

Risk Minimization and Positioning the Medical Device Start-Up for Success

By Robert R. Andrews, Foster-Miller, and Michael Magliochetti, Ph.D.,
Oxford Bioscience Partners LP

The statistics speak for themselves. Fifty to eighty percent of new products are not successful, and start-up companies fail at a rate of 85 percent on average.¹ While enough to deter even the boldest entrepreneurs, these figures are particularly frightening for life science firms, as exorbitant R&D budgets inflate the price of failure.

Attracting venture capital funding is a necessity for start-up companies aiming to secure a foothold in the medical market, which is ripe for investment despite the plentiful risks. Valued at over \$86 billion and estimated to grow eight to 10 percent per year, the U.S. medical device industry has high profit potential.² The lure of significant return multiples on investment provided by the next breakthrough product continues to attract venture capitalists.

Facing intense competition for a finite amount of available capital funding, medical device start-ups can leverage outsourced product design and development, along with a very high degree of proactive end-user feedback throughout the process, to serve as a point of positive differentiation. Minimizing risk while strengthening the probability of bringing practical innovation to market quickly, this unique strategy can optimize the attractiveness for investment in a given company and build value for subsequent market penetration and success.

This article will provide a foundational understanding of the primary diligence required to prepare for interaction with a potential investor. In addition, prospective operating options with respect to engineering/design outsourcing to position an opportunity for post-financing success will be presented

Presenting an Investment Opportunity to Venture Capitalists

A key to success in raising funds from venture capitalists for a medical device start-up is to understand the objectives of the venture capital fund. To meet the expectations of its limited partners, a venture capital fund must achieve significant return multiples on its invested capital within a tight time frame. A common expectation is a return multiple of three to five times the post-money valuation of the last round of financing with a timeline of three to four years and an addressable market in excess of \$500 million. The entrepreneur must understand that venture investors are not solely in the game to advance medicine and help patients. While this is a noble cause that will ultimately result from a successful project, the venture investor's principal objective is to earn a profit, or specifically, to provide at least a 20 percent internal rate of return to their limited partners over a ten year period (the life of the fund).

Conversely, the entrepreneur undoubtedly has the vision and belief in the potential of the proposed innovation to change the way medicine is practiced. These differing perspectives can make or break a successful union between entrepreneur and investor. Many opportunities will never see the light of day if the entrepreneur cannot convey the potential for market adoption and ultimate profitability to the venture investor.

Yet, the opportunity to present the venture investment prospect is brief, at best. Leading life science venture capital firms see hundreds of deals per year and often dedicate just minutes to screening new proposals. The entrepreneur may only have one chance to pitch a deal and homework is essential prior to the initial meeting. At a minimum, the entrepreneur should know the venture firm's historical interest in various deal stages (seed, mezzanine, etc.) and focal areas (orthopedics, cardiology, urology, etc.). Other important issues are the venture firm's fund status, past deals, current portfolio and

whether or not they typically lead investment rounds or prefer to follow. The entrepreneur must also be prepared to respond to all logical questions pertaining to the investment opportunity.

One can anticipate pre-money valuations associated with a Series A investment that will provide the entrepreneur with an ownership level in the range of 25-35 percent post-money (of course there are many exceptions). The entrepreneur will forfeit majority ownership and relinquish control, but at the same time will attain the needed capital, introduce venture expertise through years of experience to the Board of Directors, position the company if necessary for subsequent rounds of financing at potentially a higher valuation, and ultimately build tangible value for all involved.

Primary Diligence Drivers

During the initial presentation, the unique potential of the technological innovation being proposed must be concisely conveyed. Here, the entrepreneur must point out the “use-incentives” associated with the new technology. How will the technology change the way medicine will be practiced, not only from the physician and patient points of view but also from a financial perspective? Focus should be on the potential benefits for the physician, which may include increased efficacy, reduced morbidity and enhanced operations management efficiency. These attributes can be logically extrapolated to the patient, as can additional benefits such as transitioning a treatment from an invasive surgical procedure to a minimally invasive approach, switching from general to local anesthesia, and producing equivalent or better outcomes with faster healing times, for example. Most if not all of these benefits will equate to financial use incentives. Articulating these use incentives is necessary for the entrepreneur to “get past go” with a potential investor, and that is when the real diligence begins.

Maximize Investment Return Outlook with Practical Innovation

Once the venture capital firm recognizes the potential of the technology, the next step is demonstrating how the entrepreneur plans on using the invested funds. Given that R&D and engineering may consume the first 18-24 months of the venture and use a large majority of the funding, investment success is largely contingent upon a sound, innovative R&D plan. While the “make or buy” decision has long been faced in manufacturing, it is becoming increasingly common for start-up firms to outsource part or all of their R&D operations. External engineering/design firms offer many benefits and offset much of the risk inherent in start-up operations. This is evident in evaluating the key diligence screening metrics used by venture capital firms.

First, practical innovation is essential. Even the most innovative products have been known to fail as a result of not truly meeting market need. The particular target clinical indication and the applicable market size for the technology must be scrutinized in terms of the real clinical utility being proposed. This is an area where end-users must be involved, as venture investors no longer take a physician inventor’s perspective as gospel.

To address this common issue, some venture firms have taken the concept of proactive physician feedback to an entirely new level. This entails aligning physician and investor interest at the onset of the process when it is believed clinical expertise is most needed. Coupling the prospective end-user with the venture firm in proactively evaluating and addressing needs associated with a specific deal has been shown to yield an execution-driven model for the funded start-up, with vital physician feedback at the onset. This can maximize development efficiency, flexibility and ultimately provide the investors with a higher degree of risk minimization.

One can categorize this as a quality check before investing significant hours and capital in researching other critical diligence factors and to reassure the venture investor. It is analogous to manufacturers checking product quality early in the production process to allow them to scrap a sub-par product before heavily investing in labor, materials and overhead.

The entrepreneur must have a firm understanding of the addressable market, including comparables with respect to existing players and how they penetrated the market, historical adoption drivers, information on how the market may be changing, new potential players and existing competition. Identifying the dominant market leaders will provide the venture investor with an understanding of a potential exit strategy, which is something they will consider at the onset. It will also indicate firms most likely to acquire the company, what the value inflection points are and when they will occur, why this opportunity would be of interest and the relevant valuation.

One of the greatest benefits an external engineering/design firm can offer is the ability to forecast whether a proven medical technology will live beyond its initial intended purpose and be advantageous in the future. Technology forecasting is critical in shaping the start-up firm's strategic position. External partners attuned to the needs of the medical market can help the entrepreneur understand if and how the idea addresses end-user needs. Additionally, outside firms can conduct pertinent market research through interviews, focus groups and surveys to help prioritize end-user needs and minimize the risk of developing a product with unnecessary features or costs. Outside partners also lend anonymity to the project, allowing the start-up and investors to obtain first-hand feedback while maintaining confidentiality.

In addition to the end-user benefit, venture investors must understand that the innovation can be manufactured. An un-manufacturable design can delay a product launch and mire the project in costs, decreasing the opportunity for return on investment. Soon after the medical device concept is developed, the entrepreneur can leverage its partner's know-how to craft an optimal manufacturing approach and determine if standard or customized equipment is ideal. This proactive approach will prevent costly mistakes and production mishaps that might delay market introduction.

An effective design is often reliant on a multidisciplinary problem solving approach, another advantage of engineering/design firms. Highly skilled project teams with diverse backgrounds can most efficiently facilitate application of technologies potentially uncommon to a life sciences firm, but necessary for developing a successful medical product. This adeptness and industry experience is the practical approach necessary for a company to bypass learning curves, accelerate time-to-market and truly deliver a cutting-edge product that reaps investment return and minimizes the traditional business hurdles, all favorable from a venture investor's perspective.

Crafting a Regulatory and Reimbursement Approach

The ability of a medical product to gain market share is often highly dependent on its prospective payor reimbursement strategy. Many venture investors will not consider a technology unless an established reimbursement path exists. Entrepreneurs often consider FDA regulatory clearance or approval as the gating item behind the success of their venture, yet of equivalent importance is the ability to garner reimbursement for their product. Because navigating through reimbursement diligence can be difficult, venture firms often seek out expert assistance through consultants. Entrepreneurs should do the same in establishing a cogent strategy to present to prospective investors.

Regulatory strategies should be addressed early, as much time, effort and capital will inevitably be spent post-investment addressing the regulations facing the medical device start-up. The regulatory strategy can be fraught with many unknowns including overall requirements, substantial equivalence comparables, clinical trial design and primary efficacy clinical follow-up, all of which must be incorporated in an executable preclinical and clinical plan and a pro forma budget. Leveraging the contacts of experienced engineering partners and instituting a proactive approach in communicating with the FDA can help to significantly reduce the unknowns. This will lead to a more unassailable budget, and inherently lend a higher degree of credibility to the prospective investment deal.

Minimize Risk through Partnerships

Venture capitalists understand there is no start-up truly without risk. Yet, firms considering an investment in a medical start-up need the assurance that the company has taken the time to minimize potential risks such as costs, confidentiality and capital investment. The entrepreneur must understand and convey the potential obstacles that may lie ahead and how the company can best anticipate and traverse these challenges. Very often a seasoned venture capital investor will be able to quickly assess the risks associated with an opportunity during the initial presentation or even from reading the executive summary. It is the entrepreneur's challenge to communicate that these risks have been proactively considered and a plan established to best operate the business from every functional perspective.

The venture investor must also be very comfortable with the ability of the entrepreneur to compile a management team to address risks and build incremental value for the enterprise. To complement the internal team, entrepreneurs can demonstrate this viability by partnering with an engineering/design firm that provides a team of experts possessing managerial and multidisciplinary expertise.

In addition to this knowledge sharing, outside firms might also prove to be more economical than hiring full-time or temporary employees or consultants who may present confidentiality risks and deep financial burdens. Third-party firms can quickly and cost-effectively dedicate a multidisciplinary team without excess labor costs. Reputable engineering firms often have an experienced staff offering the stability to benchmark a start-up's own novel ideas, giving comfort to venture capitalists looking for an investment insurance policy.

Demonstrate Strength in Management

Entrepreneurs must also prove strength in planning ability and demonstrate a roadmap for transitioning the business concept into a market-leading medical solution.

Companies that partner with experts at the onset of product development relieve the administrative burden of the start-up's executive team from taking on more than they can handle and ensure market needs and business goals are met. Engineering partners can complement management in addressing the following administrative necessities:

- *Timeline:* Venture investors require the medical device start-up has a clear research and development milestone plan, timeline, and a strong understanding of the financial commitment including a sensitivity analysis necessary to clear the regulatory approval milestones including FDA (U.S. Food and Drug Administration) and CE (Conformité Européene) marking requirements, all necessary to get the product to market. The capability to use outside firms with expert personnel to augment in-house staff, whether for pure research, development execution, engineering or industrial design, should be considered part of the critical path to market.
- *Budget:* As with any investment opportunity, pro forma financials is a cornerstone of the diligence. In addition to using proceeds to fund operating losses to get a technology to market, the medical device start-up must have a budget that takes the company to cash flow breakeven and beyond. Inherent in this budget is the prospective cost of goods, where the company's strategy for manufacturing must be outlined. Whether it entirely entails contract manufacturing, an initial plan for contract manufacturing evolving to an in-house effort, or entirely in-house, this must be established as part of the financial model. Thus, it will be important to foster a relationship with potential contract manufacturing candidates and attain an estimate, regardless of the stage of the technology, on transfer price.

- *Intellectual Property Protection:* Another decisive factor for the entrepreneur to consider is the scrutiny the potential investor will exhibit in reviewing the existing and prospective intellectual property estate. Most often during the diligence process, the investor through legal counsel collaboration will conduct a freedom-to-operate review. The investor will also meet with existing patent counsel to understand the current intellectual property landscape and how best the company can surround its technology with more protection, after which a much deeper dive into this area may be taken later in the diligence process. The establishment of a continued intellectual property strategy for the start-up company with its associated expenses is anticipated by the investor and as such the entrepreneur must be able to articulate a plan for such protection. An engineering partner well-versed in IP issues can also guide this process.

The Bottom Line

Being proactive, establishing a business plan incorporating all of the facets of the diligence metrics described above, along with understanding options for outsourcing partnerships to maximize efficiency and minimize risk, will provide the medical device entrepreneur with an increased position of strength when approaching fund raising. Having a grasp of perceived risk, while taking the steps necessary to minimize this risk, is indicative of competent management and should prove to increase valuation for the investment opportunity.

A well thought-out plan that includes partnering with an external firm helps fill in the technological gaps of a company's own medical market experience, giving potential investors the comfort of knowing the risk of losing money is minimal. The right partner can help position medical device start-ups to easily claim market leadership by providing guidance through the process of adequately monitoring the competition, leveraging technology forecasting and taking the necessary steps to protect their proprietary products with patents held in the company's name. With these strategies in place, medical device start-ups will define themselves as viable entities well worth the investment.

About the Authors

Robert R. Andrews is Medical Division Manager for the commercial group at Foster-Miller Inc., a QinetiQ company. He has more than 25 years of medical device experience managing product development and operations. He has 11 issued U.S. medical device patents. He received an MBA from Bryant College and Bachelor's and Master's degrees in Plastics Engineering from The University of Lowell. He can be contacted at (781) 684-4639 or randrews@foster-miller.com.

Michael J. Magliochetti, Ph.D., is serving as an Entrepreneur-in-Residence at Oxford Bioscience Partners LP. He has spent his career in the medical device arena with CEO positions at RMH, HemaMetrics and UroSurge, while also holding senior positions at Haemonetics and Delta Surprenant. He currently serves on Advisory Boards for the Boston Children's Hospital and the Institute of Pediatric Innovation, and the Board of Directors of Spire Corporation. Dr. Magliochetti has been an Adjunct Professor of Biomedical Engineering at the University of Iowa and has consulted with many companies in the medical device industry. He holds B.S. and Ph.D. degrees in Chemical Engineering from Northeastern University and the University of Massachusetts at Amherst, respectively, and a High Technology M.B.A. from Northeastern University. He can be contacted at (617) 357-7474 or mmagliochetti@oxbio.com.

References

¹“The Essentials of Consumer-Driven Innovation.” Forrester Research: May 26, 2006.

²Advamed 2006