

Is Medtech Venture Capital Dead in the Water? Interview with Kevin Bitterman, Principal at Polaris Venture Partners

Scott Nelson: Medtech VCs are becoming less and less interested in healthcare because of diminishing returns. With that said, will Medtech venture capital eventually see the same fate as the Passenger Pigeon, or is well-known VC Terry McGuire right in declaring that “Darwin was an optimist?”

To help answer those questions and a host of others, enter Kevin Bitterman, Principal at Polaris Venture Partners. In this interview, we learn what Medtech venture capitalists like to see in a startup and how these early-stage medical device companies can best position themselves for success. Here are some of the points we are going to cover:

- Will the IPO market for Medtech companies ever open up again?
- What requirements would make for an attractive IPO candidate?
- Where do large medical device companies see the greatest opportunity for growth?
- What questions should Medtech startups have already answered before approaching a potential buyer?
- In terms of a potential exit, what is more, important for a medical device startup – clinical data or commercialization?
- Kevin's lasting advice for early-stage medical device companies.

Hello, hello everyone. It's Scott Nelson, and welcome to another edition of Medsider, the program where you can advance your medical device or Medtech career on your own terms without going to school. On today's program, we've got Kevin Bitterman, who is a Principal at Polaris Ventures. He's been with Polaris since 2004. He obtained his Ph.D. at Harvard Medical School, earned his BA with honors from Rutgers with a major in Biological Sciences and a minor in Philosophy. So, thanks a ton for coming on to the program today, Kevin. Really appreciate it.

Kevin Bitterman: Thanks Scott, glad to be here.

Scott Nelson: Alright, so let's first start out with the one big question, as I mentioned in kind of our pre-interview talk, is making the assumption that the IPO market is pretty dried up. What do Medtech startups need to do in order to see an M&A exit as that's the most likely option probably moving forward, at least for the foreseeable future? So, that's the big question that we're going to try to answer in this interview. But before we go there, do you agree with that assumption, that the IPO market for Medtech is pretty dried up and almost nonexistent?

Kevin Bitterman: Yeah, I would say yes, I largely do. I don't think it's completely closed. I think we did see Globus Medical, a fast-growing device company in the spine space go public not too long ago, and that's probably a 6, 7-year-old company that experienced some tremendous growth, and I think market's valuing it over a billion dollars and it's actually traded up since it's gone out. So, that's at least I think a sign of life on the device side. So, I think for the right companies, the right profiles, there is still a market there. Frankly, I think we need to be building

companies with both paths in mind because you can't build a company, at least our philosophy, you can't build a company just to be sold at a certain point of time, because however well you try to plan that you're almost definitely going to be wrong. So, building a company to be stand-alone and potentially IPO at some point is actually probably the best way to find an M&A. The best companies are bought, they're not sold.

Scott Nelson: Sure.

Kevin Bitterman: So, we can come back to that throughout the course of a conversation, but I think you're right. If you look at the numbers, exits are much more likely to be M&A than IPO.

Scott Nelson: Got you. To your point about Globus, maybe it was this week or last week, I think Sunshine Heart was another company that actually IPO'd as well. I don't know much about Sunshine Heart and I haven't dug into that. So, to your point, maybe we're seeing a little bit of IPO action. But I don't want to spend too much time on the IPO versus M&A. M&A, obviously we're seeing an uptick in activity there, but on the IPO front, you just mentioned building a company may be in essence to go in both directions if that's possible. On the IPO side, it's probably a tough question to answer, but are there certain things that would make an IPO or a company a better IPO candidate versus another?

Kevin Bitterman: Yeah, I think it's kind of the old-fashioned recipe of you need a very, very strong management team. It starts with the people, obviously. You need a full team at all levels and you really need a growth story. You need a big market. You need I think to be a market leader and you need to be showing significant traction. So, I think you need to be close to profitability and ramping up pretty quickly in a space where there's a huge upside. So, pretty simple ingredients, but I think that's what investors should kind of look for.

Scott Nelson: Sure. Okay. So, let's dig into the M&A front. We both agree that it's probably where most of the activity is and that that will most likely continue to rise. When large strategic companies, the Boston Scientifics, Covidien's, J&J, etc., Medtronic, and so on, and so on. These are obviously the big players that are acquiring some of this early-stage technology. Where do you personally see the greatest opportunity for growth, seeing it through the lens of an early-stage Medtech company?

Kevin Bitterman: You mean from a therapeutic area standpoint?

Scott Nelson: Yeah. Yeah, exactly.

Kevin Bitterman: You know, it's tough to say. We see opportunities in a lot of different areas. I think there's still going to be a lot of opportunity in interventional cardiology. You're still seeing a lot of growth there. We've been pretty bullish on the CNS space actually, and I think there's still a huge opportunity in the neural stem area. I think even though we just talked about Globus, I think the spine's been a little bit tougher that there hasn't been tremendous growth, but obviously, you can still build something special there as the Globus guys saw. So, I think what

we've been seeing primarily, I'd say cardiovascular, CNS, and I guess some interesting stuff happening in the GI space as well.

Scott Nelson: Okay. So, if I'm an entrepreneurial physician, just to throw out that idea and I come to Polaris, not that this exact situation would happen. If I've got an idea, you're not necessarily making a determination based on whether or not that idea fits within your therapeutic biases. You're just looking at the idea, the market, etc., right?

Kevin Bitterman: Yeah. In our style of investing, we start with the entrepreneur. Is this someone with a track record? Is this someone that we want to take a bet on and be partners with? Then we look at the technology. Is this a special, highly-differentiated, well-protected, potentially game-changing piece of technology? Then I think you check the boxes of generally these things are going after pretty large markets and you look at all the other factors, but we start our review with who are the people and how exciting does the technology gets.

Scott Nelson: Sure, and I actually want to come back around and ask you about maybe some of your personal investment psychology I guess, for lack of a better description. Going back to kind of an early-stage Medtech company. Are there some major questions that they need to have answered before you begin to look at a potential exit through a merger and acquisition?

Kevin Bitterman: Yeah, well, the answer to that is I think the unfortunate state of device investing today. It's what everyone's kind of scratching their head about and figuring out if we can mix. You know, we look a little bit through the prism of contrasting Medtech investing to other areas of healthcare and not healthcare. So, we're a diversified fund and each investor here has a diversified portfolio. So, we all look at biotech. We all look at Medtech. We all look at healthcare services and other areas as well. Most of the contrasting and comparing get done between biotech and Medtech.

The sad state of affairs for Medtech is that, for an early-stage company, you more than likely have to go through the increasingly high hurdles of getting technical proof of concept, getting clinical proof of concept, taking out regulatory risk, getting onto the market, and then actually taking out commercial risk and reimbursement risk, showing that you can get this paid for, showing that you can build a business around it. That's a very different profile from the biotech side where the traditional model has been taken out of technical proof of concept and get some clinical proof of concept. If you're in a big market, if you build it they will come. You have to build it much bigger generally on the device side and take it much further before a partner or an acquirer will show up.

I think that's part of what makes early-stage Medtech investing, especially for something that's a PMA path or a heavy-lifting 510(k) so daunting right now, is that it's a long road and there's not much help along the way, whereas on the biotech side a lot of these companies have platforms, can generate multiple product opportunities, can do some partnering along the way. There are more opportunities I think for nondilutive funding. So, I think this is getting to a bit of a different topic, but there may be a chance for Medtech to take a page out of the biotech book in terms of how you work with corporates, how you work with strategics, how you may do some partnering

along the way. I think that's going to help everyone in the industry at the end of the day. But to specifically answer your question, I think the unfortunate truth is that for most exits if you look at the big exits recently in the device space, they've been revenue-stage companies that have had to prove the commercial model before an acquirer shows up.

Scott Nelson: Right, and I want to ask you about de-risking that investment from the point of view of a large strategic, but before I ask that, are we at an era now whereas an early-stage Medtech company you need to be extremely strategic, very good from a strategic standpoint in dealing with large strategics if you're looking to make an exit in that path?

Kevin Bitterman: Yeah, I think you do. I think you need to be a bunch of things. I think you need more than ever to be incredibly entrepreneurial and while we're taking pages out of other people's playbooks, I think Medtech investors need to look at the software and digital media and the tech guys and see what they're able to build essentially bootstrapped or on incredibly limited budgets. I think the early-stage device entrepreneur, if there's a way that you can bootstrap a company through getting either some preclinical proof of concept or ideally figuring out a creative way to get some first-demand data without having to raise a significant amount of money, then you put yourself in a far, far better position. So, I think I may have gotten off-track of your question, but maybe you can remind me what the... Sorry about that.

Scott Nelson: No, no, you were actually right on track. No, that's exactly what I was asking. I mean, if you're looking, you mentioned kind of the platform, I guess, and biotech somewhat has that advantage and maybe their platform is a little bit wider versus deeper. So, there may be other opportunities for a large strategic to acquire that technology and build upon that platform versus maybe kind of a single kind of vertical niche, I guess if that makes sense.

Kevin Bitterman: Yeah. Yeah. I apologize, and you were asking me about what can they do with corporates and strategics early on.

Scott Nelson: Yeah.

Kevin Bitterman: I think, unfortunately for most device companies, it does ultimately, even if you start with interesting broad technology, you pretty quickly narrow yourself down to a single product or a single application of that technology. Most device companies can't afford to be putting forward a bunch of products and kind of diversify risk that way. So, yeah, I think at the earliest stages you want to be getting as much as input from corporates and strategics. I think going and asking for advice on what's the type of data you want to see or what's the target product profile, what specs do you want to see, what kind of clinical design, etc. Incredibly impactful at the early stages of the company. I think you'll find most of the big device guys willing to give you that type of feedback and work with you along the way.

So, I think erring on the side of being a little bit more open with these guys and getting feedback as early as you can. Again, I think there's a huge opportunity to sit down and have all of us think creatively about how can small companies with some of the larger ones in a way that becomes a win-win. Again, I think you're seeing a lot of new, interesting models on the biopharma side

where not to get off track, but big pharma is realizing that they just can't sit around and wait for assets to show up at their door that is post phase 2 or post phase 3. They're realizing that there's an incredible, frankly, a financial crisis with early-stage investing. They're actually rolling up their sleeves and getting involved early on and figuring out creative ways to partner with companies without ultimately limiting the fate or the upside for that company. So, I think that's something that hasn't really seeped into the device world yet, but hopeful that it will potentially.

Scott Nelson: No, that's great information. To your point, it seems like it's almost that you need that on the task list to check off that box as continuing to work early on with large strategics. Not just from a potential M&A exit but also from the standpoint of maybe there's a different model other than an M&A that may eventually happen years down the road. But if your communication is there early on, the options will be much more open for some of those...

Kevin Bitterman: Yeah, and at the end of the day everyone knows acquisitions don't happen overnight. You don't all of the sudden hit cash or breakeven or hit a certain reimbursement milestone and then the acquirers show up. It takes a lot of time to get comfortable with the technology, to get comfortable with the team, to get comfortable with a particular business model. So, starting a dialogue early and going through that getting-to-know-you phase and kind of drawing them in overtime, telling them this is what you're going to do and then going out and doing it at the right time, then a transaction can be much smoother.

Scott Nelson: Sure. Yeah. I want to ask you about one of your portfolio companies, and I think it's still in your portfolio, 480 Biomedical, is that still...?

Kevin Bitterman: Yeah, sure.

Scott Nelson: Yeah. I think that probably ties into my next question because, to answer the question, and we talked a little bit about this earlier, de-risking the investment for a large strategic. Can you easily answer the question of, where do I place the most importance, on clinical data and what my trial looks like or sales and revenue? Is there an easy way to answer that question in terms of making this purchase a lot easier for a company like J&J or Medtronic or Boston Scientific etc.?

Kevin Bitterman: Sorry, the question was putting resources into generating more robust clinical data or towards sales? Was that the question?

Scott Nelson: Exactly. Exactly, yeah.

Kevin Bitterman: Yeah. The unsatisfying answer is that it depends. In some situations, if you're going through a long PMA process, you're going to generate a lot of clinical data and you're going to publish on that, and by the time you're approved hopefully folks are a believer, and a lot of times it comes down to figuring out, is there is a commercial model here? Are docs going to use it? Are payers going to pay for it, etc. and can you make money?

If you're more of a 510(k) patent, you've got to market quickly with some clinical data, but there's a lot of open questions. You may want to focus more on generating that data that's going to make the buyer a believer because frankly, at the end of the day, they have their own philosophy and they'll be able to bring their own sales force to bear and own reimbursement expertise. A lot of times, you know, buyers...

Scott Nelson: Yeah.

Kevin Bitterman: We don't want you to screw that part up and so once they're believers in the clinical data, they'll go out and knock the cover off the ball from a commercial standpoint. So, I think it could be either/or generally you find yourself somewhere in the middle where you have to use your resources wisely to try to get some traction in both.

Scott Nelson: Sure. In terms of whether or not a large medical device company would acquire an early-stage company that is pre-revenue, do you think if the idea is novel enough, sales aren't as important as the clinical data? Like, for example, I mentioned earlier one of your portfolio companies, 480 Biomedical, that's developing bio-absorbable stents, that's an incredibly novel idea. Are sales less important in your case versus the clinical data, and if you've got clinical data, it's an easier investment for a large company to make?

Kevin Bitterman: Yeah. No, I think that's a great example of where that is the case. I think it has been a holy grail for some time if you could figure out a way to develop a resorbable for the periphery that has the very, very difficult to get all in one characteristic, constructional integrity, and bio-resorption, biocompatibility, the right resolution profile. These are incredibly challenging profiles for the product. If you can do that that there clearly is a market for that and it's just been technical challenges that have tripped people up and frankly, there's been graveyard there.

Scott Nelson: Yeah.

Kevin Bitterman: So, I think if you can show the right technical specs if you can show the right clinical data, then yeah, I don't think in that sense your commercial attraction's going to be nearly as important.

Scott Nelson: Sure. Yeah. I mean, if you meet the description of the holy grail in the therapeutic area, your challenge is probably going to be more clinical data versus what does the commercialization looks like, etc., that kind of thing.

Kevin Bitterman: That's exactly right.

Scott Nelson: Yeah. So, let's jump to another topic. Before an early-stage company gets to your door and before you hear their pitch, what are maybe some entrepreneurial ways to bootstrap early on if your team at Polaris is not ready to make that investment or maybe help in, and I haven't really asked the question of early-stage versus late stage. Are you participating in Series A versus late-stage deals but what are some of the ways that an early-stage Medtech company

can get off the ground to eventually get to your door and pitch you and work with your team at Polaris?

Kevin Bitterman: Yeah, so I think there is the kind of traditional sources, non-dilutive funding for early-stage companies, SBIRs. If you're working in a specific disease area, there sometimes can be the disease foundations that provide non-dilutive funding early on. There's obviously the angel community, finding a little bit of friend and family money and making it go a long way with some creativity. Unfortunately, there are not that many new pools that have emerged so it's kind of the old-fashioned ones, but I think you'll find that the good entrepreneurs figure out a way to scrap a little bit together and make some progress before they go talk to the venture community.

Scott Nelson: Yeah. You mentioned the friends and family, maybe some potential grant funding, etc. Are you personally seeing any of those more popular than others? The second area, what's your take on the whole crowdfunding with websites like MedStarter, for example, which is kind of a different version of Kickstarter except for the Medtech world? I want to get your take on that as well.

Kevin Bitterman: Yeah. I think that's going to be a real phenomenon on the technology side. I think the jury's still out probably on the healthcare side. I think that's terrific for an entrepreneur that can raise money that way to get through the early stages. I think this is an area though that frankly takes sophisticated, very long-term minded investors. I just wonder if there are going to be enough kind of early successes there that folks will keep coming back to this space. There very well maybe but it'll be interesting to see how well that translates. So, I think the jury's still out. Are we seeing one more popular than the other? I think you are seeing a fairly active angel community on the Medtech side. I think they've recognized there's a void.

I think there is, to revisit what I said a bit ago in terms of the long, arduous path that most Medtech companies have to take. I think there are different paths, frankly. I think you can for certain assets in certain spaces build a technology that is going to be a clear tuck-in for someone out there. You're likely not building it to be a billion-dollar exit. It may be even something you're building that's likely to be 100 million dollars or less exit, but you can do so in an incredibly capital-efficient way and it could still be a great return for the company, for the founders, for the investors. So, I think if you take your shots right there are different models and different paths you can take, but I think you have to kind of choose one or the other. If you're in it for the long haul, then you have to plan for a long road and a lot of capital needed along the way.

Scott Nelson: Sure. Sure. In essence, almost, the onus is on that entrepreneur early on. If the angels are in essence kind of replacing in theory what used to be the A round, the onus is on, how do I attract angel money? So, is that something that you help out with at all through your network, or do you play enough in that early stage?

Kevin Bitterman: Yeah, so we see enough early stage and if there's something that we think might be appropriate for an angel group or another investor we know out there, we'll certainly make an introduction. We hate to leave a company with just a, it's not for us right now. We love to leave them with some introductions or some help. So, we do that whenever we can.

Scott Nelson: Sure. As we kind of reach towards the conclusion to our conversation, I wanted to ask you a little bit more about your personal investment psychology. When you look at an idea, if someone comes and pitches Kevin Bitterman at Polaris, are there a couple of things that you look at in terms of identifying whether this is truly going to be a disruptive technology and novel enough to eventually see an exit?

Kevin Bitterman: Yeah. Listen, I think the challenge for this space is the more novel something is the more excited we're likely to get and the potentially bigger impact, but this is an environment where novelty is looked at with a lot of scrutinies by payers and sometimes regulators. I think people have complained about the FDA, but I think quite frankly the bigger issue facing the industry is, how do you prove an economic case to get it paid for? How much traction do you need to get? The reimbursement landscape is incredibly challenging and unpredictable. So, I think those are the big issues that we look at.

We were talking before the interview about one of our companies, Neuronetics, which is the first medical device using the non-invasive neural stem to treat depression, which is an incredibly novel approach. The company has generated wonderful data both doing clinical trials and now that they're out on the market and they're getting finally some really, really strong traction in the payer community, but it has taken time. It has taken time, and that's because it's a very novel approach to an enormous, enormous opportunity, but payers have looked at it with a lot of scrutinies. We're thrilled that they're coming on board, but it has taken a while.

Scott Nelson: Yeah. Do you think, because it almost seems like navigating through the payer community, to the path of reimbursement, is almost more challenging than, and not trying to put the regulatory environment and make a lot of that, but it almost seems navigating through reimbursement is tougher than navigating through the regulatory pathway in some cases.

Kevin Bitterman: Yeah, I think it is in the sense that what folks complain most about in the FDA is, "We'd love more visibility, we'd love more visibility." At the end of the day though, you have some visibility, you have communications with the FDA, you have minutes that you can take home with you that generally lay out a path for you. Sometimes that path changes and sometimes what they tell you becomes something else but generally, you know what you need to do, and you know what you need to show regulators from a safety and efficacy standpoint.

Reimbursement is very, very different. There is very, very little visibility into their thinking, into their process and it's trench work there. You just have to fight every single battle, kind of hand-to-hand combat with payers. The good thing is that there's a nice domino effect there. Once you get the first few to fall it gets much easier from there, but it's a very stochastic, unpredictable process that I think therefore makes it much more challenging.

Scott Nelson: Right, because you hear every day, not every day, at least every week people complaining about the unpredictability of the FDA, but to your point that you just mentioned, maybe it seems like navigating through the reimbursement arenas and dealing with payers is much more unpredictable...

Kevin Bitterman: Yeah. I think the bar is incredibly high, especially in this environment. I don't think it's going to get any lower, but again I think we're the believers. In some sense that strengthens our resolve that you really just need to be looking at the most impactful technology and backing the strongest teams that have done this before. We're finding in our portfolio companies, those that have navigated and had big wins on the reimbursement side. It's just incredible how much easier that process is once you kind of know the formula and you know the tactics. It becomes a matter of when, not if, but it's still incredibly challenging.

Scott Nelson: Yeah. That's interesting. Going back, kind of fishing out with your own background, I mentioned earlier that you obtained your Ph.D. from Harvard Medical School, started with Polaris in 2004. I think I got a quote here from one of Polaris' founders, Terry McGuire, I think early on he said, this is a quote about you and it's in regard to your early work with Sirtris, is that how you pronounce it? Which was acquired by GSK?

Kevin Bitterman: Yeah.

Scott Nelson: Yeah. He said, "It was pretty clear that Kevin had a lot of talent and was interested in exploring venture investing." I think that's an early quote from Terry about yourself. What attracted you? When you were finishing up your work at Harvard and then when you were working alongside Sirtris, what attracted you to the venture space versus staying more on the research side?

Kevin Bitterman: Yeah, I think it was just my naïveté. I was attracted to and I wanted to explore it because I had no idea what it was. I was a naïve grad student that thought it was a fascinating thing to watch some of the science in our lab get pulled out and start to get translated into potential therapeutics and kind of got bit by that startup. I quickly realized that a place like Polaris where you spend most of your time listening to incredible entrepreneurs and hanging around with scientists listening to their ideas and how they want to change the world, seemed like there are worse ways to spend your time. So, I didn't really know what I was getting myself into in those early days, but again just the people we're able to interact with and the entrepreneurs we're able to back makes it a pretty special job.

Scott Nelson: Yeah. Yeah, I like your description of you were a naïve grad... I should title the headline of this interview, "How a Naïve Grad Student Ended Up as a Venture Capitalist in the Biotech/Med Tech World." Joking aside, that's interesting that you say that because you're obviously incredibly smart in the world of the life sciences but you probably saw the whole world of financing and venture capital as almost a new challenge and, "I don't really know a lot, this is interesting and I want to learn more," that kind of thing.

Kevin Bitterman: Yeah, that's exactly right.

Scott Nelson: No, that's great stuff. I know we're running short on time. We've covered quite a bit here, but any lasting advice for would-be Medtech entrepreneurs that are listening to this interview and even maybe some people that are involved in the world of dead equity and

whatnot? Anything that we haven't covered that you'd like to provide in terms of advice or how-tos?

Kevin Bitterman: Yeah, I guess what I would say to maybe step back and make a few kinds of comments on the macro environment, I think first of all the death of venture capital has been greatly exaggerated. I think venture and specifically healthcare-focused venture is here to stay. The model is going to evolve, things are going to change, but there are still going to be plenty of investors out there looking for the next best thing on the Medtech side. I think the reality of the environment is that there is going to be less capital available and that means a couple of things. That means I think the best entrepreneurs and the best ideas will get backed and syndicates will form around those companies. So, it kind of becomes the world of the haves and the have nots, but that's maybe not a terrible thing.

But I think also, again, we need to all collectively think of some new models, maybe some new models for financing, some new models for working with partners and new models for creatively generating clinical data. I think it's a time where the scrappy companies are going to come out on top here but it's also we're all in this together type of mindset, so I think investors, entrepreneurs, and corporates all need to be sitting down and talking about these issues together and figuring out some solutions that are going to benefit the entire industry at the end of the day.

Scott Nelson: Right. That's great stuff. In fact, had a conversation, I did an interview actually, it's been probably six months ago now with Arun Ranchod. I can't remember his exact title. He's the VP of like Global Business Development at Parker-Hannifin. He used to be with Medrad actually kind of in a similar capacity. But he mentioned something along the lines that you just said. In fact, he thought it might actually be a good thing that we're entering sort of an era where it forces all of us to re-evaluate different models and become more efficient with less, in essence.

Kevin Bitterman: Yeah, you quoted from Terry McGuire before. Another one of my favorite things he likes to say a lot is "Darwin was an optimist." So, I think we tend to be very bullish overall in this space, but I think that means we can't be comfortable. We need to be evolving. But again, I think some great companies and [35:54 inaudible] are going to come out of this time.

Scott Nelson: Right. "Darwin was an optimist." I'm going to jot down that quote. Well, I know we're running short on time here, but I can't thank you enough, Kevin, for taking some time out of your busy schedule and teaching the Medsider audience a little bit more about your world and what it takes to experience some success in the Medtech arena in these times.

Kevin Bitterman: Thanks, Scott. Yeah, my pleasure.

Scott Nelson: Alright folks, that's it. I hope you enjoyed the interview with Kevin Bitterman of Polaris Ventures. If you want to find out a little bit more about Kevin and his team there at Polaris, go to polarisventures.com, P-O-L-A-R-I-S Ventures.com. In the show notes online, I'll also link up to Kevin's LinkedIn profile as well, and you can potentially reach out to him in that way as well.

That's it for now, folks. Until the next episode of Medsider. Everyone take care.