

***Business Plan Template for
Breast Cancer Start-up Challenge***

Business Name

Group Name

Address Line 1

Address Line 2

City, State Zip Code

Phone Number

Email

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II. About the Business Plan

The latest start date for the business plan phase is November 6th, 2013. Business plan documentation/deliverables are due on January 14th, 2014. Final pitches will be conducted January 28th, 2014. Award decisions will be made by February 4th, 2014. Important points regarding dates are outlined below:

- Rolling Start Date into the Business Plan Phase: Your team will start when you are accepted into the LOI phase
- Final Deliverables Due: January 14th, 2014
- Pitches Occur: January 21-28, 2014 as scheduled through the Center for Advancing Innovation.
Submit availability for pitches by December 14, 2013
- Award Decisions Made: February 4th, 2014
- Awards Delivered: Within two weeks of the award decisions

Your business plan should be an approximate 10 pages not including your appendix. Remember to complete your other business plan phase deliverables, which can be found on the Challenge website.

While you are writing your business plan, please keep in mind the requirements of the NIH and Clemson licensing agreements as well as potential seed funders. For example, please note the key SBIR requirements:

- Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?
- Are design and methods well-developed and appropriate? Are problem areas addressed?
- How novel is the product and the approaches proposed to test its feasibility?
- Does the scientific environment contribute to the probability of success? Is the environment unique?

Please note that this template is an example of a traditional business plan versus a business model canvas. There are other resources for the business model canvas on the website:

<http://www.breastcancerstartupchallenge.com/>; click on “resources” and then select “deliverable guidance,” where you found this template.

III. Executive Summary

Teams should write this Section last.

The executive summary should be two pages or fewer. Imagine your executive summary as being content that your team covers in your five-minute “live” pitch. The executive summary should act as a strong opening statement to your business plan and should be able to stand alone as a document independent of the rest of the plan. You should attempt to intrigue your audience to learn more about your business with this section.

Explain the basic elements of the proposed business. Below are some things you may want to include (but are not limited to):

- A. Company Overview:
 - a. What does the company do?
 - b. Who are your target customers?
- B. Product(s)
 - a. What does your product do?
 - b. How is it differentiated?
 - c. Include information on ownership of the technology
- C. Competitive Analysis: What is the current competitive landscape?
- D. Business Strategy / Model:
 - a. How are you going to make money?
 - b. What are the benefits for payers? Venture capitalists? Etc.
 - c. Who is going to give you money so that you can achieve your strategy?
- E. R&D Path and Major Milestones
 - a. R&D, Regulatory, Commercialization
 - b. Exit plan
- F. Operations:
 - a. Marketing, and Sales
 - b. Manufacturing
 - c. Other
- G. Management
- H. Financial Summary
 - a. Include your projected positive cash flow vs. your burn rate
 - b. Include the financial value proposition to prospective investors and payers

IV. Company Overview

Be very specific about what area the company is working in. Give a concise but detailed description of your company, target customers and product area. Note that this is big picture and deep dive is later on. **Be optimistic but realistic.**

Background: An Introduction to your Company outlining what business/industry your company will be in and what it will do. Introduce the founders and their backgrounds as well

Mission Statement: Many companies have a brief mission statement, usually in 30 words or fewer, explaining **why your business exists** and your guiding principles for conducting business. Your mission should be formulated relative to the unmet need/target customers in business/industry that you are planning to enter

Vision of Success: Where do you imagine your company when you are profitable or when you exit? What constitutes success for your company and what will you do next once you achieve it?

Goals and Objectives: What does your business ultimately want to achieve? This can be in terms of financial performance, product commercialization, and/or other measures of business success. List out what objectives and milestones will need to be met and when they will be achieved

Market Analysis: Who are your target customers? What is the current state of the industry you are entering? What is the current Market Size and how will your product fare with current and potential competitors?

Business Strategy: How will your company create economic value and sustain profit? What partnerships or licensing agreements will you require so that your company may flourish? Is the company's business strategy one that has a high potential for success?

Core Competencies: Describe your most important company strengths and core competencies. What are your major competitive strengths? What background experience, skills, and strengths does your business have within this industry? List any additional assets and intellectual property your business may have (methodologies, etc.)

Value: Describe the value your company will create for key stakeholders, e.g., customers, payers, venture capitalists, etc.

Ownership: Who are the stakeholders in your business, what is the legal form of ownership (Partnership, Corporation, Limited Liability Corporation, etc.)? We understand that you have not formed a company yet, but propose what your company would do in the form of ownership

V. Product / Services / Solutions* – Current R&D

*Solutions are a combination of a product and service typically using unique assets

For this section remember that while being scientific, you must be descriptive and easily understood. Your audience will range from scientists, to CEOs, to KOLs in the field. Not all will have a Ph.D. background in your product's background.

Throughout this section keep in mind these metrics:

- How do you envision your technology will be used? – Therapeutic, Vaccine, Diagnostic, etc.
- Therapeutic Area and Indication
- Patient Population(s) – Race, gender, age, parity, etc.
- Stage
- How it works – Target, Mechanism of Action, etc.
- Differentiation – improve efficacy, less recurrence, improved specificity and safety, etc.
- Novelty - Does this technology affect a unique target or unique mechanism of action? Is this technology a new drug? "Novel" indicates that an invention has never been created before; it is new or does not resemble something formerly known or used
- Statistical Significance
- Clinical application
- Unmet Need – how does this fill an unmet need in the current/future market(s)? For example, if the current mammograms give a 30% false test, there may be a call for a better diagnostic
- Current Intellectual Property protection

Current Research & Development:

- What is the product/service/solution? Provide a detailed description
- What is the current stage of development on this product? Outline key points from R&D. Were these findings statistically significant? Are these findings better than prior/current research? Can and have the experiments been reproduced? Were they retrospective or prospective? What kinds of samples were used? Mice, Human or Cell Line?
- How do you envision your product will be used? For example, do you have an idea of the dosage and frequency of use for your product? How does this differ from current products?
- Clinical Applicability: What are the characteristics of your product that can be applied, relevant, or appropriate to be used in clinical practice?
- Market Differentiation: How will your product compare to other products in price, availability, and/or effectiveness? See Above
- Explain any strengths and weaknesses of the technology keeping in mind the metrics above

VI. Product – Future R&D

Future Research and Development: What are the next steps for developing this technology (short-term and longer-term)? What specific geographies will be covered? What stages will your technology need to go through from its current stage to production? Also include R&D that you may undergo post commercialization including any additional products you may be developing. What will your R&D consist of after your first product is on the market?

Milestones and Timeline: Provide a detailed timeline of your proposed milestones and dates. Include your go / no-go decisions on major objectives

Development Complexity: What challenges are there in further developing your product? Is there a precedent in developing similar technology? Are there similar technologies currently being researched? Is the patient population large enough? How will these and other factors affect your product's development?

Regulatory Paths: Define a clear regulatory path for any regulatory body, in particular, the FDA and EMEA (if relevant)

Intellectual Property: Include in your plan suggested dates for product patenting, licensing, and/or other technology commercialization. Please include guidance for executing the [NIH Start-up Exclusive License Agreements](#)

Collaborations: Please include any collaborations you plan to have in all phases of product development. Include the purpose of your collaborations and the value that each one brings to the table

VII. Market Analysis

Unmet Customer Needs: What important customer need(s) is the market not currently fulfilling? Specify the target customer and why; note that this should include the specific customer, for example, if your customer is a patient, think about race, gender, location, etc.

Target Market: Define your target market. Will your product be formulated for individual use, research and development, hospital care, or other? Start out being very precise about your particular market area. There may be several markets that your product may have the ability to enter, but be realistic and focused. What is the main market(s) you plan to enter? If there are additional exploratory opportunities for your product you may state them in the last two sections below

Current Market Size and Market Opportunity: Total size and demand of the current market. Also include the **addressable market size and demand**, where addressable is the size after market limiters such as adoption rate, user applicability, ability to diagnose, affordability etc. are applied

Market Trigger Points: Events that will create your market opportunity. Think about the things that will happen to create a large opportunity, for example, a current drug going off patent, new healthcare laws, etc.

Potential Market Penetration: What percent share of the addressable market will you have? How will this percentage change over time?

Market Growth Potential: Identify addressable market growth rate past and current (think about incidence, prevalence and mortality rates and how these may evolve). Identify current and past trends in product development in this market. How will the current market remain sustainable by the time your product reaches the market? What market factors are keeping it from evaporating?

Industry Trends: What trends relative to your industry do you see and what are the key drivers?

Additional Market Opportunities for your Product(s)

Note any additional operational, market, funding/investment, collaboration, geographic factors, etc.

VIII. Business Model and Growth Strategy

Business Strategy/Model: Describe your strategy for creating economic value for your company and potential funders (venture capitalists, private equity, angel funders, etc.). Write “a statement of how [your] firm will make money and sustain its profit stream over time.” Some things to consider when designing your business model:

- Value proposition
- Target customer segments
- Revenue Model
- Cost Structure
- Partnerships/Collaborators
- Funding (dilutive/non-dilutive)
- Licensing Model
- Core Capabilities and Assets that enable you to achieve this

Growth Strategy: How will your company sustain profit and growth? Although your target market may see positive growth, how will your company remain differentiated from the competition? Will you create additional products or seek additional markets for existing ones? Consider trigger points as patent expiry, future R&D milestones, future competition, generics, etc.

Exit Strategy: Does your business have an exit strategy? What is your endgame for your company? How long will it take to achieve your endgame? Will your company continue to exist or will your business model set up your company for eventual mergers and acquisition?

Investments: What investments are required? Who are your target investors? How much will you get? What creative mechanisms do you have for financing and/or reducing risk for investors?

IX. Competitive Analysis

Definition of competition: How do you define direct vs. indirect competition for the business? What kinds of products and companies will be in competition with you? Competition can come from anywhere. Competition does not mean there is a product like yours, but means are there products that currently and could potentially fill your specified target market.

Overview of competition: Will the competition affect your business across the board, or for certain products, or for certain facets of your product (customers, location, etc.)? What is the current competition and future competition? Please be sure to analyze clinical trials in clinicaltrials.gov to determine if there could be upcoming competition. Also, search the patent database to identify any similar inventions that could serve as substitutes for your invention.

Direct Competition (by geography, customer segment, etc.):

- Products in the market
- Products in the pipeline

Indirect competitors: What potential indirect competitors are there? For example, if you have a therapeutic for triple negative breast cancer and there's a vaccine coming out for triple negative breast cancer, the vaccine will prevent triple negative breast cancer, and, therefore could be considered an indirect competitor.

Competitor matrix: By product, by price, by company, geographic region, customer segment or other important dimensions; think through all the bases/characteristics upon which you compete

Competitive Advantages: What advantages does your product possess and how will your business/product react to current and future competition?

X. Operational Plan

Detail the daily operations of your business, including facilities, personnel, and processes. Note that you could operate completely virtually and rely on a supplier network for operations.

Location / Facility: Where will your product be produced? Where will you keep your inventory? How many facilities will be needed and where? What equipment will you need at each location?

Manufacturing: How you will manufacture your product. Include your methods of production, quality control, and product development. Note the GMP regulatory requirements and also the policy requirements of NIH. If you will be outsourcing your manufacturing provide these details as well.

Supply, Distribution, and Inventory: Outline how you will keep inventory of your product. Who are the key suppliers and your distribution processes?

Back Office Operations / Overhead: Administration, Finance/Accounting, Human Resources, Technical Support, Customer Service, etc. Include approximate personnel as well as any training requirements that will be needed.

Strategic Partnerships: For any of the above list strategic partnerships you will be entering in order to execute your operational plan (e.g. CROs, CMOs, collaborators, outsourced manufacturing, etc.)

Operational Costs: What are the costs of each step in your operational plan? What financial resources will be needed to conduct your plan?

XI. Licensing, Market and Commercialization Plan

Licensing:

- What is your licensing schema? Will you sub-license, out-license, in-license?
- How will your revenue be split amongst your business and the owner(s) of the licenses?

Pricing of product/service:

- How will you charge for your product? (Consider performance based pricing.) What is the price of your product? What is your strategy in pricing your product and how does this compare to the competition?
How does contracting, hedging, forward pricing, options, insurance, government regulations or other pricing factors affect your strategy? Hedging, forward pricing, and options are investment positions used to reduce losses/gains by future market changes.

Payors:

- Who will pay for your product and why would they want to pay? (Note this includes insurance companies as well as patients)
- How will your product be worth the switch? Consider what is on the market now and whether your product will allow a smooth transition from the current products, without a significant increase in cost or inconvenience to the payor.

Marketing Strategies:

- Advertising, promotions, public relations, **brand strategy (Think about naming your product.)**
- Marketing Alliances
- Marketing Goals
- Marketing Action Plan and Timeline
- Marketing Budgets

Sales Strategies:

- Where will you sell? When? Where? How much? Why? How? (Provide assumptions.)
- Outlet you will use to conduct your sales (direct to customer, hospitals, pharmaceuticals, etc.)
- Sales Goals
- Sales Action Plan and Timeline

XII. Risk / Mitigation

Think about risks in the following categories

- **Dependencies:** Are there any dependencies for your product in terms of R&D, distribution, or product use? (e.g. X-rays, mass spectrometry, other tissue dissection techniques, specific genetic tests, dual therapy, etc. required) What are the costs if any?
- **Operational Feasibility:** Patient recruiting, funding, non-market forces, legal, political, failure rate, mortality rate, development complexity, media, payers reimbursement, regulatory approval etc.
- **Other Risks:** Other risks or barriers to entry

Identify Mitigation Tactics: How will you face and mitigate any of the risks above?

Outline each risk, your mitigation plan for each as well as your evaluation of risks based on:

- What is the probability of the risk occurring?
- What business impact will the risk will have?

XIII. Management Team and Ownership Model

- **Officers**
- **Key Employees / Management Team**
- **Board of Advisors** - gives professional and knowledgeable advice to the organization in individual areas of expertise
- **Professional Support:** Legal, accounting, consulting, mentors, CROs, CMOs and key advisors
- **Optional:** Board of Directors

Organizational Chart: Provide an organizational chart displaying the management hierarchy

Core Competencies: What experience does each person bring to the business? With your proposed management team, outline the company's core competencies

Recruitment: How will your company recruit new employees? Is there a plan for continuation of the business if this person is lost or incapacitated?

Compensation: What is the proposed compensation for your management team

Ownership: What is the ownership structure for the company? Who are the primary stakeholders of your company?

Company Model: What is the legal entity of the company (Partnership, Corporation, Limited Liability Corporation, etc.)?

XIV. Financial Analysis

Explain your research, assumptions and how you arrived at your forecasts of revenue and expenses. Give sources, amounts, and terms of proposed income, grants, investments and loans. Additionally outline any and all partnerships or ventures you have entered, how much has been contributed by these partnerships, and what percent ownership each will have.

Remember to be clear about all your assumptions. All of your data and assumptions should be properly sourced. Be as specific as possible.

Financial Summary

- Sales Projections – should have sales per population channel and with penetration rates
- Income Projections
- Manufacturing and Distribution Costs
- Research and Development Costs
- Sales and Administration Costs
- Partnership costs (from licensing agreements, royalties, etc.)
- Cash Requirements (based on structured deals, up-front payments, milestones, etc.)
 - Start-up Costs
 - Milestone requirements
- Sources of Financing
 - Personal
 - Venture / Private Equity
 - Partnerships
 - Licensing
 - Grants
 - SBIR/STTR
- Additional notes on Financial Statements

Required Financial Statements (can be placed in Appendix)

- Profit and Loss Sheet
 - 1- Year
 - Multi-Year
- Cash Flow Statement
- Balance Sheet
- Break Even Analysis

XV. Appendix

Please include financial and valuation models as well as any additional information you feel is required. Also, if you have assumptions in your financial models, please source them all.