

Section 2. Develop a Business Plan

Content and references that were presented under the “Key Points” and “Challenge” tabs.

1. Business & Product or Service Descriptions

Start your business plan with these three basic descriptions:

1. Executive Summary

Your business’s focus, its mission, the products or services offered, the ownership, and a summary of your plans.

2. Company Description

The company name, location, key people, history, and nature of the business.

Goals and how you will achieve them.

Funds needed and how you will use them.

3. Product or Service Description

What the product or service is and how it works.

The value proposition, which is the reason someone will want to do business with you, including...

- The customer’s need or problem.
- The benefits of your product or service.
- How the benefits solve the customer’s need or problem.
- Why your solution is the best.

References

Conrad M, Chan V, Miller L. [Writing Business Plans for a Life Science Startup or Clinical Program](#). *Academic Entrepreneurship for Medical and Health Scientists*. September 27, 2019;1(2 Finance):Article 2.

Excedr. [How to Write a Business Plan for Your Biotech Startup](#). Excedr. February 7, 2022.

Tips from *Business & Product or Service Descriptions*

Make your business plan concise and clear for the audience reviewing it.

Show why you care about your product or service and why others should too.

Challenge from *Business & Product or Service Descriptions*

Sarah Johnson, PhD is starting a company to produce antiviral peptibodies and described her company and product in her Story above (Please [review](#) before answering this challenge). She wants to understand how close she is to interesting potential investors in her company. Please help her by evaluating whether her planned business, *ViroPep*, appears to meet the following investment criteria. Make your choice and compare your answer to the average rating by (fictional) investors, then click next to proceed.

1 2 3 4 5 6

This business is a sound idea.

Strongly
disagree

Disagree

Neutral

Agree

Strongly
agree

Average potential investor rating: Neutral

Reason: The idea has the potential to lead to a disruptive technology, that is, one that could have a major impact on the antiviral industry if all research results go as hypothesized. However, more product development and data is needed before investors can determine whether it is likely to succeed and is a sound investment.

✓ 2 3 4 5 6

The business has a proof of concept prototype.

Strongly disagree Disagree Neutral Agree Strongly agree

Average potential investor rating: Disagree

Reason: Although laboratory results are favorable in vitro, a proof of concept needs to be completed in vivo.

✓ ✓ 3 4 5 6

The quality of the management team is good.

Strongly disagree Disagree Neutral Agree Strongly agree

Average potential investor rating: Disagree

Reason: Although the scientist is impressive in her scientific accomplishments, she does not have business experience or a management team so far.

✓ ✓ ✓ 4 5 6

The company has enough strategic relationships to succeed.

Strongly disagree Disagree Neutral Agree Strongly agree

Average potential investor rating: Strongly disagree

Reason: The business has yet to start building strategic relationships.



The product is already being produced or service is already available.

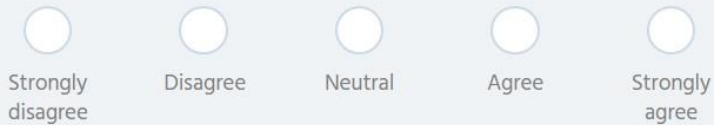


Average potential investor rating: Strongly disagree

Reason: ViroPep has not yet produced their product.



Sales to date indicate success is likely.



Average potential investor rating: Strongly disagree

Reason: ViroPep has no sales so far.

2. Business & Management Structure

Part I: Business Structure & Your Management Role

Business plans describe the business structure, which includes who will own the business and the company's legal status. Business plans also describe the management structure, that is, who will run the company and what roles they will play. Determine who else you wish to include in your founding team. To develop an excellent business rapidly, try to attract a talented and diverse team, one that is capable of doing what is needed.

Business Structure

The business model you choose will define who owns the company, what legally defined structure you will follow, the effect on taxes, and your personal liability for business debt. Most startups choose the structure of a corporation eventually, but many start as a limited liability company (LLC). Both protect the founders from lawsuits against the business.

(Entrepreneur, 2023; Leonard, 2015; SBA, 2023)

LLCs vs. Corporations

Limited Liability Companies (LLCs)

LLCs protect personal assets from liability while passing profits and losses to your personal income tax, thus avoiding corporate tax rates. LLCs are often used for startups, especially initially. LLCs can also have tax advantages for individual investors.

Corporations

Corporations are separate, legal entities owned by shareholders and guided by a board of directors. Corporations offer the strongest protection from personal liability but cost more to form. The types of corporations most often used for biotech companies are . . .

S corp – A type of corporation with some tax advantages. Profits and losses pass to the owners, which avoids corporate tax rates. There are some limitations on stockholders and class of stock issued.

C corp – This is the standard form of corporation. Owners or shareholders in the business are taxed separately from the business. Income tax is paid at the corporate level, and shareholders pay taxes on the profits distributed as dividends. C corporations have fewer restrictions on ownership and stock options than S corporations.

Management Role

Decide what role you will play and who will be the founders and key personnel. Before taking on an executive role, consider whether you have executive experience, how well it went, and whether you could commit a lot of time (potentially unpaid initially, beyond typical business hours, and during crises). Note that some academic institutions do not allow their researchers to take on executive positions in companies arising from their research. You could choose to focus on any of the following business roles or focus on science and leave running the business to others.

(Heaslip, 2021; Investopedia, 2022)

Potential Role Choices

Founder

Founders are engaged in starting the business. If this is your only role, after founding the company, you would hire someone to fully develop the technology and run the business. This would free you up to continue a research or academic career or to start another company.

Chief Investigator/Chief Science Officer ([CSO](#))/Chief Technology Officer (CTO)

As CSO/CTO, you would run the business's research and development. You could also play a less active role by being on the company's scientific advisory board and remain in academia.

Chief Executive Positions ([CEO](#), [COO](#), or [CFO](#))

- Chief Executive Officer (CEO) – Highest-ranking position, reports to the board and maximizes the business value by focusing on long-term aspects of the business and setting future strategies. It is important to fill this position early.
- Chief Operations Officer (COO) – High-ranking position, maximizes business value by focusing on current operations.
- Chief Financial Officer (CFO) – High-ranking position, strengthens business value by using financial data to generate insights needed to make decisions.

References

Entrepreneur. [Business Structure Terms | Small Business Encyclopedia](#). *Entrepreneur*. March 3, 2023.

Heaslip E. [Executive Job Titles: What Do They Mean?](#) US Chamber of Commerce. March 8, 2021.

Bloomenthal A. [What is the C Suite?: Meaning and Positions Defined](#). Investopedia. July 25, 2022.

Leonard MJL. [Choice of Entity for Biotech Startups](#). San Diego Corporate Law. November 9, 2015.

SBA. [Choose a business structure](#). Small Business Administration. Accessed March 6, 2023.

Tips from *Business & Management Structure – Part I: Business Structure & Your Management Role*

- Invest in a lawyer with a sound understanding of corporate law when you incorporate rather than using a less costly one who specializes in something else.

- When you select managers, be sure to consider the opportunities available for women-owned businesses (defined as being more than half owned and managed by one or more women).
- Your business structure affects what taxes you will owe.
- You may switch your business structure later to gain different advantages.
- Although it may be possible to incorporate without an attorney, they can help you avoid costly mistakes.

Challenge from *Business & Management Structure – Part I: Business Structure & Your Management Role*

Drag the business and management structure terms on the bottom to their matching definitions.

: Protects personal assets from liability, Passes profits and losses to personal income tax, and avoids corporate tax rates.

: Owned by shareholders and guided by a board of directors. Offers the strongest protection from personal liability.

: Focuses on long-term business aspects and future strategies.

: Runs the business's research and development.

: Strengthens business value by generating data-based insights.

Chief Scientific Officer - CSO

Limited Liability Company - LLC

Chief Executive Officer - CEO

Chief Financial Officer - CFO

Corporation

Check

Answers:

Drag the business and management structure terms on the bottom to their matching definitions.

Limited Liability Company - LLC: Protects personal assets from liability, Passes profits and losses to personal income tax, and avoids corporate tax rates.

Corporation: Owned by shareholders and guided by a board of directors. Offers the strongest protection from personal liability.

Chief Executive Officer - CEO: Focuses on long-term business aspects and future strategies.

Chief Scientific Officer - CSO: Runs the business's research and development.

Chief Financial Officer - CFO: Strengthens business value by generating data-based insights.

Chief Financial Officer - CFO

Chief Executive Officer - CEO

Chief Scientific Officer - CSO

Limited Liability Company - LLC

Corporation

0/5

Retry

Poll: If you were to start a business, what role (s) would you like to play?

- Founder
- Chief Science Officer
- Scientific Advisory Board Member
- Chief Executive Officer
- Chief Operations Officer
- Chief Financial Officer

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Part II: Founding Team

Cofounders and Partners

As you plan your company, decide whether you want to be the sole founder or have cofounders or partners. Consider who else you want on your founding team.

Pros and Cons of Cofounders and Partners

The right partner(s) and team can free you from having to know or do everything. The wrong partner may not supply what you need or may even limit your progress. Most experts on entrepreneurship recommend having cofounder(s) or partners, but they warn that you should choose them wisely.

What to Learn About Potential Cofounders/Partners Before Committing

- Make sure you share goals and values.
- Look for compatible work styles, business philosophies, visions, and ethics.
- Decide who will be considered a founder and how much equity you should each get.
- What connections and potential sources of money do they bring?

- What other commitments do they have?
- Agree upon responsibilities and time commitments.
- How much salary do they need, and can they defer it if needed? Are they financially stable?
- What would lead them to leave the partnership?
- How do they deal with problems and handle stress? Make a plan for conflicts that are not easily resolved.
- How long did they stay at their jobs, and what accomplishments do they have?

(Gascoigne, 2018)

Reference

Gascoigne Adriana. [*Tech Boss Lady: How to Start-up, Disrupt, and Thrive as a Female Founder*](#). Seale Press. October 9, 2018.

Dividing Equity Among the Founding Team Members

Be sure to talk with each member of the founding and executive team about equity distribution. The proportion of equity is typically determined by the value an individual brings to the business and includes consideration of. . .

- Who had the business idea.
- Who did the work.
- The extent of each person's involvement after the inception of the business.
- Value added to the business by a scientist's or executive's reputation for past work.

(Krawczyk, 2023)

Work out these details early with a lawyer. Plan carefully so that founders are left with some equity despite dilutions from investors.

Reference

Krawczyk R. [How to split equity amongst founders? \(Updated in 2022\)](#). RST Software. 2023.

Tips from *Business & Management Structure – Part II: Founding Team*

- Keep in mind that investors look for a management team that can implement the business plan.
- Make sure you can see yourself working intensely with a potential partner for several years.
- Look for partners and management who have the same vision and goals for the business.

Challenge from *Business & Management Structure – Part II: Founding Team*

Instructions: Please review this transcript of an interview with a potential business partner (fictional) and rate how much you would like them as a partner. Submit your response to compare your answer to that of others.

What goals and values are most important for you if we partner in this business?

I put the success of the company above all else, except for my health and my life partner.

Please tell me about your work style and business philosophies.

I will work 12 to 18 hours a day for a few years and expect the same from my partner.

How many founders are you willing to have and how much equity do you think we should each get?

If we do this, I don't want any other founders and want equal equity with you.

What connections and potential sources of money do you bring?

I don't have financial resources to contribute, nor any connections with money. But you can count on me being knowledgeable about how to get SBIR funding.

What other commitments do you have?

I have a life partner who is on board with me committing to this partnership, but I will consider their wishes before making further commitments. Other than that, this company will be my top priority.

What responsibilities and how much time can you commit to at this point in time?

I think we can work all that out later as we go.

Are you financially stable and secure enough that you can defer a salary if needed?

I can defer a salary for up to a year and expect you to do the same if we need it for the company to survive.

What would lead you to leave the partnership?

Anything unethical or if you do not fulfill your part of our agreement.

How do you deal with problems and handle stress? What do you propose for conflicts that are not easily resolved?

I give the most effort to the most important problems. To avoid conflict, I think it is important to have good communication. I would really listen to my partner and try to see their point of view. If we cannot work it out, we could engage the help of a neutral third party.

How long did you stay at your jobs and what accomplishments do you have?

I have jumped around every year or so in different biotech companies and different types of positions, to gain a broad understanding of the industry.

Question:

Would you like this person as a partner or
cofounder?

- Not at all
- A little
- Somewhat
- A lot

3. Seek Professional Assistance

Attorneys, Accountants, & Other Professionals

You will need a good lawyer, accountant, and other expert assistance to start and run your business. Look for professionals with experience in the specific field where you need expertise and whom you trust and work with well. For example. . .

- Accountants – Look for experience working with small business startups and SBIR funding. For taxes, seek a business tax expert.
- Attorneys – Look for familiarity with life science startups and licensing. Attorneys are needed to help set up the company, identify and record your obligations, and deal with intellectual property (IP), licensing, and investors' rights.
- Bank Officer – Look for a bank that is familiar with and able to provide services for a life science company from startups through later stages.
- Insurance Broker – Look for experience with business insurance.

(Thiefels, 2019)

Example: Hiring an Attorney to Protect Intellectual Property

What are the advantages of establishing your intellectual property legally?

1. It is attractive to investors and customers.
2. It deters infringement lawsuits from others claiming some or all of your technology is their idea.
3. It may deter others from working on something similar.
4. It adds value to your company's assets and can increase your leveraging power.

(National Law Review, 2018)

References

Thiefels J. [5 Professionals Every Business Owner Should Work With](#). ThriveHive. January 3, 2019.

[What Start-ups Need to Know About Intellectual Property](#). *The National Law Review*. September 25, 2018.

Tips from *Seek Professional Assistance*

- To find professionals, take advantage of state and local resources available to small businesses, often free of charge. The Small Business Administration (SBA) website has a searchable database of local resources.
- Some law firms will provide services at a low cost if your business looks like it will be a good source of future income.
- You can charge part of the expense of hiring professionals to the indirect costs in grant awards.
- You may want to employ a personal attorney to represent your interests—for example, if your interests diverge from the business's interests.

Challenge from *Seek Professional Assistance*

See how much terminology you know about protecting intellectual property or give it your best guess and learn some definitions of important terms to know.

Instructions: Drag the words at the bottom into the boxes you think correspond with the correct definition.

Matching

- – The ownership of a collection of ideas and concepts.
- – Preserves the confidentiality of information in order to preserve its value.
- – The right granted by the government to prevent others from making, selling, or using a unique invention for a period of time.
- – An invention that was already available or publicly known, even in part, before you applied for your patent.

Answers:

4. Market Research

Market Research: What to Research Before Starting a Business

Learn about. . .

1. Alternative solutions to the problem your technology solves and how they compare in terms of cost and performance.
2. The industry you will be in, including its risks and obstacles.
3. Your customers, including their characteristics, the problem your business solves for them, and why they would prefer your solution.
4. Market size, which is the percent of the total potential customers who are likely to adopt the product or use the service. The target market should be large enough to make a profit and/or should be growing rapidly.
5. Other stakeholders' requirements and motives, including the end user, payer, and state, local, and federal regulators.
6. Suppliers, the challenges involved, and availability of backup suppliers.
7. Competitors, including their market share, similarities, and differences.
8. Regulatory requirements, such as [FDA](#) approval.

References

Compliance Online. [Biotechnology Regulatory Compliance Best Practices](#). Compliance Online. 2021.

Entrepreneur Media Staff. [The Best Ways to Do Market Research for Your Business Plan](#). *Entrepreneur*. January 20, 2015.

[SBA. Market research and competitive analysis](#). Small Business Administration. Accessed March 7, 2023.

University Lab Partners. [The Importance of Market Research in Biotech and Medtech Startups](#). University Lab Partners. December 11, 2020.

Tip from *Market Research*

Use the searchable database [NIH RePorter/Matchmaker](#) to learn your competitors' overlap with your product or service, their target customers, and their science.

Challenge from *Market Research*

Based on the description that Dr. Leslie Bowen gives of her business in her Story, which of the following are a part of the business's value proposition?
(Select all that apply)

- Leslie may make enough money to funnel back into her research, which will help keep her lab functioning between grants.
- Because Leslie will grow the neurons in bulk, the cost to other scientists will be lower than if they grew the neurons themselves.
- Supplying neurons ready for research saves other scientists time, allowing them more time to focus on their research.
- Leslie will be able to write publications on her research with these neurons, which will help her advance in her academic career.
- Leslie's focus on quality will result in a higher success rate for her customers' experiments.
- As a scientist in the same field, Leslie's lab-grown neurons are more likely to meet the specific needs of researchers in her field, which she understands better than large manufacturers.

SUBMIT

Feedback:

The value in “value proposition” is from the customer’s perspective, not the business owner’s. So Leslie making money for her research and being able to write publications is of value to her but not part of the “value proposition.” All of the other choices are correct.

5. Financial Analysis and Projections

Components of Financial Analysis and Projections for a Business Plan

Even if you have a partner or someone you hire handling the financial aspect of your business, you need basic knowledge to understand their reports and recommendations and to evaluate their work.

You will need to gather the following information to generate a financial projection:

1. Establish your price.
2. Develop an order fulfillment strategy.
3. Estimate costs for raw materials, salaries, activities (e.g., travel), rent, and equipment.
4. Estimate how long it will take to produce your product or to provide your service.
5. Project your sales revenue and other income.
6. Analyze cash flow and balance statements.
7. Estimate a year's worth of costs, including any loan repayments and the income you want/need.

A [worksheet for a projected financial statement](#) can be downloaded from the SCORE.org website. The results help indicate whether your business is likely to succeed.

How long does it take to bring a product or service to market, and what does it cost?

Successful biotech companies have started rapidly with under \$200,000 (ULP, 2020). However, more typical scenarios involve years and much higher costs.

- Diagnostics, medical devices, and molecular tests can take three to seven years and cost millions (Biolyse, 2018).
- A new drug or biologic could cost around \$2.5 billion and take 10–15 years (ULP, 2020; Biolyse, 2018).
- A business that provides a service, such as running a lab or a [contract research organization](#), typically can be developed faster and cost less. However, there are time-consuming steps, including registrations, licensing, and finding the financing to purchase enough equipment at the outset. For example, CLIA registration is needed to run a clinical laboratory.

What is the success rate for biotech companies?

The startup success rate for health tech, which includes hospital management, health monitoring software, and telemedicine, is 20%, comparable to the overall success rate for all startups in the US (SPD Load, 2022). The success rate for pharma startups is 18% to 37% if success is defined as having an initial public offering or being acquired by another company and achieving required approvals (Melchner et al., 2021). Although non-biotech startups often create more net value, more biotech startups are acquired by established businesses than non-biotech companies, often before the initial public offering (Black, 2021). The most common reasons for failure in health tech are not determining the business's [value proposition](#) and choosing the wrong strategy to prove it.

References

Biolyse. [How To Start A Biotechnology Company Fast](#). Biolyse. August 21, 2018.

Black S. [Are biotech companies really high-risk investments?](#) ScienceBoard.net. January 7, 2021. Citing a study by the Bentley University Center for Integration of Science and Industry.

Melchner von Dydiowa G, van Deventer S, Couto DS. [How large pharma impacts biotechnology startup success](#). *Nat Biotechnol*. March 2021;39(3):266–269. [doi:10.1038/s41587-021-00821-x](#).

SCORE. [Business Feasibility Analysis](#) – SCORE 4.15. July 29, 2021.

SPDLOAD. [Startup Success Rate in 2023 by Stage, Industry, Location](#). SpdLoad. Accessed December 30, 2022.

University Lab Partners. [Finding Funding for Your Biotech Startup](#). June 8, 2020.

Tip from *Financial Analysis and Projections*

To reduce initial costs as you start your business, join forces and share resources with other small businesses rather than setting up your own laboratory, or operate your office virtually.

Challenge from *Financial Analysis and Projections*

Topic: Cost and time projections in the biomedical/biotechnology industry

How long do you think it takes to develop a moderate- to high-risk (Class II-III) medical device?

- 12 to 28 months
- 31 to 54 months
- 94 to 140 months

Guess how much it costs to develop a moderate- to high-risk (Class II-III) medical device.

- \$1 to 18 million
- \$18 to 31 million
- \$31 to 94 million

Feedback:

It takes around 31 to 54 months to develop moderate- to high-risk devices. Note that different technology sectors differ in development costs and time. For example, medical products often take longer and cost more than environmental, agricultural, or food products.

The estimate by University Lab Partners (2020) for Class II (moderate-risk) devices was around \$31 million and for Class III (high-risk) devices around \$94 million.

Reference

University Lab Partners. [Finding Funding for Your Biotech Startup](#). June 8, 2020.

6. SBIR/STTR Grants

Part I: Overview & Initiating Grant Proposals

[Seed funding](#) gets businesses started by financing product development, market research, and business formation. Seed funds that are [non-dilutive](#) (do not give any ownership of your business to the funding source) are very attractive because you get to keep ownership of your business and its profits. This also helps attract investors later.

The Small Business Innovation Research ([SBIR](#)) and Small Business Technology Transfer ([STTR](#)) funding supply non-dilutive funds for many startups in the life sciences. Other non-dilutive seed funding sources include university seed funds, entrepreneurship competition awards, [crowdfunding](#), and some foundations interested in your product or service.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Funding

The SBIR and STTR programs are among the largest sources of early-stage financing for small businesses in the US and lead to innovative commercial products and services. To obtain funding, scientists at eligible small, US, for-profit businesses write proposals and submit them for review in a competitive process.

- SBIR/STTR money is not a loan, so you do not have to pay it back.
- Unlike most other funding, the government does not gain equity in your business, so you will still own 100% of your company.
- You can write the proposal with co-investigators.
- You can include an appropriate salary for yourself in the proposal.

The National Institutes of Health (NIH) and the National Science Foundation (NSF) provide most life sciences and biomedical funding. Other agencies providing some SBIR/STTR funding include the Department of Defense (DOD), the Environmental Protection Agency (EPA), and the Biological Advanced Research and Development Authority (BARDA).

Reference

NIH. [SEED – Helping Innovators turn discovery into health](#). SEED. 2023.

Preparing to Write an SBIR Grant Proposal

1. Determine the eligibility of your business for SBIR/STTR.
Your business must. . .
 - Be a small business, organized for-profit, and be US-based.
 - Have a limited number of employees (< 500).
 - Have majority ownership by US citizens or permanent resident aliens, be independently operated, and meet other [eligibility criteria](#).
 - Spend the money in the United States.
2. Complete several business registrations.
 - System for Award Management (SAM). The Unique Entity Identifier (UEI) number is also obtained during SAM registration.
 - Grants.gov.
 - Electronic Research Administration (eRA) Commons.
 - Small Business Administration (SBA) Company Registry.

(See Registrations in this game for details on these registrations.)
3. Identify the best NIH Institute for your proposal and identify who to contact.
 - Use the searchable database NIH RePorter/Matchmaker to identify agencies or institutes that fund research similar to yours.

- Look for SBIR grant opportunities in the NIH's omnibus solicitation on the NIH website. Read descriptions of each funding agency's programs and research topics. Learn their interests and who to contact.
- Learn proposal deadlines for the institute you selected. The NIH has three standard grant proposal submission/review cycles per year, currently September, January, and April. The NSF accepts proposals any time. Check dates for other agencies, which also differ.
- Contact the agency or institute's representative early to ask if your idea fits with their mission and current goals. Send a brief email with your grant proposal's specific aims (NIH) or an executive summary (NSF).

Tips from *SBIR/STTR Grants – Part I: Overview & Initiating Grant Proposals*

- Find the agencies offering SBIR/STTR funding that have a mission and goals aligned with your research.
- When applying for an SBIR or STTR grant, build a relationship with your program officer. They are there to help you!

Challenge from *SBIR/STTR Grants – Part I: Overview & Initiating Grant Proposals*

Small Business Innovative Research (SBIR) Grant Numbers Challenge *(Take a guess if you don't know)*

How many standard grant proposal submission and review cycles does the NIH have per year for SBIRs/STTRs?

- 1
- 2
- 3
- 4

Feedback:

The NIH has three standard grant proposal submission/review cycles per year—currently September, January, and April—when you can submit a proposal. You can submit a proposal to the NSF at any time. Other agencies providing SBIR/STTR grants and other types of NIH grants have different submission/review cycles, and some have only a single one each year.

Part II: Writing and Submitting Grant Proposals

Help with Writing an SBIR/STTR Grant Proposal

Several government programs are designed to help you write proposals or develop the commercial potential of your business, such as the Applicant Assistance Program (AAP) and Technical and Business Assistance (TABAs).

- **Applicant Assistance Program (AAP)** – The AAP helps new investigators in underrepresented groups (women, minorities, and people from certain regions) write and submit Phase I SBIR/STTR grant proposals. It provides coaching and guidance on application needs assessment, preparation, and review.
- **Technical and Business Assistance (TAB A)** – For investigators already having at least a Phase I SBIR award, TAB A provides a needs assessment and commercialization report. TAB A funding may also support commercialization needs, such as market research or regulatory or manufacturing planning, during or after Phase II.

Parts of an SBIR/STTR Grant Proposal

- **Abstract**
A summary of the project that includes a brief, simplified description of the significance, relevance to the institute’s mission, innovation, aims, and long-term objectives. Limit: 30 lines of text.
- **Specific Aims**
A brief statement of the significance and innovation of the project followed by a list of several main objectives. Limit: 1 page.
- **Research Strategy**
A more detailed description of the significance of the research, innovation, and your approach to conducting the research. Limit: 6 pages for Phase I, 12 pages for Phase II.
- **Facilities and Equipment**
Describe the physical facilities where you will conduct the research and the equipment you have available.
- **Human Subjects or Animal Subjects**
If your research includes human or animal subjects, describe the plans in detail and the status of your application to the institutional review board that governs your research. The review and approval process can take several months.
- **Other**

- Biosketches – Follow a specific NIH format, which includes a personal statement of why you are suited for your role in the project. Limit: 5 pages.
 - Letters of Support – These should be from potential customers and scientists who can describe the need, importance of the innovation, or likelihood of success.
 - Subcontractors and Consultants – Who will help complete the project?
 - Budget – Allow plenty of time to complete this.
- **Commercialization Plan**

This section is included in Phase II proposals and describes the proposed product's or service's market potential, including market and competition, the strategy for commercializing the product or service, how you will generate revenue, and the resources needed. Limit: 12 pages. Phase I recipients can apply for a program called Innovation Corps (I-Corps), which is a seven- to eight-week training in entrepreneurship that helps a business prepare for commercialization.

You Finished Your Grant Proposal. What Happens Next?

Submit your proposal electronically on time using. . .

- The **Application Submission System & Interface for Submission Tracking (ASSIST)** program found on the NIH's online portal, the Electronic Research Administration or [eRA Commons](#).
- The **FastLane System** found on the NSF's [Research.gov](#), or Grants.gov.

Proposal Review – The scientific review takes around two months. At the NIH, your proposal is assigned to a **scientific review group**, composed of NIH staff and non-NIH scientists. Three group members comment on and score each part of the proposal separately and the proposal overall. The best possible score is 1, and the worst is 9. Only the top-scoring proposals are discussed and scored by the whole group. The reviewers' comments and scores are combined in a **summary statement**, which is sent to you.

Impact Score and Funding Process – Your proposal is given an overall “impact” or “priority” score, which is the average rating by the members of the scientific review group times 10. The lower your score, the better. Scores of 10 to 30 have the best chance of being funded. Scores over 45 are rarely funded.

A council meets around a month later to determine which proposals to fund. They consider the impact score along with their institute’s mission, current interests, and funding of similar projects.

Consider Resubmitting If Not Funded – Review your summary statement and talk with your [program official](#) to determine whether resubmitting seems indicated. Ask if they have any further advice.

Review sample summary statements available on some NIH institute websites to learn how other businesses were able to address reviewers’ concerns, resubmit, and obtain funding. For example, the NIA offers [examples of proposals and summary statements](#).

References

NIH. [How to Apply | Seed](#). SEED. 2023.

NIH. [SEED – Helping Innovators turn discovery into health](#). SEED. 2023.

Tips from *SBIR/STTR Grants – Part II: Writing and Submitting Grant Proposals*

- The NIH’s [SEED](#) website describes all aspects of SBIRs/STTRs, including how to apply, and offers webinars on proposal writing. [America’s Seed Fund](#) is the NSF’s website.
- Ask a support person to read your proposal drafts.

- Budget limits in May 2023 allowed up to \$295,924 for Phase I and \$1,972,828 for Phase II. It is expected and acceptable to ask for enough.

7. Venture Capital & Other Funding

Funding Source Options Beyond Government Seed Money

Startups need funding to continue developing technology after the seed money is exhausted. The time before your company starts generating revenue is a vulnerable time, sometimes called the valley of death because of the potential to run out of money. You need money for approvals, marketing, and unexpected expenses. Identify potential funding sources ahead of time, including rapidly available sources.

Funding options include. . .

- **Angel Investors** – These individuals who provide capital to business startups must have a high net worth to qualify as accredited investors. They usually invest early in development in exchange for preferred shares or partial ownership of the company.
- **Venture Capital (VC)** – Funds provided to a startup that investors think has long-term growth potential. The investments are made in return for significant ownership of the business. Investors look for indications that there will be a high rate of return, such as a strong market and product or service competitiveness, superiority, and innovation. Investors want to know [strategies](#) that will allow them to make a profit, such as whether you plan to sell the business or sell stock shares to the public ([IPO](#)).
- **Accelerators** – Groups or individuals that connect startups with mentors, resources, funding, and training for a limited period to advance a startup's growth. Accelerators offer connections, advice, and acceleration of time to market. Disadvantages are that you lose some control in decision-making and that the accelerator typically gets equity in your company.

- **Startup Loans** – Banks are more likely to lend money to companies with solid business plans, financial projections, and expense sheets. The Small Business Administration guarantees loans for some small businesses having trouble securing bank loans.
- **Foundation Grants** – These include organizations that raise money to help cure or treat specific diseases or groups of people. They may provide funding if your product or service potentially benefits their cause.
- **Friends and Family** – Think carefully about mixing business and personal relationships since divergent goals may cause conflict and tensions and may make investing less attractive to others.
- **University Internal Investment Funds** – If you are employed by a university or similar institution, there may be internal investment funds available in exchange for equity in your business.
- **Partner with an Existing Company** – Many biotech startups partner with established corporations that have an interest in the product being developed. They may buy out the company after the product is successfully developed. This is common practice for pharmaceutical companies.

(Adjogatse, 2022; Excedr, 2022)

References

Adjogatse E, Hernandez B. [How to find investors for your biotech startup](#). Probacure.com. September 2, 2022.

Excedr. [Biotech Funding for Startups: What Are Your Options?](#) Excedr. June 14, 2022.

Make Your Business Attractive to Investors

- Find ways to gain investors' trust in your ability to succeed and in your management team. Show your ability to inspire others and execute plans.

- Show progress in the milestones that are most important to your potential investors. These are often milestones that reduce risk or bring in money.
- Avoid family or other non-accredited investors who may need to get their money back for personal reasons when it might hurt your business.
- Seek clear ownership of your [intellectual property](#) (IP) through patented technology. Avoid infringing on the intellectual property of others.

(Castrillon, 2019; Morgaine, 2016)

References

Castrillon C. [How To Make Yourself Attractive To Small Business Investors](#). Forbes. November 10, 2019.

Morgaine B. [11 Foolproof Ways to Attract Investors](#). Bplans Blog. March 21, 2016.

Tips from *Venture Capital & Other Funding*

- Look for courses on how to be an investor-ready entrepreneur.
- Attend meetings where investors talk with people in your industry to look for investment opportunities. Prepare a brief pitch (elevator pitch) and have lots of business cards available.
- Learn everything you can about potential investors before meeting with them.
- If you want to sell your company to pharma or another large business, attend conferences where these companies meet with biotech startups.
- Once you have investors, involve them in your financial plans.

Challenge from Venture Capital & Other Funding

Life Sciences/Biotechnology – Investor Conferences

Life science startups often make vital connections with potential investors, strategic partners, and companies interested in acquiring technology at conferences specifically organized for this purpose.

To learn more, try taking a look at these examples:

- [Biotech Showcase 2023](#) – Provides biotechnology and life sciences companies the opportunity to network with potential investors and executives from companies that may be interested in buying a company.
- [Life Sciences Summit](#) – Connects emerging biotech companies with early-stage investors to find capital and strategic partners.
- [Redefining Early Stage Investments \(RESI\)](#) – Conferences to connect startups in the 4 Ds (drugs, devices, diagnostics, and digital health) with early-stage investors.

8. Product or Service Development & Marketing Plan

I. Product Development

Innovation can be supported through trying new ways of doing things to create your product and iterative product development in which you create many versions and learn from failures. Each product version is tested and then modified according to the results. Even after you develop a successful prototype, products are often modified to gain regulatory approval, reduce costs and time involved in mass production, or respond to customer feedback.

Product development goes through the following stages (Calvello, 2022):

1. **Prototype Development**

Develop a prototype that proves your concept is feasible. Decide whether to develop the prototype yourself in-house or to outsource it.

2. **Transition to Product Production**

Transition to the efficient production of a viable product. Work under a non-disclosure agreement with industrial designers, user interface and user functionality designers, engineers (e.g., mechanical, electrical, software), and project manufacturers.

Plan for the following aspects of production:

1. Refine the design for mass production.
2. Plan for technical challenges, costs, and time. The cost per unit must be less than what the market will pay.
3. Find a manufacturer that can produce the volume you need. Choose materials and tools with engineers and designers.
4. Plan testing to show your product meets any requirements.
5. Plan to scale up production to respond to demand.

Technology Readiness Level

Technology readiness level ([TRL](#)) describes how close a product is to being available to customers (BIRAC, 2023; Hook-Barnard et al., 2013). There are nine TRLs, with the lowest being “basic research” completed and the highest being a product that is “ready for deployment.” You might need to describe your technology’s TRL in an application for a business loan, a grant proposal, or a [pitch](#) to potential investors. See the “Challenge” tab to learn about the levels.

References

BIRAC. [BIRAC-TRLs: Technology Readiness Levels by BIRAC Across Areas Under Biotechnology](#). Biotechnology Industry Research Assistance Council (BIRAC). February 14, 2023.

Calvello M. [How to Go From Product Conception to Manufacturing: A Step-by-Step Guide](#). SCORE. December 6, 2022.

Hook-Barnard I, Norris S, Alper J, et al. [Technology Readiness Levels in the Department of Defense](#). Washington: National Academies Press (US); December 31, 2013.

II. Marketing Plan

Marketing Strategy

Most biotech and life science companies are sold business-to-business, so your strategy needs to target their decision-makers. Use the results of your market research to understand how best to reach them, familiarize them with your brand, and convince them to buy your product or service. To stand out from other companies. . .

- Make your product seem exciting and dynamic, such as by using videos. Show the positive outcomes of using your product or service.
- Highlight a commitment to quality.
- Portray your team’s positive qualities.
- Show satisfied customers using your product or service.
- Invite potential customers to visit your facilities.

- Break complicated technology down into a few selling points that highlight the most exciting features.

Marketing Vehicles

Mechanisms often used to market biotechnology include. . .

- **Social Media** – Use this essential tool to make your target customer aware of your brand and drive them to your website, blog, or podcast. LinkedIn and Twitter are particularly important channels for marketing in the life sciences (Manosso, 2020).
- **Website** – Learn about search engine optimization. Use keywords that your customers will use to find you. Use data analytics to understand the source of your website’s traffic.

Effective features on your website include. . .

- Relevant, useful, and easily consumed content, such as blogs, podcasts, or webinars.
 - Videos to help potential customers understand your product and give it a dynamic presentation.
 - Testimonials from satisfied customers.
 - Easy access to your sales department.
- **Trade Shows** – Post a schedule for the shows you plan to attend. Offer free samples if possible.

Product or Service Sales & Distribution Plan

Decide how you will sell and deliver your product or service. For example, will you. . .

- Use online ordering?
- Sell directly to the customer or to a vendor who will sell the product to individual customers?
- Extend credit or offer a bulk discount?

These questions and many more will need to be answered as your business moves into the stages of development beyond the steps covered in Steps to a Startup.

References

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Padhan N. [The Complete Guide to Digital Marketing for Biotech Companies](#). LinkedIn. December 10, 2021.

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Tips from Product or Service Development & Marketing Plan

- Learn from failures as early as possible while it costs less.
- Track the history of your design and who made what changes, especially if you are creating a medical device.

Challenge from *Product or Service Development & Marketing Plan*

Which of the following technology readiness levels (TRL) best describes Leslie's business at this point?

- Level 1: Basic Research – Hypothesis that development is feasible.
- Level 2: Applied Research – Progress in applying basic research, not yet optimized.
- Level 3: Proof of Concept Demonstrated – A single, small-scale lab success.
- Level 4: Proof of Concept and Function Established – Lab testing/validation of alpha prototype.
- Level 5: Early Stage of Validation – The process of large-scale development works.
- Level 6: Early Stage of Validation – The development process works repeatedly and consistently.
- Level 7: Technology Demonstrated in the Environment – The product works consistently where it will be used and performs as designed and without harmful consequences or failure.
- Level 8: Pre-Commercialization – Technologically allows scaling to market demand.
- Level 9: Ready for Commercial Deployment – Manufacturing, quality control, order fulfillment, and delivery processes are in place to meet the promised standards and timely delivery.

Feedback:

Since Leslie has peer-reviewed research publications that used the neurons, it appears that her business has achieved technology readiness level 6 (validation that the development process works repeatedly and consistently). It would be considered level 7 (technology works as designed in the environment where it will be used); however, hers is the only lab where these neurons have been used. It is possible that others will not be able to reproduce her results. If she

does let several other scientists use the neurons and they are able to use them successfully, Leslie's business will have achieved level 7.

Reference

BIRAC. [BIRAC-TRLs: Technology Readiness Levels by BIRAC Across Areas Under Biotechnology](#). Biotechnology Industry Research Assistance Council (BIRAC). February 14, 2023.