Lessons Learned from Building the Renal Denervation Market with Ardian: Interview with Shaun Bagai, CEO of RenovoRx

Shaun Bagai is the CEO of RenovoRx. He has over 16 years of medtech experience across multiple functional areas like clinical research, sales, marketing, and market development. He was instrumental in developing the European market for renal denervation, which led to the acquisition of the first renal denervation company, Ardian, by Medtronic in 2011.

Most recently, Shaun led global market development for HeartFlow, which included directing Japanese market research, regulatory/payer collaboration, and Key Opinion Leader (KOL) Development to create value resulting in a company investment to form HeartFlow-Japan.

Here are some of the things we're going to cover in this interview:

- Shaun's reaction to Medtronic's acquisition of Ardian back in 2011.
- The power of mentorship and networking and their impact on Shaun's career.
- How Shaun landed in medtech with TransVascular before it was purchased by Medtronic in the early 2000's.
- How Shaun's experienced in a field-based sales capacity has helped him throughout his career.
- Shaun's transition from Medtronic to Ardian and the biggest challenges he faced while developing the market for renal denervation.
- Shaun's cross-functional experiences while helping to build HeartFlow-Japan.
- What Shaun and his team are building at RenovoRx and what lies ahead for the company.
- Shaun's favorite business book, the CEO that inspires him, and what he would tell his 25-year old self.

Scott Nelson: Shaun, welcome to the program, I appreciate you coming on.

Shaun Bagai: Thank you Scott, I appreciate the opportunity.

Scott Nelson: Before we talk about RenovoRx, the company that you're currently CEO of, let's start with Ardian. Take us back to the time when Medtronic acquired Ardian in November of 2010. What were you doing for them at the time?

Shaun Bagai: Given both my clinical research and my sales background, I was pulled into Ardian to help wrap up their existing clinical study, which had very positive results. I then transitioned



more into market development and sales. At that time, we had a pilot launch in Europe, and my role was mostly European market development, Germany being the biggest market.

I've really spent most of my time in Germany. In fact, I was flying there almost every week to get the product off the ground. So my job, or my role, was training physicians. I became one of the lead trainers at Ardian, in market development and sales.

Scott Nelson: I wanted to start there because I think most of my audience will be familiar with Ardian, considering the size of the acquisition by Medtronic. It was certainly a very sizeable acquisition, considering the size of Ardian at the time. Did the large acquisition surprise you as much as it did a lot of people, from an outsider's perspective?

Shaun Bagai: To be honest, it didn't surprise me all that much. Given the market potential there, living through many years at Medtronic and the stent wars, we were basically creating a market in hypertension that's four times the stent size, as far as market size goes. It was really creating a brand new market for something that hadn't really been paid attention to. Ardian found a way to potentially treat the core of the disease and the market potential is huge.

There were about 70 companies that had started to embark down a road of development in that same space to the acquisition, and to date, a lot of companies were wiped out and a lot of the funds dried up. But including Medtronic, there are a lot of companies that are trying to revamp the technology, take the learnings, both from the positives and the mistakes that were made previously on study design and even technology to some small degree, and make that successful.

So I don't think it was very surprising. I think the results of the next clinical study were the most shocking, especially for people on the inside. We all worked very closely with the physicians firsthand and we've seen patients that were really able to reduce a lot of the medications, increase quality of life and potentially life extension as well from the treatment. So I think the technology definitely does work. I think the study is going to be designed better and that's what I believe Medtronic has restarted the next study for the next generation of device as well. Surprising acquisition? Not so much. Surprising results in the next clinical study? Absolutely.

Scott Nelson: That is a good point. Shaun, even though you are not necessarily involved in the renal denervation space anymore, are you still hopeful that it will become a therapy that most patients will have access to at some point in the future?

Shaun Bagai: Absolutely. I'm actually very bullish on the technology. That's one thing I love about being in this type of career is I get to dive into the science very deeply. Denervating the sympathetic nervous system definitely made sense. If you looked at the early studies that Ardian did, we actually denervated one kidney at a time and we showed a reduction of hormones that were then caused by the cascade of the sympathetic nervous system. We definitely proved the concept, the science was working and definitely made sense.



I think the aftermath is really clinical study design. Patient selection could become a primary player in this. As far as treatment goes, I'm not sure if ablating each artery with RF energy, X number of times is the most optimal. I think whether it's RF ablation or cryoablation or some other way of attacking the sympathetic nervous system that's hyper active or over active, given lifestyle choices and the diet that people take, it makes sense.

I'm not sure what the end result will look like, but I think some level of the denervation for hypertension is going to be a major treatment option sometime in the future. Without having a crystal ball, I'm not sure if it's a few years away or many more than that.

Scott Nelson: It seems like those involved in the space all think along the same lines. Those that you included, as well as others that were closely involved with the early trials, are still very bullish and very positive on what that may eventually look like.

Tell us a little bit more about what you're doing at RenovoRx, the product that you will eventually commercialize in the general therapy or disease state that you're after.

Shaun Bagai: Of course. RenovoRx has developed a delivery system, if you will. It's a dual balloon catheter that provides a lot of flexibility and adjustability on delivering therapeutic to the peripheral vasculature. The advantage here is we're able to stop blood flow to a segmented part of the artery and deliver at high volume, high doses of therapies.

Initially the catheter's been used in gonadal vein sclerosis, and used for liver treatments. We're doing a couple of studies right now in the pancreatic cancer space, given the large unmet need for pancreatic cancer. One of the biggest issues with pancreatic cancer treatments to date is that the drugs simply do not get in the tumors. The tumors, unlike other solid tumors using liver as a comparison, are relatively avascular or hypovascular, meaning that there aren't a lot of feeders feeding the tumor, so there is no easy target to deliver localized therapy to.

It also poses a problem when you give systemic chemotherapy; the systemic chemotherapy favors going everywhere except for the pancreatic tumor because of the lack of blood supply. So this catheter, the RenovoCath, is able to isolate segments of the artery that feed the tumors and we're able to give high doses of chemotherapy and we've been studying this now in a post market registry study to date. So really the first focal point from a clinical research standpoint is pancreatic cancer where there's a large unmet clinical need.

Scott Nelson: Thanks for the review there, I appreciate it. You did receive a CE mark back in late 2015, correct?

Shaun Bagai: Correct. In fact, we're CE marked and subsequent to FDA clearance. We were cleared back in late 2014 for the broad indication of delivering therapeutics to peripheral vasculature. If you look at the space of localized target of delivery, most catheters in the space, including interventional oncology, have a broad indication. It's very difficult to get a drug device combo cleared, as you can imagine. In this space, it's very common to have a broader indication



and let physicians decide which vessels make most sense to treat and what therapeutics to deliver.

Scott Nelson: Let's dive a little bit deeper into your background, and your career. Tell us a little bit about your first foray into the world of medtech, that experience, and what got you into the medical device space?

Shaun Bagai: It's funny, sometimes careers happen by luck. To even rewind the clock a little bit further, I met TransVascular back in '97 when I was doing a summer internship with the Stanford Animal Lab and the clinical research manager at that time said, "Hey, if you ever need a summer job or maybe even a winter break job, we've got research associates if you want to come join us that would be great."

When I was applying to med school, I had a year off basically between what would have been university and med school and I called up and said, "How about a job for a year as opposed to a summer?" They had someone similar as a research associate departing for med school who was helping with pre-clinical research and different clinical research aspects, and after a few short interviews, I was able to secure that. I spent a year of TransVascular more as a research assistant or research associate, or at least that was the plan before I then go up to med school.

I was very lucky to then gain Josh Makower as a mentor who, over the course of months, steered me to maybe consider different options than going to med school. So I started off taking pictures of pig hearts and packing catheters for animal studies and was quickly able to get in a position of doing more physician training, more animal work, and then eventually taking over the clinical research activities at TransVascular.

A funny story is that Josh came up to me and closed the door. I kept peppering Josh with questions on why he didn't practice medicine as an MD, given that I was med school bound. He finally said, "Look, I think you'd be great in the industry given what you've done in TransVascular so far. Why don't you tell your boss you're not going to med school and then when you get into med school, make a more difficult choice because by then, your career should have taken off and you'll probably do something more than just taking pictures of pig hearts."

From there I did just that and knew that med school may be an option but I wanted to see where my career could take me in the meantime. I got into Temple Med School in Philadelphia, and by the time I came off the waiting list and got my acceptance, I was already managing clinical research, taking over the three clinical projects we had at TransVascular, primarily in Europe, and I could definitely see a path forward in the industry.

One of the things that resonated with me most, and this is why Josh has been such a great mentor to me is that one, I loved diving in a technology and then shifting and I think my career has shown that where I've been able to dive in the science of different technologies. I'm not sure if you call it ADD or just having fun with different areas of medicine. The other thing you



recognize, and this is something that he was very passionate about, is that as an entrepreneur, he's been able to affect many more patients through different companies that he started and helped build.

That really instilled a lot upon me when I decided not to go to med school—the fact that I can affect many more patients by helping build companies and helping do things. This will play into the Ardian story and why I went to Ardian when we talk about that later, but that's how I got my start in medtech and fell in love with the devices, the medical technology, the science behind medicine, and then layering the business pieces of my career groove from there.

Scott Nelson: What do you think Josh, or Dr. Makower, saw in your early days that sort of caused him to encourage you to pursue more of an industry track versus the medicine route?

Shaun Bagai: It's funny you ask, because there was one thing that always resonated with me and it was that whenever I was given something to do — and this is what I recommend any kind of young person getting started in any career do, for that matter — is I devoured whatever that project was. I tried to do it the best I possibly could, no matter how small the task, and learn the most I could during that time period and take on as much as possible.

Being naïve and hungry, I think it was month three in the company when I asked Josh if I could attend one of the board meetings to learn. Being a CEO now, I know that's definitely not something that a research assistant does—pop into a board meeting. In fact, my older client made fun of me for the question, but in retrospect I think that was just my personality. I wanted to learn as much as I possibly could.

I think the other piece that he saw that he mentioned to me is I like driving things to completion. That's something that he saw. On trying to get things done and projects done, there are so many different things and tasks to be done in the industry to any position that having the ability and the skill set and desire to drive things to completion would probably suit me well if I stayed in that course, if that makes sense.

Scott Nelson: That certainly makes sense. It's two characteristics that are easy to understand yet a lot rarer to experience firsthand. Someone that's really ambitious, but at the same time wants to execute and wants to see something go off from start to finish. That's a great story. Dr. Makower's name keeps coming up in these conversations. I recently interviewed Ted Lamsen at NeoTract, and obviously he's colleagues with Dr. Makower. They go back to their Acclarent days, and even before that at ExploraMed.

Shaun Bagai: Ted was the R&D manager or director at TransVascular. So I worked very closely with Ted and in fact we had some great trips to Europe together doing first demand. In fact, I've got about four or five mentors and Ted was the one who was not my direct boss but he really helped guide and shape my early career by being the mentor and the voice.



In fact, he is a doctor by PhD, Dr. Lamson, but he knew more about what we were doing than any clinician we ever met. So he was the one who taught me how to train physicians. I think he really helped shape my early career as well.

Scott Nelson: One of the big takeaways I had from my conversation with Ted was that he is just so down to earth and willing to share what he's learned along the way. I was very appreciative of that conversation.

Let's transition on to your move over to Medtronic coming out of TransVascular. You spent about six years in a field based capacity, both as a clinical marketing rep and a peer place sales rep as well. It seems like quite a bit different than what you were doing at TransVascular. Talk to us a little bit about that, and what I really want to hone in is your experience in the trenches with physicians and how that's translated into some of your other moves at Ardian, HeartWare, and now RenovoRx?

Shaun Bagai: It's a valid question because, again, I can't emphasize enough how important mentors are in building one's career and I'll take you back to two exact things that push me towards Medtronic, three people if you will. One is as I decided not to become a physician, my goal at the age of 24 to 25 at that point was to someday be able to help build medical device companies just as Dr. Makower was doing with TransVascular at the time that he was CEO and founder.

He said, "Look, Shaun, if you want to do this at some point, knowing inherently how products are sold, and being in the trenches, and getting the sales experience is paramount to success as an executive down the road." Both coming from Dr. Josh Makower and also Dr. Renu Virmani, who is a relative of mine and is very famous in the cardiac world. She said exactly the same thing, "If you're not going to med school, go do sales." Being acquired by Medtronic was such a stellar sales channel, and having the opportunity to get my foot in the door.

In fact, I've been trying to guide younger people in how to get a job at Medtronic in sales and it's very difficult to get that level of sales position. It would have been an invaluable experience. I did just that and the goal there, I think [Allen Melanazo] was head of sales around that time and he basically said, "Look, come on board. If you can be a marketing manager and train all of their sales reps and sales trainers and physicians on the technology acquired by TransVascular, then that might be a good transition after a year or so into a sales position." It sounds like a perfect fit and opportunity given where my mentors were guiding me.

Coincidentally it took about two years before a sales territory opened up where I had a manager take a chance on someone with no sales experience in that position. After a year of training sales reps, I actually went back to Ted Lamson who has remained a mentor of mine and said, "Look, I've been training sales reps, does that count? Can I go get my next job yet? Do I have to actually do sales?" As a good mentor would, he said, "Absolutely not."



Carrying a number is very different than carrying a bag in the sense that you really learn what sales reps have to do, what the mindset is, how you really incentivize the correct behaviors. Getting the sales experience besides learning how to work with physicians and learning how to train physicians, but really carrying a number helps one get that perspective of how to build and run companies.

Scott Nelson: That is such great advice. I listen to a fair number of other podcasts too, and I can always tell when a founder or a CEO of an early stage company has had sales experience because their interviews are always that much better. They intuitively get what actually works and what is really going to resonate with their ideal audience, and it seems like that's always the case. It's interesting that you say that, because I myself spent my early career largely in a field based sales capacity in medtech.

When I first came into marketing, I was really just surprised at how little folks that had spent their entire careers internally inside a large company grasped about what really works. What kind of messages resonate with whether it's a physician audience or other healthcare provider. So I can completely relate to what you are talking about. To be fair, a sales rep that thinks they can run a company without spending time internally doesn't have a true appreciation for the full circle of a medtech company either.

Shaun Bagai: You bring up a very good point. Because it goes both ways and I think having that marketing stint at Medtronic for the first couple of years gave me more appreciation for what went on in-house. As I trained sales reps from the country, when I became more of a sales trainer in certain product lines in Medtronic, I definitely felt the frustrations of the sales reps with the in-house people. The marketing manager never get it, whereas the sales reps usually think they are omniscient.

It was actually great to be able to translate that knowing the regulatory hurdles that had to be overcome, knowing the internal politics that have to be overcome to make things happen, having that perspective on both sides of that line was definitely helpful. So I think you definitely appreciate the breadth of experience necessary to certain things.

Scott Nelson: Yes, no doubt. Let's move on to your previous two experiences before RenovoRx, the first one being at Ardian. I know we already touched on this, but how did you end up transitioning form your role as a coronary sales rep to your time at Ardian?

Shaun Bagai: I can't mention enough about how mentors play a role in my career. At the time, Andrew Cleeland was a good friend of mine. We probably started drinking beers together through very close friends in my early 20's and over the years he was kind of a more of a life mentor to me on which direction I should be taking my career, to whether or not I should breakup with my girlfriend, things like that.

I think over multiple conversations with Andrew about what I'm doing with my life in general, he started to see a fit as Ardian was planning on transition from a clinical company to a



commercial company, given my clinical research background and my sales background. He introduced me to Greg Bacon, who was head of sales and marketing at the time, and this was very premature for a med company or tech company to hire a sales person.

It was basically a bunch of fun; either happy hours, breakfasts, and lunches with Greg Bacon on him asking me — and this is someone who had extensive market development and marketing experience but zero sales experience — on how I would approach the market with the Ardian technology. After a few months of this kind of free advice and getting to know Greg, it made sense for me to come on board and to kind of take over and help with market development with Greg and Mike Welch, who was the director of marketing development at the time.

So it was almost an ongoing dialogue that made an easy fit. I don't think I actually had a formal interview for that entire process, it was more of a no-brainer by that point. That's kind of getting into the Ardian part. As far as the exiting Medtronic piece, it was an interesting time because my goal was to go into sales, learn it and get out. I spent about five years in sales and I really hadn't seen a technology that was going to change medicine as much as Ardian.

So I think it was a perfect fit for me and perfect timing where I was looking for something to then do more than just sales. The opportunity in Ardian was a perfect culmination of my previous experiences, especially from an intellectual stimulation standpoint. I got to work with animal studies, I was there with their early technology, I got to train physicians. I was helping with clinical research and then helping with market development and sales.

So it was basically everything that I have done before with that piece of me that didn't go to Med school that thought someday I'm going to change medicine and given that we're opening a new market for hypertension, this is my first chance in more of a management level to having an effect on health care.

Scott Nelson: It looked like the move from your role at Medtronic as a coronary sales rep to what you were doing at Ardian seemed to be a pretty big stretch. But hearing you describe your background at not only TransVascular but especially your early days with transitioning under the Medtronic umbrella, it seems like that did make a lot of sense.

It's interesting hearing you describe how you made that move into Ardian, talk about the power of internship and networking. I think most people would have loved to be in that role at that time, but it probably wasn't all roses. Do you recall one of the more challenging aspects of your time and what you learned from that experience?

Shaun Bagai: I looked up to mentors and people have taught me a lot of things, but the most challenging piece was trying to figure out how to commercialize the technologies. We were going from a clinical company to commercial company. We were going back and forth on pricing. There is a piece of capital equipment, the disposable catheters, and we were deciding what the sales footprint should look like. We were a few market development managers, which were a blend of clinical and/or sales people, mostly in Europe.



The most challenging period is when we weren't hitting the enrolment numbers or sales numbers right off the bat, and this helped teach me a little more strategy as well. It was a matter of if we don't have enough resources for this and Greg Bacon barked at us, "Well, if that's the issue let's get more resources. I never want to hear that excuse ever again. Let's strategize on how we're going to attack this market, and if it's more resources, we'll put more resources there but I never want to hear that excuse if we say we don't need it."

So I think that was a big learning experience for me is that people can always make excuses to buy things that don't happen. But it's really important to step back and put plans in place to actually gain success. Coming off of that, we re-strategized how to enter the market, which positions we should be talking to, what the barriers were, and we overcame them and we really blew it out from a sales perspective with that early market adoption in Europe after that.

Scott Nelson: That's a great best practice and that there are some challenges that if you're knee deep, you think they are going to be extremely difficult to cross. But taking a step back and looking at things from a fresh lens, you get the sense that there's always an underlying solution to that challenge that is waiting to be found if you can take a fresh look at things.

I want to ask you a few questions about your experience at HeartFlow. At HeartFlow, you built a foundation for what is now HeartFlow-Japan and HeartFlow is another company that was acquired by Medtronic. So talk to us a little bit about what you built for what eventually became HeartFlow-Japan, especially in regards to the cross functional experience that you had when you are dealing with regulatory-payer collaboration, KOL development, and clinical research.

Shaun Bagai: So I've been in the med device space my whole career and HeartFlow was a diagnostic, even a software as a service diagnostic for assessing cardiac disease. I was brought in to help commercialize it primarily in Europe was initial plan. I was the first sales person, and soon after the VP of sales there was hired they failed the primary endpoint of the study, which was comparing the HeartFlow technology to an invasive diagnostic approach. The VP of sales subsequently left the company and I was working directly with the CEO for quite a while.

So given that the primary endpoint failed, commercialization efforts pretty much went down the tubes as well, as you can imagine. I actually helped run the next study that put HeartFlow back in the map. So my role at HeartFlow actually almost reverted to a clinical research position where I ran a clinical study, like a sales person would, on how do you increase enrolment? How do you increase quality of enrolment? I was training the physicians as well.

The fun part for me was moving the company strategically. I was able to utilize different people from different divisions in the company — and that's why I say cross functionally — to help run each site. So we had a marketing person, for example, cover a couple of sites in London. We had more of a research person cover sites in Australia with different backgrounds. So it was a good experience on trying to find skill sets within people that isn't their core skill set, if that



makes sense. So in a startup environment, many people have to do different things so it was a good way to find skill sets and match those up.

So during that year or two at HeartFlow, it was a matter of running the study and at the same time, we were looking into Japan. The reason why Japan was of interest was because their value of propositions make a lot more sense for what HeartFlow is doing. A, they utilize CT technology to assess heart disease, which is what HeartFlow is based on. Two, the physicians are salaried so there's not an incentive to do more diagnostic testing and put more sense in.

So the first few trips were assessing the market there. Pretty soon thereafter, we used a couple other sites as our clinical research sites. So I was able to both drive the clinical research process and see if there's potential business there. From that point, I was very lucky to pull in a few good resources and I think my biggest mentor there became Campbell Rogers, who came in and take over as chief medical officer. He had a lot of connections with physicians in Japan from his coronary days and was able to open a lot of doors that I was able to go back in and make connections with the top physicians to form advisory boards, work with local consultants to get us in front of their version of the FDA, which is called the PMDA, and their version of CMS, which is called MHLW.

So it was really having those initial meetings to prove out the value of propositions in the country, start the initial dialogues and get the process going. That eventually became the basis for what's now HeartFlow-Japan. Towards the end of my tenure, they actually hired a general manager based in Japan and now have a whole team that are building that market. They just did receive PMDA approval and reimbursement should be soon to follow. So I think, as far as the revenue source, Japan is going to be the biggest revenue stream for HeartFlow in the very near future.

Scott Nelson: Let's spring board into your time now at RenovoRx and before we jump right into the current time, are there a couple of experiences that you can think of at HeartFlow that you find yourself going back to that have been either key learning points or just things that you've been able to use now at RenovoRx?

Shaun Bagai: I think one of the things, which came true with Ardian and HeartFlow, is that more and more I think there are certain medical technologies that cross different specialties of medicine. I will rewind a little bit to talk about that. With Ardian, as much as the technology was to be used by Interventional radiologists and Interventional cardiologists, the patients were really controlled by the hypertension specialists and nephrologists.

So the sales aspect of the market entry aspect was two fold; how do you get the users and the physicians who like to use the technology to use it? But more importantly, how do you overcome the barriers of their opposition to the nephrologist and hypertension specialists? HeartFlow is the same thing; it was a matter of we have CT physicians and radiologist who want to maybe send patients for HeartFlow exams.



But the interventional cardiologists controlled the patients and they would rather put the patient on the table and do an intervention and/or an invasive diagnostic. RenovoRX is very simple. With RenovoRx, it's a matter of overcoming the barriers of the medical oncologists who deliver chemotherapy systemically and we're looking at more of a targeted approach. So I think the lessons learned from in fact both of those companies have really helped allow RenovoRxmake sure that you don't ignore specialties when there is disease state or a patient base that is really across specialties.

Scott Nelson: Yeah and that makes a lot of sense. Really understanding that patient pathway and who controls the patient or who influences the patient decision the most along that journey. I have to think with your experience in a field based sales capacity, I would imagine that probably comes naturally to you now.

Shaun Bagai: I think it does, but I think a lot of it is really paying attention, getting out in the field and talking to physicians to really make sure that the market is there. That is something that I think is one of the most gratifying parts of my job, is actually being front and center and that's something, being in a small company and being the CEO of a small company, I get to do is get out in the field, work with physicians, be in the operating room and really see. Exactly like you said, how does a patient pathway work? I think that definitely helps to be successful in different areas of medicine.

Scott Nelson: So let's talk a little bit more about RenovoRx. I know you gave us a high level overview, and you mentioned that you are currently enrolling patients right now in a U.S. trial, is that right?

Shaun Bagai: Correct. We have a post market registry study in the U.S. that's ongoing. Prior to that, we actually just finished a safety study in pancreatic cancer patients in the U.S. as well. So we're tracking patients right now to see how they do in a general population.

Scott Nelson: So when you were at HeartFlow, how did you end up getting to RenovoRx? Was it another story of your connections and your network that brought you here?

Shaun Bagai: Exactly. It seems like at that point, U.S. launch was not eminent given both the FDA and reimbursement. In fact, I still have several close friends there. I think I had a bet with who was going to get an FDA clearance first, HeartFlow or RenovoRx, and I think I won by a couple of weeks. So there are some headwinds in the U.S. HeartFlow-Japan was getting off the ground. The founder of RenovoRx, Dr. Ramtin Agah, from El Camino Hospital was coincidentally a customer of mine when I was with Medtronic many years ago.

One of the things that I've always tried to do is keep in touch with everybody that I can and so he approached me a while back about the fact that their CEO had stepped down for family reasons and they are looking for a replacement. To be honest, I thought I wasn't ready for a CEO role yet. I feel like I still had some more things to learn. Then months later, timing worked out where the previous potential CEO candidate dropped out of the race and they're



interviewing a few candidates and he said, "Look come meet the board, I think this is right for you given your experiences and backgrounds." He had me come interview with the board of directors, and the rest is history.

Scott Nelson: So where are you at now in terms of life cycle of the product? You've got regulatory approvals in Europe and in the U.S., you are enrolling patients in a post market registry, so do you envision commercializing this at some point in the near future?

Shaun Bagai: I do potentially. So maybe I'll rewind little bit. As far as the timing of when I came on board, we had just applied to the FDA — and this is one of the reasons I think why Dr. Agah thought this would be good for me and why I think for me is a good fit — is that they had just applied to the FDA. Design for manufacturing was done for the most part so we began manufacturing. The next stage of the company, or since I took over, we've got an FDA clearance, we've gotten our device patents issued, we've done our first in human in a few different disease states, and we finished our safety study in the pancreas.

The next phase of the company is to finish off a post market registry. The data is looking phenomenal where at least pancreatic cancer patients are living longer without side effects that they will see from systemic chemotherapy. As far as where this is going, that's always a double edged sword for every small device company is do you raise funding and hire a sales force, or is this actually a great tuck in for one of the larger companies? That's yet to be determined.

The great thing about the markets we're looking into is that they are a very concentrated group of hospitals that do these types of procedures. So one could attack the market with a small sales force, but I could definitely see this as a fit with a larger company down the road.

Scott Nelson: Makes ton of sense, especially as more and more large strategics start to get into the interventional oncology space. It seems like when you look at that, that IO space, there are a lot of large strategics that aren't in it. It seems that maybe they are sort of just on the cusp of maybe getting into it, so it makes sense from a MNA standpoint, but I also couldn't agree with you more in regards to rolling out a very targeted sales force to that select number of hospitals and IDN's that do these types of procedures.

I know you've raised a little bit of money, and for the last question before we get to these last three rapid fire questions, do you have plans to raise additional rounds of financing in the future?

Shaun Bagai: I think that is one thing that I have learned as a CEO is that CEOs are always fundraising. So I think this has been an interesting exercise for me. This is probably the least funded company I've worked with and being small and nimble and having very dedicated founders giving a lot of time with the company, we've been extremely capital efficient.



In the next few months we're trying to put together strategic plans for the next couple of years, but I could see a funding round potentially coming up. Right now, we're talking to strategics to see what other milestones would be necessary for some type of a partnership and try to lay those plans out. But I wouldn't be surprised if we're looking into funding in the not too distant future.

Scott Nelson: Very good. I think it would be fun to do a round two of this conversation. Anything else you want to share before we get to this last three rapid fire questions, Shaun?

Shaun Bagai: Especially now since we were involved with the Stanford Start X program incubator, given how many mentors have shaped my career, it's been fun giving back a little bit and mentoring younger entrepreneurs, and younger CEO's. If I could give a couple of piece of advice: one is always do what you say you're going to do. I find it very interesting how, as you go through especially different groups of medical device professions, sales marketing, business training, a lot of people promise things they don't' deliver on.

I think that's one thing I learned very early with my mentors is definitely deliver what your promises are, and keeping in touch with people has been invaluable. I think, Scott, given what you've done with your site, you probably seen that more often than not that people kind of fall off the radar. But keeping in touch with people, and I've connected with physicians across different companies and it's amazing. There are a couple of doctors in Germany that worked with a few different companies and just an email now and then — I'm not a big Facebook fan to be honest, but email or phone call, here and there definitely goes a long way to serve you in the future.

Scott Nelson: That's such good advice. You're right. I certainly experienced that, I wouldn't say I'm a master at that by any means, I certainly could do a lot better, but just a simple phone call, text message, you know, a short two sentence email, it does wonders for sure, Very good stuff.

So let's get this last three rapid fire questions. They are rapid fire in nature, you don't necessarily have to answer the questions in that sort of theme. Let's start with the first one, what's your favorite business book?

Shaun Bagai: You know, this has something that's come to me recently and it's proven invaluable for this job. It's a book called *The Hard Thing About Hard Things* by Ben Horowitz. It's been almost a bible about how to try to sleep better at night when you're trying to run a company, especially the first time being a CEO.

I think the advice in there and seeing running and building a company through someone else's eyes when you don't' have a lot of people to talk to about it who have a vested interest in different part of your business, can be very helpful.

Scott Nelson: That's a good one. Is there a CEO that you're following or one that has really inspired you in the past?



Shaun Bagai: Honestly I think I've mentioned two so far that have really been a big part of my career growth. I met Dr. Josh Makower and Andrew Cleeland at two very different stages of my career and both have definitely helped me out a lot on what I should be doing, and what I should be thinking about.

Scott Nelson: Very good. Last one, if you had a chance to rewind the clock, what would you tell your 25-year-old self?

Shaun Bagai: I think my career was taking off and I think the biggest thing looking back when I was 25 is maybe tell myself to be more humble. Certainly success comes with an arrogance that you might ignore missed queues that will definitely help your growth. If I could turn back the clock, that's probably the one piece of advice to give myself.

Scott Nelson: Great way to end in the conversation, because I think it's healthy advice for anyone. Shaun, thanks a ton for your willingness to do this conversation and for taking the time out of your day.

Shaun Bagai: Thank you a ton Scott, I appreciate it.

