

Writing Business Plans for a Life Science Startup or Clinical Program

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Topic Relevance by Timeline

Summary

- The business plan is an important tool for raising capital, finding strategic partners, recruiting, and providing an internal guide on how to drive a company's growth.
- The plan should include an executive overview, introduction to the management team, market and competitive analyses, value proposition, operating plan, financial projections, and potential risks.
- The plan should be concise, well written, and dynamic. Details behind key assumptions should be included.
- Common business plan pitfalls include focusing only on the product without framing it in the context of the consumers/patients, the market dynamics, and the ecosystem in which it will be launched, as well as giving financials that are too aggressive and precise given the stage the company is in.
- New founders should consider engaging experts to help test assumptions as they develop the key parts of the business plan, including the financial projections.
- Many of the same concepts for writing a business plan for a startup apply to creating a business plan for a new clinical program or expanding operations within a health system.

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Introduction

Building a life science startup is a long and complex endeavor, and the skills required are very different from the knowledge and training that academic scientists undergo. The process of developing a business plan ensures the team has tested their vision/strategy, and the plan can be used as a roadmap to guide their operations. It also serves as an important communication document when seeking investment in the business. Topics familiar to experienced grant writers—such as the significance, innovation, and approach topics from National Institutes of Health (NIH) grant applications—are relevant and necessary for framing the business plan. The plan also helps to keep the management team accountable, but sage entrepreneurs will recognize that they will often have to revise the original plan over time, based on clinical trial results, regulatory milestones, and market changes. There are several kinds of business plans, generally described as either one-page plans (business model canvas or lean launchpad) and traditional, full-length plans. While one-page business plans are a useful and simple tool for rapid, early iteration, the startup team will ultimately have to write a more detailed plan to secure funding (“Business Model Canvas”; Osterwalder and Pigneur). In this chapter, we focus on the later and will outline the key elements of a full-length biomedical business plan, highlight the pitfalls to avoid, and provide potential resources for new founders to get their plans started.

It is important to note that developing a sound business plan is also highly relevant for supporting smaller-scale clinical programs, operational investments, and intrapreneurship efforts (see the chapter on "Intrapreneurship: Strategic Approaches for Managing Disruptive Innovation in Your Clinical and Research Projects"). Please see the section at the end of the chapter that outlines the key differences for these types of business plans.

Key Elements of a Business Plan

A) Executive summary

The executive summary is a one to four page overview of the existing problem/need in the market and how the new product or service has a unique value proposition that addresses that need (Markowitz). It is the reader’s first impression of the business, and investors often read only the summary, so it is important for it to be compelling (Figure 1). Consider it a concise but more formal “elevator pitch” that highlights what the company is and why the product or service will win in the market (Cohen). The remainder of the executive summary should include the short- and long-term goals, key points in the strategic plan, the business model, summary of financial projections, and information about employees and location (Valentin).

Figure 1. Elements in an Executive Summary.

B) Management team and advisors

This section introduces the management team, their backgrounds, and how their expertise aligns with their particular roles in the business. In addition to the management team, there should be a Scientific Advisory Board (SAB), which helps to guide technology decisions, and a Board of Directors (BoD) which helps to guide all key decisions for the company. SAB and BoD members should be chosen based on their ability to provide industry knowledge and key industry connections that can help the company grow. Having industry experts involved in the company gives assurance—especially to investors—that the technology and operations have been vetted and are supported by those who know the market well.

C) Market Overview

This section should describe the overall landscape of the market, including the size of the market, key segments, historical and expected market growth, and key drivers or trends that may impact the problem the startup is trying to solve.

Market size estimates for life science businesses often include the incidence and prevalence of the disease/condition related to the problem, the estimated medical cost burden—in the U.S. or globally—associated with the condition, and the estimated cost for the consumer/patient with the current available solutions (see the chapter “Conducting Insightful Market Research”). It may be useful to describe any relevant preclinical and clinical data that support why this problem exists

and highlight the market need. While a large market size is usually viewed positively, it is important that the information provided focus on the market size relevant to the startup's specific solution. For example, a business plan for an intervention to treat prescription opioid addiction should include details about the global market for opioid drugs, the most recent trends and the expected growth rate of prescribed opioid use and abuse, the morbidity and mortality associated with opioid abuse, and the estimated annual cost for the treatment of opioid abuse and addiction, including the subsequent medical and mental health costs. To demonstrate market size in this example, estimates would include the number of emergency department visits, hospitalizations, intensive care unit admissions, and procedures for overdose or opioid abuse-related complications, as well as the current number, length, and cost of drug rehabilitation admissions.

In terms of the current market, it is useful to describe how the market is divided into customer/patient segments, which may be by geographic region, demographics, psychographic, or customer type (in healthcare, this might be pediatric vs. adult, or inpatient hospital vs. outpatient setting), among others, who are using a certain type of product/service. In the above example of the opioid market, there is segmentation in application (pain relief, anesthesia, cough suppression, diarrhea suppression, or treating addiction) and by geography (North America, Europe, Asia-Pacific, South America, and the Middle East/Africa, which can be further broken down by key countries), which can then be mapped to the types of opioid products with different mechanisms of action (for example, short acting vs. long acting opioids). If the market has clear customer/market segments, there are likely different drivers of demand in each of them, which should be well understood since the startup will want to provide product/service offerings that meet the needs of those segments. Describing the market structure, how this market is segmented, and projected growth rate of target segments will make it easier to determine which segments are the most valuable and to describe how they will be targeted.

As the market data are outlined, it is important to tie back to the product/service offering and how it is uniquely positioned to fulfill the unmet need(s) within the particular target markets (see the chapter "Identifying Unmet Needs: Problems that Need Solutions"). Use market research, economic trends, and even patient and provider behaviors, if appropriate, to determine what sector(s) of the market the product fits best. Understand the needs of patients, providers, and hospitals and why the startup's strategy will meet these needs, in order to better prepare the marketing plan for the product. Moreover, it is important to highlight the attributes of the market that support the offering, such as a large addressable market size, rapid growth in the market segment(s) of interest, and/or the level of competition in these segments. These are dimensions that are critical to stakeholders when they evaluate the business plan.

D) Competitive Landscape

The problem the startup is seeking to solve is one that multiple incumbents are likely already addressing today, either directly or indirectly. This section should provide an overview of the current offerings in the market, where they fall short, and how the new offering fills a current gap in the market. In the above sections, the problem should have been outlined and framed in a way that there would be critical dimensions that matter to stakeholders (patients, physicians, providers, payers). It would be helpful to describe how these competitive offerings compare across these dimensions, which sets up the next section on value proposition.

Understanding the competitors' product and services, market share, current and past strategies, strengths and weaknesses, the threats they pose to the startup, and the opportunities they make available are integral to a thorough and useful analysis of the competition. This is not just an exercise to learn about other businesses; it will also help identify the strengths and weakness of the startup's business strategy (see the chapter "Startup Company Formation and Management"). Consider developing a basic profile of each of the current direct competitors in the market with these characteristics and include it in the Appendix.

Typical sources of information are company websites and marketing materials (Hisrich et al.). Academic libraries can also provide a wealth of information through their subscriptions. Other helpful strategies include browsing media outlets for press releases and public relations information, social media, and former customers' testimonials on how they perceive the competition.

E) Value Proposition

Building off the market need and competitive landscape analysis, the value proposition of the startup's solution should be articulated in this next section. Against the dimensions that matter to stakeholders, this section of the plan should describe how the new solution will outperform the competition. The value proposition statement is a key way to succinctly demonstrate the measurable benefit that the patient or provider would get from the new product or service, and why patients or health care providers would choose it over existing solutions. Money savings, time, and convenience add to the value of a product. It is important to explain this in a way that can be understood by both scientific and nonscientific audiences. Describe the product/service without revealing too much proprietary information since the business plan may be distributed beyond the intended recipients.

The research results that led to the development of the new product should be shared. This may include pilot data, preclinical/animal model studies, and/or clinical trials, depending on what stage of testing the product has undergone (see the chapter "Pre-Clinical Animal Models"). Provide preliminary data and reference specific publications that support the product. In addition, any results of prototype testing should be included.

In the life sciences realm, even if the product solution meets the needs of a patient, ensuring that it fits into the medical ecosystem is imperative. Understanding the infrastructure of a hospital, including the physicians, the administrators, the insurance payers, and whether or not the new offering will improve a patient's quality of life or improve outcomes such that payers will reimburse the startup for its technology is critical to success. It is also important to articulate (if applicable) whether or not the offering can be dropped into existing treatment algorithms/processes or if changes will need to be made to how work is done to adopt the solution. If a lot of re-training or adjustments around the rest of the ecosystem are required, the value proposition will be more challenging since a lot of changes will need to be made to adopt the solution.

F) Operating Plan

With the market and competitive landscape outlined, and the company's value proposition defined, this section should describe how the company will execute to capitalize on the opportunity. The operating plan should begin with a thorough explanation of the business model—how the company will work successfully with clients, suppliers, manufacturers, and partners to generate profit. Include here the organizational structure of the company. Next, describe all critical technical, regulatory, and strategic milestones. Finally, outline any functional details about daily execution (Friend and Zehle).

There are numerous business models, and any one industry may have several examples of successful companies using different approaches. For example, is the company going to adopt an integrator model, where they will build out everything needed to launch the offering, or will they adopt an orchestrator model, where they will partner with people for certain core competencies (e.g., manufacturers) to bring the solution to market? The operating plan should describe the selected model and explain why it is preferable to alternatives. Referencing the leading players highlighted in the competitive landscape section and contrasting against their business models may also be helpful.

Healthcare businesses must deal with reimbursement, fee schedules, billing systems, managed care contracts, and licensing, along with operational issues. The operating plan must address how these challenges will be handled and how the company will get paid, either through insurance reimbursement, by employers, on a fee-for-service basis, or directly by consumer payments. The long sales cycle in most health care businesses is particularly challenging for startups and requires keen long-term planning.

Reimbursement by third-party payers to hospitals and physicians is one of the determinants in whether or not a product will ultimately make it to market, whether it will be used by healthcare providers and patients, and how accessible the product will be. For most technology in healthcare, the payers account for most of the purchasing. Understanding the payers' reimbursement process,

their reimbursement terms, their method for determining the amount to be paid to the provider, and their policy on out-of-pocket cost sharing with the patients is integral as the reimbursement method will impact return on investment for the business (see the chapter “Reimbursement Strategies and CPT Codes for Device Development”).

After establishing the business model, it is important to provide an overview of the significant milestones the company foresees. Include any remaining technical development goals, any regulatory approvals the company will face, and other strategic imperatives, such as licenses to related technology, critical partnerships, or protecting intellectual property. Biotechnology and biomedical devices may also need to go through extensive regulatory and legal processes before approval. These processes are outlined elsewhere in this textbook (see the chapter “FDA Device Regulation: 510(k), PMA” and, “FDA Drug Regulation: Investigational New Drug Applications”).

Each of these milestones should include a description of the task, due date, budget, and responsible person. Due dates and budgets should be ranged since it is difficult to have 100% clarity; milestones function as the management team’s commitment to investors, and the company’s ability to complete these goals will be assessed.

Young businesses should also provide details about the market entry strategy to penetrate the targeted market effectively and to reach revenue and profit expectations. To develop this strategy, engaging with and understanding the ecosystem early on can help improve the design of the new offering and ensure that the solution can be reimbursed. Ideally, during this process one should meet with representatives across the ecosystem to understand what they care about and what the startup will need to deliver in order for them to embrace the new offering.

The technical side of the operating plan should include tactical steps and a timeline for implementing the plan and making the business operational. As a reference point, mention what has been done thus far. Explain how the business will operate, describing the current production process but also the planned process once the company is at scale. Include high-level details about labor, materials, technology, facilities, equipment, manufacturing processes, distribution plan, supply chain, and quality-control measures.

G) Financial Projections

In this section, the team must articulate the financials of the company and show that they have a solid understanding of their expenses, future revenue, and the projected timeline for achieving revenue goals. There will be many assumptions that go into these estimates, so it is important to provide ranges and to explain the assumptions behind the projections. Potential investors will review them to gauge the robustness of an entrepreneur’s understanding of the challenges that lie ahead.

A startup's financial statements should detail the anticipated financial performance over time (for example: expenses, assets, liabilities, and working capital). Since the financial performance of the startup is dependent on future events (e.g., regulatory approvals or clinical trial partnerships), the financial projections will likely need to be in the format of a 'pro forma' budget, which projects future revenues and expenses based on a set of assumptions. Projections of financial statements should go far enough into the future to help readers see where the business can go when it matures or reaches an exit point. Outlined below are the three major parts of the financial plan (Kolchinsky; Friend and Zehle).

- 1) The income statement shows the revenue, expenses, and profit for the business over a specific time period. If there are multiple sources of revenue, these may be itemized for future comparisons over time. Early on in the business development, this may be generated monthly and eventually quarterly or annually. An income statement showing earnings before interest, taxes, depreciation, and amortization (EBITDA) acts as a frequent proxy for a cash flow statement.
- 2) A statement of cash flow projections shows what the company expects to bring in and how much it will be spending each month. This includes tracking the cash revenues and cash disbursements for the month, and reconciling these two against the opening balance from the previous month. It is important to demonstrate that the startup can adhere to a budget and not overspend consistently. Thus, conservative estimates are preferred; this will increase the level of expenses, but the company should be able to justify why those expenses are needed. Additionally, the statement should show how much working capital the startup needs to pay the bills early on, and how long it will take to have a positive cash flow (bringing in more money than the company is spending). By estimating conservatively, the team can ensure that the company will have enough financial support (i.e., runway) to achieve the milestones without falling short of cash and going bankrupt.
- 3) The balance sheet highlights any major working capital requirements and includes assets, liabilities, and equity. Rather than showing trends, the balance sheet reflects these as of a set date.

The additional components of the financial plan detail how the company expects to make money selling the product. These include:

- the cost of the product, what factors go into the unit cost, and the plans for bringing these costs down when the company is at scale;
- cost estimates for equipment, facilities, inventory, and day-to-day operations, including salaries;
- the price the company expects to receive for the product and why it is achievable, especially in the context of reimbursement.

Due to the long process of taking a product to market in healthcare businesses, there should be a section in the financial plan about the capital required for the various regulatory milestones. As outlined in the operating plan, all product development, technical, and regulatory milestones would come with an estimated budget and timeframe for completion. Included in this is the cost of the Food and Drug Administration's drug review process—a major consideration in the financial projections for life science startups. From preclinical research to the Investigational New Drug application, to clinical trials, to the New Drug Application submission and review, this process is expensive and takes many years to complete. How far along a product is in this process will factor greatly into how much money will be necessary to complete Phase 1, 2, and/or 3 trials, as well as the subsequent regulatory requirements.

Clinical trials can incur substantial costs beyond distributing the study drug/device and the associated study procedures. Site costs, fees for storage, technology solutions, and safety monitoring, core lab fees, and study staff salaries—for scientists, physicians, project managers, data managers, research coordinators, biostatisticians, and site management, including regulatory visits and investigator meetings—all must be budgeted into the cost of each phase, and the timeline to complete the data collection should be considered. In addition, up to 30% of any grant funding may need to go toward administrative overhead to carry out the study, if implemented at an academic medical center. In some cases, academic entrepreneurs can establish sponsored research agreements that allow components of the preclinical or clinical research to occur at their university (see chapters on “Post Alliance Agreements and Sponsored Research Agreements” and “Understanding Conflict of Interest for Academic Entrepreneurs”). As mentioned earlier, many of these projections may be pro forma because they will rely on the achievement of other milestones prior to implementation.

H) Risks/Anticipated Problems

All business plans should include a section on anticipated risks/problems and potential alternative strategies. This can demonstrate to investors that the entrepreneur has thought through potential challenges and has plans to either prevent them from occurring, or backup plans to mitigate the consequences. Generally speaking, a balanced approach is helpful here—not hiding or obfuscating major challenges, especially those that have befallen other companies, but at the same time not overwhelming the reader with negativity. At the very least, this can be a thought exercise for the startup and may identify issues that had not previously been considered. While a business plan is not a legal document or binding contract, intentional distortion of facts can come back to haunt a company.

Business Plans for Clinical or Operational Programs

There will be many situations where an idea is not yet at the stage of becoming a company, but requires investment to drive growth or sustain operations. Examples include developing a new clinical program or service (e.g., a novel surveillance protocol postsurgical intervention that will result in diagnostic testing revenue) or expanding operations (e.g., building a new facility to treat patients who have an eating disorder). These situations also call for business plans in order to garner support and investment—in this case, the investment would be coming internally from the health system or institution rather than outside investors.

The key components of these business plans are executive summary, background, proposal description, market and competitive analyses, operating plan, metrics for success, financial projections, and potential risks. Many of the same concepts from earlier apply, but the key differences include: 1) the business plan should specify the dollar amount of the resources needed to make the plan operational; and 2) the proposal description, operating plan, financial projections, and risks should take into account the impact of the plan on the existing operations of the system.

As mentioned earlier, most health systems will have internal strategy and finance teams, which are helpful resources for developing business plans and should be consulted early on to help with the financial projections as well as the anticipated system impacts of the plan. The remainder of this section outlines each part of the business plan and focuses on the key differences from a startup business plan.

Executive summary: In addition to the points covered in the startup executive summary, the executive summary for a new program/service/facility should include the “ask”—what resources (e.g., capital, new full-time employees, or other operating expenses) are being requested to support the new program. The executive summary should also state the expected financial return on the investment from the perspective of the institution (usually in terms of annual steady-state contribution margin or total incremental contribution margin over a period of time, usually seven years).

Background: This section should describe the current state of operations. If the authors are proposing a new clinical program, for example, they should describe the patient population being addressed, how they are currently being served, and the current volumes. It should also describe the limitations of the current state, the unmet need, and what factors necessitate a new solution.

Proposal description: The authors should describe what new program/service/facility is being proposed, and how it addresses the current challenges. This section should also describe how the proposal will lead to growth—will the program reach a new patient population not previously

served? Have a greater geographic reach? Result in greater utilization of other services at the institution? This is also an appropriate place to describe other benefits of the plan, including improved quality, safety, patient experience, efficient resource utilization, etc. It is important for this section to align with the institution's priorities.

Market and competitive analyses: This section should look very much the same as described above in the startup business plan.

Operating plan: This section should build on the proposal description and go into more technical detail. Details should include how the program will be staffed, what type of services will be delivered, where they will be delivered, hours of operation, pricing and reimbursement, and what the impact will be on downstream services and the rest of the institution. Thus, it requires a detailed understanding of how the institution currently operates, so the new proposal can realistically be integrated without excessive disruptions to operant workflow.

Metrics for success: The authors should list two–three measurable metrics that will show the success of the program. These can include volume, financial, patient/staff satisfaction, or other related metrics. Ideally, there should be targets for each metric (e.g., “increase volume by 10% above baseline by year 3”). For plans where measurable impact will not be realized until several years out, milestone-based targets are also acceptable as near-term goals (e.g., “achieve regulatory approval by X date”). It is preferable that these metrics be ones that the institution already monitors, thus enhancing alignment with current priorities and facilitating the ability to add this new project. In some cases, though, it may be necessary to develop new metrics, which should be done in consultation with the institution's leadership.

Financial projections: This section should include all components outlined above, with the exception of a balance sheet, since the plan is only describing a subset of operations within a larger system. For the pro forma income statement, it is useful to show multiple views: a base case view (if applicable), which shows current operations of the program/facility; an incremental view, which just shows the incremental revenue and expenses associated with the proposed plan; and a strategic view, which is the addition of the base case and incremental. It is also highly recommended to have a separate section outlining the assumptions used to develop the financial projections (e.g., data source, patient population, growth projections, operational start date and ramp-up speed). As these business plans are usually in the context of a large academic institution, it is helpful for planning purposes for the financial statements to specify the organizational entity to which the projected revenues and expenses will accrue (e.g., Hospital vs. Practice Plan vs. Research).

Risks and mitigation: This section should look very much the same as described above in the startup business plan. In addition, the plan should consider potential risks/negative impacts to other parts of the institution. For example, if the plan proposes to build a new facility in a suburban

location, will it potentially cannibalize volume from the main location, and if so, what is the plan to mitigate revenue loss?

The same tips on business plan writing apply here. Since clinical and operational programs need to function within the environment of an existing system, socializing the plan early and often is especially critical for gaining support, both for funding the plan and for implementing it. In some cases, this may involve obtaining regulatory approval from internal institutional entities, such as the institutional review board (IRB), legal counsel, or information services (especially if information protected under the Health Insurance Portability and Accountability Act (HIPAA) is involved). Factoring time for these approvals is crucial.

External Resources

In academic entrepreneurship, there are a host of extra challenges that must be considered, including who owns the intellectual property, technology transfer agreements, regulatory procedures, and conflict of interest, among others (Kolchinsky). At the same time, being part of an academic institution provides many resources not available to non-academic entrepreneurs, including business planning, legal, and funding support. Networking and taking advantage of other schools within the academic system who have experts in these fields will improve the entrepreneur's knowledge, especially when entrepreneurship is not one's first career or when this is one's first experience with developing a product. This can be particularly valuable when estimating costs related to preclinical and clinical research. Many academic centers have clinical research offices that have pre-populated budget templates, which can help to ensure that all aspects of the clinical trial are adequately budgeted. Most academic systems also have corporate Strategy and Finance teams that can help with business analyses as well, such as market/competitive dynamics and projecting future demand (whether that be in terms of patient volume, demand for the product, etc.). In addition, university libraries may provide online access to publications and market research related to the product and the industry. For specific tasks, such as preparing an exit strategy that involves an initial public offering (IPO), extensive external legal and financial consultations are generally required.

Tips on Business Plan Writing

Remember that a business plan is dynamic, changing with the growth of the company and as the company pivots due to unexpected challenges or market trends. The plan should be comprehensive, and key points, data, and strategies should be consistent throughout. Be mindful of including important details without going into excessive minutiae. Lastly, this is a professional document, and it can be the first and lasting impression of the company on potential investors, so appearance

matters. To this end, recruit trusted editorial support to make sure the plan is consistent from beginning to end and to check for correct spelling, grammar, and formatting.

Conclusion

Writing a business plan is a process. It requires brainstorming, researching, prewriting, drafting, revising, and editing. The business plan is not only an internal company tool for thinking about the future, it is also about presenting the company's idea, solution, marketing strategy, financial projections, and long-term vision to prospective investors. It is an introspective exercise that each executive team should utilize to help identify misconceptions before they become costly, to organize and streamline team members' efforts, to focus on the big picture rather than getting caught up in short-term actions, and to establish performance standards for the company (Valentin). It is important that all key stakeholders participate in the development and writing of the business plan. As the money at risk increases, the benefits of having a well-developed business plan increase as well.

Resources

1. U.S. Small Business Administration: <https://www.sba.gov/business-guide/plan-your-business/write-your-business-plan>
2. BPlans, produced by Palo Alto Software, is a free resource for new entrepreneurs with tools, webinars, and templates for writing a business plan: <https://articles.bplans.com/writing-a-business-plan/>
3. Business Plan for Scientists: <http://biobm.com/2011/06/business-plans-for-life-scientist-inventors/>
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Chapter Last Updated 9/27/2019.

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