Why Keeping the End in Mind is Critical for Every Medtech Entrepreneur: Interview with Erica Rogers, CEO of Silk Road Medical

Scott Nelson: In this two-part, interview I was lucky enough to sit down with Erica Rogers, CEO of Silk Road Medical. We first spoke a few years ago and then again much more recently to catch up on what had changed at Silk Road since our first conversation during the catch up which you will hear in part two. Unfortunately, the audio quality isn't as good as I would have liked but we did discuss how Erica led her team at Silk Road through the PMA process, successful insurance coverage, and reimbursement strategy, which led to a very rewarding public offering for Silk Road, which opened up at an incredible $20 a share.

This resulted in the opportunity to continue the company's goal, which is to change the standard of care in carotid artery disease through their TCAR procedure. Much of our first conversation, which you'll hear shortly, was about Erica's career trajectory and how she was able to successfully and gracefully exit multiple medtech companies. Her lengthy career inside as a medtech thought leader is just as interesting today as it was when we recorded our conversation back then. Before leading Silk Road by way of background, Erica was the COO of Medicines360 a non-profit pharmaceutical company, developing drugs and devices for Women. Erica was also the founder and CEO of Allux Medical, as well as the co-founder of Visiogen which was acquired by Abbott Medical Optics back in 2009.

Prior to that Erica has spent over 12 years at Boston Scientific in a variety of sales and marketing positions, and she first began her career in pharmaceutical sales after receiving a BS in Zoology from San Diego State University. Erica also holds a five issued and 15 pending US patents for a wide variety of medical devices in nanotechnology. As you can imagine there's a lot of things that we cover in both parts of the interview with Erica. But here are a few things that I'd like to highlight:

- How she felt when Abbott purchased Visiogen in 2009, the company that she initially co-founded.
- Why keeping the end in mind is absolutely critical for every medtech entrepreneur?
- The key lessons Erica learned at Allux Medical when they were forced to shut the company down.
- Why every medical device entrepreneur absolutely needs to start with a problem first, so you don't end up with a solution looking for a problem.
- Specific to reimbursement why it's imperative to put yourself in the shoes of CMS and/or societal stakeholders.
- Why Silk Road ended up going public and what led to their overwhelming success?
- Lastly, Erica's favorite business book, the CEO she most admires, and what she'd tell her 30-year-old self.

Of course, there's a lot more we cover in this wide-ranging discussion with Erica. All right, so without further ado, let's get to the two-part interview with Erica Rogers.

Part I

Scott Nelson: Erica, welcome to the program. I appreciate your coming on.

Erica Rogers: Well, thanks for having me, Scott.

Scott Nelson: All right, let's start with Visiogen. You co-founded that company back in 2000, I believe the 2000 timeframe if my notes are correct here on my end. Then you left in 2004 to start Allux Medical. So, let's go back. I want to set the stage here for when Abbott finally purchased Visiogen back in 2009. So, I think that was about five years after you initially left. So, with that in mind, you know, any thoughts as to where you were in time, and what you're mindset was when Abbott pulled the trigger on Visiogen after building, that company back in the early 2000s.

Erica Rogers: Yeah, well, I was absolutely overjoyed for a number of reasons. First of all, obviously, as the founder or co-founder of that company, I had an extraordinary, vested interest in seeing that technology come to fruition and to the market. We were taking on a massively huge challenge there at Visiogen which was to create a true, accommodating, intraocular lens, one that would provide more accommodation power than any lens prior to that time. The structure of that lens is very, very complicated. It was a huge validation of the bet that I had placed in my career to do Visiogen in the first place which began with starting at Three Arch Partners as entrepreneur residents and [06:09 inaudible] out of that.

So, it validated the whole decision-making process around the unmet need there, around the technology, and all of that. Also, as a founder, I still had a reasonable position in the company. So, economically it was good for me as well. In terms of was it bittersweet? Yes, of course, you'd love to be there at the exit end. It's never the end, the technology lives on and all of that. But yeah, it would have been great to be there for that kind of victory lap. Also, what I learned in hindsight many years later is that because it wasn't there when the company actually exited I didn't really get credit for the exit, even though I was one of the first. So, that was a little bit of a bittersweet pill for sure. But the reasons for leaving in the first place were kind of twofold.

One was the company was heading into what was going to be a very long, protracted process with the FDA and by the time I left, I was at that time running marketing. So as the co-founder originally I was doing a bunch of things, wearing a lot of hats, clinical, regulatory, and marketing, and some office R&D thrown in and office management on the side. Then you narrowed the role obviously, over the years to marketing. So, it was both a personal decision around geography, just needing to be back in the Bay Area and then, secondly, wanting to place another bet because I knew it was going to be long and drawn out at Visiogen. I thought, well, I want to go do another startup and place another bet and not have all of my equity eggs in one basket if you know what I mean.

Scott Nelson: Sure, yeah, that's a good anecdote. I want to ask you a few more questions here later on in the conversation about Allux Medical and your decision to place another bet after founding Visiogen. Let's go and set the stage for the audience. I provided an intro and your bio at the beginning of this discussion, but you joined Silk Road Medical as President/CEO in 2012.

We're recording this conversation in early 2017, it's about five years ago, four to five years ago. So, can you provide us an overview of the device you're commercializing now at Silk Road and really, how it's different than carotid stenting or carotid endarterectomy? Then give us a little bit of a take, and I want, a little bit of a long-winded question. But give us a little bit of a take on where you're at in terms of commercialization both here in the US and abroad.

Erica Rogers: Sure, feel free to interrupt if I'm going long on either of those multiple parts of that question. Really Scott, it all starts, the Silk Road story really all-stars with stroke and stroke is, as you know, a devastating and often fatal disease and carotid artery disease is responsible for about 1/3 of all strokes in the United States. So, unfortunately, one of the downsides of performing a procedure to fix that carotid lesion and prevent the future stroke that it could cause is in the process of fixing it, you can cause a stroke during or in the periprocedural period. So, today, carotid artery disease is typically treated with an invasive surgery called carotid endarterectomy or CEA.

CEA is super good at protecting the brain, preventing future strokes and strokes during the procedure but it's pretty invasive. It's a long incision down the neck, meticular surgical dissection, collateral damage, cranial nerve injury, and heart attacks, and room complications and things like that go along with invasive surgery. So, to your point over the last call at 15-plus years industry has attempted to solve for that morbidity around this invasive procedure called CEA.

We did that with a minimally invasive catheter-based approach called CAS, carotid artery stenting. That is from the trans-femoral route. The problem is, as it turned out, CAS actually increased the procedure-related stroke risk relative to CEA due to inherent design and technology flaws and in particular, starting from the groin. So, surgeons and peers weren't willing to make that trade-off of excess stroke risk in and around the procedure just to get the minimally invasive benefits.

So, Silk Road has been able to go to school on 15 years of trial and error around carotid stenting and really honing in on where the shortcomings lie. It's really all about delivering the stent safely. So, TCAR which is Trans Carotid Artery Revascularization which is the procedure we do. It starts in the neck. It's direct access to the common carotid artery. We set up a flow reversal shunt that's outside the body, returns blood into the femoral veins and we place a stent under that flow reversal so that any debris that's rendered is captured and never, ever had a chance to hit the brain.

So, we published our first results from a big US trial in the Journal of Vascular Surgery in 2015 and showed a 1.4% stroke rate in all patients, which was the lowest published stroke rate of any modality, whether it be surgery or carotid artery stenting up until then. So, that's what really put Silk Road on the map, got everybody's attention, and last year we got a very favorable Carver's decision, which we can talk about later if you want to. We commercialized the device last year really in earnest in April and had a phenomenal first year with each of our territory annualizing it over a $1,000,000. So. we're off to the races.

Scott Nelson: Really cool success story for sure, especially for watching an early stage medtech company actually commercialize a technology here in the US without having to be acquired by a larger strategic for sure. So, it's cool to see what you and your team have done up to this state so far. So, we're going to circle back around and talk about some of those more specifics. But let's take this opportunity now to go back in time a little and learn a little bit more about your career and some of the challenges that you faced over the time as well as some of the lessons learned that have brought you and forged a path where you're at now with Silk Road. So, let's go back to your days at Boston Scientific. I know you were there from, like, the mid-90s to around the 2000 timeframe. So, what first brought you into the medtech space, and what was your role like at Boston Scientific over the span of those five years?

Erica Rogers: So, I'm going to tell you the true answer, which is I had spent the early part of my career in the pharmaceutical industry. So, I was out in hospitals and physician offices and things like that, and every time I would pull up to a hospital in my Ford Taurus and I would park next to somebody who would get out of their BMW, and I would ask that person what did they do? They would say, well, you know, I sell medical devices. Back in the day was pacemakers and so it became really clear to me early on the cool jobs were over in the medtech space. So, that's the honest answer to the question that why did I start paying attention to that area of medicine in the first place? So, I started Boston Scientific as a sales rep, literally carrying the bag. I was super drawn to that role and that company.

It was a company called MEDITECH at the time. It was before it was even called Boston Scientific and before the IPO. Now you should understand I was a child prodigy. I was really only 12 years old when all this happened. So, if anyone is doing the math on how old I am it's really embarrassing. So, I was around when Boston Scientific went public, and I have one of the very first shares still framed in my office. So, what drew me there was obviously interventional medicine was just getting started and it was obvious this was going to change the world. The whole vascular bed was poised for from the big open surgical procedures to these minimally invasive things. It started with a really simple angioplasty of iliac arteries and obviously, history speaks for itself. That's what really drew me into Boston Scientific. This was the beginning of something really, really big.

Scott Nelson: Glad that you mentioned that. That's the point about being in the pharmaceutical space and seeing your colleagues in the device base just leading a much better quality of life in terms of income. I'm sure a lot of those people, including myself, that are listening to this interview can absolutely appreciate that perspective. The roles that you had at Boston Scientific leading up to when you left in 2000. So, I presume you eventually went in-house.

Erica Rogers: Yeah, sort of. That's a complicated story, so I did work up through the ranks in the sales organization and sales training in particular and ended up in leadership roles there. But there was a need for me to move physically to Boston, and I was unable to do that for personal reasons. So, I kind of maxed out in what I could do at Boston which is why I ended up in Target Therapeutics and I crossed over into Target did market development at the very, very early days

of aneurysm coiling. Literally, I started at Target Therapeutics within days of the 510(k) clearance on the first aneurysm coils.

My role there was market development. So, it was figuring out how to go from the five doctors in the world who could coil an aneurysm to taking over all of the intracranial aneurysm therapy and what were all the things that we were going to need to do to solve that puzzle and it was everything. Everything from reimbursement to additional data to randomized trials against aneurysm clipping. It's just a giant puzzle that had to be solved on the market development front at Target Therapeutics. So, when I think about my Boston Scientific years, I lump them all together because I left Boston Scientific and went to Target Therapeutics and within about 90 days of me going there Target was acquired by Boston Scientific. So, I was back.

Scott Nelson: Boomerang. Yeah. Boomerang effect.

Erica Rogers: Yeah. Now there's a real lesson there Scott and that lesson is how do you exit companies exit them with grace such that when those kinds of acquisitions happen that you're invited to stay and in fact, that's what happened. Many people in the original Target organizations were let go in that merger because there was duplicity. I was preserved and in fact, elevated in my role in the organization in neuro and was able to stay in California and move up the ranks at Target Therapeutic inside Boston Scientific.

Scott Nelson: Got it. Okay. Take me back to that time frame because I have when you first founded Visiogen in the early 2000s. When you went to Target and then Target was acquired by Boston Scientific do you recall the dates?

Erica Rogers: Oh gosh!

Scott Nelson: I'm asking you to go back in time yeah. I was just trying to get a better feel for the timeframe to help people track along.

Erica Rogers: It was like four years doing neuro inside Boston Scientific. So, it was around '96.

Scott Nelson: Got it. Okay, Okay, that makes sense. So, you were inside. You went to Target, which was obviously a very early stage company, Boston acquires Target and then you go to Three Arch Partners. So, walk me through that and how did you end up as an entrepreneur in residence at Three Arch leading up to the eventual formation of Visiogen.

Erica Rogers: Well, that's one of my favorite parts of the story. When we take these right turns, and we decide to pursue the road less traveled. I was very happy at Target Therapeutics. We were just knocking the cover off the ball there and making enormous strides in intracranial aneurysm therapy and getting into an ischemic stroke. It was super-hot and super exciting, and I was working for great people and I had a great team under me. Then I got introduced to Three Arch Partners and they were looking for an entrepreneur in residence who had some background in the stroke arena, which is how I came across them.

I was really torn as to what to do because I had never been inside the venture community. I'd never done a startup. I didn't know what an entrepreneur in residence even was and how would my success be measured and all of those things. I was coming out of this giant organization Boston Scientific and one of the partners at Three Arch sat me down and he said, look, if every single aneurysm in the world were coiled instead of clipped what would happen to the value of your Boston Scientific stock? I said, well, this is 2000 we're talking about, 1999-ish. I said, well, not a whole lot because at that time it was all about coronary and stocks rose and fell on the basis of coronary market share and coronary market entrance and stents and all of that stuff that was happening in the cardio Cath lab.

So, what he was trying to tell me was that I had reached a point in my position there where I could no longer have an enormous impact on the state of Boston Scientific. He said, if you come here and you do this very early stage thing, you will have an enormous impact because you will go and found something if we do this right. I said you're right, I have to go do that. So, that was what was behind the decision, Scott. But then there was also this other small voice in my head that said, they're probably not going to ask me twice. Probably go do this with the leading venture capital firm in Silicon Valley at the time.

Scott Nelson: What do you think was it that attracted the partners of Three Arch to pursue you and want you to come on board as an EIR?

Erica Rogers: I have asked myself that question. I don't have the exact answer. But here is what I think. One is I had real core confidence in all things intracranial. Aneurysm and stroke that was a hot area of investment at the time. Three Arch obviously had some deal flow in that area. I would be helpful there as an Entrepreneur in Residence and a Principal in that capacity. It was one of the areas that they wanted me to incubate around. I knew all of the citizens globally, so that was helpful to them.

But I also think that you can have an entrepreneurial spirit inside these large companies, and I think they picked up on my entrepreneurial spirit and wanted to tap into that. What separates some entrepreneurs are if you are an entrepreneur that has that spirit and that gut, and you also know what it's supposed to look like at the end. When it's a big company, you can connect the dots from early, early all the way up to what it needs to be at Boston Scientific. So, I think they became convinced that I could do that. I could start something very, very early, and nascent and I could take it all the way through and make it look and act like a big company

Scott Nelson: The notes that I am jotting down here is the ability to see the end in mind for a medtech startup. That's a powerful thing when in retrospect sort of looking at it under the guise of having 2020 vision. Let's fast forward your time now at Visiogen and then at Alex Medical. I think there's probably some interesting things to pull through at Alex Medical. But you're at Three Arch and then you decide to place a bet at Visiogen and slide back into the operator position. So, what led up to founding Visiogen back in the early 2000s?

Erica Rogers: Well, it really started with looking at a bunch of unmet needs in various diseases and therapeutic categories. One of the categories that my then thought partner at Three Arch, a

phenomenal gentleman by the name of Reza Zadno, and I were kind of joined at the hip there at Three Arch to figure this out. One of the disease areas that were looking at or therapeutic areas was with presbyopia, the loss of near vision as we age, the change in vision as we age. So, we were two people from vascular backgrounds and invented this intraocular lens and we pitched it, I don't know, three or four times inside Three Arch to say this is the thing we want to go do because we're absolutely convinced that we're on to something and this is going to be big and going to be transformational in ophthalmology.

We got the typical response. What the heck do you guys know? You're two people from vascular. How can you actually know anything about inventing a lens in the eye? What do you know about ophthalmology and running a business in ophthalmology, etc.?. We were turned down multiple times. So, we had to really hone the arguments and hone our own skillset. Finally, we got it right and they allowed us to spin it out and then they dedicated the first financing, and we were off and running at Visiogen. So really, we were trying to solve presbyopia, and we were doing it with a cataract replacement lens which would give people at the time of cataract surgery back their full range of vision. It was an extraordinarily complex problem, and the learning curve was very steep. I did not know a whole lot about optics going into that. But I came out knowing a lot about optics and the eye and all of that. Did you also get into what led my departure or?

Scott Nelson: Yeah, Yeah. I was going to ask you one follow-up question before we go there. But I'm interested in getting the name of the other partner who helped you co-found Visiogen. What was his name again?

Erica Rogers: Reza Zadno.

Scott nelson: Reza. So, you both had a vascular experience. But yet to the point of some of the other Three Arch Partners who evaluated that deal and said what are guys doing with vascular experience trying to attack the ophthalmology space? Help me get inside your head because I think for most people they'd probably gravitate towards something.. If a company they were going to found and their domain expertise is in the interventional vascular medium they're probably going to gravitate more towards that space. But you both didn't considering your experience. So, was it the disease state, or was it just the new challenge? What was going on in your head and why did you decide to do a new therapeutic arena with Visiogen?

Erica Rogers: So, we were tasked with as I said looking at just becoming smarter around several different areas, and at that time, obesity was really hot, and ophthalmology was really hot and stroke. There were a couple of others. So, we would go to the major medical meetings in those huge categories. So, we went to the major ophthalmology conference is and they're relatively dull and boring overall, but we walked around the various breakout session and didactic sessions. We realized the ones where they were standing room only, and the rooms were packed, and you couldn't get in were the ones that we're talking about presbyopia. So, just through observation, we said well, this is interesting. People really care about this presbyopia. It's obviously a hot topic. So, we just dove in and one of the things that that one of my bosses said to me back in the Boston Scientific days. He said to me, "You know what I like about you, Erica, is that you're so brave and you'll just dive into anything because you actually have no idea that you can't do something." So,

it never occurred to Reza or me that we couldn't invent an intraocular lens. We simply figured we have the skillset to study the problem and if we study the problem carefully enough and talk to enough people and do enough of the back of the envelope math and things like that we'll probably solve that problem, and we did.

Scott Nelson: Is that something that you believe is innate to your character or is there something that you learned over time?

Erica Rogers: I think it's innate.

Scott Nelson: Yeah,

Erica Rogers: I would love to be able to say you can learn it over time, but it's been kind of a tenet in my entire career, which is just taking these giant leaps into the unknown with absolutely not a thought that I wouldn't be successful. I was just like I'm going to go do that and I'm going to go do that and I'm going to be successful at doing that. Not in a cocky way and certainly I don't want to mislead you. I'm very aware of my shortcomings in doing so. So, the key to success in these leaps of courage is knowing what you don't know, being hyper-aware of knowing what you don't know and surrounding yourself with the people who know what you don't know.

Scott Nelson: Sure.

Erica Rogers: So, that is the only thing that allows me to take these giant leaps of faith.

Scott Nelson: That's a really good point because it's not like you're just jumping off a cliff per se. You're intentionally surrounding yourself with people that are going to have the expertise that you don't bring to the table or some value that you don't have and making sure that you're around those people that can bridge the gap in those situations. It's interesting you bring up this point. I remember listening to an interview of a serial entrepreneur in the tech space, and I think he made some comment a lot along lines of look... He was speaking to a pretty broad audience and he mentioned that you know, look, I get to the plate and swing more often than most people. So, of course, my batting average is going to be higher because I just swing more. Do you know what I mean? So, I think it's probably appropriate to somewhat of a similar analogy to your comment about willing to swing where most people maybe wouldn't. So, that's good stuff.

For the sake of time, let's move forward because I do want to circle back to your decision to join Silk Road back in 2012. But I'd like to ask you a question in regards to Visiogen and then Allux. So, if we move forward in the timeline of your career, you said earlier that you were at a point with Visiogen that there was going to be pretty extensive regulatory hurdles, that you were going to be running into in the future, so you wanted to take another bet with Allux Medical. So, I think if my dates are correct, you joined Allux Medical in 2004. So, what did you see at Allux and why make the leap? Then talk to us a little bit about when that shut down, I think maybe around the 2008 timeframe what you learned from that experience.

Erica Rogers: That's a long tale. But let me start with Allux. Interestingly, when I made the kind of personal decision, it was time for me to exit Visiogen against both for geography reasons and also wanting to place another bet. I went back to the investors that were around the table at Visiogen and they said, well, let's just incubate you to go do something else and we'll do it up in the Bay Area where you need to be. So, it started with an incubator. I brought in another partner at that time, a physician and we were funded by Three Arch, Venrock, and Prospect to incubate a bunch of new ideas. Again, it was kind of back to where are the big unmet needs and looking at the clinical problems first, which I'm a huge fan of.

Let's first look at the problem and then solutions to the problem and what we see a lot in our space is people who have solutions trying to find a problem. That is not what I do. I start the problem and then go try to find a solution. One of the things that we were incubating at the time was allergic rhinitis and the whole continuum of airway disorders, which is allergic rhinitis, nasal polyposis, acute sinusitis, chronic sinusitis, functional endoscopic sinus surgery. That whole continuum. Here we are again. I'm taking this massive leap into ENT. I didn't even know an ENT when I was incubating this idea.

So, we found some technology over in Europe that had not only received the CE Mark but had already published papers on the use of ultraviolet light in the interior airway and downregulating the immune system for the treatment of allergic rhinitis, polyposis, and sinusitis. That's what we did. So, I and this partner and these three investors we sat around and said this is enormous. I mean, rhinitis and allergic allergies are just an enormous market not to mention chronic sinus disease. So, we went after it knowing that there this published paper and data to rely on. We licensed the intellectual property from this team in Europe and we started down the path to get into the United States. The good news was the technology had been mostly developed.

We had to tweak it a little bit and we were very, very quickly into a clinical trial in the United States. We conducted a 350 patient trial during an acute allergy season, applying this ultraviolet light inside the nose, and we massively failed to hit the endpoint. So much so that way had to look ourselves in the eyes and say, how could this possibly have happened? There's a published paper already on the results of this technology. The thing that I learned, I completely underestimated, failed to appreciate how difficult it is to run a trial in patient-reported subjective outcomes. The outcome measure for allergic rhinitis and all those diseases was things like, how much you're sneezing, how much you blowing your nose, how much are you coughing, stuff like that. Patients have to report this in a diary every single day and they have to turn these diaries in at the end of everything.

It turned out there is tremendous noise in that subjectiveness and in the patient-reported, although validated, patient-reported scales. This is why the drug companies that did you know Claritin and all the rest of those drugs literally have to enroll thousands of patients, two, three plus thousand patients to see the signals. That was completely lost on us. That was probably the closest example to a real in your face of you don't know what you don't know. Not having deep-seated experience in that whole disease state really took us by surprise. We surrounded ourselves with experts.

We were working with a really well-known allergist. We hired some people who were experts in an allergy and immunology, but it was all lost on us. So, all of this was kind of crashing and burning right at the time of the economic crisis in 2008. We had a choice of raising a bunch more money and trying to figure out what we're going to do next or shutting the company down and cutting our losses, which at that time were very small. We hadn't raised that much money. Three investors, for them it was easier for them to write it off honestly in 2008 than it was for them to continue to figure it out. So, that is what happened.

Scott Nelson: Wow. So, the fact that you were able to surround yourself with experts in the space and you would think that something like that, someone would have noticed that along the way. Like, hey, this clinical trial, it's heavy on patient-reported outcomes that are very subjective. In hindsight, obviously, it seems like someone could have solved for that along the way. But do you ever look back and think? Wow, we could have done that differently or how did we miss that?

Erica Rogers: Oh, absolutely, for sure. I think we relied too heavily on the previously published work, which has been a very small study, smaller than what we did. Yet they showed a signal. So, always be skeptical about other people's data, even though they're published in peer review journals. That's one note of caution. I think the other thing is we actually parse the data out and ended up discovering that the sickest of the patients actually did respond. So, I think the lesson there was if you're going to do a patient-reported outcome study, and that applies to a lot of things like headaches and pain. Those are two really tough spaces that are patient-reported. Although validated through scales in many cases, they're tough. So, I think had we chosen the sickest of the sick patients, to begin with, in other words, had the inclusion/exclusion criteria been such that we would have had very sick patients we would hit the endpoint.

Scott Nelson: I'd say, without a doubt, a good lesson for other medtech entrepreneurs that are listening for sure. Even your common about always be skeptical of others' data and where your clinical trial could potentially go wrong, I guess is such valuable feedback. So, I want to be sensitive to time. In the fact that I'd like to get to Silk Road Medical. But one other question about your background before we come up to the current time. But you spent some time at Nanosys and then joined Medicines360 as COO before joining Silk Road. So, your position at Medicines360 as COO, that strikes me as a little bit of a surprise considering. your strength in commercialization and building companies. Is there a rationale that others could learn from in regards to your move to Medicines360 before we jump to Silk Road?

Erica Rogers: Yeah, well, let me take them holistically, Nanosys and Medicine360. Both of those were driven by a desire to check a box for me. One was in nanotechnology. I really felt like nano was going to play an important role in medical devices, and I wanted to get smart about it and so I went and did that and that was super helpful. Medicines360, I had always wanted to be able to run a pharmaceutical company. Although I had a strong operational background and devices, I've never run a device company. I'm sorry, a pharma company that has all of its unique and different regulatory constraints and all of that.

So, what was cool about Medicine360 is a drug-device combination. and the challenge that they were facing were on the device side. It is a very successful intrauterine device for contraception.

They were having issues around the device piece of it. So, it gave me this brilliant opportunity to come in and be operational, solve all the device-related problems, and also get really, really smart about what it means to run a drug company. It was just a fantastic experience.

Scott Nelson: That's good stuff. I don't think I would have expected that response, but just the ability to like move outside your comfort zone and pick up on skillsets that maybe you wouldn't have other otherwise acquired along the year. That makes a ton of sense. Let's fast forward to 2012. You get the call to join Silk Road Medical but obviously, you have a lot of interventional and vascular experience, especially as relates to the crowded space. So, what were your initial thoughts when you got that call? Are you thinking why would I ever want to join a carotid company knowing how carotid stenting didn't pan out despite the hype?

Erica Rogers: I'm laughing. Yeah, it was no, and hell no. I think it was no and hell no like three times over the phone with the lead investors who were trying to get me to at least take a look at this deal. So, finally, they were persistent enough. I said, okay, okay, well, I'll at least sit down and listen to the story. I was very happy at Medicine360 as well so it's hard to extract someone to go do something crazy when they're really happy. So anyway, the investors sat down and told me about the approach which was very novel as I described earlier trans carotid approach. Not only was the approach novel, but their target customer made sense.

They were targeting the vascular surgeon and a vascular surgeon has always and will always own the carotid domain. The problem with not only all the technical issues that transdermal Cath's had in doubling the risk of stroke compared procedurally but all those technologies were also aimed at the interventional cardiologists predominantly. The referral pattern didn't go that direction. It was going to be incredibly disruptive to a lucrative and procedure that vascular surgeons really liked. So, they were going to hold on vehemently to that domain and they did.

Did everything they could to squash carotid arteries stenting and very successfully. So, this Silk Road was going to go straight after the vascular surgeon and say, look, we want to keep carotid in your domain. We want you to evolve, you the vascular surgeon who has evolved everywhere else in the body So, they had, in the late 90s and early 2000s learned all the endovascular skills, obviously dominating the triple-A space doing atherectomies, [38:39inaudible], stents, everything else in the periphery. So, they were starting to convert their open surgeries to endovascular procedures. So, it made perfect sense to me. It was the right technology at the right customer. Still, there was the cloud of, well, what about coverage particularly CMS? But I thought, well, if we generate the right data and we do what's right for patients that will solve itself in the end, So, I took again a leap.

Scott Nelson: A leap. Yeah, no kidding. I've got to think that leap may have been even harder considering your domain expertise. It's just a hunch but sometimes those leaps could be given could be the most challenging when you feel like you really have an understanding and deep expertise in the therapeutic arena to make a jump like that. Before, I do want to touch quickly on the topic of coverage because as you mentioned earlier, you had a big win when it comes to CMS coverage last fall. But you have a unique relationship with Cordis right now where, from a procedural standpoint, you're leveraging their stent technology. So, walk us through that decision

not to develop your stent technology, but instead partner with a large strategic in Cordis and Cardinal and utilize their platform instead.

Erica Rogers: Yeah, Well, first of all, I can't take credit for the genius idea. It happened before I got to Silk Road. The idea was to leverage the years and years and years of clinical data around an existing carotid stent because what we did carotid stents is that they were durable. Once you've got them safely, they were durable and provided the same protection against stroke in the long run as carotid endarterectomy. So, the only thing that had to be sold was how to get them there safely. So, we were able to leverage on existing PMA approved carotid stent and vastly shortened the PMA pathway is really what it bought us. We licensed that whole technology from Cordis and through the supply agreement they act as an OEM supplier for us.

Scott Nelson: Got it. I guess we don't have a lot of time to dig into that but that's a very interesting point. The fact that if you were to develop your technology, you're going to have to most likely, at the very least a 510(k), but most likely a PMA to your point. That is going to be so expensive. So, if it's going to take so long, why not partner with someone else instead? So, I'd love to learn more about how that came about. But we certainly don't have time. Nonetheless, it's a good learning lesson for other folks out there that are potentially at that point in time where they could develop their own technology but instead, maybe it makes sense to partner with someone else if it makes sense.

So, before we get to the last three rapid-fire questions, let's touch on coverage. Obviously, Silk Road had a big win last fall when it comes to CMS coverage. I've got to think that there's probably a lot of complexities there, a lot of conversations, considering the fact that carotid stenting was really never widely covered I think unless patients were involved in the clinical trial. Help us understand how you went about that and maybe is there a good lesson for other medtech entrepreneurs to learn from in your approach to getting CMS coverage?

Erica Rogers: Yeah, by far this is the most significant thing that's happened to Silk Road, and it's something we're super excited about it. So, let me just start by saying in all my years in doing this in early-stage companies, this is the first time I've ever seen an early-stage company less than one year into its commercial life, achieve the trifecta, really of reimbursement, which is codes already in place, appropriate and good healthy payment levels in place and now a favorable coverage decision. Really, what is a brand new therapy apart from anybody else in the early stage arena? So, what did we do? Well, it starts with we solved several people's issues.

So, we looked hard at what was the goal at CMS and the goal of CMS was to solve for the morbidity associated with carotid endarterectomy without trading off a stroke risk. In particular, in their high surgical risk patient population, elderly females, which happen to be the vast majority of the Medicare constituents. So, they did have a real desire to solve this. It's just that transfemoral Cath's wasn't the answer in their minds. So, it starts with that and existing under the national coverage determination, which covers all of angioplasty and stenting all over the body and buried in that are the rules around carotid artery stenting. So, there was a real desire on their part to figure out how could we work within the existing infrastructure without starting all over and having to host medtech and all of those complicated things.

So, the first thing we did was really understand where CMS goes, what was in it for them, what it meant to their constituents and what was important to the people at CMS, and how much work was going to create for them in a very constrained environment. That was number one. Number two was working with the Society of Vascular Surgery and understanding what was important to them. We knew that carotid artery disease was one of their top priorities, and research in carotids was one of their top priorities. We also knew that they were trying to advance a program called the Vascular Quality Initiative, which is they're putting these database modules in every hospital in America to collect data on all vascular surgery procedures to do hospital to hospital benchmarking and comparisons, to do regional comparisons, to leverage that to look at physician to physician comparisons.

It was all about improving the quality of vascular surgery care across America across all of the procedures. They wanted to create more and more reasons for hospitals to participate in this quality initiative. They also had a desire to do something with CMS. They were trying to figure out could the Vascular Quality Initiative be tied into CMS in some way. So, what we did it Silk Road was simply solving other people's problems and come to them with an idea, which was let's make coverage dependent on two kinds of stipulations. One, that coverage for TCAR should require FDA approved TCAR devices, trans carotid devices.

Turns out, Silk Road is the only company that has those currently. The second stipulation would be every one of the TCAR procedures will be logged into the Society of Vascular Surgeries registry, their VQI, their Vascular Quality Initiative and that would drive hospitals and physicians to participate in VQI and it would provide coverage for this really promising new procedure that CMS is very interested in and was, of course, leading research priorities for the society. It happened on the heels of our very, very promising early data from our original clinical trials.

Scott Nelson: Yeah. So, certainly, all the pieces were there for things to come to fruition quickly. But there's so much that I wish we had time to unpack there because, to your point that trifecta that you mentioned earlier I mean, it is very, very unique for medtech and I wish we had more time to unpack that answer. But you know what stood out for me, honestly, was your approach to CMS and the Society of Vascular Surgery and really putting yourself in their shoes, asking yourselves what they want. How hard is it going to be for them to get this done etc? There is such a good lesson there. But I know we're running short on time. I want to get to the last three rapid-fire questions. So, let's go and get to those and I'll try to squeeze these into the last minute here Erica if you don't mind. So, first, do you have a favorite business book that comes to mind?

Erica Rogers: I have a favorite book. I don't know if I'd call it a business book. Every single person needs to read "Daring Greatly" by Brene Brown. It is absolutely my favorite book. It is my Bible. It is how I want to run my company. It is how I want to run my life.

Scott Nelson: "Daring Greatly." I have actually not heard of that one, but definitely is getting jotted down in the notes. That's good. Second question. Is there a CEO or a business leader that you're either following right now or one that's really inspired you in the past?

Erica Rogers: Yeah, sure. So, the one that inspires me is my husband who is a CEO. He's like my behind the scenes board member, He is absolutely amazing. But the one that I am following is Omar Ishrak at Medtronic. He is big in a way; a big way and he is looking at the whole broad category of the episode of care. What does that mean for coverage, for device development, for providers, for hospitals, for payers? He is approaching it very holistically, not just what are the widgets that Medtronic sells, but can they solve this entire continuum of the episode of care, and I'm super impressed by what he's doing there. So, I'm following everything thing that he writes about.

Scott Nelson: I couldn't agree with you more. Last question and admittedly it's a little bit hard to answer in rapid-fire fashion. But if you had the chance to rewind the clock, what would you tell your 30-year-old self?

Erica Rogers: To settle down.

Scott Nelson: Settle down. Have some patience. That's good advice officially coming from a serial medtech entrepreneur. So, thank you, Erica. I'll have you hold on the line real quick. But thanks again for your willingness to do this interview and to those listening, as always, Thanks for your attention until the next episode of Medsider everyone take care.

Part II

Welcome back to Medsider Radio. Your second appearance really looking forward to this recap conversation on the latest and greatest in the world of Silk Road.

Erica Rogers: Well, thank you. Scott, it's great to be here as always.

Scott Nelson: Just to level set things. We had a really interesting conversation that was very wide-ranging about two years ago by the time we're recording this really all about your entrepreneurial journey in the world of medtech, that sort of led up to some of the more formative years of Silk Road Medical. Since then you guys have had a ton off of successes, namely the IPO, which some consider maybe one of the best medtech IPOs in history or at least recent history. So, maybe let's start there and talk a little bit more about that IPO and why it was such a success in your opinion, and then we'll cover some of the other of lessons learned and the latest things that you've uncovered in the journey with Silk Road over the past few years.

Erica Rogers: Sure, we could start with the IPO and I think it's interesting to frame up success and we've heard this before. Silk Road was a very successful IPO and I think it really comes down to how are we measuring success and what does that really mean to people and why are people saying that? If you think about what the goal of the IPO is typically and it's no different in our case. It's an opportunity to raise additional capital to continue the mission, to continue to do what we set out to do which was to change the standard of care in the treatment of carotid artery disease with our procedure called TCAR.

So, if you look at it from through that lens, certainly one would say was successful. We more than met our goal in terms of the amount of capital that we were seeking to raise at the time of the IPO and that simply means that we can continue on our commercialization share trajectory and we can continue to explore pipeline opportunities and growth outside the United States and other things like that. I think the other reason people feel it was so successful was the changes in evaluation, and I can talk about those because it's in the public domain.

We filed an S1 with a certain price on the cover. We ended up repricing right before the IPO itself and then, of course, there was a nice lift in the stock price on the day of and subsequently thereafter. So, what is really behind that? Well, it really starts with the quality of the story and for us, it's always been the same story at Silk Road which is we really are seeking to overcome the very last vascular domain that has yet to go endo fully. If you look at arteries across the body and even veins certainly now. But if we just look at arterial beds across the body from head to toe. Personally, every single one of them has undergone this transformation from open surgical repair to some endovascular procedures.

Obviously, you guys know I spent a lot of time in intracranial aneurysm repair. That's just one example of a procedure that used to be this big, open, invasive surgery and is now done with endovascular coiling and the like. So, every arterial bed had gone that way over the last 20, 25 years, with one exception and that exception is the carotid artery. There were some attempts back in the 90s to introduce interventional tools, namely in the form of transferable carotid artery stenting or CAS, and CAS really never met the challenge which was to provide a safe alternative to carotid endarterectomy. The stroke rates were just too high with CAS in multiple randomized trials.

So, fast forward to get to the answer to your question, which is where we are finally a solution that measures up and finally an opportunity to convert this very last market that is really a billion-dollar opportunity just in the United States alone. Just the conversion of the existing treated patients converting them to our procedure TCAR. So, I think that really resonated with investors. They've seen and made money on this open to endo conversion over the last 20 to 25 years, and this is literally the last chance, the last artery. So, I think that lead to a fair amount of interest in the company and what we were doing and had a nice lift in valuation as a result.

Scott Nelson: That's a really interesting way to contextualize that. I hadn't really thought about it previously, to be honest, Erica, that to your point this is really the last vascular bed that hasn't been sort of disrupted by endovascular techniques. That idea of just converting open to endo and the market opportunity that exists around that is phenomenal. So, I thought about that and normally that probably rings true with you after carrying the carotid bag way back in the day with Cordis.

Norbert Juist: Well, the technology that Silk Road encompasses is just so amazing. I mean, you know, as you're talking, Erica, I can't help but think what is preventing all doctors from jumping on board. You talk about it's a billion-dollar opportunity. I mean, you should have all of that billion-dollar money because the technology which you guys use is amazing. What is your biggest hurdle with the docs? Is it just the status quo changing the mentality or what are you seeing?

Erica Rogers: Yeah, I think the best way to answer that question is to look closely at the current standard of care, which is carotid endarterectomy. This is a procedure that has been around for 65 years. If you are a vascular surgeon in your mid-forties on up, you were trained on this procedure. It is the dominant way in which you've treated this disease state over the course of your career. Maybe you've even done hundreds of these procedures in your career and therefore, in your own hands of as a surgeon, you completely understand the strengths and weaknesses of that particular procedure and whether or not it's perfect is not necessarily the question for some surgeons.

It's really this is the surgery that I know and that I trust. So, that is what we are up against and obviously, the tailwind to that are clinical data and we have been very much a clinical data-focused company. We believe clinical evidence is the way to really move the needle in this market. So, we've continued to amass very large amounts of clinical data. I think as that builds surgeons will be able to have different conversations with referring physicians and patients about the proof of TCAR as we continue to grow the evidence base.

Scott Nelson: That's actually a nice segue into what's next for Silk Road. Maybe you can speak to that over the next maybe 1 to 2 years and then you know if you feel the freedom to speak to, even, maybe the next three to five years after that.

Erica Rogers: Yeah obviously, you know I have to be a little bit cautious about what I see here just now that we are a public company but certainly the thing to really stare hard at is the opportunity that's immediately right in front of us, which is this conversion of the already treated patient population in the United States. If you think about where we are today, this is in the public domain. We've stated this publicly. We ended the year last year at less than 5% penetrated in that market. So, there's just a ton of room to grow over multiple years just in this US conversion opportunity. But one way to think about it is that stroke and carotid order disease aren't unique to the United States. So, certainly, looking to deploy these technologies and other geographies around the world is certainly in our sights and as well, we have ah, fairly robust intellectual property portfolio. Within that intellectual property, the portfolio is other disease states that can be uniquely treated from this trans carotid approach. So, we'll look to expand our exploration of those patented opportunities along the way as well.

Scott Nelson: Very good. I mentioned this sort of at the outset of this kind of part two of our conversation. In part one we talked a lot about your entrepreneurial leading up to where Silk Road was at the time and I believe this was early 2017 timeframe, something like that. We talked about the concepts of exiting gracefully from previous startups. We talked about not to sound cliche but pursuing roads less traveled and the ability to keep the end in mind. So, Erica, when you think about really the past, maybe a few years and some of the challenges or big wins that stand out from your perspective. Can you name a few of those or maybe speak to a few of those?

Erica Rogers: Yeah. I mean, look, when I started as a CEO of Silk Road in 2012 we were just on the eve of enrolling the first patients in the ROADSTER One Trial. So, we had yet to get through an IDE. We had yet to get through 510(k) clearance and PMA approval. We had yet to tackle reimbursement and we had to get to really formulate a commercial strategy. So, there was a lot

of wood to chop between 2012 and where we sit today. So, all of those are considered winds along the way.

Certainly, I cannot take singular credit for any of those. This has been a team effort all along. I am incredibly blessed to have really the world's best management team. I know everybody says that but mine is truly the world's best management team and together we've taken down each one of these major milestones along the way. Whether it was completing the clinical trial, obtaining FDA approval and clearance, building a commercial team, getting through those first early commercial years, tackling reimbursement. All of that is kind of in the rearview mirror.

Scott Nelson: Major milestones to say the least. Massive ones that shouldn't be underappreciated. I know in our part one conversation, one of those sorts of rapid-fire questions, I asked is what would you tell your 30-year-old self if you had the opportunity to go back in time. But maybe I'll change that question up a little bit and say, Erica, if you had to go back to 2 to 3 years ago would there be anything that you would tell your CEO self at that point in time?

Erica Rogers: Yeah, I think it's similar to what I would say to my 30-year-old self which is to be patient if you are seeking to change the world which is what we're seeking to do here. We aim to become the standard of care in our current disease state which is carotid artery disease and that takes real-time and the accumulation of real clinical evidence, which takes time. So, this transition doesn't happen overnight. The transition to obtain commercial momentum doesn't happen overnight. So, I think good advice to myself back then would have been patient, this is a long, long haul. Back in 2012 if someone had told me in 2019 you will be the CEO taking this company public on the NASDAQ. I probably wouldn't have believed it at that time.

Scott Nelson: The sage advice holds true. Keep your head down and be patient. That actually reminds me of an interview I recently listened to with Reid Hoffman and Anne Wojcicki I believe is how you pronounce her last name.

Erica Rogers: Wojcicki.

Scott Nelson: I'm not sure if you run in her circles at all or know her, the founder and CEO of 23andMe, and most people I think listening has at least heard of 23andMe. I think that the overarching narrative of her conversation with Reid, the founder of LinkedIn for everyone listening to this. I'm pretty sure everyone listening to this knows LinkedIn. It was really around what to do with gatekeepers? To go a little deeper what Anne spoke to is that most people that are ambitious Erica like yourself, have a tendency to kind of drive hard, right and Anne mentioned that it was a mentor and her and her life that basically encouraged her to said, look, what do you want to do with 23andMe. If you mean to sort of change the world as you just referenced Erica the advice given to Anna was, like keep your head down and be patient. This is a long haul. This is a long journey but be patient and work with the right people and I think that really reminds me of what you just really spoke to.

Erica Rogers: Yeah, it's a really interesting story. I know the story 23and Me and they obviously went a little bit crosswise with FDA in the early days. They wanted to provide individuals and

families with their disease history, genetic information, and the FDA had an issue with that. So, Anne very admirably dealt with that gatekeeper, meaning the FDA in a patient and a careful way which was to say, okay, we're going to follow the rules, and we're going to one by one by one on these genetic tests obtain the proper FDA approval. She's been very successful in launching these, one by one. I was fortunate enough to have done 23andMe before all of that, so I got grandfathered in and saw a lot of my disease state genetic history. But I think the theme really resonates with us here at Silk Road and that we have been extraordinarily mindful of all of the constituents all along the way.

The most primary constituent, of course, is the patient with carotid artery disease but really it encompasses vascular surgeons and, in particular, the Society of Vascular Surgery. It encompasses CMS as the primary payer of people over the age of 65 who suffer from carotid artery disease. Most of them are older, so CMS is an important constituent FDA, obviously a very important constituent and, of course, investors and all of the rest of the constituents around the table. So, I think it's important for entrepreneurs to understand all of those constituents, so-called gatekeepers on the front end and really dig deep into what matters to those constituents.

Are we solving problems for those constituents or making their life worse? Which some technologies and start-ups do. So, it's important to really understand all of those constituents and bring them along, all along the way with continuous communication, continuous understanding of what matters to them. Because this is a community. Health care is a community and it's not just all about Silk Road and our technology. It's about making sure that we have solved a real problem and that we've done that in a way that matters to the rest of the constituents.

Scott Nelson: Such great stuff and hearing you describe or provide that advice is the better way to put it. It sounds so simple and straightforward but the reality of it, it's so true. it's so true and often we get stuck in this my product or my service does X, Y, and Z or it solves this need and we forget to realize all of those "gatekeepers" (using air quotes here for the listeners) or "stakeholders." that are interested in moving things along too. So, understanding that you are trying to address their needs along the way is extremely useful and such good advice.

Norbert Juist: I can't imagine that staying patient is that easy, either because you have to be looking at this growing obesity epidemic in our country, and you talk about the patient age is 65. I can't help but imagine that age is coming down every five years. It probably is coming down another couple of years and your pool of potential people, patients that you can help has to be growing exponentially.

Erica Rogers: Yeah, well, exponentially, maybe not, but it certainly is growing Norbert. It's a good observation in that cardiovascular disease, in general, is on the rise. I think there was a period in time where we all thought that smoking cessation and the real success that the country had in reducing the number of people who smoke that, would have a real meaningful impact, coupled with the advances in Statin therapy. If you think about statins and aspirin and smoking cessation is kind of the three biggest drivers to reducing cardiovascular disease. But along came obesity, the sugar epidemic and as well, sedentary lifestyle and those two things are counterbalancing these other things that might have reduced cardiovascular disease, the prevalence. So, yes, it's

on the rise. Certainly, the population is aging. That's another dynamic in the United States leading to increased cardiovascular disease. In fact, we did see a single-digit lift in the number of diagnoses of corroded artery disease from 2017 to 2018. So, you're right about that.

Norbert Juist: Interesting.

Scott Nelson: Erica, I know we're getting close to our allotted time. I want to be sensitive to your schedule, considering, I imagine it's pretty chock full. So, maybe I'll end it if it's okay with you with one last question around advice. Considering that in a lot of scenarios we speak to medtech entrepreneurs here on Medsider radio and knowing that most of our listeners have heard about your early journey leading up to Silk Road and then have learned a little bit more about where Silk Road is at now and this the successes and challenges you've been able to overcome. What's then maybe one piece of advice, maybe other than patience that you would tell another sort of medtech entrepreneur or, someone that's ambitious in medtech and wants to do the next big thing.

Erica Rogers: Sure. Well, I get asked that question a lot, and I think what has positioned me for success and certainly what was the thesis behind me taking this role at Silk Road was ultimately to become the commercial CEO of Silk Road, even though it was really early in the trajectory of the company. Obviously, I've been a founder, I have over 15 patents, etc. So, I certainly have done the entrepreneurial side of things. But really, the key to success now, and even arguably at the beginning of these early-stage companies is that I know what it's supposed to look like when you get there. The only reason I know what it's supposed to look like is that I spent real-time in my career in large medtech. Obviously, most of that was at Boston Scientific, as you know, from the prior interview. So, my advice to entrepreneurs is if you want to be an entrepreneur and you want to survive through to the day on the NASDAQ, spend some time in your career in a large company in a significant role in a large company and really understand what it's like when it gets very, very big.

Scott Nelson: That's good stuff, not the answer that I expected you to provide, but really solid.

Erica Rogers: What was the answer you expected?

Scott Nelson: I don't know. Maybe something along the lines of some start-up advice or something like that. But it's good. I mean, I can speak to my personal career and I'm still grateful for the time that I was able to spend inside Covidien and Medtronic two massive, organizations. Now, I'm obviously running a different startup. To have that experience of what things can look like at scale and how to overcome certain challenges in a good way, how to overcome in more of a painful slog too. That's such good stuff. I mean, it certainly resonates with me for sure.

Erica Rogers: Great.

Scott Nelson: Well, with that said, Erica, I can't thank you enough for taking the time out of your schedule to do a brief part two to the original interview catching us up on some of the wins, the successes and you've got a lot of them over the past few years with Silk Road Medicals.

Congratulations on all of those aspects, Major, congrats to you and your team. That's really, really cool to see especially when some medtech companies struggle to get to the point that you've taken Silk Road to. So, major congrats. Thanks again for doing this. Norbert, anything else to add.

Norbert Juist: No, I also would like to thank her, and it'll be fun to watch the trajectory and success of the company and maybe do a follow-up to the follow-up again a couple of years from now and you've introduced possibly Europe or new products to the market or new areas of disease that you're going after.

Erica Rogers: All right. Well, Scott and Norbert, thanks so much. I'm honored to have been asked to do this today. I really appreciate your time.

Scott Nelson: Excellent. Thanks again, Erica. Really appreciate it.

Erica Rogers: Bye-bye.

Scott Nelson: All right, take care.