

Roundtable: Medtech Funding and Investment

Industry experts discuss the realities and expose the myths surrounding the current financial climate of the medical device industry.
Moderated by [Steve Halasey](#)

Entrepreneurs operating in the medical device industry take all shapes, from new entrants emerging from academia and related technological and clinical fields to seasoned industry veterans looking to establish and grow yet another successful device enterprise. But no matter their level of experience and expertise, the ultimate success of all medtech entrepreneurs hinges on one thing: their ability to raise adequate funds to bring their ideas to fruition.

To find out more about the current climate for medtech funding and investment, *MX* recently spoke with six experts in the field (see sidebar). In this excerpted roundtable discussion moderated by *MX* editor-in-chief Steve Halasey, these industry experts discuss funding availability for new medtech ideas, challenges faced by start-up companies, and strategies for success in today's investment environment.

MX: In today's medical technology environment, what kinds of people are most commonly seeking funding for new medical product ideas? Are they predominantly academic researchers, clinicians, or engineers, or perhaps a mixture of these?

Anne DeGheest: In my experience, it is a mixture. I frequently see practicing clinicians, some of whom have teaching credentials, coming up with new ideas for medical products. I also see some engineers coming out of established companies and setting up their own firms to develop products.

Dennis W. Wahr: Useful new ideas often come from people who not only have a window into the current state of the art but also a window into what the market is demanding. The people who have such windows are commonly clinicians. It is less common for engineers to produce ready-to-go ideas than it is for clinicians. Engineers are more likely to develop a concept, but those concepts often require refinement before they can address an unmet clinical need.

In your experience, how knowledgeable or sophisticated are these entrepreneurs? Are they more knowledgeable than entrepreneurs might have been five years ago or a decade ago?

Jay Watkins: Yes. The root idea obviously has to stem from an understanding of a clinical need. It is pretty rare to see a lone engineer develop something that falls right in step with the needs of a clinical practice. More commonly, these projects represent a team effort.

One of the things that has changed in the idea origination process is that there are many more experienced serial entrepreneurs in the medical device space, including clinicians, engineers, and businesspeople. The teams we see developing include people with deep experience in the industry.

Lars Enstrom: More clinicians are teaming up with business executives because they realize that it's not good enough to just have a great technology. They need to present the business case for the opportunity and show that it can be commercialized and sold.

When you first encounter these entrepreneurs, what kind of knowledge are they usually missing that they should work on getting before they seek out investment?

DeGheest: It depends. If the idea comes from a clinician, there is usually a bit of naivety and lack of understanding of what it takes to turn a clinical idea into reality in regard to cost savings and the

value that must be created for buyers, users, and payers. That is one of the complexities of this industry.

If the idea comes from an engineer, there is usually a different type of naivety involved. The idea may represent a great technology, but it might not respond to a clinical need strong enough to serve as the basis for building a company around it.

Allan W. May: Entrepreneurs need to associate with somebody who can mentor them in order to improve their success rate. Often, entrepreneurs don't know how to talk to venture capitalists or angels. They don't understand dilution. They don't know how to arrange their various rounds of financing so that everybody wins at every stage. They don't know how to balance a price with dilution. They don't know how to determine the amount of money to seek in order to hit their milestones. They need somebody to help them do that. That is where the previously stated points regarding teamwork and entrepreneur naivety coalesce.

Baiju R. Shah: All of this depends on where a person is coming from in terms of the knowledge gap. And it is not just the individual entrepreneur's knowledge gap that must be taken into account, but also the gap existing within the entrepreneur's network. Many entrepreneurs come looking for investment funds when they are not necessarily investment-ready. This is not necessarily due to a lack of mentorship. Often an entrepreneur might not understand how to tap into the resources of advisory boards.

Watkins: More so than specific domain expertise, I find that first-time entrepreneurs generally lack a set of characteristics. Of those characteristics, patience is at the top of the list. First-time entrepreneurs frequently lack sufficient patience. Second, because they are in a hurry, they generally do not ask as many questions as they probably should. The third required piece—and this is a tough skill to perfect—is the ability to tell the difference between good advice and bad advice.

Opportunities and Requirements

In the current environment, how much money is required to take an early-stage medical technology company from start-up through liquidity? Are there factors driving the cost of medical device development now more than they might have previously?

DeGheest: It depends on the type of product the company is developing. For a high-risk technology requiring a premarket approval (PMA) application, right now a company is probably looking at \$40 million to \$75 million to get to the point of some type of commercialization of the product, as well as a potential exit through an initial public offering (IPO) or acquisition. For a company in which the risk is more market-based and the company's application builds on existing technology—requiring lower levels of FDA scrutiny and lower reimbursement pressures—a company may be able to achieve an exit with \$20 million to \$40 million. Again, it depends on the type of product.

May: The cost associated with getting a company off the ground is too great. The system is broken. The estimates of about \$40 million to \$75 million for a PMA and \$20 million to \$40 million for other devices are correct. Post monies can be \$60 million, \$80 million, \$100 million, and take-outs are very rarely more than \$100 million in terms of exits in liquidity. The system has to go back to more-capital-efficient development.

Enstrom: In general, I believe the ranges that have been cited are accurate. Clearly, clinical and regulatory expenses have been the major contributors to these increasing costs. Many companies have coped with these expenses by remaining virtual longer or by relying more on consultants rather than employees. Nevertheless, the huge costs imposed on small companies mean that more capital

has to be raised before a liquidity event. Companies have to mature to become self-sufficient because early funding from an IPO does not exist now and acquirers are waiting longer before buying companies.

Watkins: One solution is to make start-up companies more capital efficient and ask the acquirers to acquire early. The other solution is to focus on building companies that will last and that are designed to be stand-alone companies over the long haul—companies that don't count on a take-out.

Managing Growth

There has been a lot of comment on the dearth of seed funding available to entrepreneurs at the very earliest stages of establishing a company. Is there in fact a gap of funding, and who is filling that gap?

DeGheest: According to PricewaterhouseCoopers/National Venture Capital Association reports, between 1995 and 2005, the combined total of seed- and early-stage funding dropped from 39% of all venture money invested to 19%. That is a very significant drop.

Angel investors are stepping in. But the problem is that while angels can contribute a certain amount of money, a company must still reduce its risk enough to get the venture industry interested. That gap in funding is widening, so the amount of money the angel investor community has to invest is getting larger and larger. I think that is why some of the angels are getting themselves organized—in order to have enough power to bridge that gap.

Do you think that the organized angel groups are enough to fill that gap? How well are they doing?

May: Yes and no. The Angel Capital Association, a program of the Ewing Marion Kauffman Foundation (Kansas City, MO), tracks this issue. Its data indicate that the growth of organized angel groups following the 2001 bursting of the dot-com bubble has been relatively explosive. The number of angel groups has risen from less than 100 to more than 250 in this period of time. However, their level of investing has remained relatively stable. There is approximately \$29 billion to \$30 billion nationwide in angel activity.

As for what people consider classic technology start-ups—device and biotechnology start-ups in particular—the data show that angels can take companies through organizational stages requiring \$1 million, \$2 million, or maybe \$3 million. According to the data, somewhere between \$2 million and \$5 million is the chasm that seems to be a little bit difficult to bridge.

Organized angel groups are now beginning to syndicate their deals with one another. Some are looking to raise side funds in order to close that gap so they can control the deal up to the \$5 million mark. Being able to do so reduce the risk associated with attracting follow-on venture financing.

Shah: While angels are clearly the largest pool of alternative sources of funds, we're also seeing two additional sources beginning to emerge. One is institutions that have captive seed funds that are being used for translation work. Such institutions include the Cleveland Clinic and Case Western Reserve University. There is a growing movement among technology offices of large institutions to have somewhere between \$5 million and \$10 million available to fund translational work and to hire initial professional management teams.

The second emerging source of seed funding is individual states. Some have stepped forward to fill the funding gap. For example, Ohio has a program called the Third Frontier, which allows institutions to collaborate with start-up companies—whether they emerged from an entrepreneur within the institution or from the outside—and fund the translational work to the tune of millions of dollars. Entities emerging from this program include a neurostimulation center with several spin-offs, as well as a center focused on atrial fibrillation that has several spin-offs. These entities have been able to get the monies required to advance them to the venture world.

What I have not yet seen happen in the device world that I have seen happen in the biotech world is the emergence of disease-specific foundations as financing sources for advancing technologies.

Enstrom: More states have finally recognized that they have a vested interest in creating jobs in new industries to make up for jobs lost in more-mature industries. They have also realized that in many cases state universities offer a great many useful assets both in terms of intellectual capital as well as physical assets, such as buildings that can function as incubator space. One of the companies I recently financed had a partnership with a major university and was housed in a research park on campus. In addition, the state made an equity investment in the company.

Wahr: It has become very common for large research institutions around the country to develop sophisticated licensing and technology transfer offices. These offices serve two functions: One is to be a regional economic development vehicle for the institution's city or region. The other is to be a long-term source of potential revenue for that institution through licensing agreements.

The technology transfer offices of large academic institutions typically encourage and often assist their faculty to develop ideas that can be licensed to independent entrepreneurs. The key to this process is the identification of a talented, passionate entrepreneur. In my experience, it's unusual to find a scientist or inventor who is willing to abandon an academic career. To ultimately attract VC financing, a full-time talented entrepreneur is essential.

Shah: It is in situations such as this that the better technology offices—those that have a captive funding source, whether it is a seed fund or just operational funds—are smartly investing in management rather than just investing in additional validation work for the technology.

Do academic and clinical institutions have a realistic sense of what it will take to commercialize their intellectual property, and therefore what its value is likely to be?

Shah: This varies on an institution-by-institution basis. The ones that are more experienced have a realistic sense of what the value of a bucket of IP is. They have realized that not only is patenting important but freedom-to-operate opinions and the like are also important if the institution is going to commercialize its technology. These experienced institutions have the sense that their intellectual property alone might not be the basis of a company. It might need to license technology from other sources. In negotiating its deal terms, the institution might also have to make sure it is accommodating the needs of a venture group or a corporate licensor.

Even if it is not directed at early-stage ventures, does the overall availability of capital increase the number of companies that are looking for investment?

Watkins: Yes. Like everything else, this is a business of cycles. And in this cycle, the headline news is that there is plenty of money for medical technology investing. This encourages entrepreneurial teams to make their pitch. Due to the favorable environment, they think that even an idea they might have abandoned a couple of years ago might have a chance of getting funded. So there is a clear relationship between the amount of money that is available and the number of plans being presented. Back in 2001 and early 2002, there was not nearly the same level of capital available for investment

that there is now, and entrepreneurial activity in the medical device industry was noticeably lower as a result.

Wahr: Despite the fact that there is more venture money for life sciences out there than ever before, or at least as much as there has ever been, the number of investigational device exemption applications and investigational new drug applications to FDA is down substantially. Because of how difficult the regulatory environment has become and how large the trials need to be, VC firms are becoming much more sophisticated and selective about the concepts they fund. However, when they do choose an organization to fund, they are willing to put much more money into the development of those fortunate companies.

Many people are surprised when they hear of the decline in applications to FDA supporting novel products or drugs that require formal premarket approval, but they are down substantially.

Exits

What are the current expectations of investors in terms of a timetable for exit? When they think about an exit, do investors generally lean toward acquisition or IPO?

DeGheest: Everybody would love to reach an exit four to five years from the time of investment. And everybody would like to get a seven times or a 10 times return on their investment. But if you look at the top quartile, the reality of returns in the industry is two to three times, over a period of five to six years.

The IPO market is dependent on the public sector. In medical technology, acquisitions represent a majority of the deals. Unfortunately, the two to three times returns are only seen by lucky companies. Companies are spending more and more time developing and commercializing their products so they can be acquired. Therefore, their returns are getting lower. Companies must invest more money and more time, yet the mergers and acquisitions (M&A) exit garners the same price.

Enstrom: VC investors have typically relied on IPOs as liquidity events. The problem with IPOs is that the window opens and closes rapidly, and it's also hard for VCs in all but the largest IPOs to exit within a reasonable amount of time. This inability of VC investors to exit makes an IPO not a liquidity event but rather another corporate structure with which to raise capital. So, in the case of an IPO, a VC could be in the investment for seven years or more. For these reasons, VCs are beginning to realize that an M&A takeout is really the only true liquidity event.

Wahr: Most medical device or biotech start-up companies are one-product companies, and the IPO markets don't like one-product companies. That is the dilemma that explains why most of these companies are going to exit by M&A.

I personally believe that every company should be built from day one to be a go-it-alone company. Companies can never bet on the fact that they will be able to orchestrate an M&A. Additionally, when entrepreneurs focus on a fast, near-term M&A, it can create problems with their company's development that will slow overall development should the M&A not materialize.

On the other hand, when companies cross the crucial line from the development stage to the commercialization stage, they require much larger sums of financing. This is the point at which they will need to develop their own sales forces and marketing teams. An M&A transaction often makes sense at this point because the acquiring company typically already has the sales force in place. If an

M&A does not materialize at this point, the company will need to raise large sums of cash from VC firms, develop its own sales force, and point to a future IPO.

Last Thoughts

What advice would you offer to entrepreneurs who are seeking funding for an early-stage company?

DeGheest: You need to be a missionary, not a mercenary. You need to have the passion to go for the journey.

May: There has not been a better time to be in the biotechnology or medical device industry since the early 1980s. This is a great time to be in the business. The needs are there, the business dynamics are there. Don't mess around with incremental improvements to existing products. Go for products that change the nature of medicine—but don't try to change the practice of medicine too much. Change the cost structure and benefit patients, and you will do very well in this business.

Shah: My one piece of advice is to build an advisory network early that is going to be able to help guide you through the multiple facets of bringing a product to market, getting a company financed, and ultimately getting clinical acceptance.

Enstrom: Spend the time needed to create a thorough business plan. Make sure you understand your company's value proposition and are able to articulate it succinctly.

Watkins: I encourage entrepreneurs to remember that when they look at broad trends, they are looking at averages. The important factor to consider is the quality of their own deal. They shouldn't give up because the average tells them that it is harder to get early-stage capital than it used to be. They should recognize that there is capital available for those ideas that are worth the effort. They need to have the patience to deliver on the promise of their ideas

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