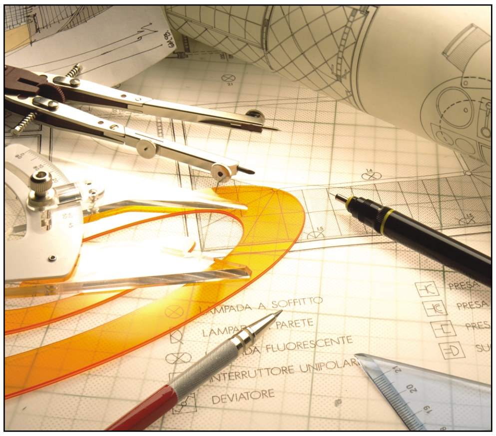
Writing your business plan

Lorin Cohen describes what you need to include in your business plan to ensure that it is an effective tool for fundraising.

After three years in the laboratory, your research team has made an unprecedented scientific breakthrough. Further evaluation confirms the value of this discovery, the potential of which is even greater than you first expected. In fact, the research has so much potential, you are certain investors and angels will be falling over themselves to fund your work and turn it into a commercial venture. Think again.

Like many other bioentrepreneurs, you are now about to experience one of the most challenging aspects of product development—securing the capital and resources needed to bring a technology to market. Although there will always be investors interested in exciting opportunities, you will have to be well prepared and patient to successfully raise capital today.



Commercialization of science, especially the development of a new drug, costs hundreds of millions of dollars and can take 15 years or more. The majority of these expenses are typically underwritten by outside sources, which must be solicited and secured by the management team. Whether you are soliciting venture capitalists, strategic partners, investment bankers, or private equity, you will need a business plan with which to initiate the dialogue.

However, most "professional" investors see more than a hundred plans every week—so if your plan does not grab the reader's interest, you may not even make it to the initial analysis round. To that end, it is imperative that your plan provide potential investors with confidence that your technology will lead to revenue, profit, and significant market share, based on the company's fundamentals and the marketplace.

Although each plan is as unique as the business it describes, there are key elements that should be present in any plan. Here we offer an overview of the most common topics and key strategic elements that should be included in your business plan. These suggestions are based upon a proven methodology that has been used to successfully complete hundreds of business plans over the past two decades (see also "Business plan do's and don'ts").

Executive summary

Your plan should start with a brief (two- to five-page) summary providing the reader with a solid overview of your business. The opening paragraph should be strong, giving the reader an instant understanding of your ultimate goals. An effective summary should be able to stand alone, and should entice the reader without giving too much proprietary detail away. Specifically, an executive summary should include an overview of the technology, the company's near- and long-term objectives, the key points of the strategic plan achieve those goals, the revenue model, and summary financial projections.

The market

The market section should discuss the parameters of the key sector in which the company operates. There may be many potential applications of your innovation, but if your parameters are too broad, most investors will see the flip side—that you will be spread so thin that you will not have enough resources to apportion a sufficient amount to each goal. Therefore, limit your efforts to one or two objectives in the near term.

It is also important that these sectors be well defined. Is the target market substantial and sustainable? Who are the customers—are they patients, doctors, drug manufacturers, clinical research organizations (CROs)? What trends and regulations might influence this sector in the future: for example, are certain brand-name pharmaceuticals soon to come off patent?

If there are no figures available for the size of the market in question, you can lead the reader to the appropriate conclusion using anecdotal information. For example, a client developing a new diagnostic for Alzheimer's disease cited the increasing size of the popu-

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lation of people over 65 years of age, as baby boomers reach the age of onset of the disease, as an indicator of the projected market.

Competition

Investors will expect you to be well informed about the competitive environment. Do not make the mistake of stating that you have no competitors—you certainly do. Your customers are already meeting their needs in some manner, even though they may not be achieving the level of satisfaction or efficacy that your new solution will provide. For example, the drug they take today may provide some relief for their symptoms, whereas your pill will eliminate them. Perhaps your diagnostic is accurate in 98% of cases, as compared with the competition's 87% accuracy rate.

Your objective in the business plan is to illustrate the current unmet need within the market and how your product fills this gap. Specifically, explain how your product is, for example, faster, more reliable, and more cost-effective than what is already available and how those advantages will benefit the user and other members of the market, making a clear case that there is a demand for this benefit. For example, you would not be justified in taking five years and $100 million to develop a digital thermometer for consumers that is accurate to the thousandth of a degree. It is also important that you indicate how long you anticipate maintaining your competitive advantage; for example, you may hold a patent that puts you 18 months ahead of the competition.

Science

You are probably thinking, "At last, science, that's the easy part"; but remember your audience. You are writing a business plan, not a white paper or peer-reviewed journal article. Whereas you want to generate interest in, and support for, your work, the readers of this business plan are looking for evidence that your technology could generate income—the more, and the sooner, the better.

You will certainly need to describe your technology within the business plan; however, it should be explained in clear, familiar terms. Like most bioentrepreneurs, you are likely quite passionate about your technology, having lived with it for quite some time. It might be best to have a "detached" party read the science section before you submit your plan. Make sure they can understand it and can recount it to you accurately.

A strategy for growth

The strategy for the growth of the company is the essence of your business plan. How are you going to achieve your goals? How will you differentiate your product from the competition? What efforts are you going to undertake in the pursuit of these objectives? Common activities include the sale of a product in less regulated international markets, pursuit of licensing agreements in unrelated sectors, securing "fee-for-service" research contracts, establishing joint ventures with strategic partners, and the like. Each campaign must be geared toward achieving the company's long-term objectives.

Be specific—establish milestones that can be measured. Investors will want to know how long their financial contributions will last you, and what they will be used for. Your chance of success with investors improves substantially if they feel you can account for the funds. Thus, if you tell investors you need $2 million to hire a manager to take a product into phase 3 trials, recruit patients, and commence manufacturing of the product for these trials, and you achieve those objectives within the budget, they are far more likely to provide you with additional capital when you move on to the next phase of development. If you miss the mark and do not accomplish your goals, you will have to return to your supporters hat in hand, and spend much time explaining your shortcomings rather than your successes.

Investors will also want a detailed account of how much capital you need, the timing of the infusions, and your intentions for "their" money. Be sure that all items discussed in your growth strategy are accounted for in the projections. What will additions to the management team cost (e.g., benefits, stock options, advisor fees)? What are the expenses associated with engaging an experienced CRO? What type of travel will be required to oversee your operations in, say, the Pacific Rim? What will it cost you to manufacture your product under Good Manufacturing Practice guidelines so that you can complete phase 3 trials? If you are fortunate enough to have an application that is or will soon be generating revenue, what is or will be your revenue model (product sales, licensing fees)?

Often the best way to get a handle on these expenses is to tie them together in a flow chart. Map out each of the activities necessary to achieve your goal and assign a cost to every one. This will enable you to visualize and prioritize all the efforts that must be undertaken to reach your goals. Do not forget to include the day-to-day expenses, or "burn rate," associated with running your operation. Often companies underestimate these needs during a time of growth. How much space will you need for another laboratory to initiate testing of a new compound, and can a team of three truly oversee your national sales drive effectively?

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Management

It may be a cliché, but it is true that whereas some investors bet on the horse, others bet on the jockey. You should therefore show that you have a management team with the skill set necessary to execute the action plan, and that they have the necessary commitment to succeed. Provide short biographies of key members of senior management and key advisors, including all relevant experience and associations. It is not, however, necessary to provide a 12-page résumé on each

Business plan do's and don'ts

Do:

- Highlight the business opportunities associated with the venture's science
- Be realistic in establishing milestones
- Create the plan around "moderate" assumptions
- Plan an infrastructure that will accommodate growth
- Write clearly and use graphics when appropriate

Don't:

- Mistake an exciting technology for a business
- Ignore the weaknesses in your company or plan
- Overlook the competition
- Include untruths, semi-truths, or wishful thinking
- Write anything you cannot defend in meetings with investors

board member; that information can be forwarded to interested parties on request.

Financial projections

The financial projections essentially present your business plan in dollars and cents. You should include three- to five-year "Statements of Operations and Cash Flow." If your company is beyond the research and development stage (that is, it is operational and is generating revenue), you will also want to include a balance sheet.

Potential investors will want to see financial projections; however, they may be equally interested in the underlying assumptions. An investor reviewing your plan may have questions regarding your projections, and if they have to contact you to ask questions and review figures, that may be enough of an inconvenience to stop the process. It therefore is critical that your plan include a comprehensive overview of the factors used to generate your projections. These figures do not need to be refined down to the cent, but they should enable the reader to determine, for example, your pricing, units sold, operating expenses, and items included in research and development costs.

This information enables the reader to challenge the projections provided, adjusting the assumptions based on their own experience. For instance, a potential strategic partner might evaluate your projections differently knowing that their purchasing capabilities would reduce the price of raw materials by 25%.

Final thoughts

Raising capital is a difficult and time-consuming task. Investors will not typically provide you with funding much beyond a 12–18 month horizon. They will likely feel that their funds will perform better under their own management rather than in your bank account. Because the expenses associated with the commercialization of a new technology typically range into the hundreds of millions of dollars, it is likely that you will have to go back to the "well" several times during your development process. Even if you find a powerful strategic partner with deep pockets, you will regularly have to justify your budgets. This process can be daunting, even for experienced business professionals, but a clear and concise business plan will serve you well in many ways. The mere exercise of creating one should provide you with insight into your company's strengths and weaknesses.

Be sure to get the input of key personnel in the various divisions of your business in writing the business plan, because if they do not "buy into" the plan, your chances of success are reduced. If you do not feel that your team is capable of developing an effective plan in a timely manner, do not hesitate to contract a professional to manage the project on your behalf. Professionally written plans are common within all industries and will serve you far better than an internally generated plan that is incomplete.

Finally, remember that this is a business *plan*—it is not scientific document and it is not written in stone. With an open mind and an aptitude for flexibility, you will be able to raise capital and pursue viable opportunities. The resulting document not only will be a valuable tool in raising capital, it can be used to secure strategic partners, recruit, and serve as an internal roadmap for growth.