Strategies for attracting healthcare venture capital

Date received (in revised form): 8th March, 2002

Beth Silverstein and Carl Osborne

Abstract Scientists or entrepreneurs in the area of biotechnology seeking to convert their discoveries into commercially viable products can find the effort daunting given that it combines the well-recognised challenges inherent in any start-up company, the complex and changing regulatory requirements for marketing approval, and the uncertainty of biology. Significant capital is required at each step from discovery to manufacture to preclinical and clinical testing, and venture capital investors are an important source of this funding. This paper provides some basic guidance to early stage companies on how to attract venture capital funding.

Keywords: venture capital, drug development, biotechnology business plan

Beth Silverstein MS, RAC is the Director of SciLucent, LLC, a US-based management, regulatory and technical services consulting firm dedicated to helping healthcare product companies maximise the value of their businesses. She has 12 years' experience supporting biotechnology and pharmaceutical companies in the areas of scientific and regulatory due diligence for mergers, licensing, and acquisitions and strategic, scientific and technical support for global product development.

Carl G. Osborne, DVM is the Managing Director of SciLucent, LLC. He has over 20 years of experience helping healthcare product companies make sound investments, efficiently comply with applicable laws and regulations, and effectively manage their business and product development processes. He is a former reviewer and compliance officer in the US Food and Drug Administration Center for Veterinary Medicine.

Beth Silverstein
Scilucent, LLC,
5433 North 22nd Road,
Arlington,
VA 22205, USA

Tel: +1 703 538 1098
Fax: +1 703 538 1099
E-mail: bsilverstein@scilucent.com

Introduction

Converting a pharmaceutical or biotechnology discovery into a commercially viable product can be a daunting effort given that it combines the well-recognised challenges inherent in any start-up company, the complex and changing regulatory requirements for marketing approval, and the uncertainty of biology. In order to move a company's ideas forward toward commercialisation, it will need financing – sometimes lots of it. Angel investors and venture capital firms are two common sources of funding for growing biotechnology and pharmaceutical firms. Venture capital firms typically review over 3,000 business plans per year but only make 10–15 investments per year. How can a growing biotechnology company maximise the likelihood that its product or technology gets funded? This paper provides some key tips for scientists, entrepreneurs and growing companies involved in healthcare innovations in the areas of biotechnology, pharmaceuticals, drug delivery systems and bioinformatics, to impress a venture capital investor and improve their chances for funding. In the present economic environment, the challenge is even greater, as many venture funds are choosing to focus their time and energies on companies already in their portfolio.

Keys to impressing a venture capital investor

Any presentation made by a company to a venture capital investor, describing its healthcare product or technology and its company's goals, must capture the investor's attention quickly and get the investor enthusiastic about its product or platform technology – the strength of the company's management team, the strength of its development programme and the potential return on investment. The information a company provides to the investor must be well organised, reflect the investor's criteria for investing, and must be backed by sound scientific, marketing and

financial data, wherever possible. All too often, poor investor approaches lead to lost opportunities for funding and a slow spiral into obscurity.

There are several keys to impressing a venture capital investor: present the investor with a well-thought out business plan; clearly communicate what you want from the investor; understand and respond to the criteria the venture capital investor uses to invest in a healthcare company; have someone introduce the business plan to the investor; and prepare for a persuasive first meeting with the investor.

Present the investor with a well-thought out business plan

A company's biotechnology business plan is a document that describes the major selling points of its idea, its business strategy and its management team. It must be persuasive, but at the same time realistic. It is intended to generate investor interest in the company's product or technology and encourage investors to discuss the company and its ideas further. It is a living document that will change and be revised as a business evolves.

The business plan is a succinct document usually less than 50 pages long. Careful attention should be paid to not overproducing the document (flashy graphics, etc.), avoiding incorrect spelling or grammar, avoiding numbers that do not add up, ensuring good organisation and, most importantly, ensuring that key assumptions and statements are supported with independent, referenced sources, to the extent possible. The business plan for a biotechnology company covers many subjects including the company, the product or technology, the market, the product or technology development plan, the regulatory and safety and efficacy testing strategies, and the financial needs of the company.

Executive Summary

The Executive Summary is the first and key element of the business plan because it is that section of the document initially reviewed by the investor. It must persuade the investor to follow up his/her review of the business plan with a meeting with a company and a more thorough assessment of its product or technology. The Executive Summary tells the investor where there is a need for the technology or product, how the company can fill that need, why the company's management is ideally suited to lead the company, where the company is in its development, and how much capital the company needs to reach the next milestone. Where appropriate, it is helpful to point out how the product or technology will address an unmet medical need or pioneer new areas of business. Include an overview of the company, the company's goals, the strengths of the management team, the uniqueness of the product or technology, a description of the market size and projected growth, the regulatory strategy and the financing needs.

Description of the company

This section of the business plan provides investors with information about the history of the company – when it was formed and for what purpose. Include a discussion of the company's short-term and long-term goals here as well.

Description of the management team/ organisation

Venture capital firms feel strongly that the strength of the management team is *the* key decision criterion for venture capital investment. This section of the business plan provides a potential investor with evidence of management success with similar or other ventures. Include here the *curriculae vitae* of key executives, details of their responsibilities and their prior experience with similar companies, success with the commercialisation of similar products, recruitment plans, the management philosophy and information on the board of directors.

Description of the product or technology

This section of the business plan describes the science behind the product or technology and presents the evidence that supports its safety and therapeutic efficacy in the patient population for which it is intended. This is perhaps the most technical portion of the plan, although every effort should be made to write this section to a relatively non-technical audience. Graphs, tables and charts are useful in this regard. Include here a discussion of the medical/scientific need for this product or technology; demonstration of proof of concept and existing data (with key scientific references); product weaknesses, as well as strengths; and the strength of the intellectual property protection (patented v patent pending). Clarify what technology is owned, what technology the company has rights to, and demonstrate that existing patents can be defended.

Description of the regulatory strategy

The regulatory approval process can be a long one and may involve the preparation of submissions seeking approval to conduct clinical studies and approval to market. How quickly a product reaches the market and begins to generate cash flow depends heavily on the regulatory strategy implemented and the ability of a company to identify and reach those milestones leading toward product approval. Provide information in the business plan about whether the product has been approved in the USA for another indication or in other countries for the same or another indication, the intended regulatory strategy for this product and the current timeline for product approval, and prior marketing submissions and their success.

Description of the preclinical and clinical testing strategies

The business plan needs to provide evidence that the preclinical and clinical programmes designed to establish the safety and efficacy of the product are designed, conducted and documented in such a way as to maximise the potential for regulatory agency approval. Strategies should also be outlined. Provide information about the extent of preclinical testing of the product and whether it is adequate to support initial and future human testing or whether additional studies will be conducted. The importance of a sound clinical development strategy cannot be underestimated. Provide information on what labelling and claims will be supported by intended clinical trials, what clinical data have been collected to date, and how the clinical testing programme is intended to support market approval.

Market analysis

This section of the business plan provides information about the value of the market in terms of market growth rate, market size (domestic and international), market served, and market potential and projected changes over the next several years. Include here information about the company's anticipated customer(s) (eg cardiologists v heart patients v managed care organisations), key factors that influence usage and buying patterns, and most importantly, how the company's product or technology meets the needs of the target market selected. Where possible, this information should be supported by independent research and reliable data.

Description of the competition

This section of the business plan provides information about the company's competitors and how they might affect the company's share of the market now and in the future. Include here information on the relative size of competitors, their strengths and weaknesses, how their products are perceived by the market, why the company's product or technology is better than the competition, and what barriers have been defined that will keep its competitors away. Address the regulatory status of competing products, ie how soon

will those products be approved by the regulatory agencies for marketing.

Description of manufacturing

This section of the business plan addresses whether the product can be efficiently manufactured in quantities suitable for clinical testing and in commercial quantities. Include information on the anticipated method of manufacture, manufacturing facilities and necessary personnel for manufacture. Numerous companies have failed because they could not produce clinical trial material of adequate and reproducible quality in a timely manner.

Schedule

In this section of the business plan, a Gantt chart can be useful to identify key milestones in the development of the healthcare product or technology especially those for which funding is crucial. Such milestones can include, for example, demonstration of proof of concept, optimisation of drug substance, manufacture of product for preclinical/clinical testing, submission of regulatory documents (for example, clinical trial exemptions, investigational new drug applications, marketing authorisation applications, new drug applications), clinical testing, proof of concept in humans, etc. Ensure that the development programme is focused and that the timelines are realistic.

Exit strategies

This section of the business plan considers the possible exit strategies for the company whether it is a merger with another organisation (eg a large competitor or another company that wishes to diversify), sale to a strategic or financial buyer, or going public.

Finance

This section of the business plan provides information on the company's gross margins from the sale of products, revenue projections, the time until profitability, and the need for follow-on capital. Include balance sheets, income statements, cash flow statements and a capital investment plan. Provide financial statements from the last three years, if available. Some venture capitalists wish to see an income statement month-by-month for the next six months, by quarter for the following six quarters, and then year-by-year for three years. Discuss here how much financing is sought and for what purpose as well as how far the financing will carry the company.

Clearly communicate what you want from the investor

Before meeting with a venture capital investor, it is important to understand and effectively communicate the company's need for funding, whether seed or early-stage investment or second round or subsequent investment, and how much. Also, specify how the money will be used/allocated and when the company anticipates additional funding might be necessary.

Understand the criteria used by a venture capital investor to invest in a healthcare company

A review of a number of venture capital firms with interests in healthcare technology revealed consistent criteria by which investors chose companies and technologies to fund. Companies seeking funding must demonstrate:

- a novel technology that is a significant improvement over current technologies;
- strong intellectual property and patent protection;
- a solid management team with seasoned executives who can steer the company and make it grow;
- a comprehensive clinical development plan;
- a market sufficiently large to build a company;
- the potential for partnering, out-licensing or co-development; and

- the potential for a high rate of return on the investment.

Both the company's business plan and any subsequent presentation to a potential investor should ensure that sufficient data and information are available to address these issues.

Have someone introduce the business plan to the investor

Venture capital firms only rarely accept business plans without a formal introduction. A company can maximise the likelihood of having its business plan reviewed by a venture capital investor by having it introduced on its behalf. This can be done through an accountant or attorney who works closely with a firm or an executive of a company that the venture capital firm has previously funded. Another valuable strategy is to have the plan presented by an individual or company currently investing in the company. In any case, identify a venture capital fund that is focused on the relevant industry and whose fund's investment size requirements match the amount of funding the company seeks. Also, the venture capital community is a relatively small one and information is exchanged among venture capitalists. As a result, rejection by one firm may influence other firms so it is imperative to put the company's best effort forward the first time and have it properly introduced.

Prepare for a persuasive first meeting with the investor

Once a company has interested a venture capital investor in its product or technology, often the next step is to meet directly with the investor to present information on the product or technology and the company's development plan and begin the due diligence effort. The information presented at this meeting is a synopsis of the business plan, and the presentation should include information on the product, the company and its management, the market and the financials. The most effective presentations to investors have the following in common: the presentation takes not more than 30 minutes to deliver (without questions); key members of the management team (including the individual responsible for financial projections) are in attendance; the presentation is directed at the technological level of the audience; the data and assumptions are well supported; and investor questions are anticipated and answered with hard evidence.

Conclusions

Scientists and entrepreneurs with novel products or technologies seeking funding to advance their development can benefit from understanding the venture capital process. By providing the scientific, market, management and financial information these investors need to consider in a succinct, objective manner, a company can maximise the likelihood that its business plan will be read by potential investors and funded. A few activities are key to maximising success. First, prepare a realistic business plan and use it as the basis for your efforts, remembering to update and revise the plan as the company grows. Two, be the toughest critic of your product, your data and your financial projections. Three, anticipate investor expectations and questions and respond to them with well-supported answers. Four, remember that first and last impressions matter; produce and provide a well-organised business plan and presentation.

Further reading

Fox, A. W. (2001), 'Clinical development – look before you leap', *Nature Biotechnol.*, Vol. 19 (Supplement), pp. BE27–BE29.

Lee, C. and Keen, P. (1999), 'Issues in seed and first round financing', *J. Comm. Biotechnol.*, Vol. 6, pp. 68–76.

Stewart, J. J., Allison, P. N. and Johnson, R. S. (2001), 'Putting a price on biotechnology', *Nature Biotechnol.*, Vol. 19, pp. 813–817.