

David Narrow of Sonavex

Speaker1: [00:00:04] This is the Investor Connect podcast program. I'm Hall Martin. I'm the host of the show in which we interview Angel Investors, venture capital, family offices, private equity, and many other investors for early stage and growth companies. I hope you enjoy this episode. Investor Connect is a 501 C three nonprofit dedicated to the education of investors and startups for fund raising. Please consider donating \$100 to the program to help others in their investor and entrepreneur journey. You can find the donate button on the Investor Connect org website.

Speaker2: [00:00:38] Hello, this is Hall Martin with Investor Connect. Today, I'm here with David Narrow , CEO at Sonavex, Sonavex is a venture backed clinical stage medtech company spun out from Johns Hopkins with two FDA clearances. The company's technology uses deep learning to improve AVF maturation times for patients with end stage renal disease. David, thank you for joining us.

Speaker3: [00:00:59] All. Great to be here. Thanks for the opportunity.

Speaker2: [00:01:01] So where does this podcast find you today?

Speaker3: [00:01:04] I am at the home office here in Baltimore, Maryland.

Speaker2: [00:01:07] Great. So tell us more about your background. What did you do before this?

Speaker3: [00:01:12] York. So I started my career as a biomedical engineer. I did my graduate work at Johns Hopkins, which is where I met a professor and surgeon who I co-created the technology for our business together with and ended up starting the company Sound of X together. Before we did start the company, I went up to Boston to do health care strategy consulting primarily for medtech clients, but also therapeutics, diagnostics and some digital health work as well. And then after a stint there, I realized that the technology we had worked on at Hopkins that had advanced far beyond my technical aptitude in the lab of my colleagues, got to a really exciting point, and there was a really compelling commercial opportunity as well

to really bring this to patients. So I came back to Baltimore, spun out the intellectual property, and we formed around that technology.

Speaker2: [00:02:00] Great. Let's talk about starting a business in the area of medtech itself. What do you find is the major opportunity there?

Speaker3: [00:02:07] I think the biggest opportunity is that there's a lot of purpose behind what you're doing. So with any early stage company and then a lot of work, there's a lot of challenging times and you're busy, you're stressed, there's a lot of things going on and it can feel overwhelming. But when you know that there's purpose at the end to really get this to patients and really help not only patients but also other stakeholders in a meaningful way at scale, it's really helpful, motivator and can get people who are involved in starting the company. Then also new employees who are joining the mission to get really excited about that and to really bond together. So I think that's a unique attribute of our space that has made things more impactful and brought our team closer together.

Speaker2: [00:02:50] And so what you find is the main challenge in starting a business in this space.

Speaker3: [00:02:54] I think with MedTech and I'd say the same is probably true with Therapeutics, you're generally looking at a pretty long path from when an idea is originally ideation to the point at which you're showing substantial revenue. And, you know, in the medical device space, you have your initial concepts, you have prototypes, you have to get that patented, you have to get the thing built, you have to get it manufactured. You have to get it tested. You have to show that in sometimes animals, in cadavers, in benchtop testing, in human testing, you have to go through regulatory hurdles. There are reimbursement hurdles. So there's a very long path of sort of validation and inflection points of value that you need to achieve and milestones in order to get to the point where you can really start growing the business in a traditional way of growing revenue. So really making sure that you understand and that your stakeholders understand that, look, this isn't a quick 18 month turnaround from creating an MVP to showing what the revenue looks like. And you really do have to plan for a longer road to get to the point where you really have shown all that value and then have been able to sort of build that foundation to then scale from there. But I think the exciting opportunity associated

with that is you're able to create a lot of objective value along the way before you get to the point where you're scaling up those revenues so that the industry sort of recognizes value for a certain parts of that path. And as long as you're aware of what that journey looks like, it's a really fun path to take.

Speaker2: [00:04:28] So what is the potential reward? For example, how much are companies selling for here in today's market?

Speaker3: [00:04:33] Yes. That's one attractive place about the dialysis market in the medical device arena and some of the things that are existing investors have been particularly excited about. So there have been three deals in this dialysis access space that we play in that have happened over the last few years. And they've ranged in exit values from \$225 million up to 1.1 billion. And those the stage of those companies have ranged from clinical stage companies that have no revenue to ones that have just gotten across the FDA 510 K milestone and then one that is taking the company to early commercial traction. So these are pretty exciting exit values for fairly early stage assets. So there's really a lot of interest in this market given the size of the population, the growth of the market, and the amount of money that the federal government spends caring for these patients and how much can really be saved and how much more efficiencies can be created by delivering better care to their price.

Speaker2: [00:05:31] Right. So what are the differences between you and your competitors?

Speaker3: [00:05:35] So our primary value proposition is to help get information that clinicians know they need without relying on the patient to have to travel long distances routinely to be able to enable experts to be able to collect this information. So what I mean by that is in this specific area, it's really important to understand whether the what's called AV fistula, which is a way to deliver dialysis for patients with end stage renal disease, whether that fistula is functional to be used for dialysis, there's a proven method to assess whether or not it's ready to be used, whether it needs an intervention or whether it needs to be replaced. But right now, in order to get that information, patients need to travel to a specialist. There are not many of these specialists. They're often very far away, and therefore the routine with which those patients are getting assessed is very infrequent. And these patients, they live pretty tough lives as well. So in the dialysis clinic, three times a week or 4 hours a day, many of them don't have

reliable access to transportation, spending your off day, so to speak, not getting dialysis, traveling for a couple of hours to get your extra appointment and wasting half or all of your extra day on your day off is a huge pain. So there are compliance issues. So what we do, the competitors aren't able to do is we meet the patient where they are. We enable and empower the people that work in these dialysis centers to collect proven, robust information to help deliver better care without requiring that patient to make that trip, which often doesn't even happen. So we're bridging a challenging workflow gap with technology with our solution.

Speaker2: [00:07:11] Great. So what advice would you give to someone entering into the MedTech space?

Speaker3: [00:07:16] I mean, I think the there are a number of things to consider. I think with any medtech company, you have to look at a number of things. First, you need to look at a clear unmet need. You need to be in a space where if you're able to deliver a solution in the space, it's exciting enough to change clinical practice. You need to be looking at a market that's large and ideally growing. Just given the amount of funding that goes into these businesses, there needs to be an exciting enough opportunity on the back end. Make it worth the investor's. While you need to really understand what the regulatory and reimbursement landscapes look like, to understand really what that budget and timeline is going to be, to go from creating your solution to getting it to a point that it can actually be used in practice. So I would for sure start off by getting a bunch of advisors who have been through this this journey before you to be able to give some insights there and folks that can open up their networks to be able to really get in touch with experts across product development, manufacturing, regulatory reimbursement, all of these critical components that clinical expertise, all these critical components of the business that all need to be really done in a robust manner in sync to be successful. Whereas the people that might be coming into the company might have an expertise in one or two of those areas. But in order for the business to be successful, you really need to have that breadth of expertise across all of those different domains.

Speaker2: [00:08:38] Great. So what online information source do you find most helpful in your work?

Speaker3: [00:08:43] So we've had just a ton of public information. The two resources that we've used most routinely are FDA guidance documents. So a lot of people don't realize that the FDA publishes a ton of very clear and comprehensive documents that are very dry, but they're very clear for a lot of different technology types about what is expected, what type of testing needs to be done, and how to prepare for a submission. So we've benefited from reviewing those documents and then showing that we have a clear understanding of what's necessary to advance our technologies. And then one of the things that seemed daunting when we started the company was quality management systems and the need how much to document, when to document it, how much effort to put into that. And then a group called Greenlight Guru that provides an electronic quality management system started publishing a ton of really great information on a blog that I started reading early on. It was totally free, and I'd recommend anybody starting a company who doesn't know a ton about quality management to just read their stuff. It really helps boil the stuff down into simple language that anybody can understand and really help prepare your business accordingly. So I recommend looking at both of those different resources. Great.

Speaker2: [00:10:01] If you could start a business tomorrow in this space, what would that business be?

Speaker3: [00:10:06] So we've we've had the opportunity to really understand the challenges associated with this end stage renal disease or dialysis patient population. And you start to really feel for the patients who have to go through the current standard of care in order to really stay alive. And while our technology right now we're able to improve a lot of the issues associated with dialysis and eliminate catheter dependency, which is a big driver of morbidity, mortality and cost, if we can just eliminate that entire problem of needing dialysis in the first place, that would just be such an instrumental thing that we could deliver to these patients. So with the appropriate resources, I think focusing on either an artificial kidney or some novel way to deliver dialysis that was less disruptive to a patient's life and would enable them to really live more of a normal lifestyle would be an area that I'd like to pursue.

Speaker2: [00:11:01] Great. What's one thing your business did that you didn't expect?

Speaker3: [00:11:05] One thing that our business did that I didn't expect is I think we got early on the first regulatory clearance milestone. We got to very efficiently. We were very fortunate that, like I mentioned before, we were able to find some experts early on that were able to give a lot of time to us and really mentor. Some of our plans and connect us with experts to make sure that we were using resources efficiently and were able to get to some of those early milestones. So some traction, I think that was really helpful to be able to show some results early on. And I think one of the things that was really impactful is that we were able to also get some phenomenal early hires onto the team. And when we first started the company, we always knew that you need to have a great team, but I don't think we verbally understood. How much of an impact having phenomenal early employees would be to solving problems quickly and efficiently? And, you know, it's hard to identify and retain great talent, but if you do that right, it's just a phenomenal positive impact in your business. And it makes putting in long hours a lot more fun when you're working with smart, hardworking people that care a lot. So across our core team and our advisory team and our board are able to get some really incredible folks around the table. And that has just made this process really enjoyable. And we've all been able to learn from each other, and we've been really appreciative of that.

Speaker2: [00:12:35] Right. Well, in the last minutes that we have here, what else should we cover that we haven't?

Speaker3: [00:12:39] One. One thing unique to businesses in Maryland in the health care domain is that there is a program from the state that provides a 33% cash back incentive to investors to support biotechnology and medical device companies in our region. So folks that are interested should look at the program online from the Maryland Department of Commerce. And if there are attractive companies you're looking into in the state, provides a really nice boost to investors to allocate some capital into our region.

Speaker2: [00:13:14] That's great. So how best for listeners to get back in touch with you?

Speaker3: [00:13:18] Best is probably email or LinkedIn. So my email address is first initial last name De Niro at suning.com. And then my LinkedIn. You can just search for David Nero on LinkedIn and shoot me a message.

Speaker2: [00:13:30] Great. We'll include those in the show notes. I want to thank you for joining us today and I'll be back for a follow up soon.

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