sales through value-added resellers or other distributors
- Joint venture
- Licensing
- Service

Two Key Questions:

- 1. Which potential buyers should the company attempt to serve?
- 2. How much customization should the firm offer in its programs, i.e., at which point on the market continuum will the firm construct plans:
 - Mass Market Market Segments
 Market Niches Individuals

Place

Channel Design

- Distribution via direct, indirect, or both ways
- Proper design of contracts, good communication
- Channel Management
 - What policies and procedures will be used to have the necessary functions performed by the various parties?

Promotion

- **Market** to whom is the communication to be addressed?
- **Mission** what is the objective of the communication?
- Message what are the specific points to be communicated?
- **Media** which vehicles will be used to convey the message?
- **Money -** how much will be spent on the effort?
- **Measurement** how will impact be assessed after the campaign?

I) Risk Analysis

This section describes all possible risks to the proposed to be developed product and mitigation strategies.

	Opportunities (external, positive)	Threats (external, negative)
Strengths (internal, positive)	Strength-Opportunity strategies Which of the company's strengths can be used to maximize the opportunities you identified?	Strength-Threats strategies How can you use the company's strengths to minimize the threats you identified?
Weaknesses (internal, negative)	Weakness-Opportunity strategies What action(s) can you take to minimize the company's weaknesses using your identified opportunities?	Weakness-Threats strategies How can you minimize the company's weaknesses to avoid the threats you identified?