Medtech Risk Capital? Anything But. A VC Roundtable from IN3

By Mary Stuart

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Executive Summary

A year and a half after the September 2008 collapse of Lehman Brothers and the official start of the economic recession, a panel of venture capitalists and other financiers in the medical device industry came together at the IN3 meeting in Boston. We asked them if they've had to change the way they look at deals. What is the trade-off between expensive, de-risked later stage deals and the kinds of returns that can be achieved by backing a winning company from start to finish? Where would they place their bets: cost-effective technologies for tried-and-true markets or novel products for unmet clinical needs, the "evolutionary vs. revolutionary" debate? And what can one do about tired syndicates? Our panel let us in on the kinds of discussions they've been having around the table at weekly partners' meetings.

Medtech Risk Capital? Anything But. A VC Roundtable from IN3
At a recent medical device meeting in Boston, VCs let us in on their thinking about the future of investing in medtech.

by Mary Stuart

Saving for a rainy day; sticking it out through thick and thin; these phrases were recently uttered, not by someone's depression era grandpa, but surprisingly, by venture capitalists assembled at a recent medtech conference in Boston. The Investment in Innovation (or IN3) conference sponsored by Elsevier Business Intelligence called upon a panel of financial types - four venture capitalists and one debt investor - to tell us where they most likely will be investing their capital in the short- and long-term future. An air of optimistic caution hung over the room. Speaking on the panel, Paul LaViolette, the former COO of Boston Scientific Corp. and now a venture partner at SV Life Sciences, described his firm as conservative, noting that the notion of conservative risk capital, as oxymoronic as it sounds, does speak to the uncertainties facing the medical device industry today.

The foundation of the medical device industry is rock solid. Population
increases, aging baby boomers, and 32 million additional insured lives coming into the health care system provide growth opportunities for the medical products industry. Large medical device companies will still need to rely on innovative start-ups for the products that will drive their growth. But the pillars resting on the foundation are a bit shaky. Almost two years into the economic recession, and as the provisos of health care reform begin to take shape, VCs are strategizing on how to craft investments around some of the new fundamentals in device investing. As has been frequently discussed, we are now seeing longer regulatory time lines as the FDA demands more from PMA products and rethinks what was once the expedient and less expensive route for getting products to market, the 510(k); cautious acquirers are making fewer, more selective acquisitions each year with the goal of rapid accretion. Start-up companies thus are spending more time in development and in building a presence in the market place to impress potential strategic acquirers (in the absence of the IPO exit alternative), which cause investors to carry companies a year or two longer than they initially anticipated. A resetting of valuations that has Series B investors looking for Series D rounds at Series B prices, and a crumbling of the resolve of limited partners, some unwilling or not able to support additional rounds, are feeding back into VC's thought processes about what kinds of companies they are willing to fund at the early stages, and whether they might not be better off investing in less risky, later-stage deals.

While several of the fears relating to health care reform have begun to be dispelled - the impact of comparative effectiveness research on devices, and new, stringent rules about physician-device company relations - a new threat recently emerged. Now VC partners are analyzing the effects that a medical device tax will have on both strategic acquirers and the start-ups they look to for innovation, as well as the impact that these new costs might have on acquisition values. (See "Health Care Reform: Further Taxing The Device Innovation Model," IN VIVO, April 2010 "Health Care Reform: Further Taxing The Device Innovation Model" - IN VIVO, April 2010.) Acquisition prices are already, for the most part, questionably low with respect to the large amounts of capital it takes to sustain companies these days, apart from the occasional splashy deal like the acquisition of Acclarent Inc. by Johnson & Johnson's Ethicon Inc. for $785 million, Stryker Corp.'s purchase of Ascent Healthcare Solutions Inc. for $525 million, and the recent $2.6 billion merger of ev3 Inc. with Covidien Ltd. According to research from Richard Ferrari, a managing director at De Novo Ventures, 68% of the medical device companies sold over the past decade were priced at $150 million or less. Of course that number says nothing about the returns venture investors have gotten from their portfolio companies, but the changing premises of device investing have dampened those, too. According to a recent analysis by Elsevier Business Intelligence, over the past five years, only a minority of device exits yielded more than a 5X return for their venture investors. (See "Device VCs Find New Hope in Old Exit Path," IN VIVO, July 2010 "Device VCs Find New Hope in Old Exit Path" - IN VIVO, July 2010.)

Do investors need to change the way they look at deals? What is the trade-off between later-stage, more expensive but de-risked deals and the kinds of returns that can be achieved by backing a winning start-up from inception to successful exit? What is the tension between cost-effective technologies for tried and true markets and novel technologies for major, unmet clinical needs, the "evolutionary versus revolutionary" debate? Will these debates result in a polarized industry, with many low-cost bets placed at the early stage, in anticipation of culling losers early, and at the other extreme, high-cost bets made in late-stage companies with an eye to large, premium acquisitions? If so, will this cause a funding chasm for any kind of company in the middle?
We asked our panel of investors to let us in on the discussions they've been having around the table at weekly partners’ meetings. At our table were three traditional VCs, including Tamara Elias, MD, a principal at health care-focused Essex Woodlands Health Ventures in New York, which has almost $2.5 billion under management, Stephen Bloch, MD, a general partner at Connecticut-based Canaan Partners, which has $3 billion under management divided between health care and IT, and as mentioned, venture partner Paul LaViolette of SV Life Sciences, a health care-focused VC firm with $2 billion under management. Representing the corporate venture capital viewpoint was Andrew Jay, head of the venture capital arm of Siemens AG, the Siemens Medical Solutions Fund. The final guest was an alternative investor, Parag Shah, senior managing director and group head of Life Sciences at Hercules Technology Growth Capital, which provides venture debt and equity to venture capital and private equity-backed life science companies.

Leading the discussion were Tom Salemi, venture capital bureau chief of Elsevier Business Intelligence, and David Cassak, VP, content at Elsevier.

Q: David Cassak: We have here a distinguished panel of investors and one debt financier and we’d like to start with an overview of the investment climate right now. We’ve heard a lot about the difficult time the venture capital industry is facing these days. We’re now about 18 months removed from the September 2008 collapse of Lehman Brothers, which symbolizes the beginning of the economic recession [although it probably started sooner than that]. I wonder if the panel members would take us inside a typical partners’ meeting or the kind of planning session you guys are having these days. Describe the mood; tell us about the kinds of conversations you’re having. How concerned are you about the future? Has your thinking about the kinds of deals that you’ll do changed?

Q: Tamara, why don’t we start with you? We’re inside your partners’ meeting at Essex Woodlands; you’ve got a bunch of things on the table. What’s the general mood, and what’s the general conversation like? And is it informed by the economic downturn?

Tamara Elias: That is an extremely relevant question. First, a word about Essex Woodlands, and it will help everyone understand my answer to the question. Essex is a 25-year-old health care only venture capital and growth equity fund. We closed our last fund just over a year ago with $900 million, which was obviously a great feat in the economic climate at the time. In this fund - Fund VIII - as well as in the fund before it, we have increased our focus on late-stage deals. We have dedicated about two thirds of this current $900 million fund to later stage, and what we consider growth equity - that is, revenue-generating companies. This is not only about revenues, though, but about eliminating risk. These days you can’t have regulatory risk, reimbursement risk, clinical risk. You might have one of the three, but probably not all three. And these days, especially with syndicate issues, there’s also a real possibility of financial risk. So we look for ways to either be in deals that have less risk, or at least have outlined a straightforward path to reducing risk in any one of those categories.

So yes, our focus has been influenced by the economic climate. That said, we’re actually pretty excited, because in general it is a great time to be investing if you have a lot of money in a fairly new fund. Valuations have come down. Obviously, they always lag the public market valuations a bit, but now, 18 months out, reality has set in.

Q: David Cassak: Do you have any sense, at Essex Woodlands, whether the
switch to late-stage deals is temporary? Would you still have a bias within your firm toward early-stage deals if the timing were right? Or is there a growing consensus that perhaps you should in fact be a late-stage firm? When we met in 2007, you had a preponderance of early-stage deals. Now, what do you see as the ideal balance between early- and late-stage deals?

Tamara Elias: I would say that there has been somewhat of a change between 2007 and now. Our $600 million fund, Fund VII, which we closed in 2006, split growth equity to venture capital at 60/40. Fund VIII has about a two thirds/one third goal which is not so different. We have added personnel in the last few years who contribute to assessing and investing in later stage deals - operators, including former CEOs, for example. We have recently partnered with Dan Lemaitre, former president and CEO of CoreValve, to target growth equity investments in medical devices. (See “Essex Woodlands Partners with Lemaitre to Start White Pine,” IN VIVO, February 2010”Essex Woodlands Partners With Lemaitre to Start White Pine” - START-UP, February 2010). About half the money in Fund VII went to medical devices. In our latest fund, which is just over two years old, we have done five medical device deals so far. We started investing in December of 2008, and one of our first investments was in [heart valve company] ATS Medical [ATS Medical Inc.], which is obviously a public company and very much in line with our desire to be in later stage. The company was actually just acquired by Medtronic Inc. [in a transaction finalized in August 2010, valuing ATS at $370 million], [See Deal] so that one obviously worked out. Three of the other device deals are either commercializing products or are at the near ready-for-commercialization stage, [Entellus Medical Inc. in ENT and TearScience Inc. and QSpex Technologies, both in ophthalmology] and one is a company that is actually a seed-stage investment, but with an entrepreneur we've backed before.

There is a lot of innovation to be had, and we still look at early-stage deals for potential investment. We have an interest in those deals, partly because of the 25 investment professionals - 13 of us have MDs, PhDs, or both - so there is very much a clinical focus in our fiber. So we are just beefing up our later stage deal flow. The focus will always be split among the two, and let's also not forget that $300 million is not a trivial amount to spend on traditional venture capital, so there is still quite a bit of money available for early-stage deals. But going forward, Essex Woodlands will be more focused on later stage.

Q: David Cassak: SV Life Sciences is among the most aggressive dealmakers, and among the most active in the device space. I know you guys well, and it seems to me that you are cautious, if not downright gloomy, about the overall climate. How are you guys reading the device opportunity right now?

Paul LaViolette: We raised a fund in the past year and that gave us a lot of face time with LPs and a lot of feedback on what they are looking for out of venture capital in health care. I can reflect on what they have seen over the past several years, which was this bloating of venture capital with too much money chasing too many companies, which obviously dilutes everything in the pool - the talent, the quality of ideas, and the return potential. We love diversification; we have been in services, therapeutics, devices, and we fully intend to stay that way. We have diversified across stage, with the majority of our activity in the early stages. We aren't going to chase later-stage deals, and for the most part the LPs want to see a restructuring of the venture world. They understand it is going to be painful, but it is necessary. They perceive it as a cleansing process. They do see quality out there, but they are finding it harder and harder to pick out that quality from the hyperactivity. So as the firms collapse and a lot of the companies fold, their view is that these next years will be a great time for a
That's how we view it, too, and we are fortunate to have a good track record, which permitted us to raise new money in the toughest climate. I agree that there are great ideas out there and we can be highly selective. Based on our size, we are capable of scaling up a little bit to put more money to work in later-stage deals. We have the operating experience to lend there as well. Our view is to be opportunistic about late stage, and some of that might be in existing portfolio companies, where syndicate weaknesses have become manifest.

You mentioned that we might be a bit cautious or gloomy, but I would rather say that we are conservative. To be a conservative venture capitalist seems oxymoronic, but it really speaks to focusing on the risks and the capital, which includes how much capital you reserve for your companies under the premise that no plan ever comes together the way the entrepreneurs expect. No launch goes as expected; no regulatory path goes as expected. If you have that money in reserve, you're going to be prepared for the rainy day. And I think that's where we find ourselves now. We have ample reserves for the existing companies, and we can put more capital into the ones that we know really well, and that we think have been risk-reduced.

Q: David Cassak: We're sensing angst and hearing the oft-quoted numbers that something like a third of venture capitalists have gone out of business. Andrew, let me ask you this: is this all irrelevant to Siemens Venture Capital, because it's a corporate venture group rather than a traditional VC? Or does what our panelists have said resonate with you?

Andrew Jay: Our thinking about investments has definitely changed over the past couple of years. Today we view the venture capital world as being Survivor maybe eight weeks into a 16-week season. And a lot of people aren't going to be left around the table. So even if you look at this panel . . .

Q: Tom Salemi: Look to the left, look to the right. These are the people who are not going to survive . . .

Andrew Jay: But seriously, the people on this panel have been successful in raising funds. They've got good track records. These are the people who are going to survive. But what we're not seeing on this panel are funds like the one in Wisconsin that had $50 million, which isn't here any more, and firms like that won't be.

Now when we look at investments, we don't look at where this round or the next are going to come from, but the one after that, because it always takes one more round than you initially think. Where is that round going to come from? Who is sitting at the table? Do they have the money to continue to support this company? That has become much more of a factor than ever before. We used to think, well, everybody eventually gets the money they need. But we know it's not going to be that way going forward. That's how our thinking has changed.

Q: David Cassak: So syndication is a big issue for you because you want to make certain you're at the table with the right folks. How active a role do you play in syndication? Do you like to bring in the stable of folks you're comfortable with? Or is it a matter of just scrutinizing the opportunity that's presented to you?

Andrew Jay: At Siemens Venture Capital we are in a challenging position because on the health care side, we're active in only a few businesses. When we mention capital equipment, which is one of them, some venture capitalists
will hold up garlic and crucifixes and say, "Back!" So it's a little harder for us to say that we've got a stable of venture capitalists that we regularly invest with in capital equipment deals. Generally, they're willing to stick their toes in the water on one or two and see how it goes. But they're not going to invest across the board. Are there firms we like to work with? Yes. Are there firms we like to work with less? Yes. But you've got to play the cards that are in your hand.

**Q:** David Cassak: Stephen, I think of Canaan Partners as very much of an early-stage firm, cut in the mold of SV Life Sciences. But the early-stage firms seem particularly hard hit in this kind of environment. How has the thinking within Canaan changed in the course of the last couple of years, if at all?

Stephen Bloch: I actually don't think we have been hit hard. I think we're in a great position, and luckily, what you're seeing at this table are a couple of firms that have capital. That's what's going to fuel our business. We raised a $650 million fund at the end of 2007, at the worst possible time. The world was collapsing, and we got very lucky because of our historical track record and success. But what makes us different from the other funds here is that we're a diversified IT/health care fund. In a $650 million fund 40% of our dollars are in health care and 60% are in IT. LPs invest in us because they want diversification and they like the historical track record.

**Q:** David Cassak: But is a track record as much of a predictor as it used to be, given everything that's happened? Or do the good firms survive these kinds of climates because they know how to manage?

Stephen Bloch: You don't know the answer until your next fund, right? Then the LPs will tell you the answer, so you'd better do a darned good job. At the end of the day, it's about money back in their pockets, because they're not going to keep funding you. We've been successful over 25 years. We've raised $3 billion historically. When we go out to raise another fund in a year or so, the market will tell us.

**Q:** We are actually more diversified in terms of stage than is apparent on the surface. Historically, we have called ourselves an early-stage fund, but we really are a multi-stage fund, especially on the health care side. I'll give you an example of the types of things that may be successful in this environment and lend themselves to the creativity of venture firms. It's not an early-stage asset, but it was an early-stage company. It's a company called Advanced BioHealing [Advanced BioHealing Inc.] This came from the scraps of Advanced Tissue Sciences that were left in San Diego. ATS had a public market cap of $800 million, but they couldn't quite make a commercial go of it. [Advanced Tissue Sciences was a tissue engineering company with a skin replacement product called Dermagraft] (See "The Rebirth of Dermagraft," START-UP, February 2008 "The Rebirth of Dermagraft" - START-UP, February 2008.) Smith & Nephew stepped in and couldn't make a commercial go of it either. The product was approved. It's a regenerative medicine cell therapy product for diabetic foot ulcers. I picked up the assets in a fire sale; I put my own team around it from another portfolio company of ours that was close by. I sited it right down the street from us in Westport, Connecticut, where, believe it or not, we have a thriving biotech industry. And since 2006, when I picked up those assets, we have gone from three people to 300 people today, with 120 sales people on the ground, and we are extremely profitable. So that was a late-stage asset, early-stage company.

**Q:** We have all options open to us. We can invest in a public company; we can sell the company; we can run the company. As you think about the kinds of
companies that can succeed in this environment, it's those that have all their options open.

Q: I wanted to add one thing to the discussion about the importance of syndicates. If you really want to know the gossip around the tables in venture capital partner meetings, especially our meetings, it's about the strength of syndicates. We have a lot of concern about syndicates not being strong enough, and being tired, and a tired syndicate can drag down a company. So it's really important as you think about who you want to invest with and bring into your company, that they are people who have like-minded goals and have deep enough pockets to carry companies through. Carrying companies through in this environment is incredibly important. You have to have the capital resources because you can't predict the outcomes. You have to be able to kind of make it through the thick and thin.

Q: David Cassak: When you talk about a tired syndicate, is it deepness of pocket? Is it how creative they are as thinkers? Is it just an exhausted feeling? What is it that you are looking at?

Stephen Bloch: It's both deep pockets and strategy changes where they say, "We're not going to support this company any more. We don't think they can get there, so we're going to walk."

Paul LaViolette: It's the math. They're sitting there with their portfolios, their reserves. They're adding up how many companies they think are going to make it, and they're going to try to re-juggle the list so that they're in the ones that have the greatest potential for return.

Q: David Cassak: Parag, Hercules is offering an alternative; you're offering debt. When you hear these kinds of discussions, particularly discussions about syndicates, does that create an enormous opportunity for you? Or when you're in your planning meeting, do you feel that it's a problem to lend money to a company that might be a problem down the road because the underlying team isn't strong? How is the current climate affecting an alternative source of capital like Hercules?

Parag Shah: To give my answer some context, Hercules is an alternative investor, a debt investor that focuses on providing less dilutive capital to the industry alongside equity or in between rounds. To the question of syndicates, we would say yes, the syndicate definitely matters in terms of carrying it. But it's all in the context of the business plan and the strategy for the company. For example, if you are in a later-stage company it is really much more about market risk and execution risk. The syndicate does matter, but not as much as in an earlier-stage company where you've got a long path, many potential R&D hiccups that need to be supported along the way, and changes of strategy. I think you have a slightly different equation there. I mean clearly, if you had a choice, you'd rather have a strong syndicate around the table.

We are really identifying risk. We've heard a lot of talk about risk - de-risking, risk-reduction - but I'd like to re-frame that and say it's more about identifying the risk, and then applying the appropriate capital structure to that particular company. On that note, I also don't necessarily agree that the largest funds are the only ones who are going to survive or do better. If some of the smaller funds are focused on the right strategy and looking at more capital efficient businesses, they're the ones that you need to go to, especially if your business plan only calls for $10, $15 or $20 million to get to an exit. Many of the larger funds won't even look at you, so you need to go to some of the smaller funds out there.
We're in the mix, too, and we're a little different. We're a publicly traded fund. Our fund doesn't have a predetermined life, so we don't have time pressure about returning money. We've committed about $1.6 billion, and we do have the same internal debate about whether to focus on later-stage, earlier-stage, small cap, public or private. We've chosen to take the diversified route with teams that focus on those different segments because, frankly, they require different skill sets and have different structuring criteria. In the case of the early stage, you're identifying risks around IP, R&D, technology, and the management team that can do that. In the later stage, you're looking at execution and market risk. It's a little bit more about number crunching and making sure you have all your numbers lined up. There are very distinct buckets, and we're putting money in both.

Adiana [women's health company offering a permanent contraception device] was one of the companies that we got involved with. We got in on a Series A alongside Abingworth, and it was later acquired by Cytyc and Hologic [Hologic Inc.] [See Deal] On the other side, we're in a company called Barrx Medical [Barrx Medical Inc.], which is a commercialization-stage company [with an interventional treatment for Barrett's Esophagus] to which we provided capital to ramp up the sales force.

Q: David Cassak: So let's suppose that I am running a company that's been around for a couple years. We raised a nice Series A and Series B. We've got some cash left, but I'm anticipating the future, and I went to Tamara, Paul, Stephen and Andrew and they all said no. Do you say, "Great, you've come to the right place?" Or do you say, "If they said no, what makes you think I would say yes?"

Parag Shah: Well, it can happen that you get 90 venture firms that say no and two that say yes, and that's all you need. But let me put it this way: debt is not a replacement for equity. It can never be. Debt is not supposed to take that risk. It is supposed to go in conjunction with equity, but at periods of time when it could be used instead of equity because of the current situation, for example, problems with the syndicate, as we've discussed. I'm sure this is going on all around the table. Two members of the syndicate have plenty of capital, but three don't have much left. So there's a real dynamic around the strategy of the company, and it's not necessarily being put forth based on what is the best thing for the company. It's a debate about the best thing for the firms that are investing in that company, right? On one hand, this company should really just go out and raise a larger round, but it's going to mean the others will get crushed. On the other hand, they're incrementally funding it right now because that's all that the entire syndicate can agree to do, until somebody steps up and just does the recap. So in that situation, because we believe in the company and the technology, we've been putting money in to help it continue, but only if there's a coherent strategy and enough money around the table each time we get there.

Tom Salemi: Paul, I'm curious about your recent fundraising. You mentioned the LPs' view on venture capital and what they anticipate will happen. Do they have a specific view on devices? And how does it compare with biopharma or the other health care areas that you might invest in?

Q: Paul LaViolette: When you're raising money, you have to give LPs as much analytical support for your request as they would like. We provide returns by sector. So that's something that's very much on the table. At the same time, the LPs are looking longer term. You can point to recent exits in your fund or in the
marketplace; and you can talk about market dynamics. As you can imagine, raising a fund in 2009, everybody is focused on health care reform. In that scenario there are plenty of strategic questions about devices. But in the end, they're betting on you and they're betting on the track record. If they could invest directly without you they would. They're betting on your team, your firm, your expertise, and the general environment.

**Q:** Their sense is that the general environment for medtech is healthy over time. They don't see health care reform as punitive to medtech. They see demographics and global dynamics in medtech as generally buoyant and creating demand. They look at strategic buyers getting larger and needing growth and being more aggressive in M&A over time. So I think the field is generally very fertile. However, on a macro basis, pointing at medical devices and looking at aggregate venture capital and returns over time, it isn't necessarily that healthy. When we go into these discussions, I would say there's a general concern or skepticism about long-term medtech performance, but there's more than enough interest in it, at least for the time being, to continue to support it.

**Q:** David Cassak: I think a decade ago, or maybe even seven or eight years ago, a lot of VCs were moving away from biotech and into devices, because they felt it was a less risky space. Devices were a hedge. Either in your current thinking in terms of what you're anticipating or what you've experienced over that period of time, do you still believe that? Is that still true?

Stephen Bloch: Well, I think you have to be smart about expectations for the medtech investor. The average medtech outcome is something like $90 million, at least the last time I saw a number, so you have to gauge the capital plan to fit that sort of exit. There are always outliers, and that's a wonderful thing. But you really have to plan for a company that has an outcome that's going to be in the eight figures or low nine figures if you're trying to figure out space to play. I think what's concerning people about the device sector right now is what I call the great big doughnut hole that has to be solved. The doughnut hole is like this: FDA has ramped up the requirements for device approvals, and they're starting to look a lot like drugs. So that makes the whole pathway longer and more expensive, and you have to decide how you're going to navigate that, and how much risk you're going to take on with FDA. The medtech executives out there have to make sure that they listen to what the FDA is saying. A lot of medtech executives grew up in a different world, and some people have trouble making that transition.

Second, there is obviously concern about reimbursement. I think there's risk in future bundling of medical devices. Longer term, people look at that and say, "How are we going to get this reimbursed?" Without a clear reimbursement pathway, where it either fits into an existing code, or an existing pathway to reimbursement, an investor has to carry that company until it's able to establish that reimbursement. It can be a time-consuming, lengthy process, payor by payor, state by state. That's hard. I think we've also seen the complexity of devices increase, and there have been some notable failures - all PMA devices - that were incredibly capital-intensive. I don't want to point fingers, but there was a big one in the last two weeks where more than $100 million had gone into it; it looked pretty good on the Phase II-type data, and it failed. That doesn't help the sector.

Again, it goes back to looking at things that are less complex, have less regulatory risk. And then you have to think about the end strategy in devices. I do see big buyers consolidating and wanting growth. At the same time, it's a narrower group of buyers that only can digest so much. As you know, some of
those big buyers are pretty much up to their eyeballs digesting older acquisitions, or have some financial challenges of their own. So we're always thinking of where it's going to fit in somebody's slot or bag. Right now people are buying, things are fitting into channels. I think it's really important to work the problem backwards and make sure that your device company and device concept fits the paradigm that's out there.

Tamara Elias: I'd like to react to the last couple of questions. To Stephen's point about whether the industry's going to contract or not, LPs and we recognize that you can't just say, "Oh, well, right now we're going to tone down what we're doing in medtech because it was so rampant and flush with too much cash, in the past," because in the next cycle, it could be that biotech is flush with cash, and we have to be ready for all the cycles. We recognize that; the LPs recognize that. On the positive side, there are device companies that are very flush with cash. Covidien just bought ev3 and Abbott Laboratories [Abbott Laboratories Inc.] and Medtronic seem to be on buying sprees. Device companies are more likely - than pharmaceutical companies - to look outside rather than within for transformation, and to look to other companies that are venture backed to find their new transformative device.

I think the market by definition has to expand. Health care reform, obviously, is very important and at the top of all of our minds. This is true, obviously, for devices, drugs, everything, but not only is the market obviously increasing by population increases and baby boomers, but 32 million new lives are coming into the system. That's got to be good for the industry. For America, unfortunately, there's no cost containment in the new plan, but for those of us investing in these companies, there's a lot more business to be had. We're also of a generation that is very interested - perhaps selfishly so - in procedures that may be more self-pay. So there's the potential to have really impressive returns in companies that may invest there. I think that those factors are all positive.

This isn't a new era. Windhover published an analysis showing that between 2006 and 2008 75% of all medtech exits were less than $150 million. (See "Medtech Venture Capital Heads into Unfamiliar Terrain," START-UP, November 2008 "Medtech Venture Capital Heads into Unfamiliar Terrain" - START-UP, November 2008) So nothing's changed with this new economic downturn. It was the same thing back then, only then, when you talked about capital efficiency, everyone kind of talked a big game and said, "I'm sure that will only take us $10 million." And if it took $20 million, that was OK. But now the reality is, back to the syndicate question, people around the table don't have money, so if you say $10 million, you have to do it for $10 million. Nothing has fundamentally changed; there are cycles. I think medtech is still a very interesting sector that you want to be sure to be in when 32 million lives come into the system.

Q: David Cassak: Paul, you said earlier that we are, if I may paraphrase, experiencing a cleansing of what had been a bloated market. If we go back to 2006 and 2007, there really was a lot of hype about how great the medical device sector was, and we saw record investment numbers. I've heard that anywhere from $3.8 to $4.1 billion dollars went into devices in 2007. It was the guys at SVLS who were saying, "Wait a second, some of the fundamentals have gotten out of whack; we're putting too much money in, chasing too many bad companies." But at that time, you were on the opposite side at Boston Scientific [Boston Scientific Corp.], looking at a lot of these companies. What's your perspective on whether the device opportunity, relative to other sectors, has remained a better place to put your money? Or are we still seeing a carryover effect from the kind of financing excesses of 2006 to 2007?
Paul LaViolette: Listen, everybody has their favorites. We're in services, and we do really well there, whereas a lot of venture firms have moved away from services because they failed to make any money there. We have a pretty big biotech group, and there are certainly, within companies that I work with, some new investors who are primarily biotech investors but are moving more into devices because they want to diversify. There are a lot of biotech investors out there who've said, "Boy, it's really hard to make money in biotech." So I actually think there is no particular safe ground. It always gets back to your strategy, the depth of your team, your domain knowledge, and what you're good at. If you go back to '06, '07, I think SVLS was helped by the bias we had, which was operating experience and having been buyers. Of course at that point, I was still a buyer myself, but David Milne [former corporate business development VP at Boston Scientific] had joined SV. Having been a buyer, he moved in and said, "OK, I know what I've been paying over the last number of years. Now I'm seeing all of these competitive processes where term sheets are flying out of the fax machines as fast as possible." It was getting overheated. The team at that point was simply prudent in thinking that it didn't add up. You go back to the data on the value of exits, you look at what you need to put in with large funds, you look at how you need to control the capital to get a certain multiple, and it just doesn't add up. So our team decided to take advantage of our diversity, and put money into services, become a little bit more like small private equity at that point, small growth equity, and put a little bit more on biotech. We cooled down in devices. But I do think it's coming back. Now we're seeing a lot of Series D, and we saw those deals at Series B.

Tamara Elias: But you're seeing Series D financings at Series B prices.

Paul LaViolette: We are. That's the point. The prices have come back, and it creates opportunism. But this is what is causing the collapse in venture now. The folks that made a lot of those Series B investments are really grinding their teeth. They're asking themselves, "When do we take new capital in? How much do we fund it ourselves? Is there enough strength around the table? Do we take the recap hit?" I mean this is really tough stuff for everybody, and that's just the way it is. As buyers, we just had the experience to say that it didn't add up.

Parag Shah: I think it would be interesting to hear from the panel, given health care reform, where the FDA is going, and given budget issues in the country and in hospitals, are we going toward funding more revolutionary or evolutionary ideas? It seems to me that incrementalism, the next me-too products, are going to have a harder time getting approved as we get to comparative effectiveness. That might not be such a bad thing, because at the end of the day, the big ideas that are truly going to unmet needs should be getting funded. But that flies counter to the de-risk, un-risk, no-risk talk that we've been having up here.

Tamara Elias: If you can actually decrease cost to the system and have clinical benefit, you'll be just fine. In talking about what's changed or not changed, in the past we've always given lip service to that. But now it's for real because of comparative effectiveness. Now they are only pilot programs, but assume that in 2014 to 2015 they'll be implemented as full-on programs. Those are the companies that we'll be backing.

Andrew Jay: When you have the FDA involved it's never that simple. You can have a device that reduces cost, is better for patients, but getting through the FDA can be a nightmare. Aeris Therapeutics [Aeris Therapeutics Inc.] went all the way through Phase II trials as a device. About to enter III, they're told, "Well, you use a fibrin plug in your treatment for emphysema; therefore, we want you
to do this as a drug." So now they need to do two studies. They would also need survival data, not some type of surrogate endpoint. They had to downsize the company from 50 people to 13 people, and start again with the device they had in progress, using, instead of fibrin, a different material. Yet it improves outcomes and reduces costs for these emphysema patients. But it's just not that simple at the FDA. A number of companies in this interventional pulmonary space have run up on the rocks of the FDA, through no fault of their own.

Paul LaViolette: That's debatable. I think I may be the oldest person on this panel, and I've had dozens of PMAs, and the biggest combination products. FDA generally is pretty predictable. They're going to be conservative. They're going to occasionally throw curveballs, but they're really focused on science, and generally speaking, there's been a lot of complaining in the marketplace about how unfair the FDA is. If they really look in the mirror, a lot of those companies are predominantly responsible for their own failures.

Andrew Jay: When you're talking about interventional cardiology, you get the "A" team at the FDA. But if you move into some of these other fields, you get the "B" team. Other sections could be even weaker. There's a lot of difference across the FDA. And I think everyone in this room will agree with this.

Q: David Cassak: Fairness aside, we are concerned about the 510(k) debate right now. This very clear and simple regulatory path that we had counted on for an inexpensive development path now will potentially get a lot harder.

Tamara Elias: There has been a lot of conversation about the 510(k) process and how the PMA process is also probably going to get a little tougher. The conversation is around how it's going to cost more and take longer. But the real issue, I think, is just the uncertainty of what's going to happen with those processes, and that has made people a little nervous.

I don't think there's any doubt that if you look at a 2-by-2 grid of clinical benefit to riskiness, and if you put high on both ends, so if you're in the upper right hand corner, you're offering high clinical benefit but also high risk, less of those deals will be getting backed. And back to my original comment about financial risk, reimbursement risk, regulatory risk, and clinical risk, you can have only one, maybe two of those these days. Five years ago you could have had all of them. So I think there will be less of the kinds of more risky products, even if they do offer both cost containment and clinical benefit.

Q: David Cassak: But to speak to something both Andrew and Parag said, we're still talking about finding new, novel, interesting solutions. There is a sense on the part of a lot of people that if you move outside of a few core areas that the FDA is particularly expert in, it's especially difficult if you are presenting to the FDA something completely novel in a new clinical space.

Q: Tom Salemi: Going back to health care cost, how granular in detail does a company need to be in presenting what savings its device will produce? I turn this over to you, Parag, since you mentioned Barrx. Its treatment is an alternative to careful watching. Careful watching isn't all that expensive. Is that going to be a challenge for that company or future companies? What happens when you are going to be basically replacing a clinical paradigm that doesn't cost anything?

Parag Shah: It is going to be an issue for Barrx and any other company that is competing against a modality of operation where a particular doctor set feels that "normally we do this, now you're asking me to do that." I think that only
happens over time, and the question is, what's the adoption curve, how long will that take, and when do the core long-term publications come out to show not just one year benefit, but five year benefit, and that it is continuous? For Barrx, fortunately, that's been happening. They have published five-year data, so you're seeing the adoption curve. They're increasing their indications. But it's absolutely the right question. And I think to that point, we're definitely looking a bit more these days at companies that are more on the revolutionary side because I think that ultimately, although it might not be the two- to three-year flip company where you get that quick return, those are the companies that are going to get the much bigger exits and the much bigger adoption, if you're willing to wait just a little bit longer.

Paul LaVioLette: I think it's very specific by physician specialty. If you look at Barrx, gastroenterologists are generally not that aggressive, and in the end you can bring them a treatment that is categorically better for patients; it's been proven over time, it's a minimally invasive approach, all the right boxes are checked. But they're just not aggressive assimilators of new technology. Pulmonology and gynecology are probably good examples, too. So you can have very comparable assessments on paper, and great clinical outcomes, but the nature of the physician specialist, I think, is one of the greatest variables in what will ultimately define a grand slam opportunity that will manifest, versus a grand slam opportunity that will languish.

Parag Shah: I totally agree. I think that at least gastroenterologists are better targets than lung surgeons. The pulmonologists are still waiting for that market. A lot of companies die on the vine unless you get some sort of regulatory mandate like you did in GI where everybody has to have an endoscopy done.

Tamara Elias: But do physicians have the final word, or is cost really going to come into play? Can you convince a physician of the clinical benefit and that's the end of the story? Or are you going to face the greater challenge of convincing the hospitals that yes, we need to still pay for that; we need to buy this expensive system, and we need to keep buying supplies? Is that going to be a greater challenge going forward? And how are you figuring that into your equation when you're looking at companies?

Stephen Bloch: I'll take a crack at that. I started my career selling services to HMOs. I started one of the first radiology benefit management companies in the 1990s, and I've actually had a long association with Blue Cross in Massachusetts. And from the health plan perspective, every new technology purports cost savings, but the reality is it's usually additive, or logarithmic, to be honest with you. Stents are a great example. Now we put stents in people who never would have been bypassed before. At the end of the day, despite lots of talk about how HMOs operate, the reality is that most physicians, most HMOs, most people in the health care industry really want to see definable benefits to the patients. That's what really counts. That's why stents are reimbursed, and that's why there isn't that much scrutiny of those sorts of things now. Now they may be hammering on prices and things like that, but they're not scrutinizing the placing of stents at this point.

Q: David Cassak: I've spent a lot of time writing about national accounts and group purchasing, and they were very effective in getting needles and syringes down from 15 cents to three cents, but when it came to drug-eluting stents or orthopedic implants, they just absolutely hit a wall. No one wanted to challenge the doctors on that one.

Stephen Bloch: Right. I mean there's no doubt hospitals are under incredible cost pressure. You have to be very clever, a little bit lucky, and offer real patient
benefit because they see a lot of people knocking on the door, and it's hard to penetrate that unless you really offer something that a physician is pounding the table for. It starts with patient benefit. The cost stuff, you do have to define. If you don't have a good sense of where it fits well into other technologies and paradigms, how it impacts all the costs - not just the device itself, but the ancillary costs that go along with that - you haven't really solved the equation. You have to be prepared with all those things. You have to be thinking about cost-effectiveness data when you're running your trials, because it's an important part of the story. But it's not the only part of the story. At the end of the day, if you have great patient benefit and you're neutral on cost, or even if you're cost-additive with great patient benefit, you'll get there. It's when it looks like it's expensive and another me-too technology that you can [should it be 'can't'] get it in the door.

Tamara Elias: One of the first questions we ask is, "How is this saving the system money?" I am a physician by background, so I would love for the clinical benefit to take priority every time, but we recently passed on a deal I won't name, exactly because the product had a procedure code, but did not have a facility code, and the facility was losing money by doing this procedure. And I'll also mention that there seems to be a consolidation of MD practices wrapped around the hospital system in super-practices. So on the cost-savings side, it is important to think about whether you're saving money for both the physician and the hospital, because now there's such integration of the two systems. That's also an issue for the sales force: how are you going to sell this to the doctor and the hospital at the same time. It's a very important question for us.

Q: David Cassak: Let's address some of the concerns of the start-ups in the audience. At the conference yesterday, a lot of VCs explained their criteria for what they look for in a deal, and they didn't seem all that different from what they would have put up six or seven years ago. So going back to the set-up question here, when you're in your planning meeting, are you not doing deals today that you would have done a couple of years ago? If so, why? And what has changed? Is it the type of company you're looking for? Are the deal terms changing? Valuation is always one that you'll push back on to get a Series C deal at a Series B price. But in terms of the kinds of dialogs and conversations you have, both with companies and internally about the companies you want to invest in, what's changed?

Paul LaViolette: We are careful about how we define white space. To whom is it white and how white is it? This notion of going after unmet clinical needs is nice. But if it is complex technology, if it really is a long haul, if there is a sequence of barriers that one will have to overcome, if there really is no clear exit partner, but someone's going to have to just wake up and recognize it later on, I don't care how big the unmet clinical need is. That's probably not a great investment unless you are looking at a 15-year return.

Tamara Elias: Right. At Essex, now we're much more methodical than we may have been in the past about going through all of the check boxes, from, is this really a great, unmet clinical need to how are you going to meet your milestones and de-risk along the way, and where is this capital that I'm putting in going to get me to? How much are you going to burn to get there, and what is the exit potential? And let me actually go and talk to potential acquirers. We will go to great lengths to understand the real likelihood of it getting acquired, and at what price versus how much money we think we might actually need to put into the company to get there.

There's much more of a stringent methodology before we'll say yes to doing a
deal. But as we said before, today versus yesterday, as we focus more on later stage, it's about accepting less risk. Before, when you were talking about the GI docs and how long it will take to get adoption, for us now, we kind of need to see the adoption getting started. That's especially the case when we look at diagnostics. There we prefer see that the dog's eating the dog food for us to take a hard look at a diagnostics deal.

Q: David Cassak: As a corporate venture capital firm, Andrew, how do you deal with white space opportunities? Is Siemens really open to anything? It would seem to me that you would be driven by Siemens' strategic changes of direction.

Andrew Jay: We have found that in many ways, the venture capital arm drives the organization into white spaces. I'll give you an example of that. We have an investment in the digital pathology field. [The company is BioImagene [BioImagene Inc.], which, in late August 2010, Roche announced that it would acquire.](See "The Digital Pathology Revolution: Breaking the Glass Ceiling," START-UP, May 2009) Digital pathology involves digital imaging; it's got an element of diagnostics to it; it's got cancer involved in it; if you look at medical imaging, about half of all the medical images taken are cancer related. So digital pathology is a logical place for Siemens to play. But interestingly, when we ask diagnostic folks what they think about digital pathology, they say, "Hey, we're in diagnostics. We're focused here, here, and here. It makes sense, but we're working on all these other areas." Then we go to the imaging guys, and they say, "Well, yes, it does involve imaging, but we're here, here, and here." Ultimately, it was the VC arm interacting with folks in Germany and saying, "Nobody is willing to sponsor this, but it's where we need to go."

Q: David Cassak: So what's the outcome for you, then? Do you hope eventually to convince someone at Siemens that this is a great business to be in? Or are you now looking for a financial return with any investor?

Andrew Jay: I'm looking for a financial return, absolutely. That's how I make my carry. But, and this is relevant to everyone else in the room who's trying to raise money for their companies, when you deal with a strategic investor, you've got to get to the key decision maker. For me, that key decision maker was the head of Siemens Medical in Germany. I sat down in his office. He had 15 minutes. I said, "Look, here's the situation. I need a sponsor. It's in the best interest of the organization to do it. Will you be my sponsor?" No one lower down in the organization had the ability or the clout to make that decision. When you're talking with strategics, you need to find out who's got the ability to make that decision.

Q: David Cassak: I have one final question. The period 2009 to early 2010 has been interesting from the perspective of exits. We saw one IPO, although I don't know how successful you'd deem the IPO of AGA Medical [AGA Medical Holdings Inc.](See Deal), but there were a lot of big, high-profile deals: CoreValve [now Medtronic CoreValve LLC; acquired by Medtronic in 2009], Acclarent, and most recently ev3. But 2009 itself registered a record low for number of deals and deal dollar volume. How do you read the exit climate right now? Are we moving toward a climate where the buyers are basically going to wait a bit longer to get more risk out, in exchange for paying more at the end when there's greater certainty? And if so, will we see both more failures and bigger exits?

Stephen Bloch: From what I'm hearing from the corporate buyers, you're right
on target. From the investment standpoint, it goes back to the issue about capital intensity and stage of deal. It makes the idea of doing more growth equity and later-stage deals more attractive. You're going to have to carry them awhile, and there are some opportunities in terms of pricing that make those attractive. Still, if you're going to get a financial exit in a reasonable time frame, you're going to have to prove out the commercial model. I think that's the big issue that we are struggling with on the device side. You need to have a certain amount of revenue traction to prove out the commercial model. Big buyers want to see that, and it has to fit their channel. So revenue traction isn't enough in and of itself, it also has to be accretive and synergistic to what they're already doing. That's a little bit different than early-stage device investing.

**Q:** David Cassak: Would you be comfortable with a model, which seems almost like the biotech model, where you make more money when you exit, but you also have a lot more companies that people just don't want to buy?

Stephen Bloch: Yes. This model requires us to be very selective and careful. You place your bets on the companies that are making traction, and they're the real winners in your portfolio. When companies stumble, venture has not been always very good about parsing through them and deciding what should and should not be supported. It's a tough decision-making process, and it gets back to the syndicate discussion. Unfortunately, business is tough, and not everybody can win. If you have a long-term perspective, I still think there are early white space device opportunities in narrow, defined, not too capital intensive, not too complex on the regulatory front sectors, but I think all of us on the venture side are looking a lot more at later-stage opportunities because of what the buyers seem to want, given the lack of a public market as an alternative.

Tamara Elias: If you listened to Medtronic's investor day recently, they actually said something like - and this is hard for me to believe - they'll have 60 major product launches within the next year and that they won't be doing many big acquisitions. My guess is for Medtronic, that means that they'll still do three $1 billion and under acquisitions. And I bet that between all of us at this table we have those three deals. They're in our portfolios. Obviously, the challenge for us is just to pick the deals that those device acquirers are going to go after.

Paul LaViolette: The catch is selectivity. There is no question that the world is becoming more selective, and that just creates some challenge. The buyers, in fact the whole medtech space, got a punch in the belly last year. We're looking for signs of recovery, but the essential fundamentals of the space have not changed. The basic pricing structure hasn't changed. Growth in basic demand hasn't changed. The outlook is pretty positive. The cash-generating capabilities of the major players are as strong today as ever. They all get rewarded on PEs. All those PEs have come back to the field. They're all looking to grow those, and they have to do that by growing the top line, by expanding. They're all very big in their space; they all need to continuously merge outward, and when you generate one, two hundred million dollars a month of cash, and you need to fuel your PE, you're going to put that cash to work in growth strategies. You might use it to buy stock back, but that doesn't really get anybody all excited. So how are you going to grow the cap of your company if you're sitting around the executive table of one of the biggest 10 or 15 companies? It's about growth and your R&D pipelines. Having managed one that's got 50, 60 programs in it, they always disappoint.

Parag Shah: I think everybody's talked about looking at later-stage opportunities and attracting the attention of bigger players who have a lot of cash by showing that the dogs are eating the dog food. But I think in all of that, we also need to
look at differentiating factors, and we can borrow something from biotech. We like a company that has those characteristics, and also has a platform; it's good at one thing but also could spawn other opportunities for the acquirer or for the company itself. I think then you might have that billion-dollar acquisition. So in that white space, there may be a company that may not check off all your traditional boxes. It might not be the obvious choice to get acquired, and it might not have everything solved. But if it is ultimately a revolutionary versus evolutionary play and has a platform, I think you have a big winner.