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The way to a powerful business plan

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Although funding for biotech ventures is on the increase, so is the number of biotech start-ups. Gaining the attention of venture capitalists to fund a new venture remains competitive. This article provides suggestions and techniques which, when used in developing a business plan, have been proven to increase the likelihood of attracting investor interest.

Box 1. The eight core-components of a business plan

- Value proposition
- Business strengths
- Market and competition
- Intellectual property
- Objectives and goals
- Business model
- Resource requirements
- Financial forecast and funding requirements

Biotechnology is experiencing a venture capital revival. The sector had lost its appeal to many venture funds and their limited partners during the past few years, as investors pursued the quick hits and high returns associated with Internet investing. Now that the 'dot-com' bubble has burst, investors are once again seeking to diversify their holdings and the biotech sector is receiving a lot of attention. This resurgence follows on the heels of many exciting breakthroughs in the biotech industry, such as the 'genomics revolution', which brings with it numerous other innovations, such as genomics, proteomics, genetic engineering and HTS. These activities have transformed the drug discovery process and opened up many new possibilities for diagnostics and therapies, resulting in a substantial increase in capital committed to healthcare. According to the Money Tree™ survey by PricewaterhouseCoopers (New York, NY, USA; http://www.pwcglobal.com), 35 healthcare funds in the USA raised a record US$4.3 billion in 2000 – almost double the US$2.3 billion raised in 1999. Technologic Partners (New York, NY, USA) reported in the October 2001 issue of its newsletter, *VentureFinance* (http://venturefinance.venturewire.com), that for the first nine months of 2001, US venture funds invested US$1.5 billion in biotech and life-science related ventures.

Increased availability of capital does not, however, necessarily correlate to an increased likelihood of obtaining funding for a venture. Increased capital in a given sector tends to stimulate the formation of more companies in that sector; therefore, more biotech start-ups are competing for those dollars. Furthermore, although they might be interested in a given sector, investors will only invest in companies that they regard as having a high probability of meeting their investment return criteria. Therefore, it is imperative that an entrepreneur provides investors with compelling, justifiable reasons to invest in a company, because investors would forgo investing rather than compromise on their return expectations. Reasons to invest are best communicated through a well-conceived, well-written business plan.

The eight core-components

As stated previously, a persuasive business plan details the potential of the venture and the prospects for investors to realize a high return on their investment. This means addressing all the factors that impact the venture's promise – the value of its intellectual property (IP), strength of the scientific and management team, time and risk to market, size and trends of the targeted sector, competitive environment, ease of selling into the market, alliances with other firms, and so on – and demonstrating that the venture 'scores' highly on these factors, thereby giving it a strong likelihood of success. These factors can be categorized into eight core-components (Box 1).

Value proposition

This is the venture's 'pitch'; it serves as the focal point of the business plan and is supported by the information in the plan.

The value proposition should be precise and stated in one or two sentences. For example, 'ABC Biologics is pioneering the development and commercialization of gene therapy products for CNS diseases.' This sentence tells the investor a great deal about ABC Biologics. First, the term 'pioneering' indicates that it intends to be an innovator in its field. Second, 'development and commercialization' indicates that it intends to have a role not only in creating products, but also in the sale of the products it creates. Third, 'gene therapy' indicates the company's

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product focus. Finally, 'CNS diseases' indicates the market it intends to pursue. As the first sentence in a business plan, it immediately tells the potential investor what ABC Biologics has been formed to do. The investor, providing they are interested in this field, will continue reading to determine if ABC Biologics has the ingredients to fulfill its value proposition.

Business strengths

Every venture begins with some assets, tangible or intangible, which form the building blocks for growth and provide it with an advantage *vis-à-vis* existing and future competitors. A venture with a strong competitive advantage has a high probability of raising capital and establishing market leadership, whereas a 'me too' company will find raising capital difficult, if not impossible. To that end, strategic and competitive advantages should always be highlighted within the first few pages of a business plan.

For an early stage biotech firm, the most likely competitive advantage will be its IP. A strong scientific platform has significant potential value. Near term, it can result in patents, which serve as a barrier to competition. It can attract strategic partners with the financial wherewithal to fund product development and clinical trials, market the products resulting from the alliance, and finance R&D until the products reach the market. An exciting technology platform can motivate recognized scientists and business professionals to join the company, its board of directors or its advisory board, and to participate in the company's growth. All of these factors contribute to the attainment of the ultimate objective, which for most biotech companies is the development of breakthrough drugs and, consequently, realizing substantial revenues and profits.

Strategic attributes and competitive advantages vary by venture and sector; however, some of the more common ones include:

- Proprietary and/or patented science
- First-to-market advantage
- Strong scientific team
- Skilled business-management team
- Favorable market trends
- Inadequate existing solutions
- Positive results in animal and/or clinical trials
- Prominent strategic partners
- Strong client base
- Renowned scientific advisory board
- Limited competition
- Outstanding reputation in the marketplace

Market and competition

A venture's prospects are influenced by market demand and dynamics. A company that intends to develop drugs for a large, growing market for which there is no effective drug has significantly greater potential than one that is targeting a small market or a market where affordable, efficacious products already exist. This is the reason that investors and pharmaceutical firms are most interested in ventures working on drugs to fight certain cancers, cardiovascular disorders, CNS diseases, and similar large-scale conditions, where the potential financial reward is substantial.

Although market size and growth trends are important, the ability of the venture to take advantage of them depends, in part, on competitive factors. Often, entrepreneurs focus too much on their own ventures' attributes, failing to adequately consider the strengths and weaknesses of their competitors. (Competition includes established companies and solutions targeting the venture's market, as well as other start-ups possessing strong IP and having similar objectives as the venture.) An analysis of the competition leads to an understanding of the limitations of their product offerings or technology. A business model designed to take advantage of these shortfalls is much stronger than one that does not provide anything superior to the competitors.

Biotech companies also need to consider regulatory factors and how these impact the business. Although government regulations substantially increase time and cost to market, they could also provide a strong barrier to competition. A venture that is further down the regulatory process, for example, in clinical trials, has a lead-time advantage compared with a start-up competitor.

IP

For most biotech companies, IP is the foundation on which the business is based. However, IP alone is not sufficient to make a successful, fundable business. If the technology – regardless of its patent position – cannot be used to generate profits, it has little, if any, value. Therefore, there are two aspects to a venture's technological promise: first, the strength of the IP, and, second, the ability to commercialize it.

The first step in demonstrating the importance of the technology is to explain what it is and how it works. For example, a venture that has identified a substance that appears to regenerate the brain cells that degenerate in Alzheimer's disease would provide details on the substance's active ingredient, as well as the way in which the ingredient appears to affect the specific brain cells. Jeffrey Collinson, Managing Director of Collinson, Howe and Lenox LLC (Stamford, CT, USA; a healthcare venture firm), has stated that the 'how' is significantly more important than the 'what' when analyzing a potential biotech investment opportunity (personal communication). The next step is to explain the benefits of the technology (or the resulting products) to the target market on an individual basis and in comparison to competing technologies. Often these benefits stem from the way in which the technology works.

The value of the IP to venture capitalists increases with tangible evidence of its uniqueness and its potential. This is demonstrated through patents issued and/or pending, as well as through

research studies performed in a laboratory or clinical setting corroborating the way in which the technology works and the benefits it appears to provide.

Another component of the value of the IP is the time to commercialization. Underestimating the development time is a frequent problem, according to Daniel Goodman, Director of Healthcare Ventures of Falconwood Corporation (New York, NY, USA). Biotech entrepreneurs tend not to grasp the time it takes and the complexities involved in reaching commercialization. This can be resolved by creating a detailed development path or decision tree that includes an estimated time for completing each step and a discussion of any risks involved with that development. These risks are based on many factors and might include the stage of research, development tools available, regulatory requirements, and available capital. For example, a venture that needs to develop new software and hardware or is still conducting basic research will take longer to reach commercialization and will have more inherent risks than a venture that is applying proven technology or using commercially available computer systems.

Objectives and goals

The objectives of a biotech venture are likely to vary depending on its phase of development. For most biotech ventures, the near-term and intermediate-term objectives focus on advancing the technology toward commercialization, strengthening competitive advantages, hiring skilled management, building infrastructure, forming strategic alliances and, if applicable, selling services. In the long-term, the objectives are likely to be increasingly revenue and profit oriented, as products reach market or sales of existing products reach critical mass. The key to setting the venture's objectives are that they are realistic and achievable given the strengths of the venture and the dynamics of the external environment.

Business model

The venture's business model – the direction that the venture intends to take to attain its stated objectives – is based on the details discussed previously. It reflects the company's value proposition, stage of development, management team and strategic partners, as well as its marketplace, competition, regulatory issues, and so on. It must be executable and lead to the proposed objectives.

Although the specifics of a business model vary among companies, there are overall frameworks that appear to be successful for attracting investors and growing a firm. Analyzing the models implemented by thriving biotech companies in the same or comparable niches can provide significant insight for building a realistic model.

Some of the more popular answers to the question: 'What do I need to do to realize my goals?' are:

- Build the scientific team to further R&D efforts;
- Enter into strategic alliances with established firms that can accelerate and possibly fund development and commercialization;
- Identify other applications for the IP;
- Add business management; and
- Embark on or escalate sales and marketing activities to build awareness and/or revenues.

Resource requirements

Most ventures do not have sufficient in-house resources to implement their business models and need to raise capital to finance the acquisition of these resources. Such resources might include manpower, equipment, space, technology (licensed from others), consulting fees, and so on. They also might be one-time expenditures, such as the purchase of a license, or ongoing expenditures, such as the salaries of employees. The impact on the proceeds required depends on the extent of and timing for adding these resources.

Financial forecast and funding requirements

The financial forecast is the quantification of the business model and resource requirements. To financial investors, it is one of the most important components of a business plan.

The financial forecast is typically for the next 3–5 years and comprises three components: income statement forecast, cash flow forecast and planned use of proceeds. Some investors will also require a forecast balance sheet.

Income statement forecast The flow of forecast revenues and expenses should be consistent with the business model. For example, if the model includes securing milestone payments from a strategic partner, those payments would be included in the revenue forecast. If it includes marketing of services, the sales expected to result from those activities would be included in revenues and the cost of those activities would be included in expenses. Itemizing the revenues and expenses and their timing in a spreadsheet makes this cumbersome process easier.

The assumptions behind the revenues and expenses are typically scrutinized more carefully than the numbers themselves. By reviewing the assumptions, investors have a better understanding of the entrepreneur's thought processes. It also provides them with a basis from which to test other scenarios. To that end, the assumptions should be well defined and supportable. Wherever possible, actual data such as existing salaries, occupancy costs, consulting agreements, and so on, should be used. Figures should also be increased to be consistent with the growth of the business. For example, computer and telecommunication systems sufficient for a start-up team of three employees will need to be scaled-up to support an expected staff of 30. When there is no internal data, data from reliable sources can be accessed or intelligent estimates made. For example,

if the venture intends to license its IP to other firms, it can research the licensing terms of comparable companies (much of which is publicly available information) and model its forecast based on these terms. If the venture intends to retain a public relations firm in the future, the entrepreneur can contact one or more firms and get an initial estimate. When information is difficult to secure, the only alternative is to make an educated guess.

Cash flow forecast Cash flow is affected by operating and working capital requirements, capital expenditures and financings. The bottom line of the income statement shows the anticipated losses and profits from operations over the forecast period. This, combined with direct purchases of fixed assets, provides a good indication of the cash shortfall and financing requirements during the forecast period. Significant cash deficits are common among biotech start-ups because of the substantial investments required for R&D. Investors typically fund a venture's requirements for a 12–18 month timeframe. Therefore, the cumulative loss or cash shortfall during that time period is a reasonable estimate of the total amount of capital that should be raised.

The 12–18 month timeframe ensures that investors' dollars are 'at work' and not idle in a bank account. They will be concerned, however, that the funds advance the company and enable milestones to be achieved. Therefore, a venture that cannot demonstrate the attainment of major progress with the funds invested during that period is unlikely to attract funding.

Planned use of proceeds The cash flow forecast provides information regarding the amount of capital needed to be raised. A schedule indicating how the funds will be allocated is standard for business plans. It offers insight into the productivity of the funds. Uses that advance the venture to revenues and profits are the most appropriate. Funds allocated to pay outstanding payables, pay down debt, or repurchase stock are not productive uses of proceeds and are, therefore, negatively regarded by investors.

Putting it into a plan

Once the information has been gathered, the next step is to put it into a written plan. A recommended format is as follows:

Executive summary

The summary is the first, and occasionally the only, section that investors read. Therefore, it needs to immediately capture the reader's attention. The first paragraph will be most effective by highlighting the venture's value proposition and its strengths and competitive advantages. Beyond that, the summary should be an overview of the eight core components, emphasizing the merits of this investment opportunity.

Market and competition

This section should review the nature of the sector in which the company participates and the size of the target market. It should also address the competition (drugs and alternative methods on the market and in development) and the company's competitive advantages. It should be written to enable readers to recognize the potential for the company based on market dynamics.

Technology

This provides the detail regarding the venture's IP, the progress to commercialization and the milestones that remain to be accomplished. It is intended to give potential investors confidence in the IP that forms the company's foundation and the basis of its growth strategy.

The company

Operating companies need to describe their existing business, including products and services, production (i.e. how these products or services are provided), existing customer base, strategic partners and business development strategies. The strength of the existing operations can significantly enhance the valuation placed on the company.

Business model

The formulated business model is crucial to the plan because it communicates the strategy the venture intends to pursue for growth and success.

Management and organization

Investors consider the venture's management and its boards of directors and advisors as key to the success of the venture. Management and board member descriptions can be brief, but should highlight the experience relevant to the objectives of the venture.

Financial discussion

The financial discussion is a summary of the financial forecast, as well as the assumptions on which the forecast is based.

Conclusion

Business plans are a necessity when pursuing funding; they also provide significant value to the internal organization. When diligently prepared, the business plan becomes the venture's manifesto, serving as its blueprint for growth. It sets forth the plan of action that the company intends to follow to capitalize on the opportunities it has identified, and quantifies the goals that the venture intends to achieve over a specified time period. When done in collaboration with all key members of the management team, the plan is likely to lead to a greater sense of a common goal and increased cooperation between functional areas.

The time, research and thought to develop a plan that works are extensive, but the result is well worth the effort.