Executive Summary

At Elsevier Business Intelligence’s IN³ conference in October 2012, a panel of venture capital investors talked about the current difficult financing climate for medtech start-ups, although a ray of hope lights the future.

If today’s medtech companies can work around the current dearth of investment capital, they’ll find themselves ready to supply a future demand for innovation at a time of scarcity.

Venture capital investments have a certain natural life cycle. Nourished by capital, a healthy investment goes through the phases of seed, growth, and fruition. Just like a living organism, if the nourishment is withdrawn, or if a process stalls for too long at any point, the result can be stunting. The ecosystem upon which medtech start-ups rely is in disarray, and this environment is in fact stunting and even killing many start-ups. Do these environmental changes represent a rough patch of weather, or permanent changes? Will current conditions cause a future innovation gap? The answers are yes, yes, and yes, according to a panel of venture capital investors convened at the Investment in Innovation (IN³) Medical Device 360° Summit conference held in San Francisco in October 2012 (www.in3summit.com).

At the moment, almost none of the conditions necessary for medtech start-ups to flourish are present. First, there’s the dire shortage of venture capital. The PricewaterhouseCoopers MoneyTree Report just announced third-quarter 2012 numbers indicating that medical device companies received $434 million from 65 deals in Q3, a 37% decrease in dollar amount and a 27% drop in the number of deals compared with the second quarter. That’s the lowest level of investment in medtech since 2004.
Venture capital for medical devices has dried up because of poor investment returns over the past 10 years. An internal rate of return little better than 1% for many deals has caused limited partners to abandon the sector. Medtech venture teams are shrinking as well; since last year, Frazier Healthcare Ventures, CMEA Ventures, New Leaf Ventures, and Skyline Ventures have all lost medtech team members, and OVP Venture Partners has recently been discussing plans to close down. (See "VC Collapse Still Hasn’t Hit Bottom; Firms Seek Safety Of Late-Stage Deals" — START-UP, November 2012 and "Departure, Delays Signal Tough Times For Device Investors" — START-UP, April 2011.)

There is also an increasing lack of liquidity. As of early December 2012, there were only 41 acquisitions of privately funded medical device companies for the year. In deals where terms were disclosed (12 were undisclosed and appeared to be on the small side), 70% were priced under $150 million, buttressing the belief of many device VCs that device companies must use less capital to reach an exit point. In fact, a third of the companies were purchased for less than $25 million. Most strategies aren’t doing any major acquiring, a measure of ongoing internal organization and external pressures such as the pending medical device tax, anticipated to cost the medical device industry $2.5 billion in 2013, according to Ernst and Young.

New corporate partners and acquirers may improve the situation, as we’ve seen companies like Sorin Group SPA, Covidien PLC, and CR Bard Inc. become increasingly active. There are also some isolated exceptions to the trend, the overheated market that no company wants to miss out on. Today it’s renal denervation, where after the success of Medtronic Inc.’s Ardian, one of the top exits of 2010 [See Deal], many are crowding in for second- and third-mover advantages. (See "The Renal Denervation Buzz: Separating Fact From Myth; Covidien Buys Maya Medical" — IN VIVO, June 2012.) Recently, this space saw Boston Scientific Corp. pay $425 million for Vessix Vascular Inc. [See Deal] and Covidien structure a deal worth more than $230 million ($60 million up front) to acquire Maya Medical Inc. [See Deal] In renal denervation, Kona Medical Inc. managed to complete a $40 million Series C round in early December. [See Deal]

Renal denervation aside, with all these pressures brought to bear, start-ups are being urged to be more capital efficient than ever, yet they face new pressures to survive and new requirements for spending. Changes in the health care system demand both efficacy improvements and cost savings, and the studies to demonstrate both are expensive.

The times call for creativity, for tapping alternative funding sources, or moving development off shore — whatever it takes to survive. For those medtech start-ups that do, said the panel, a great pent-up demand for innovation from strategic partners looking to refill empty pipelines will help them command high prices in a time of scarcity.

We reprint here the transcript of the panel, entitled, “Medtech Investing: Where Is Capital Going?” Stephen Levin, editor-in chief of Elsevier Business Intelligence, and Tom Salemi, Elsevier’s venture capital bureau chief, moderated the discussion. Sami Hamadé participated on the panel, bringing both the venture and corporate perspectives, as a current partner at Aberdare Ventures and the former head of Guidant’s corporate venture group Compass Group. These tough times for VCs represent an opportunity for secondary buyers such as Saints Capital, represented by director Zack Scott, MD. Michael Carusi, general partner at Advanced
Technology Ventures has sat on both sides of the table, for more than a decade as a VC and formerly as a business development executive of the medical device industry. Panel member Lisa Suennen has been investing venture capital exclusively in health care for 14 years, as a co-founder and managing member of the Psilos Group. Jeremy Loh, VP of Investments at EDBI, the corporate investment arm of Singapore’s Economic Development Board, is based in California and gives expansion-stage companies a gateway to Asia. These experts weigh in on the innovation challenges facing the medical device industry.

Steve Levin: We have some experienced and knowledgeable investors here with us. Let’s start with a short summary of each of your organizations with a particular focus on your device portfolio; tell us at which stage you invest, early or late, and give us an example of some recent device investments or exits.

Sami Hamadé: Aberdare Ventures started in 1999 and focuses exclusively on life sciences, mainly medical devices, pharma, and IT health. On the device and IT health sides we have been investing throughout all the funds. In our fourth fund we are investing much more in IT health and devices that reduce costs or increase efficiencies, and we still have three or four companies to invest in this fund.

Jeremy Loh: EDBI is the corporate investment arm of the Singapore Economic Development Board. I head up our US investment activities out of Redwood City. We have been investing in health care for more than 20 years. We manage a total fund size of about $800 million and there are additional funds that we can tap into. We invest in medical devices and more recently, in health care IT. We tend to get involved at the stage where a company is considering expanding its product offering and business into Asia using Singapore as a gateway. This is our investment sweet spot. We are very hands-on investors. We help companies establish their operations in Singapore rapidly, and hopefully we get their commercialization effort in Asia off the ground swiftly as well.

Lisa Suennen: I am one of the founders and managing members of the Psilos Group, a 14-year old fund focused on health care. We focus on devices, device-like diagnostics, health care IT, and health care services. Our focus is to find later-stage medtech companies that have demonstrated methods of improving quality and reducing costs to the health care system. On the medtech side we tend to be more of a growth or late-stage investor. Some of our current investments include OmniGuide, AngioScore, Mauna Kea Technologies, which is public on the Paris Exchange, VeraLight, and Gamma Medica-Ideas.

Mike Carusi: We are at the opposite end of the barbell from Psilos. ATV has $1.4 billion under management and it is a balanced fund. We also do IT. Within health care, we do a combination of device and biotech deals. On the device side we are very much focused on early-stage therapeutic devices, for the most part. We will look at some later-stage or special opportunities. In terms of some companies we’ve been involved with, we were investors in Ardian, GI Dynamics, TranS1, MicroVention, and on the biotech side, Plexxikon. Recently, we made an investment in IPS [Innovative Pulmonary Solutions], which I would describe as “Ardian for the lung.” It is taking the idea of denervation and applying it to the lung.
Zack Scott: Saints Capital is a 12-year-old venture capital fund with $1.2 billion under management. Our fund is split between health care and technology. Health care represents about 40% of our portfolio. We are unique compared to the other panel members in that we focus on a type of transaction that we call a direct secondary, which is a fancy way of saying that we provide liquidity to other investors in privately held companies. That ranges from purchasing a position from an early founder or employee of a company to buying stakes from another institutional investor. We might purchase their positions outright, because they need to divest for whatever reason. More recently we’ve done transactions where we’ve formed joint partnerships with venture firms where, for many reasons - lack of reserves, extended time lines – they’ve needed some additional capital. Because of that investment focus, we tend to focus on later-stage opportunities, but we are not afraid of early-stage opportunities, and in fact some of our more recent investments have been earlier stage. Recently, we invested in Coherex Medical, with a left atrial appendage device, and have investments in Mitralign, with a mitral valve replacement approach, and Direct Flow, another structural heart disease company. We also invest in biotech and health care IT.

SL: Let’s start out by assessing where we are at the moment. They always say that you can’t know that you’ve hit bottom until you start to climb out. If that is true, are we still falling? Do you see this current crisis as having any long-term impact on the investment model going forward?

SH: I have a few observations. In terms of our bias in investing today, we realized that the health care system now is the patient. A lot of us have spent decades of our lives chasing big unmet clinical needs under the assumption, which worked before, that people will pay if you provide value in treating those unmet clinical needs. That assumption is, at best, on hold now. Now that the health care system is the patient, we are focusing on technologies that reduce cost or increase efficiencies. That means on the biotech side, personalized medicine. On the device side, that means intelligent devices, devices that reduce complications or decrease total health care costs, and on the IT health side the same thing. That’s where we think the demand will be in terms of liquidity events moving forward.

The other observation I will make relates to my previous job of running the Compass Group at Guidant, a corporate venture and M&A group. In the last 24 months of touring similar groups at other companies, whether Medtronic, Bard, Boston Scientific, or Abbott, I have realized that if we can skate quickly over this thin ice, in two years those companies are going to be screaming for products that give them growth. There is very little in their pipelines, and as soon as their stocks start getting pressure because the top line is not being fueled by anything they are going to have to go out and buy. Now that the CEO musical chairs have stopped – and it takes them a year to do strategic planning – they are going to be asking, “Where are the growth products?”

I don’t think we’ve hit rock bottom, but I am optimistic that if we focus on reducing costs and increasing efficiencies, on what the big consolidators are going to need, and finally, on international markets, we’ll be all right.
SL: Given what’s happened over the last couple of years and the lack of available capital, are we going to see an innovation crisis, the potential for innovation to be lost over the next couple of years? Who will step in to fill that gap?

SH: If you think about the companies that have folded in the last two or three years that were scheduled to be in the pipeline, and not through any fault of their own but for lack of funding, the changing goal posts at the FDA and the perfect storm that we are talking about, there is a gap. And there is an even bigger gap within the pipelines of the big consolidators.

JL: I think we bring a different type of capital to the table. What Steve calls a crisis we regard as an investment opportunity. We have seen more US-based companies willing to take on more risk. They are increasingly willing to bring their products out of the US into Europe and Asia, where they can get an opportunity to address a fairly significant market. Singapore is in the heart of Southeast Asia where there is a population of about a billion, and then to the North you obviously have China and India, which represent another 2 billion people.

If you want to bring a new market to bear, Asia is definitely attractive, and that’s the reason we have been getting a lot of traction for companies in the venture growth stage. Some of them have products that have already been approved – they have the CE mark or FDA clearance, or both – and they would be willing to go to Europe, but Europe is in crisis as well. Asia is really in a growth phase whereby there is liquidity out there to help the company grow at that stage.

SL: There are some people who think that a shakeout occurred, that it really was a Darwinian process where the device space had gotten overcrowded with too much money chasing too few deals, that is, it was a necessary rebalancing. But Sami and others seem to be saying that this will have a long-term impact and may result in permanent changes.

LS: I think the changes are permanent and they aren’t only related to venture capital. The venture industry certainly is under a lot of pressure because for lots of reasons the limited partners consider health care the last worst opportunity to put their money in, largely because of the uncertainty, changes in the market, and regulatory issues. By regulatory issues I don’t just mean FDA, I also mean federal policies.

But I think there is a much bigger issue that gets glossed over in the medtech meetings: the shift from the technology arms race that has been going on in medtech for many years to a cost-savings arms race that is going on in the health care system. Too infrequently do people in the medtech industry actually interact with people in the health services and payor sides of the business. If you talk to the large payors and employers about what they are willing to pay for, the answer is “not much.”

I was at a meeting of the Pacific Business Group on Health this week that included 60 of the largest employers in the US including Walmart, Intel, and companies everyone has heard of, and these guys were saying they’re not going to approve for payment any new medtech stuff that doesn’t have its own third-
party validation of clinical efficacy paid for by the vendor. They are not willing to
take chances and they are not willing to pay for new unproven products. On
average they are approving one to two new products per year for their medical
device “formulary.”

Between that and the pressure on reimbursement and the fact that now, more
than half the providers in the nation are working as employees for organizations
that have figured out that they make more money by implanting less stuff and
using fewer devices, that is a big change in the economic incentives around the
medical device industry. That is having just as much of a permanent impact as
the venture side of things.

**SL: Mike, cyclical correction or permanent change?**

**MC:** A little of both. Everything is cyclical. Warren Buffet said that the best time
to be greedy is when others are fearful, and that is the environment we are in
now. All of the money is leaving the sector. It is going to IT, Facebook, and every
other thing except health care. What’s going to happen? As Sami suggested, we
know the demand from the strategics for innovation is still there. We know that
the supply of innovation is going down dramatically. Well, it’s Econ 101. When
supply goes down and demand goes up, prices go up. That’s what’s going to
happen. If M&A prices go up, then returns go up. Returns or the lack thereof
have killed our industry for the past 10 years. They’re horrible. On average, most
venture firms have made a less than 1% IRR on medical device investing. That
number has to improve.

But when the supply and demand balance shifts, I think you are going to see
returns improve and then what’s going to happen? All the money is going to
come rushing back in, we are going to fund 30 renal denervation companies and
we are all going to lose our money again!

We have to be smart. Our mistake, in the past 10 years, was in funding too much
technological, incremental stuff. The payors, the patients, the strategics, nobody
cares about it. We have to be looking at the cost side of the equation or true
technological innovation where you are addressing a real unmet need. The days
of incrementalism are gone.

**Tom Salemi:** I want to get in my own whack at this dead horse, but
on a panel concerning deal priorities for strategics yesterday, a
statement was made that the good technologies are still getting
funded, it’s the marginally improved technologies that aren’t
getting money. Is that true?

**The Panel, Unanimously:** No!

**SH:** I was one of those people 15 years ago, and if that’s really what they are
thinking, then they just don’t have their tentacles everywhere they should. They
don’t know what is happening in the entrepreneurial world, and they are
completely blind to the consumer-centric, value-driven stuff that Lisa was talking
about.
SL: At the Phoenix conference over the weekend [Elsevier's annual conference for medical device and diagnostic industry CEOs] both Abbott and Sorin said they are getting into early-stage investing. Yesterday at this IN³ conference we heard Medtronic, Hologic, Stryker, and Edwards all agree that they are not getting into early stage. We have become accustomed to a barbell effect where there have been investors at the early and late stages, but a gulf in the middle. Now we are also seeing a gap at the early stage. What are you seeing from strategics? Are they more or less interested in early-stage deals? Do you call them early in the process now?

MC: They have always been a call for us; it is a question of which round and what is early stage. Medtronic may say they are not getting into early stage, but they are in a bunch of my deals. It is a definition issue around what constitutes early stage, and they are not going to invest in incremental stuff. We do call on them. We don’t like to give strings, and we say that they can’t just put in $1 million to $2 million and come along for the ride. They have to be a real lead by putting in $10 million to $15 million alongside the rest of the syndicate at the appropriate round, by which I mean, the company has clinical data.

SL: Someone here at the conference told me they got J&J to come in at a very early stage with a very small amount of money, no strings attached. Is this a trend that you are seeing? If so, what does that do to the conventional belief that you should be cautious about bringing in a strategic because it limits your exits going forward? With people desperate for money, is this a new twist, to have the strategics come in earlier?

SH: Strategics have been doing a little bit of everything and it’s not necessarily driven by strategy but the normal incentives: greed or fear. They do some early stage, more late stage, but what is lacking is a comprehensive strategy. They are more opportunistic. They decide that they can’t miss out on renal denervation. Medtronic has one, so we have to have one too. The good news is that the new entrants, Sorin, Bard, Covidien, are going to occupy the void left by the traditional strategics.

The lack of a strategy is one of my greatest frustrations, and there is a role for corporate venture investing to keep the pipeline going. In 2000 when the dot com bust happened I practically got an order from management. “You have a duty as a corporate venture investor to keep the eco system alive because we are going to depend on it.” I don’t think corporate venture organizations are getting that directive from the CEOs now.

SL: Zack, you have a different relationship with the strategics. What do you see as their current involvement?
ZS: A lot of the companies we’ve acquired over the past couple of years have had strategic investors, and it has been a mixed bag in terms of their participation in future rounds. There clearly has been some trimming of the fat in the strategics’ venture portfolios. On the flip side, there have been some companies with heavily weighted interests in cardiovascular disease and they have been very active in some of the structural heart companies. In the renal nerve ablation sector, we’ve seen unsolicited investments of significant size by some of the strategics. Overall, the strategics are being very selective. They are going through the same process as the broader venture community in terms of culling down to key strategic areas and responding to the changes you’ve seen in the market, where you really have to prove the value of your product, not just to physicians but to hospitals and payors.

SL: What happens if you can’t get the strategics to participate in later rounds? One thing we heard from Sorin, which is perhaps working a little harder because they are number three, is that they are willing to do things like negotiate bridge loans into the deal to potentially support companies in cases where there might be a hiccup down the road. They’re willing to be more creative. Is that an outlier or are the strategics becoming more flexible?

MC: I think strategics are being somewhat opportunistic, but they are also working through and placing their bets where they deem it most appropriate and I see them as active. I don’t see them going away. I see them increasing their activity.

LS: I agree.

SH: Not Enough.

JL: The feedback we’re getting is that the corporates have internal reorganization issues as well as changes at the top level. They’re also struggling with integrating some of the products they’ve acquired over the years and turning them into revenues. From our experience, we have some earlier-stage investments that are turning into potential acquisition targets, but the corporates are just not getting into the game until they clean up their internal mess.

SH: If you look at the big names, three of the top four corporate venture groups are being reorganized.

MC: We are all shifting strategies right now. VCs are, because on average, people have not made money in 10 years. It is true for the strategics, too. They are looking at what’s worked and what hasn’t. A lot hasn’t.

Question from the audience: I wonder if you would expand on your comment about the J&J early investment. One of the things J&J has is a seed venture group called COSAT [Johnson & Johnson Corporate Office of Science and Technology]. Have any of you seen nascent seed funds from other strategics?
LS: I don’t see a lot out there. It’s an interesting problem. On one hand, they probably do have some duty to keep the ecosystem alive; on the other hand, it’s not their job to invest in ideas that are dilutive to them. They get measured every quarter by the stock market. They should invest in things that will be, ultimately, and not forever from now, accretive to their businesses. I think that’s the way most of them think about it. Some may experiment here and there on the seed stage, and I think J&J has probably been the most creative on that front. But it’s really not what their business is fundamentally about, and they have to be careful. I think a lot of strategics overextended themselves investing in early-stage ideas, and they ended up with portfolios they couldn’t get rid of.

SH: COSAT has invested in a few Aberdare portfolio companies and a few of the Compass portfolio companies before. They have been quite active in early-stage investing. I don’t consider them to be a big venture player. Their role versus Johnson & Johnson Development Corp. versus the new centers of excellence J&J is building overseas in Europe, and in San Francisco, remains to be determined, but they will be very active. We are all looking forward to see what they come up with.

LS: If you look outside the boundaries of traditional medical technology, a whole other crop of early-stage investors has emerged in digital health or mHealth, where medical devices are built around iPhones and things of that nature. There is a whole different infrastructure/eco-system of companies that are interested in that sector: Qualcomm, United Healthcare, Humana, Blue Shield. There are five or six incubators just focused on this intersection of health IT and medtech. A new crop of corporates is involved, generally indirectly through these new incubator-type vehicles that have popped up everywhere.

SH: IT health has been very active. Here in San Francisco you have Rock Health, where a bunch of venture investors including us and two or three corporates are actively investing and selecting start-ups. Lisa is absolutely right. If you migrate from traditional medtech into IT health, there must be a dozen incubators at least playing a big role.

TS: I would like to pursue the discussion around incremental ideas that was brought up earlier. You say you are not interested in incremental products. I sat through most of the company presentations yesterday, and I don’t think anyone thought of their product as incremental in any way. How do you define that? Do you know it when you see it? Do you define it by market size, competitors? How do you personally define an incremental versus a big idea?

MC: I’m going to generalize, but it’s the faster-better-cheaper fast follower. It’s a different color or it’s shinier; it’s defined as a feature. Contrast this with Ardian where there was a physiological breakthrough. The idea of renal denervation had not been explored, and they married it with a catheter-based approach. Look at GI Dynamics and the idea of having a device that’s a physiological breakthrough to treat diabetes. Those are real “aha!” moments. The incremental play becomes the next generation Ardian. Rather than a single-point ablation solution, now you have a basket that does six ablations at once.
There is a time and a place for a fast follower, but I think companies often get stuck in this no man’s land where they are too late to be the first mover and too early to be a fast follower. Folks don’t yet know what all the weaknesses of the Ardian product are. The market hasn’t spoken yet. So you are pursuing a goal that you don’t know yet with a fast-follower strategy. A fast follower with a paradigm shift can start the cycle all over again, but what actually happens tends to be in between.

SL: Let me offer a contrarian view. Yes, the Ardians, the Acclarents, the CoreValves, have been big clinical breakthroughs, but the device industry has been built on incremental innovation, and most device exits are still in the $100 million range. Are we going to see a sea change that is going to change the vast majority of device dealmaking?

MC: A VC can’t live on $100 million exits, although there can be a few. You can if it only takes $5 million to $10 million to get there, but it usually doesn’t. So I’m saying that for us to thrive as an industry we need to come up with the $700 million to $800 million exits. That’s our strategy. Others will disagree with that. We take kind of a home-run approach where you get one or two of those in your fund, and that gets you to the 3X or better return. That’s how you make money for folks. If you are living on $100 million exits, it becomes a hits game. You’d better get 70% of them right, and you have to be very capital efficient. The history of our industry has proven that those companies tend not to be capital efficient, because they have to start commercializing those devices before they can sell the company, and then the math doesn’t work.

SL: Anyone else? Do you always need to swing for the fences or can you build a good portfolio on singles and doubles?

LS: I think it’s hard to build a good portfolio on singles and doubles. You have to get them all right. It is not impossible, people do it, but it’s hard.

I think a lot of companies fall into a trap of wanting to be venture backed when they shouldn’t be. If there is a company out there that has a good product and can grow to be a $50 million company, there is nothing wrong with that. But it doesn’t necessarily make sense for them to get money from me or Mike. There are other paths. Most of the companies in America are small companies and they are good companies that can make money for inventors and entrepreneurs, but they just have to consider other paths than venture capital because there is not a lot of it out there. Not every company can be a greater than $100 million company. You have to be honest with yourself about what you are building and the capacity of the marketplace. Every single company comes in with a slide that says it can make $100 million in revenues in five years, but I don’t really see that many where that’s true. If your company’s top limit is $100 million, that is a great company, but figure out how to finance it other than by traditional venture capital.

SH: I agree. If you are a fund with half a billion dollars, you definitely cannot do the double base hits. If you are a $150 million fund, you can do some of them as long as they are not capital intensive. There is nuance, but in general, if your
fund size is small and you can pick companies that are not very capital intensive, you can make the multiples.

As a good example of what Lisa was saying, look at what Amr Salahieh and Fred Khosravi have done in their last three companies. You have Embolic Protection Inc. [acquired by Boston Scientific] that was number three of four in carotid filters, Sadra Medical [also acquired by Boston Scientific], the third or fourth company in aortic valve stenosis, and Maya Medical [bought by Covidien] which was a really big hit for investors. That one was number three or four in renal denervation. From an entrepreneur perspective forget about us venture capital funds. If you can replicate that, that is a pretty good return for you guys. Some people have been able to do that not once, not twice, but three times. So entrepreneurs have to be mindful not just of what VCs are doing but of other sources.

SL: The fallout of the last few years has hit the huge funds the hardest, and it has become clear that it’s very difficult for billion-dollar funds to really succeed in devices. Does that argue for the fact that the survivors are more of the smaller funds that can support the singles and doubles kinds of deals?

MC: I think the billion-dollar funds don’t work; the funds should be smaller. Whether $150 million or $250 million is the right size we can debate; but even with those fund sizes, I would still argue that you have to look for the bigger opportunities. Sami is right. Fred has had a couple of very nice exits on limited capital. But is that sustainable, and how often does that happen? To Lisa’s point, you have to be really honest with yourself as to how much capital it is going to take to get to an exit.

If you make the assumption that you are going to sell once you get CE mark, and there are those examples, what happens if you can’t sell the company then? More often than not the companies can’t sell. So what do you do? Do you raise another round? Do you build a sales force? Well, the market’s not big enough to support a sales force. As an industry too many things have been funded under the presumption that it would get sold to Abbott under the CE mark or whatever milestone. If that doesn’t happen and the math doesn’t work, then neither the entrepreneur nor the venture capitalist are going to get a return.

SH: From a venture perspective, we are in agreement. You can’t depend on that, unless with limited capital you can build a stand-alone business. If you are really building something with the hope of flipping it, you might flip it 20% of the time, but if you can’t generate the competition for the deal, you are in trouble because the buyer knows that. I have been on the other side of that position. But from an entrepreneur perspective, if you have an idea that is incremental, don’t give up because lots of people have made money that way.

SL: Now let’s shift the discussion to emerging markets. Yesterday at this meeting Mark Wan talked about how Three Arch Partners has shifted all of its device development overseas. He said they are not doing device start-ups in the US any more. They have three that are in Singapore.
JL: Obviously, the lack of capital plays a part in this move. But Mark has also tried to build up an alternative fund investment out of Singapore. We co-invested in one of his companies, and we helped the company be a little bit more efficient. They had a pilot manufacturing facility in Pleasanton, CA, and they were considering whether to build a full-fledged manufacturing facility in the US. We came in and helped outfit the larger-volume manufacturing in Asia to capitalize on cost-efficiency. That's what we have been doing with our other portfolio investments as well to gain that delta in the cost-efficiency. Asia would also serve as a new market opportunity.

SL: How do the rest of you view this issue? Are you looking at companies that can launch technologies in emerging markets as opposed to actually creating companies in emerging markets? Are you moving development abroad?

ZS: We are clearly seeing the strategy of taking development and moving it to Europe across our portfolio. The barriers of interacting with the FDA are so frustrating and costly that we are focused on the European markets and getting approval and demonstrating proof of principle there when necessary in select accounts and markets, and using that to trigger possible exits.

LS: To give you an example, we have a company called VeraLight, which has a noninvasive screening device for diabetes and it is more accurate than a blood test. It takes 90 seconds. You put your arm on it and it uses spectroscopy to tell you if you are pre-diabetic. We decided that the bigger – and faster – opportunity would come from launching the product, not in Europe, although we did launch in Europe, but in Saudi Arabia and the Middle East where diabetes affects 50% to 60% of the population, and in India, where diabetes rates are more than 50%. We looked abroad both for regulatory speed-to-market reasons and for opportunistic reasons.

The issue for a lot of medical device companies becomes cost. VeraLight’s test has a very low cost basis. It’s not like a situation where you have to figure out how to make an $800 catheter into a $100 catheter quickly. Most of those emerging markets don’t have the tolerance to pay what we still pay in the US. It is coming down here as well, and soon you are going to see the opposite situation with some of the devices invented for China, India, and other places coming into the US market. In India they are using a $25 incubator for babies that works really well, and I don’t know why we are not using it.

MC: It depends on your strategy. If you look at our focus on novelty and physiologic breakthroughs, a lot of the value drivers for our companies revolve around getting clinical data. We look at some of these other markets as more efficient ways to get clinical data. Now we encourage our companies not only to do feasibility studies in Europe or other places, but also to do randomized clinical trials with control groups and really try and get a robust dataset.

In other cases you are going to target those markets for revenue growth. It depends upon the underlying asset and what you are trying to do, but there is no question that we are looking outside the US either for clinical trials or commercialization, depending upon the company’s product.
SL: Two of the most vocal critics of the FDA, Josh Makower, who spoke at the Phoenix meeting, and Tom Fogarty, who spoke here yesterday, have gone on record saying that they see a sea change at the FDA. [For more on physician-entrepreneur Dr. Fogarty, see "The Fogarty Institute For Innovation: A Device Incubator For Difficult Times" — IN VIVO, July 2011.] That hasn’t necessarily translated into faster execution and implementation of that more helpful attitude, but what do you see in terms of the agency as you work with your respective companies? Has that translated into a hesitancy to go to Europe first, whether for clinical data or revenue?

MC: I have been vocal, too, and I agree with them. We have seen a change. I will use GI Dynamics as an example. We just got our IDE approved to do a pivotal study for diabetes. I can’t look at the metrics yet and say that it’s been quicker, but what has changed is the tone of the interactions, which is less combative and more collegial. There is more give and take; more openness to listen to the experts and folks outside the agency. That bodes well, but time will tell whether or not that works its way through the metrics.

SH: Kudos go to the people like Josh and Mike who really have lobbied hard and were very vocal. The needle is moving. I don’t know if it is a sea change but we are seeing a counter current. We have recently seen it with three companies, one that went from an IDE to a 510(K), one where they changed our reviewer, and at least you can have the discussion. It does say that individual effort, lobbying, and raising your voice for the sake of something as noble as medtech or life sciences does work.

TS: If the change continues in this positive direction, is that enough to reverse the tide of this movement to Europe or Asia, or have those ships sailed? Will more testing be sent back to the US?

MC: To my mind, no. It is still going to be easier to iterate devices and to run the clinical trials over there. But it will influence the debate around the timing of US clinical trials. We have gotten to the point where we’ve said, forget it, we are not even going to do that US trial; we could do it, but we are going to wait two, three, four years. We are going to start to have that debate again as to whether or not we should get the data in Europe and then run the pivotal trial in the US on a more frequent time line. I think we are still going to try to get that data outside the US. We are not going to do the iterative studies in the US because it is just too costly and the regulation is still higher, but it may influence the debate as to when we initiate the pivotal trial in the US.

ZS: I totally agree. For two years we haven’t even been talking about starting an IDE study, and now it finally seems like the right time to do it.

LS: The opening of the FDA is great, but it doesn’t open the floodgates because it doesn’t mitigate the economic drivers that are changing our industry. I am going back to the insurance and payment issues, which are in some ways much harder to overcome.
Companies out there that are developing new products have to start talking to the payors earlier to find out what evidence they want to see. FDA approval is nice, but payors have a long list of other things that they want to see before they'll think about paying you for what you've got. That's what stops a lot of companies in the end. They get their approval from the FDA but there is nobody with a pocketbook who is willing to pay for it. You really have to start thinking about economic studies or significant clinical studies that show a real advance. You'll have to demonstrate not just parity to something they already pay for, but a true clinical advance or significant cost savings, because that's what the payors are looking for.

MC: Along those lines we are now starting to shift our lobbying effort toward the societies, which control reimbursement. The politics right now within the reimbursement process and the societies, where they are trying to protect existing codes and reimbursement levels and turf, are a real inhibitor to innovation. You have this bloc that is preventing the product from getting to market for all the wrong reasons, because they are more concerned about protecting their own economic self-interest than doing what is right for the patients and payors.

LS: You are talking about the societies, but that is only one piece of the puzzle. They may give you a code. Medicare might cover something. But there are two issues: one, if your product is not for populations covered by Medicare, then you are dealing with commercial insurers and that is a whole different set of rules. I think that 10 years from now everybody is going to be covered by commercial payors. If you look at what's happening with health reform or insurance reform, Medicare is slowly drifting into the commercial market instead of direct. The power for that reimbursement is going to shift more into the hands of the commercial payors, United Healthcare, Aetna, Cigna, and others, and even if you have a code, they don't have to pay you. They decide.

Question from the audience: Economic and outcomes studies are important, but they are costly. If a company designs a product with those criteria in mind, and gets FDA approval and CE mark and has some initial sales, but hasn't done those prospective randomized controlled studies, are you finding that the strategics will pick that up and pay for those studies?

LS: No, and it is a real chicken and egg problem. As I said, I was at the Pacific Business Group on Health meeting with 60 employers that cover 10 million people and the five largest insurers In California. Ten medtech companies presented products that they thought would save money. The employers universally said, “That is all well and good but I can’t deal with that. Work with my payors.” Then the payors universally said, “That’s all well and good, but until you can come to me with a cost study, or a real clinical study, I don’t really want to talk to you.” There was some discussion as to whether the payors would pay for some of that and there was a lukewarm “maybe.” Certainly the traditional medical device strategics are not even used to thinking about that, much less paying for it.

MC: This is why I think you have to swing for the fences because more often than not you are going to have to do more of that work around your product
yourself, and if you don’t have that big of an opportunity and you can’t raise that kind of capital around your product, that is the real conundrum a lot of companies are facing.

**Question from the audience:** It’s interesting that you focus on innovative products, but they are risky and require an awful lot of R&D. When you talk to VCs they don’t want to pay for that. Are we getting into a situation where basically you want something that has been developed with funds by government and academia, to fund the first five years of out-of-the-box stuff, at a time when those funds are going away?

**MC:** Well, we do fund that, but you’re right, a lot of my brethren don’t. But we are also not looking for academia or government to fund that. Smart entrepreneurs can find breakthroughs. In the case of the Ardian founders, the two entrepreneurs found a surgical paper going back to 1955 showing that renal sympathectomy could reduce blood pressure. The surgical procedure was horrid so nobody did it, but it was that “aha!” let’s see if we can do that with some of the less invasive technologies that we have today. It was a doctor and an engineer who came up with that idea. That’s what we’re looking for.

**SH:** But there aren’t many examples like that, and you’re right, many of our brethren have migrated elsewhere and we do have an issue there to figure out, whether it should be funded by academia, corporate venture, or groups like COSAT.

**JL:** In terms of business plans that come across my table and entrepreneurs that come in to present, for those innovative and more capital-intensive products it would be better to rely on academic grants and state funding to help overcome some of the hurdles and make as much development progress as they can before reaching out to VCs. Those are some trends that we see.

**SL:** Let’s end on a positive note. For all of the financing challenges we have talked about, the silver lining seems to be that the M&A environment is still vital, although the structure of deals has changed. We had a panel of strategics yesterday who talked about structured deals dominating the marketplace, less money in up-front payments, a larger portion of the deals spread out through earn-outs.

**How do each of you prepare your management teams for this new environment? How do you negotiate meaningful and achievable milestones? Do you still find that people still expect to get paid up front?**

**ZS:** It’s a mixed bag, especially when we’ve stepped into the shoes of previous VCs. There is definitely a lot of coaching that goes on in terms of expectations. For years companies have been claiming it’s a $350 million exit or nothing. We are seeing that reality hits the road when a group of investors has been in a company for 10-plus years and has no reserves. All of a sudden a structured
deal looks a lot better than it would have five years ago when you thought you were going to get $350 million.

LS: Different times call for different leadership. You have to pick people who understand the market is changing, who understand the need to align incentives between investors and management for the success of both parties. There is a class of medtech entrepreneurs that built companies at a time when people were willing to spend $100 million to build a medical device company. Well, those times are gone. People aren't generally willing to invest at the levels they used to to bring a company to fruition. Now you need entrepreneurs who get that and know how to be more capital efficient and come up with creative partnerships. We look for people with open minds about how to get from the beginning to the end.

MC: I can definitely end on a positive note. For those entrepreneurs who have been able to raise money for their companies in the current period, for those venture firms that have been able to raise capital, and for those of you who move forward with your companies, because of the scarcity issue, I think we are all going to make tons of money in five years. The supply and demand has gotten so out of balance that the returns are going to be there. Those that survive, and a bunch of you will survive, are going to do very well. I actually think that this is a great time to be investing and doing medical devices. We just need to convince the people that give us money that it's true and that is a hard sell.

LS: Mike is right; the folks who used to invest in venture funds are foolish to run away now because chaos breeds opportunity in a market like ours. There is great opportunity here.

JL: Any exit is going to be a good exit for a medical device company. Tom Fogarty said it yesterday: if entrepreneurs and VCs focus on building good products, then the acquisition or public offering will come.

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