Starting Up Right

Entrepreneurial medtech companies can make steady headway if company leaders pay early attention to key considerations.

Fred Dotzler

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Starting a medical device company offers many rewards. The personal ones include working with a team of hand-selected people, achieving recognition, enjoying freedom from bureaucracy, and creating wealth. A larger satisfaction comes from the opportunity to improve the health and well-being of patients.

There are costs, too, including the 24/7 time commitment, the responsibility of providing for the start-up team, the concentrated risk, and the stress of meeting deadlines. But entrepreneurs determined to start a medical device company will be more likely to see rewards if they guide their enterprise by adhering to a handful of proven start-up principles.

First Things First

Certain issues should be addressed before resources are committed, to determine whether the product idea and business strategy are ideal. Medtech entrepreneurs can send their start-ups down the right track and avoid later pitfalls by making these actions and decisions a priority.

Determination of Interest. A product idea should be vetted by potential clinical users before launch of the company. It is valuable to obtain opinions from both academic-thought leaders and healthcare practitioners. Start-up founders should listen carefully to the feedback, both positive and negative, and should ask how a device they are planning to develop might be improved for the intended use. They should try to gauge the size of the targeted market.

In addition, founders should engage venture capitalists and other entrepreneurs, seeking their informal feedback on the business model. An entrepreneur who does not receive some positive feedback at this point might delay launching the company, or might begin searching for another idea.

Patents, Reimbursement, Regulatory Affairs. Performing a patent search early is essential. That will give the entrepreneur assurance of freedom to operate and certify that an opportunity to secure a proprietary position exists. Next, the entrepreneur should determine whether reimbursement codes for the product and related procedure are in place. Another consideration is whether the product is to be approved by FDA under a premarket approval (PMA) application or via the premarket notification (510(k)) route. The former takes more time and capital, but it also serves as a barrier to entry by potential competitors.

Legal Assistance. An entrepreneur should enlist the services of a corporate attorney to incorporate the new company and to advise on allocation of stock, vesting, confidentiality agreements, in-licensing technology, and other matters that need a solid legal footing. Law firms can also be helpful with introductions to prospective investors.

Market Focus. Entrepreneurial companies do well to enter a niche market where they can demonstrate that their product performs significantly better than any alternative. They may not have sufficient resources to address the entire market, where large competitors will try to stifle their progress.

Even if the start-up is pioneering in a market that lacks directly competing products, it will usually not have sufficient resources to sell to every known prospective buyer. Success in the targeted market segment is the first priority. After that is assured, the entrepreneurial enterprise can raise expansion capital and launch an assault on a broader market with an enhanced product line.

It is helpful for entrepreneurs to focus their efforts in a clinical area in which they have had experience. They will know the thought leaders and thoroughly understand their needs. Also, they will be better able to identify appropriate prospective team members.

The Entrepreneur's Dream

Company A was the second company that Bill Doright, MD, founded. After deciding to start the new company, the experienced entrepreneur enlisted the services of a reputable lawyer to incorporate the enterprise.

Bill then recruited a talented and proven engineer to help design the company's first product. The engineer was allocated one-third the number of shares that Bill received, and the shares of both were to vest over a four-year period. The prior art was extensively reviewed by an expert; then, patents were filed.

Prior to meeting with four venture capital firms, Company A made prototypes of its inaugural product and recruited a stellar medical advisory board. Within two months, a lead investor committed to funding the company and a coinvestor was selected to round out the $4-million series A financing.

The company developed prototypes that were tested in animals during the next 14 months. The founder decided at the beginning that he did not want to run the company, so the board of directors hired a well-qualified CEO.

Company A developed and patented additional products, and then raised a $12-million series B financing at a price per share 75% above the price of the series A. The first product developed entered the market 30 months after the company received its initial financing, and sales increased rapidly following launch.

Shortly after a $7-million series C financing, a corporate acquirer bought Bill Doright's company at a per-share price 10 times that of the series A shares.

Bill was pleased with the way Company A turned out. And the energized doctor was incubating a new idea—perhaps a third company?

Money

Financial considerations are fundamental to any entrepreneurial plan for success.

Fund-Raising. Start-up company founders should allow up to six months to raise their first financing. Before raising capital, they should develop a detailed spending plan and identify important milestones. It is valuable to build prototypes and identify key management team members.

If the founders plan to raise venture capital, they should poll their advisory network to help decide which potential investors to approach. If they plan to raise $3 million, they should meet with enough investors to raise $6 million on the assumption that not all will invest. Periodic solicitation of feedback is advised. If some of the venture investors seem unlikely to invest, then the number of them to whom the entrepreneurs present their plan should be increased.

Disclosing the risks and challenges of a venture to prospective investors enables them to make an informed judgment regarding the probability of its success. It will also enhance the credibility of start-up executives. But if prospective investors are not heard from within seven days of proposal, they are probably not interested.

Entrepreneurs usually cannot dictate the price per share or financing terms, so they should be prepared to negotiate. They will be partners with their investors for several years. Consequently, checking the investors' references is prudent.

Start-ups should plan to raise the next round of financing after completing steps that add demonstrable value to the company, such as the filing of initial patents, completion of product development, performance testing in animals, and conclusion of pilot human clinical trials.

Uses of Capital. Once they have raised the money, entrepreneurs should pay careful attention to their rate of spending and their cash balances. They should be frugal with regard to facilities, furniture, and other items not critical to developing and testing their product.

People

The success of a start-up company will depend on the strength of the team the entrepreneur assembles.

First-String Team. A company founder should hire top-quality people for every position. Networking can help to identify the best candidates, who must be convinced to join the company. It is better to wait for an ideal person than to settle for someone merely good enough, even if that means delaying the beginning of a development project. Friends may join the team, but they should be hired only if they are the best available candidates.

Quality should also be a prime consideration in selecting reputable outside support, including corporate legal counsel, investors, scientific advisers, administrative consultants, product designers, consultants, and vendors. The entrepreneur should recruit reputable people as outside directors and as members of scientific and clinical advisory boards—individuals who will fill needs that have been identified. It is often useful to solicit advice from entrepreneurs who have built successful noncompeting companies.

The founder should keep the entire team apprised of the company's progress and challenges. This will enhance everyone's ability to contribute and will foster an open, creative, and cooperative work environment.

The Founder. A start-up founder often has an evolving role in the company. The founder should take stock of personal strengths and weaknesses and not assume that he or she will be CEO of the company forever. Many medical device start-ups are founded by entrepreneurs who have not had broad general management experience, or who do not want to deal with the problems of running a rapidly growing company. Their principal objective should be to maximize the value of their stock holding by having their company succeed. Founders should take comfort in knowing that most qualified CEOs are not capable of inventing and developing the products on which companies are built.

Unequal Equity. The question of how to apportion equity in a start-up company should receive careful consideration. It is usually not wise to divide ownership equally among the initial team members, because some individuals will likely contribute more than others. All members of the team, including the founders, should have their ownership positions vested over time. It is unwise to allow full ownership up front. Anyone who leaves the company should accrue equity only for the time during which that person contributed to the company's success. This will ensure that shares are available for hiring

The Start-Up Nightmare

Company F was founded by Mark Startwrong, a talented corporate engineer who during the previous 10 years had developed medical devices to address an emerging market. On his own, he conceived a promising product to serve an unmet need in that market, and so formed Company F.

Mark decided that he was not qualified to be CEO of his company, so he recruited lawyer Dave to fill that executive role. The partners agreed to split the founders' shares 50/50. Mark made no mention of vesting to Dave. Together, they wrote a 30-page business plan and identified Mark as company founder and Dave as CEO.

Mark and Dave met with three venture capital firms, all of which told them that Dave did not have the qualifications to be CEO. On the basis of this feedback, Mark informed Dave that he could not be CEO and would not be part of the company after all.

Dave hired an attorney. He asserted that he was listed in Company F's business plan as CEO, and therefore deserved his 50% share in the company. Later, several months too late and under pressure, Mark hired legal counsel to represent his company. That attorney's first task was to help resolve this issue of contested ownership.

For two years the partners battled. They ultimately settled, and Dave parted with 35% of the company. During the period of the dispute, product development was on hold and fund-raising stopped.

Freed of Dave, Mark discovered that his product infringed patents held by a large company. He did not want to expend resources fighting another (probably futile) legal battle, so he agreed to develop the product and have the large company sell it.

Mark Startwrong's Company F failed. But the would-be entrepreneur was able to earn a modest amount on royalties over the next 10 years.

replacements for those who leave.

Venture capitalists will insist on vesting over four years as a condition of their investment.

Patents

An entrepreneurial company needs to secure a very strong patent position that gives it freedom to operate and the ability to exclude others from copying its device and marketing a knockoff. Founders should engage a reputable patent attorney as soon as possible, preferably the strongest attorney possessing experience and expertise in the start-up's product or technology domain. The patent firm employed must be acceptable, but the individual attorney who will be writing and filing the company's foundational patents should be the very best that can be found.

Entrepreneurs will be partners with their **investors** for several years. Consequently, checking the investors' references is prudent.

The new company needs to develop an overall patent strategy that encompasses the technologies to protect, the countries in which patents will be filed, and other essential intellectual property (IP) considerations. It may be necessary for the strategy to include licensing patents to extend and enhance the company's IP protection.

The entrepreneur should not view patent filing as a one-time event, but should instead continually manage the company's patent portfolio. The start-up should establish a patent committee, and someone in the company should be charged with managing the patent portfolio. Sufficient resources should be budgeted for filing and prosecuting the patents needed to protect the inventions that the company will disclose as it proceeds with product development.

Broad patents will dissuade competitors from developing products similar to those of the start-up. When an entrepreneurial company is being sold or prepared for a public offering, the strength of its patent protection will be weighed heavily.

Product Development

With the team, the money, and the patent structure in place, the start-up enterprise needs to get into the market. That means developing workable, salable products as quickly as possible.

Rapid Iteration. Entrepreneurs should learn ways to accelerate the product design and testing cycle, including the use of design and simulation software, rapid prototyping, and other tools that facilitate rapid development and improvement of a product. Speed and agility are the start-up company's big equalizing advantages over large companies that will have more resources.

Start-ups should invest in tools of their own that will accelerate product development—computer-aided design programs, a machine shop, prototype molding capability, a chemistry lab, and whatever else is essential to enable the company to control its development cycle. An early-stage company does not want to rely on vendor schedules for its critical components.

Keep Only the Good. An entrepreneur's goal is to create value, not to prove that an initial product idea was correct. The innovator should keep the elements of the design that prove to work and willingly discard those that do not. There is no use in being wedded to ideas that should be dropped.

Plan for the Glitches. The product development plan should be aggressive but realistic, with buffers in place to accommodate missteps. The company should be prepared, when it encounters glitches and setbacks, to think creatively and find ways to catch up.

Feedback. As device development proceeds, the start-up should show prototypes to prospective customers and solicit feedback from them often. The devices should be used in animals as soon as possible so that what works and what does not can be observed. Continually improving the product by these means will maximize the probability that it will work successfully in human trials.

Test. Prior to market launch, the device should be tested thoroughly to ensure that it works reliably. Any remaining design and manufacturing

Ten Principles to Guide the Entrepreneur

Hard work and a willingness to take risks are necessary but not sufficient for success in starting up a medical technology company. Founders of entrepreneurial enterprises can improve their chances of achieving their goals if they:

- Establish the viability of the product idea and business strategy through up-front market, clinician, user, investor, and patent research.
- Segment the market and focus on a niche where the product will display evident superiority.
- Create a logical and realistic financing and spending strategy.
- Approach venture capitalists intelligently, honestly, and openly.
- Hire the best people possible.
- Take stock of personal strengths and weaknesses in deciding what role the founders will play in the company.
- Distribute equity in the company according to contributions over time.
- Strive to secure a strong patent position.
- Focus on ways to accelerate product development for rapid market entry, and test the product thoroughly to identify and correct shortcomings.
- Solicit feedback on the developing product to make sure that the final version will appeal to prospective customers.

problems can be corrected at this stage. Pilot trials are useful and even necessary for some devices. An entrepreneur often has only one shot at a successful market introduction, so it is essential to be certain that the device works as intended before finalizing the design.

Conclusion

Now is a great time to start a medical device company. Venture capitalists are raising significant amounts of money to invest in companies developing unique products that address potentially large markets. The amount of capital required to hire a team, develop products, establish manufacturing operations, and begin selling is in the vicinity of $25 million. An additional $10 million should enable the entrepreneurial company to increase sales and establish a position in its chosen market.

Many large medical device companies continue to acquire early-stage companies that show promise. The acquisition price for a typical device company with momentum can be $200 million or more. Entering the public market via an initial public offering (IPO) is another option for companies with the potential to continue growing.

Whatever the exit route, the return to the founders, the management team, and the venture investors in a successful medical device start-up company can be significant. The key start-up considerations outlined here, if pursued, can enhance an entrepreneurial company's chances for success.

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Business Planning & Technology Development

The steady creation of new medical device companies, driven by the lure of financial opportunity as well as the incentive to do good in the process by making people's lives better, has been an important reason for the vitality of the medtech industry. Entrepreneurs are welcomed to the strong medtech sector, but not all succeed in their business enterprises. A lesson in how to avoid that fate is provided by "Starting Up Right," an article by venture capitalist **Fred Dotzler**, managing director of De Novo Ventures (Menlo Park, CA). Trained in engineering and economics, and schooled by management experience gained at several medtech companies, Dotzler distills his knowledge into a handful of essential principles by which he says an aspiring company founder should operate. He can be reached at fred@denovovc.com. ■

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