Alternative Financing Strategies For Medtech Start-Ups

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Executive Summary

Pools of venture capital for life science companies are drying up. The good news is that there are alternative sources for young medtech companies. EBI convened a panel of experts at its recent IN3 conference to explain when and where to find them and presents here a Q&A with an angel investor, a representative from a venture debt firm, and an expert in non-dilutive grant funding.

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The health of financial markets depends on the principle that there are two sides to every story – the buyer’s and the seller’s. When one industry is up, another is down. When venture capitalists shift their money out of one market, they move it into another. Well, that might be good for investors, but it’s tough on the start-ups left behind. Young companies operating in the life sciences industries have recently been suffering from the exodus of traditional VCs from the sector. Many VCs say that going forward they’ll de-emphasize medical device investing in favor of health care and IT because medtech is just too risky and expensive these days, given health care reform, a more stringent FDA, and financing risk. START-UP conducted a life sciences venture capital survey in 2011, which revealed that two-thirds of respondents have already committed at least half of the capital in their current funds. In addition, many are pessimistic about the prospects for raising new funds. Prospect Venture Partners, Scale Venture Partners and others have opted not to
raise new funds going forward. (See “START-UP’s 2011 Life Science Venture Capital Survey: Device Investors Feel The Sting Of FDA, Economy And Reform” — START-UP, September 2011.)

In 2011, private investing in medical devices was still strong. Investors placed $2.86 billion in some 156 private medical device investments (the actual number of financings is a bit larger, but those are the transactions for which Elsevier’s Strategic Transactions has assigned a value.) Diagnostics deals, too, attracted capital in 2011; 22 private diagnostic financings collectively brought in $355.06 million. These dollars were up – way up – from last year’s slump. In 2010 a total of $1.86 billion was invested in 139 private medical device financings. However, in 2011, the distribution of the stages showed a certain weakness; 40% of the deals were early-stage (A and B rounds), 29% were late-stage (Series E and thereafter and PIPEs), and only 25% were at the middle stage (Series C and D). (Private debt deals accounted for another 6% of the total.)

The statistics show that capital is the least scarce for those companies that need it the most – the mid-stage companies pushing toward make-or-break milestones. For those companies stuck in the middle, any type of bad news makes it tough to get to the next funding round. Benvenu...
TearScience Inc., for example, opted for this type of funding in October 2011, raising $15 million in venture debt from Oxford Finance LLC and Silicon Valley Bank. [See Deal] The funds will support TearScience’s commercialization of a new device for treating dry eye by removing meibomian gland obstructions on the eyelid during a 12-minute in-office treatment. TearScience has raised about $70 million in VC funding since its founding in 2005. Today, venture debt can also serve as a way to bridge a company to a near-term milestone that will help it increase its value at the funding round – or help ensure that in fact there is a next equity round. Speaking on the panel, Dave Gravano, an investment partner from Western Technology Investment, had advice for companies on when – and when not – to take on venture debt.

Finally, Allan May, chairman of Life Science Angels, which seeks to bring angel capital to early-stage biotech and medical device companies, was very encouraging about the availability of angel capital to support good business plans. May is also a managing director of Emergent Medical Partners, which is more of a classic early-stage venture capital firm focused on medical device and health care companies. In addition to being an investor, May also is a medical device industry insider who has been a founder, board member, and CEO of a large number of early-stage medical companies, including MAST Immunosystems, Vascular Architects, and Intella Interventional Systems, among others.

The panel offered tips about how to find and approach some of these underappreciated sources of capital, why start-ups should choose one versus another, and what steps they should never, ever skip.

David Cassak, Moderator: These are trying times for venture capital investors and that translates directly into a financing challenge for small companies. We have here representatives of three firms that offer alternative sources of finance, and we’d like to ask them how appropriate their sources of capital are in today’s environment, what makes companies eligible for alternative financing, and how they can go about getting it.

Allan, let me start with you. Earlier today, when I said the world was tough for VCs right now, you said that for angels it’s not that bad. Give us an overview of Life Science Angels, what companies can expect from angel investors, and when should they not look to angels?

Allan May, Life Science Angels: First, I’ll give you a quick history of angel group investing. At the beginning of the last decade, in, say 2000 or 2001, there were probably 50 organized angel groups in the US. There are now about 350. There has been a movement toward larger aggregations of angels and the evolution of best practices in a manner similar to the venture capital industry in the ’70s when its business model developed.

We were going along merrily until 2008, when the collapse happened in the life science sector. There have been a couple of reactions. One has been to mirror the flight away from PMA and IND products that you’ve seen on the venture capital side. In most cases in life sciences, particularly in biotech and medtech, angels can’t get there on their own. There are important notable exceptions, for
example, SmartCells out of Boston: $10 million, all angel money, $400 million paid up front, and out.

[SmartCells was developing a diabetes drug with financial support from Boston Harbor Angels, Angel Healthcare Investors, Beacon Angels, Cherrystone Angels, and Common Angels. Merck & Co. Inc. bought the company in December 2010 in a deal potentially worth $500 million, including, in addition to the large cash payment up front, earn-outs.] [See Deal]

Now you are seeing a focus on financing risk. From the angel standpoint there is a big difference between “Is this a good investment?” and “Is it a good investment for angels?” When you are pitching to angels you have to be cognizant of the latter question.

DC: What makes a deal good for angels?

AM: Let me put it this way. Angels were always willing to do deals that were off the venture radar, for example, deals where markets couldn’t ramp to a size that would be interesting to venture, deals that just didn’t require enough capital to interest venture, deals where you could get a company to a reasonable point, a proof-of-concept, perhaps regulatory approval and human data, and flip them at that point rather than taking them to market. There is a whole series of things that have always been attractive to angels and they have now become more attractive. In the flight from risk, you will see more of those types of deals.

To specifically answer the question that David is asking, can you articulate a business plan where, on $1 to $2 million (I’m just making up a number but it’s somewhere around there) you can reach an inflection point that either gives you a shot at an exit that you can be clear about and articulate, or such a compelling piece of data that you are extremely likely both to attract follow-on capital and get a step-up in price? If that’s your story, you are a classic play for angels. If you need $5 million and there is just no way to shave that down, then angels aren’t for you.

DC: Notwithstanding the $10 million that SmartCells raised, you really only want to invest $1 to $2 million, but I would say that even $1 to $2 million is bigger than angel rounds used to be. Historically, you used to see angels investing $500,000 and maybe getting to $1 million. Does this suggest that angels are getting more sophisticated or bigger?

AM: No. It suggests that angels are following the VC model and are beginning to syndicate. Three or four years ago, you saw angels investing solely as one group in a deal. Now you commonly see three, four, five groups in a deal. We just started the Life Sciences Angels Network this year. We have six groups in that and we will expand it to 20 next year. That syndicate will share deals that they are interested in for the purpose of concentrating capital and taking these companies further and building greater value to give them a shot at an exit or a step-up round.

DC: One of the issues that VCs have faced post-2008 is a
diminishing pool of capital. The LPs are allocating less to venture, and a lot of venture firms are having trouble raising funds. We just got done doing a series of articles about Ireland, where venture money is not robust. (See "Medtech in Ireland -- Turning Green into Gold" — IN VIVO, October 2011 and "Ireland's Medtech Explosion" — IN VIVO, September 2011.) On the other hand, angel money is plentiful, because a lot of people who made money in the construction and housing boom (that has now gone bust) still have lots of capital but no construction projects to spend it on. Is there abundant angel money out there, or is it tougher to get angel money?

AM: Yes and no. Did we all take a hit in the market, did our house prices decline, and do we all have less money today than we did three years ago? Yes, but there is still a bucket of angels with the money and the interest in investing either individually or collectively through groups. So there is plenty of angel money for good deals. It comes down to the business model pitch. Reorient the pitch away from the technology, engineering, or science. Instead: On $2 million in 18 months can I get good human data, or can I go cash positive in a particular market? It is a business model problem. If you can articulate a compelling business model there is money.

DC: Companies here want know, “Where can we find these angels?” You are part of Life Science Angels, an organized group in the Bay Area, which is expanding out. We tend to think of the classic angel in medtech as a physician who has a lot of money and knows a lot about the technology. How savvy about the technology are angel investors, and where do you go to find them? Is Life Science Angels the best place to go, or is my neighbor, who happens to be a cardiologist, a good source?

AM: There are huge geographical differences across the country. In general, the angel concentration tends to mirror the venture concentration that you see in PricewaterhouseCoopers’ MoneyTree, although it is more geographically diverse. Where to find them? AngelCapitalAssociation.org is a good place to start. But don’t spend years on your technology and science, and experiments and business model, only to throw your business plan over the transom and send a bunch of e-mails blind to people. Work just as hard to find a mentor or champion; enlist people who know the angels who are interested in your sector to make personal introductions. I don’t understand why people omit that step when they’ve done years of work already. There is $20 billion a year in angel money, and the life sciences sector gets 30% of that money, but you still need to network your way in.
DC: If my company is in Minneapolis or Atlanta, does it make sense for me to talk to a West Coast group like LSA or should I be looking for angels in my neighborhood? We tend to think of VCs as geographically constrained, are angels even more so, or would LSA entertain a company from Atlanta with a great technology?

AM: LSA will, and so will all of the groups in the Life Sciences Angels consortium, and when we expand it, all of those expanded groups will. We insist though, that the local angel group in your area be an active investor in your deal and that it has someone involved in the company on the board, as a consultant, or otherwise, who knows that sector and who can add commercialization expertise to the deal. When you syndicate to the group, you build on that local presence and local intellectual capital and you add in that broader access to financial capital.

DC: Let’s open up the discussion to debt financing. The financial crisis that has hampered venture capital is essentially a credit crisis. Is debt financing available today? Is it still as viable as it was before the 2008 crash?

David Gravano, Western Technology Investment: I think it is still a viable option. As always, it is a drug that needs to managed and taken under the supervision of a trained professional! There are many sources of debt capital; they all come with different approaches to the market, return expectations, and risk tolerances. We happen to have a fund structure, and we are structured exactly the same way as venture capital funds are structured. We are able to take a little bit more risk, but we also expect a better than average debt return in exchange for taking that risk. Like Allan, we are more business model- than technology-focused. We don’t ever become experts in the respective technologies; we really want to understand the milestones that lie ahead for the companies, their financing strategy, and how our capital can complement the equity, partnering, or strategic capital that comes in alongside.

DC: I know there have been companies that have taken in venture money and have later regretted it; are there companies that shouldn’t take venture debt? What are the pitfalls?

DG: The biggest pitfall is not having a clear financing strategy aside from the debt. We are best used when debt can help extend or complement the existing financial strategy to buy more time, in case there are delays in the clinical process or in case there are other technologies that need to be developed. Timing is very important, and there is no doubt that folks have taken debt when they shouldn’t have.

DC: Because you need to see the possibility of execution ahead that is going to allow the company to repay the debt?

DG: That is correct. One of the worst times to take debt is when you have a very limited amount of existing liquidity, there is a clinical milestone that is in the
relative near-term and somewhat binary, and you take debt with the hope or expectation that the result will be successful or satisfactory, only to find out that it isn’t. Then you have challenges raising additional equity that are exacerbated by an additional debt load that needs to be dealt with.

**DC:** It’s not necessarily commercialization that allows a company to repay debt. Is it appropriate to repay debt with the next round of venture funding?

**DG:** In this context, we are frequently repaid by subsequent equity events so we take that finance risk, and that’s why the financing strategy needs to be clear. We pay close attention to what that strategy is and what the milestones are. With early stage companies, we’ve done deals with LSA and others where the company still has a long way to go before it will be in a position to commercialize the technology. That’s OK. We will do those deals.

**DC:** Allan suggested that the classic deal for angels was a $1 to $2 million investment to get to a certain milestone. Is there a classic profile of a venture debt deal?

**DG:** Our capital can be used at any and all stages, ranging from seed stage all the way through to companies that are publicly traded that may want to window-dress or are acquisitive. We are stage agnostic, and the capital can and has been used throughout a company’s development cycle.

**DC:** Valuation is always a critical issue in venture capital. As a debt equity provider, are you also concerned about valuation, and do you negotiate separate terms? For example, when I go get a $250,000 mortgage from the bank, I don’t get a different rate than my neighbor.

**DG:** We don’t ever get involved in setting valuation. We are not equity investors and we typically piggyback off valuations that have been set. However, we do pay attention to valuation, because at the end of the day valuation can present challenges for companies that want to raise additional equity or exit at sufficient multiples, and therefore it can create challenges vis-à-vis our debt. So valuation can on occasion present some downside risk.

**DC:** If I raise venture money and I miss my milestones and have some struggles, which are actually a common occurrence, a couple of things can happen: my VCs can still love my project and put some more money in or they may shut me down. What happens if I don’t repay my debt?

**DG:** If you don’t repay the debt there are very clear rules of engagement as to how these things are wound down. As a partner in the fund, I am empowered to sit down with the management team to try to extract as much value as quickly as we can. There are a lot of legal steps that we take, but at the end of the day it comes down to us working with the management team, which has the most
We really want to foster and enable innovation. Part of that involves the inevitable volatility that these situations present. – David Gravano

AM: If I may make one commercial for Western Technology Investment: I think they are the best company in the country to deal with. Start-up companies always get into trouble, they commonly miss their milestones, it always takes longer to raise money than it’s supposed to take, and when you take venture debt, one of the biggest risks that you take is that banks, which typically do venture lending, act like banks. When you get in trouble the last thing you want someone to do is enforce collateral or the contract and legal rights. You want a partner who will work with you to figure out how to go forward and make the company a success. I have personally seen these guys do that in very complex situations and I’ve never seen them fail to do it.

[For example, WTI provided venture debt to Vascular Architects Inc. (operating in the peripheral vascular space) of which May was CEO. See "Venture Debt: Device Financing Lifeline or Anchor?" — IN VIVO, March 2008.]

DC: So ironically, you almost want venture debt firms to act like classic venture capitalists, committed to seeing some longer-term significant return.

DG: At the end of the day, we have been around a long time, and we really want to foster and enable innovation. Part of that involves the inevitable volatility that these situations present. We have fortunately had more successes than failures.

DC: David Hood, let’s talk about grants now. My angels may run out of patience and cash, I might not be able to pay back my venture debt, and you seem like the solution to my problem because a grant is non-dilutive and the grantor has deep pockets, in the case of the military. Why doesn’t everyone start with you? How do I get this capital? What special profile do I need to have to be a candidate?

David Hood, DH3 & Associates Inc.: I would like to first give you some perspective so you’ll understand where my comments are coming from. I was an entrepreneur, an intrapreneur at a fortune 100 company, and then I was selected to run a spin-out that became very successful. During the course of that we raised $37 million in non-dilutive funding, and that can dramatically change your cash-flow statements and how much of a personal stake you retain in the company.
We were very fortunate to take something from ideation through patenting, product development, and, ultimately, deployment. We were able to see it deployed in a number of prestigious places like the White House and Air Force One, and we were introduced to governments around the world. So I’m going to talk about grants, but then I’m going to focus in on the military medical community, because I think it’s one that people really underestimate.

In fact, I see here 37 presenting companies and only a couple of you are recipients of DARPA funds. But when I look through the program, I would guess that nearly two-thirds of the companies are eligible to pursue the military medical community.

DC: So who should be doing it and what do they have to do?

DH: People aren’t aware of the military medical community, but each year it funds in excess of $2 billion in medical R&D. They are a potentially a great partner because they can do three things. First, they can give you non-dilutive funding, and you own any IP that’s generated. They also come with a tremendous resource of clinical know-how, so you get very good people who become active in your development in a very positive way, and they are great at credentialing your technology. In addition to technical validation, you may also actually have your first customer. However, most people don’t realize what the military medical community is interested in.

DC: Both David and Allan pointed out that they are not particularly technology sensitive. Is the military in fact very technology oriented?

David Hood: The Army is; the military medical community is definitely technology oriented. They will also ask you for a business plan because they are solution oriented, even more so than the NIH [National Institutes of Health], for example, which is principally interested in research. But if the military medical community chooses to work with you, they are hoping you are going to come up with a solution to one of their issues. They want to make sure that most of the products have commercial parallels. The area that is most obvious is trauma, because that is a combat-related condition. However, the military medical community’s interest goes beyond trauma. Of course they are interested in people fighting in wars, but they are also interested in the veteran community, which is a very large hospital association. They are also interested in the war fighter’s family. For the war fighter to be committed 110%, he has to be reassured that his family is well taken care of. That is a pretty broad perspective.

So, they are very interested in trauma, in everything on the continuum from point-of-care to stabilization and ICU. But they are also interested in a lot of vaccines and pharmaceuticals for infectious diseases, from the perspective of biowarfare and countermeasures.
DC: We saw a very interesting presentation this morning on a company with a device to help people swallow. [Phagenesis Ltd.]

(See "Phagenesis Ltd." — START-UP, January 2012. That's not something that affects soldiers per se, but if it results from a battlefield injury or affects the family of a soldier, might it be a candidate?

DH: Absolutely. There has been a tremendous focus on clinical rehabilitation. Rehab and recovery are big concerns from a physical and emotional standpoint. The military medical community has put out a lot of information on traumatic brain injury, post-traumatic stress disorder, and psychological health. Another big area the military is interested in is operational medicine, or what we call fitness: fitness to fight, to sustain the fight, and recover from the fight.

DC: So let's say that Life Science Angels probably passes on 90% of the companies that approach them. For grant money, what is the key? The ability to write the grant? How do I convince the military to give me a non-dilutive grant?

DH: With respect to NIH, you are usually going to respond to requests for applications, put in a grant, and respond to reviewers. There are a lot of NIH funds available. Remember that SBIR budgets are 2% of the overall R&D budgets. But in the military community you are forging a relationship. You want to find synergistic interest, something that is on the track for your company, but also of interest to the military medical community. When you have that kind of meeting of the minds that is a good situation.

DC: What if they haven't solicited a technology like mine, is there still an open door?

DH: Absolutely. They want to dialogue with you and there are mechanisms to do that.

DC: So, since congress holds the strings for the Department of Defense budget, should I go to my local representative who is supposed to help me navigate the pathways of Washington and tell him or her that I'm interested in this military grant money?

DH: Certainly endorsements from your local representative are a good thing. But now there is pretty broad bipartisan reception in congress to support our military, their families, and veterans.

DC: Is there a cap on grant money? Where do I turn after my initial grant?

DH: They will follow you through the continuum if they are interested. You may initially be on a grant mechanism and later on a contract mechanism, but it is all non-dilutive funding and may in some cases be contract R&D on your cash-flow
statements. They fund anywhere from $25,000 to $10 million, and sometimes in excess of that.

**Question from the Audience: What role do you see family offices playing?** They tend to have a longer-term investment horizon than typical venture capital investors, and would seem to be a good alternative source of capital. [Family offices are professionally managed funds of ultra high net worth families].

AM: There are two national groups, the Angel Capital Association and the Angel Resource Institute, both created by Kauffman Foundation, and there you are seeing a clear move to involve family offices in the whole process. As the system has collapsed around us and funding for medtech and biotech has essentially evaporated, you are seeing new ways of working together that were unheard of five years ago. The Angel Capital Association in particular is reaching out to family offices and vice versa, and you are seeing new combinations, in terms of family offices putting up side funds to angel groups, co-investing in specific deals alongside angel groups, and helping to syndicate in areas of interest to them. It is not clear yet where that is going, but the idea of family offices working with angels is right in the center of the radar.

**Question from the Audience: How do you guys work with Europeans?**

AM: Not well! There is EBAN [the European Trade Association for Business Angels, located in Brussels] and a number of good angel groups that are nationally or regionally focused, some focused on life sciences. My answer has to do with the fact that this is still a value-added game. The only place where you can just write checks and make money is Vegas. Angels know that in addition to writing checks they need to add value. Companies need somebody who knows how to commercialize what they have. They’ll get there on $4 million versus $1 million if they don’t do it right. We can’t add that value in Europe or Asia, because we don’t know those markets and those regulatory scenarios.

DG: We do deals in Europe as well and we have done deals in Israel and China, so we are not precluded from working with companies overseas.

DH: I’d like to add that while a lot of people think that government non-dilutive funding is for US companies only, that’s not necessarily the case. The SBIR grant program is a US stimulus package, but the DOD military community is looking for the best of the best from around the world. Those opportunities are independent of nationality.