Raising Venture Capital: Tips For The Medical Start-Up

Presented by:

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Savvy entrepreneurs need to do a lot of homework and planning before seeking funds from venture capitalists eager to invest in medical start-up companies.

If you're ready to go into business for yourself, you can increase your chances of raising capital for the start-up through good planning and an understanding of potential investors. Venture capital firms have money to invest (over $10 billion during the past four years), and many are interested in medical start-ups because returns on medical investments have been good. This article is focused on the needs of companies specializing in biotechnology, pharmaceuticals, medical devices and equipment, drug delivery, healthcare services, and healthcare data and information.

The Business Plan

Before beginning a search for venture capital, most start-ups will write a business plan describing what they plan to do and how they plan to do it. The objective of this document is two-fold: to set a direction for the company and to capture the interest of potential venture capital investors. Exhibit I shows an outline of a typical business plan for a medical company. Good business plans are usually between 20 and 50 pages in length, with optional supporting data (articles, glossary of terms, endorsement letters) placed in an appendix or addendum. Here's a summary of what should be included in each section of the plan.

I. **Executive Summary** – Highlight your business strategy, emphasizing why you believe you will succeed. Describe your products and explain why they are proprietary. Summarize the market need for your company's products. Include a sales and earnings forecast, and outline your financing strategy.

II. **Technology/Products** – Describe the basic technology and explain how it will be developed into marketable products or services. Make sure you answer the following questions. What are the resources (capital and people) required to complete development? What are the development milestones, and when will they be achieved? What are the most significant obstacles? How will you protect the technology? What is the ratio of price/performance to competitive technologies? What is your lead time over someone starting today? What is the probability of obsolescence? What are the regulatory hurdles? How can the technology be used in other products?

III. **Markets/Marketing** – Describe the markets for current and future products or services; review your marketing strategy; include a sales forecast. What is your product/company positioning? Who are your primary customer prospects (physician specialists, nurses, technicians)? How many are there? What competitive products are they now using? Why? How does your product compare with those of competitors? How will you create buyer interest in your product (via medical journal articles, trade shows, advertising, direct mail, public relations)? How will you sell your product? What will you charge and why? What are the steps in the selling cycle, and how long will each take? How will you train customers to use your product? What is your strategy for international markets? Answers to these questions will help you forecast sales.

Analyze the effect of healthcare, demographic and economic trends on the company. Discuss, for example, the effect of government legislation on healthcare cost containment and the financial impact of new technology or services. Review areas directly relevant to your business, such as the fixed dollar amount hospitals receive in Medicare reimbursements based on the patient's diagnosis, the increased competition for patients stemming from the physician glut, and the increased demand for medical intervention due to longer average life spans. Mention the effect of negotiations by private insurers, HMOs and PPOs for lower hospital and physician charges. Analyze these and other trends in terms of whether they will help or hinder your business.

To help you predict the degree of demand for your product or service, analyze your product on three dimensions: economic impact, efficacy and operational considerations. Because of DRGs and managed healthcare plans, it is more difficult today to sell technology that does not provide financial savings or revenue increases to the purchasing institution. Despite the increasing emphasis on economics, improved efficacy or patient outcome is still very important. Try to prove that your product will improve patient care. Since healthcare institutions (like many other institutions) are reluctant to deviate from established procedures, try to show that your new product or service will have greater acceptance because it will not interfere with or change existing habits.

If your product or service is compatible with the existing operational system, your chances of success are better. For example: high-volume x-ray departments take routine steps in processing patients for chest x-rays. If you have a new piece of equipment that adds five minutes to each patient encounter, you materially affect throughput and thus diminish the chances of selling your product.

Investors know that medical institutions' interest in buying a new product is a function of some weighed-value algorithm that includes efficacy, economics and operational compatibility. Position your start-up accordingly.

Make contact with potential customers and your distribution channel as early as possible to help assess demand for your product. (A well-prepared questionnaire or interview guide will help ensure that all topics of interest are covered during these market research sessions.) Summarize interviews with prospective customers in the business plan to help potential investors gauge your prospects' interest in your product. Letters of intent to purchase the product, if obtainable, will help sell your business proposal.

EXHIBIT I
BUSINESS PLAN OUTLINE

I. Executive summary/company strategy

II. Technology/products
   - A. Technology description
   - B. Development plan
   - C. Proprietary protection

III. Markets/marketing
   - A. Markets
   - B. Selling and distribution
   - C. Competition
   - D. Forecasts

IV. Clinical/regulatory

V. Manufacturing and operations
   - A. Facilities
   - B. Equipment
   - C. Process
   - D. Cost of goods sold

VI. Management team

VII. Financials
   - A. Profit and loss
   - B. Balance sheet
   - C. Cash flow (sources and uses)

VIII. Risks

IX. Appendices

IV. Clinical/Regulatory – Outline your strategy for gaining marketing approval from the U.S. Food and Drug Administration (FDA). For medical devices and equipment, note whether 510K approval (premarket notification) is feasible or whether it's necessary to pursue a more rigorous premarket approval route. For a drug, define whether an Abbreviated New Drug Application (ANDA) will be permitted or whether a New Drug Application (NDA) is mandatory. For a biological product, you must file for marketing approval under a Product License Application (PLA).

Outline the entire spectrum of required preclinical studies (toxicology, immunology, pharmacology, animal studies, etc.) as well as clinical trials. How many different centers must you involve? How many patients must be studied? What are the clinical outcomes or endpoints that you will measure? How long must you follow the patients? If you are uncertain about regulatory requirements, hire a consultant familiar with the regulatory process, or work with the Division of Small Manufacturers Assistance of the FDA (telephone 800-638-2041). If you are starting a healthcare provider company, include an analysis of licensing, accreditation and zoning.

In selecting a medical advisory committee, find people who can truly help you. A good advisory committee can help you write the protocol for clinical trials, help select physicians who will conduct your clinical trials, give feedback on ideas for new products, and help establish credibility with potential investors and customers. For any medical procedure or disease, you can find a small group of researchers or clinicians who are acknowledged leaders or experts. Enlist them to serve on your advisory committee. But make sure they completely understand your company's strategy before you mention them in your business plan, because potential investors may phone them.

V. Manufacturing and Operations – Describe how you will manufacture your product. What are the requirements for a manufacturing facility? Are there any single-source or difficult-to-purchase components? What is the estimated manufacturing cost – labor, materials and overhead? Your manufacturing facility and procedures, including packaging and storage, must comply with FDA guidelines for Good Manufacturing Practices (GMP).

VI. Management Team – Biographies on your complete management team (research and development, marketing, manufacturing, finance and accounting) must be assembled. Otherwise, your hiring plans must be spelled out in the business plan. The strength of your management team is very important to potential investors. Venture capitalists want to invest in people who have the ability and motivation to build a company. Every management team member should have relevant industry experience and functional expertise.

The president is the team leader and must be capable of hiring strong team members and motivating them. If a start-up company does not have a president, most venture capital firms require that a plan for hiring the president be agreed upon prior to investing. Among the proven skills investors look for in a president are a marketing orientation, exceptional "people skills," the ability to identify and solve problems, and a high energy level and sense of urgency.

Soon after deciding to build a company, the founders should decide how to divide and share equity among themselves and key individuals added later. The founders should be willing to share equity with others in order to induce them to join the team and to motivate them. The amount of equity allocated to each person should be commensurate with their expected contribution to the long-term performance of the company. A stock vesting program, usually four years, is ideal for ensuring that the equity payoff is directly related to each team member's continued employment.

VII. Financials – The financial summary should be concise and should include a projected five-year profit-and-loss statement, balance sheet and cash flow statement. The first-year financials should be shown monthly; years two and three can be shown quarterly; and yearly data are sufficient for years four and five. Back-up data should be available so that potential investors can do a more in-depth financial analysis if they choose. Your cash-flow analysis should show when and how much capital will be required. Include all assumptions concerning timing of payables and receivables, use of debt and leases, and taxes.

VIII. Risks – Disclose all risks and obstacles the company may face. Most venture investors are risk takers – they are not afraid to invest money when the outcome is unpredictable. On the other hand, they must know what the risks are so that they can calculate the probability of success and the rate of return they require on their investment.

Company Valuation and Investment Terms

Negotiations between company founders and the venture capital investor fall into two areas: valuation of the company (price per share), which determines what percentage of the company the venture capital investors buy when they invest; and financial terms of the investment. When negotiating pricing and terms, understand the needs of the investors.

Valuation – The price that venture capital investors are willing to pay for equity in any start-up is a function of the following: the amount of money they will contribute over the life of the investment; the amount of money they will receive as a return on their investment; the dates when they will invest money and will receive their returns; and the probability that these events will happen as planned. Based on this information, potential investors can calculate the expected rate of return and decide whether they want to invest.

High-margin device and drug companies typically have higher price-earnings ratios and higher valuations than equipment and service companies, and the investment returns on these companies may be higher. If you are starting a company to build magnetic resonance imaging cameras, you will require much capital, but your company may produce a high return on the investment. If you are forming a medical device company that intends to market its first product in two years, pursuing a 510K regulatory strategy, your financing needs are lower, and sales and earnings growth may occur within a three-to-four-year period, with a high rate of return. If you are starting a biopharmaceutical company, your financing needs are significant and commercialization is a long way off; any return to investors, although potentially significant, will probably occur after seven years.

Terms of Investment – Most venture capital investors will want to purchase preferred stock in your medical start-up. The rights and preferences of this preferred stock are negotiable, but venture investors usually ask for some of the standard terms described in Exhibit II.

Selecting a Venture Capital Firm

Anyone starting a medical company needs investors who understand the nuances of the healthcare industry. The regulatory climate is different from that in any other industry. The rate of adoption of new technologies is often slower because of the conservative nature of the medical profession. The product must be used on a number of patients, and results of clinical trials must be published in peer-review journals before rapid adoption occurs.

It is important to work with a firm that routinely finances start-up companies. A seed/start-up venture capital firm will know how to tackle many of the problems you may encounter on your path to commercialization. Personal chemistry between the founding team and venture capital investors is essential. You will probably spend many hours with these investors and rely on them for advice and help. Before investing in your company, they will check your references to qualify your strengths and weaknesses, your ability to manage, and your integrity. In turn, you should check references on the venture capital individuals and their firms. Talk with the founders and presidents of other medical companies funded by them.

Most venture investors will want one of their principals to be a member of your board of directors. Spend time with the partner who will work with your company. Try to determine whether this individual can add value to your business. Can he/she provide the following?

Feedback and assistance in developing strategies for your products, marketing, regulatory affairs and overall business.

Identification and recruitment of key personnel and outside board members.

Knowledge of potential corporate partners; input on negotiating strategy.

Identification of professionals (e.g., lawyers, accountants) skilled in helping start-up businesses.

Help in organizing future financings and establishing banking relationships.

A sounding board for operating and management problems.

The news is good for entrepreneurs in the healthcare industry. Venture capital is available for medical companies pursuing large markets with products based on proprietary technology. You can increase your potential for success by planning carefully and striving for a good fit between your start-up and the venture capital investors. Remember: your investment is as great as theirs.

EXHIBIT II
SUMMARY OF INVESTMENT TERMS

Registration rights. Venture capital investors usually buy preferred stock in a private placement. Since this stock is not registered with the SEC, there are restrictions on resale. Investors want the right to have the company register their stock in the future with the SEC so that it is salable.

Liquidation preferences. Liquidation preferences define in what order common and preferred shareholders will receive the proceeds from a liquidation, sale or merger of the company. Venture capital purchasers of preferred stock usually request return of invested capital prior to any distribution to common shareholders.

Antidilution provisions. Antidilution provisions protect the investors in the event that money is raised in the future at a lower price. A pre-negotiated formula is used to calculate the number of additional shares that will be issued to current investors if a financing is completed at a lower price.

Redemption provisions. The redemption provision may give the investors the right to sell preferred shares back to the company at a specified time (usually not sooner than five years), at a price equal to the purchase price plus some increment. An investor will use this provision only when the company has sufficient cash and little stock appreciation potential, with no other avenue to liquidity.

Protective provisions. Under protective provisions, some percentage of the preferred shareholders (usually a majority) must vote in favor of certain corporate transactions, such as an acquisition of the corporation by another company or the sale of all corporate assets. Preferred shareholders usually request the right to vote on any action that alters their rights, preferences or privileges, or creates a new class of shares with preference over, or at parity with, their preferred stock.

Dividend provisions. Preferred shareholders are usually designated to receive dividends before any dividends are paid to common shareholders. This provision prevents the company from distributing earnings to common shareholders only.

Information rights. Preferred investors usually want rights to monthly, quarterly or annual financial statements and the annual budget.

Right of first refusal. Preferred investors usually want the right to invest in future financings.

Co-sale agreement. The co-sale agreement specifies that investors have the right to sell shares on a pro-rata basis if any of the major common shareholders find a buyer for their common stock. This agreement prevents founders and managers (common shareholders) from selling stock without also allowing preferred investors to sell stock.

Conversion provisions. These provisions specify the terms and conditions under which preferred stock will convert into common stock. The usual trigger for conversion is an initial public offering of a specified amount (for example, $7.5 million) at a price per share that is a multiple of the original investment. The preferred shareholders thus retain their rights until certain actions occur.

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De Novo Ventures is a lead venture capital investor focusing on the early stage financings (the seed, start-up and first round) of medical companies in the western U.S., particularly in California.

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