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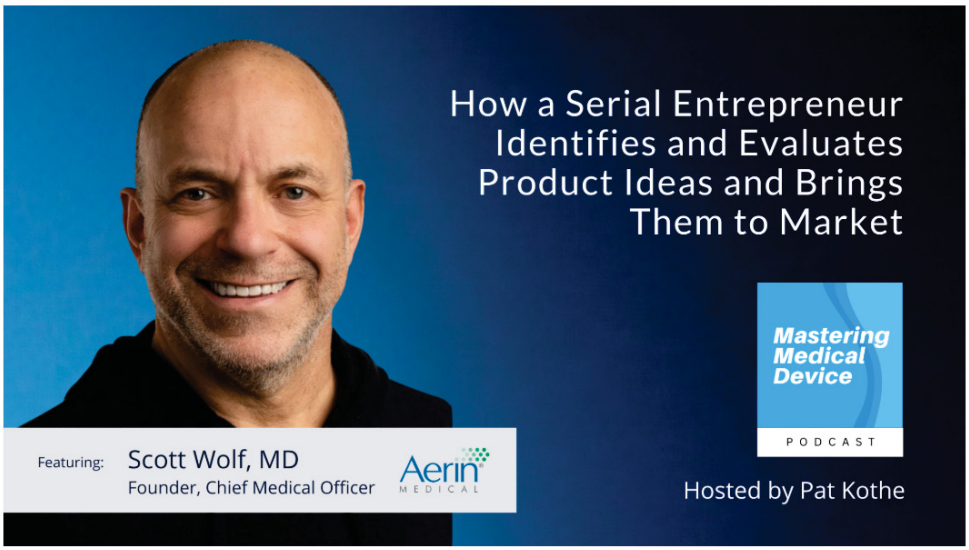
How a Serial Entrepreneur Identifies and Evaluates Product Ideas and Brings Them to Market



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Scott Wolf, MD is the Founder & Chief Medical Officer of Aerin Medical, where they are providing products to bring relief from nasal airway obstruction and chronic rhinitis. Scott is a prolific medical device entrepreneur across a broad range of therapeutic areas, and has also been a venture capitalist. In this episode we discuss how he identifies ideas, what criteria he uses to select ideas to work on, how VC's evaluate opportunities, what entrepreneurs should know before they meet with investors, the problems Aerin is addressing, and how they are serving the ENT community.

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Episode Transcript

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Our guest today is Scott Wolf, founder, and Chief Medical Officer of Aerin medical where they're providing products to bring relief from nasal airway obstruction and chronic rhinitis. Scott is an MD and he's also a prolific medical device entrepreneur across a broad range of therapeutic areas. Prior to founding Aerin Medical, Scott founded Zeltiq, Aesthetics to maker of CoolSculpting, the leading non-invasive method, method of fat reduction for body sculpting. Scott's other startups include EndoGastric Solutions and Cardiac Dimensions. Scott was previously a partner at Prospect Venture Partners. And a vice-president at Frazier Healthcare Ventures, both

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[00:00:00] **Pat Kothe:** Welcome! Serial entrepreneurs are a rare breed. What drives someone to chase after a dream when the numbers show there are many more failures than there are wins. Stepping out on a ledge with no net below is not for everyone. And for those of us that have done it. You better learn fast.

Our guest today is Scott Wolf, founder, and Chief Medical Officer of Aerin medical where they're providing products to bring relief from nasal airway obstruction and chronic rhinitis. Scott is an MD and he's also a prolific medical device entrepreneur across a broad range of therapeutic areas. Prior to founding Aerin Medical, Scott founded Zeltiq, Aesthetics to maker of CoolSculpting, the leading non-invasive method, method of fat reduction for body sculpting. Scott's other startups include EndoGastric Solutions and Cardiac Dimensions. Scott was previously a partner at Prospect Venture Partners. And a vice-president at Frazier Healthcare Ventures, both leading life science venture capital firms. In this episode, we discuss how he identify ideas, what criteria he uses to select ideas to work on, how VCs evaluate opportunities what entrepreneurs should know before they meet with investors, the problems Aerin is addressing and how they're serving the ENT community. Here's our conversation.

Scott, you've had an interesting career journey. You're a physician, an entrepreneur, and you've also been a venture capitalist. So after starting your career, you quickly pivoted to startup world. Can you tell us a little bit about that transition and moving from practicing medicine into this unique space that we're in?

[00:02:31] **Scott Wolf:** Sure. Yeah, there's a handful of people out there like me, you know, um, uh, doctors who, who've gotten into either the, uh, investment world in medical devices or the, or the, uh, the startup world of medical devices. But, um, When I was in, uh, medical school, I started to think, you know, to practice medicine effectively, you really can't use your imagination. You can't, innovate as you're going along. There's a way to treat diseases that's accepted and, that, it didn't really fit my personality. I like to think of new ideas and, was always interested in science and science fiction.

So I started to look around, you know, and. See, maybe if there were other people, like me who had this thought and there was actually a doctor in New York, who was,

forming, um, biotech companies. And so I, I reached out to him and after my internship, he gave me a job. So that was my start.

This was, uh, before, before the internet. So he gave me a, a phone book and a desk and told me to find some cool technologies that we could start companies on. So I was there for a couple of years, got to see, what that world was like, and then, heard about some, folks who were, it was a, venture firm at the time called Vanguard Venture Partners who were doing, who were creating a, a medical device incubator with Medtronic. And so I, begged them to let me run it. And, they did. So I moved out to Minneapolis for a few years and, did that with Medtronic and got to, see the, home base of medical devices and, how big companies did things and, and got my first taste of the startup world and, really just, kept going from there. And I really enjoyed the startup process and, the thinking about new ideas and, thinking about unmet needs in medicine.

So really, it really put a lot of my interests, together and along the way I had the idea I wanted to be a venture capitalist cause that is, quite a glamorous job. So after forming some more companies. I, I hooked up with a venture capital firm in Seattle. I actually approached them about a startup.

I had the idea that, you could non invasively reduce fat in the body, right? And if you could do that, that would be a great thing, that you don't have to do a lot of market research to know that people want to have fat removed from their bodies. And The bar is a pretty low hanging bar in terms of, getting, if you could do even a little bit, it would be a very successful product.

Then they said, okay, come on board and, we'll fund you to build that company. And, and that's what I did. That's where I found some inventors. At Mass General, really smart guys who had invented CoolSculpting. And so I licensed CoolSculpting and, and then formed Zeltiq with this venture capital firm, Fraser Healthcare Ventures.

And, they were, very supportive of, of that company. And then,and then moved on to another venture capital firm, but really realized that I didn't really want to invest in other people's companies. I like the actual process of creating something from nothing, creating, building, something from an idea on paper to, To a product, this act of creation was meaningful to me.

So that's when I went back and formed Aerin Medical.

[00:05:53] **Pat Kothe:** Many of us, um, learn and pivot based on new things that happen to us. Looking back on, on your transition, you go into medical school, you spend all that time, you prepare for it, you get in, and then you say, geez, this is not for me. Was your personality always... like it is today or was there something that

happened in medical school that says, I need to move out of what I'm doing I mean Did you fool yourself into saying medicine was gonna be good for me if you were you always an entrepreneur? Or did something

[00:06:28] **Scott Wolf:** This is a, I was always an entrepreneur, but this was a cultural thing. My father, didn't go to college. My parents, neither parent went to college and they said their kids were going to get educated and become professionals. And so I was tapped. My older brother was supposed to be the doctor, but he didn't, he hated the sight of blood. He'd faint at blood. And so then they said, okay, well, you know, Scott will be the doctor. So I was tapped. as a kid that I would go to medical school and in, certain cultures, you don't really, you know, like, I'm sure, I'm sure this resonates with a lot of people, who are hearing this because, I didn't question it.

I just said, Oh yeah, I'm going to medical school. That was it. I can do it it, and it would provide me the kind of life that my parents weren't able to have, so it seemed a great thing to do as an honor, to get into medical school and be the first one to do it.

But yeah, then I got there and it wasn't, it didn't fit my personality. It was eyeopening though, When I had this realization, oh wow, I actually don't have to practice medicine. I can use this medical degree. I felt like a weight had been lifted off my shoulders.

You know, I, it worked out for the best. but yeah, it took a lot of realization.

[00:07:41] **Pat Kothe:** Yeah, we have to make our own paths. Uh, my, my older brother, uh, my, my parents had, had, uh, dubbed him. He was going to be the priest. Um,

[00:07:52] **Scott Wolf:** Right.

[00:07:52] **Pat Kothe:** that, that never happened. they wanted me to go to the Air Force Academy and, I did a little bit of, applying there and then finally said, you know what, that doesn't fit my personality, so we made those decisions a little bit earlier, uh, but as you said, I mean, sometimes you've, you, you've got a great opportunity ahead of you and at, at some point in time you figure out this isn't

[00:08:15] **Scott Wolf:** Yeah.

[00:08:16] **Pat Kothe:** But obviously entrepreneurship and building things is what turns you on.

[00:08:22] **Scott Wolf:** Yeah. Yeah. It's what, you know, I'm, I'm one of those people who, want to be, um, think I'm doing something meaningful and important and if I can feel that I can, you know, I can really give my all to it and, um, and that's how I feel when I'm building a medical device company. Creating a new, a new treatment for people who are suffering from a disease condition, Yeah, I find it to be quite fulfilling in a lot of ways and, fun to boot, it's really fun I think when something that you, conceive of, it comes to fruition, and that you be able to really help people through that. To me, that's just a, it's a fun feeling yeah. I think of artists who create, works of art and, musicians who, you know, just this active creation to me is, is really something that, that, that drives me.

[00:09:16] **Pat Kothe:** So speaking of creation, you've created or founded a few different startups. how many startups is it now?

[00:09:24] **Scott Wolf:** I have been either, founder or co founder of, um. six, and so, uh, and some have been, you know, I've had the full range of medical device, experiences and founding companies. So some have not worked, for various reasons, either funding, we couldn't get funding. one failed in late clinical trials, which is just, like a really tough lesson to learn.

You don't want that to happen. to happen. You want to ring out, all the risk,as early as possible, ring out risk. it's going to work, if you can get to that point. And then, companies like I'm, I'm at now Aerin Medical, which, uh, you know, is, uh, we have, two FDA approved products, on the market and everything is doing very, well we're growing fast.

So it's, it's, it's, you know, so there's, I've, I've seen the full gamut, the, uh, you know, pain of, of things not working out and, and the fun of, of having them.

[00:10:20] **Pat Kothe:** For those that say they've never failed in a startup, it's really a question. Uh, the comment is, is

[00:10:28] **Scott Wolf:** yet. yeah,

[00:10:29] **Pat Kothe:** because you will, you will for a variety of reasons. I've had it happen. It's as you said, it is not fun. It is pain associated with it. So let's talk a little bit about, you know, six, six startups that you've founded.

I want to talk about finding ideas and how you find ideas, where ideas come from. Because I'm sure you founded six, six companies, but there's a lot more than six ideas that you've run down. So what are you looking for when you are looking for ideas? How do you find them?

[00:11:04] **Scott Wolf:** So that's a, it's a big question. My main guiding principle is the idea has to, um, be worth the effort. At the end of the day, this has to be a big idea. This has to be something that can change the way medicine is practiced, that can make things, easier and more effective for the patient.

And it has to be something in a very large market, because the effort and money... required to bring something from an idea to fruition in medical devices is measured in hundreds of millions of dollars. This is a very, expensive, thing to do, and it's very difficult to raise money along the way, so it has to be, it has to be an idea that, at the end of the day can generate hundreds of millions of dollars in revenue, for a company, so that's, unfortunately, my, number one, rule, the other, the other,

[00:12:02] **Pat Kothe:** Let's pause there for a second because, um, that is.definitely, an opinion that's out there that, you know, pick, pick a huge unmet need to go after, uh, because it does, does take, but, but medicine is also, and devices are also incrementally improved. So If you don't incrementally improve on those devices, there's missed opportunity as well.

How do you balance that between looking at opportunities that are incremental and large markets versus that huge opportunity?

[00:12:40] **Scott Wolf:** I think it's the, the role of the large companies and the established companies to incrementally improve things. And it's just, there's not, um. Um, you know, again, you can have, you can have devices in large markets, let's say AFib, for instance, that's, an incredibly large market with, unending need and, so if you have a device that is incrementally better and have patent protection for it, and, um, you know, have a path to market, that is something that could probably support, a startup company.

But for most startup companies, you really, you just need, there's so many things, so many check boxes that you have to have patent protection, right? So an incremental improvement, is less likely to have a good patent portfolio. And if you don't have a good patent portfolio, you're not going to be able to get the financing.

The general rule, I think, still stands, that it has to, it has to, it doesn't have to be alone in its field of attacking this, this very large market, but it has to be a new idea

[00:13:47] **Pat Kothe:** So a couple of things here, one is, you, obviously nothing happens without money. There's a couple of different sources, main sources of money in our space. One's angel money, one's VC money, and sometimes this incremental stuff can be done with angel money and not VC money, and VC money may have different criteria of investing than angel money does.

So I think that, that may be kind of one of those other things. But the other thing I wanted to ask you about is when you say big market, large opportunity, what's big for you? Is it a hundred million, 500 million, a billion, 5 billion? What's a big market?

[00:14:27] **Scott Wolf:** I think, 500 million on up and the ability to generate, to have your product, generate over a hundred million dollars in revenue, every year and is, is, the, yeah, that, that's how I would define it. If you have ideas that, that, are going to generate less revenue, let's say one day, that doesn't mean you don't, you can't start a company on it, or that can't be developed, it's just different from what I do, cause I really only know one way of, of doing things, you know, so I go the route of, um, of, of trying to find one of these very large markets, getting angel financing, the angel financing, then we'll lead in later rounds, after you've run out some risk to, to venture capital financing and, so that's how you continue to keep funding these companies.

[00:15:24] **Pat Kothe:** So your first, screening criteria is market opportunity. What other things are you, What other things are you looking to evaluate, whether it's worth your time to, to, devote

[00:15:35] **Scott Wolf:** Um, so, that there is a path to FDA approval that's reasonable. I think, the FDA does a good job of protecting us, from dangerous medicines, medical devices, but as medical device developers, we have to have a path, through that. So, if the FDA is going to require a thousand patient clinical trial, that's usually not workable for a startup company. So you look at FDA path, you look at path to reimbursement. Getting reimbursement is, just the fact that we need in medical devices, we need, CPT codes, for physicians to get paid for what they do. So, uh, we need either an existing, the best is having an existing code and next is the ability to get, a good new code.

As you're going through your criteria then on, on the FDA side, our PMA devices in or out, uh, for you, um, and as, uh, our new reimbursement codes, does that mean it's, acceptance or non acceptance, uh, criteria?

Um, I'll do both. For instance, Aerin Medical, we, recently, got, new CPT codes for both of our products. So it's an overarching, question of can I fund this, can I keep this company funded, so what are venture capitalists, looking for also, so I'm not averse to PMA products, but I, yeah, I haven't done one in quite a while. I have been sticking with, 510ks. but we're, but in a lot of ways, the PMA process, isn't that much, different than a 510k with clinicals. But yeah, I've been, I've been sticking with 510ks just because it's, just a little bit safer, easier route.

[00:17:23] **Pat Kothe:** Other things like, patent protection, like competitive landscape, like, uh, opportunities, buying, companies buying, the

[00:17:32] **Scott Wolf:** Yeah, no, all those things. You've probably named the next three. So patent protection, you have to be able to, have a, not only freedom to operate, but the ability to prevent other people from, from fast following you. It's nice to have natural acquirers in the field, Fields like AFib, I mentioned, you know, there's lots of acquirers very interested in the next thing. That's always nice because it gives you this dual path. You don't have to rely on, an IPO eventually. You can have a dual path either acquired or go IPO eventually. Yeah, and then you look obviously at competition. What's out there right now and how well does it, how big a medical need is this?

[00:18:12] **Pat Kothe:** is it, something that, that your idea is going to be that much better than the competition. And one of the overarching things that you talk about is it fundable? Um, it's, it's, it's interesting to me. It passes my criteria for something that I want to get involved with. And I think I can get it funded.

That's that. Yeah. Because, and I think it's also because I've been through, you know, like the funding process is painful, there's nothing fun about it and if you like, unless you like to be told no a hundred times in a row, and told, it's just, And your baby's

[00:18:51] **Scott Wolf:** Your baby's ugly. So that's really what this funding process is. Now, you only have to, you have to keep reminding yourself, you only have to be told yes once or twice, and then things, then you keep, going on. but when you've been through companies that can't get funded, then that is, it's really painful and you don't want to, go through that again. That's always in the back of my mind.

Friend of mine Dan Hawkins talks about, you know, founding Shockwave and, and, um, with, uh, with John Adams, uh, uh, and, uh, he couldn't get funded. And so he said. Okay, we'll stop trying for a little while and then, either the world changed or his story changed or something changed and then he got financed, so there's a lot about the cycles of, of, of financing.

Sometimes it's just not, there's no funding available, through no fault of anybody's really.

[00:19:49] **Pat Kothe:** We didn't talk about team and that's one of the things I'm sure, when you're on the other side of the table, that's one of the main things, but when you're evaluating an idea, how do you put team in there too? Is that some, is that a risk that you're, you're weighing as an entrepreneur or are you assuming that you can, develop that team?

[00:20:08] **Scott Wolf:** That's why I live in the Bay Area is because I'm assuming,I can develop that team here. The team for, for Aerin startup was me and then, um. Andrew Fraser, who's our, our VP of engineering now, and he joined, he's just a, uh, a true engineer who can, uh, you know, if I have, I have an idea, he can build a prototype in a couple of days, hand it back to me and we can go to the animal lab.

To me, that's the perfect team. I never have any idea or I haven't come across any ideas that require You know quantum physics yet. So I think I we can build a team around here.

[00:20:47] **Pat Kothe:** So what, what we've kind of discussed is, uh, two people have been through the startup thing and learned a lot of tough lessons along the way. Uh, and have, have come to, you know, talk a little bit in, in short, you know, short, shortcuts of things that we've learned. Uh, six startups. Didn't all go well. You learned all of these lessons along the way, and in between those six startups, you were moving in and out of the venture community.

So let's put your venture hat on for a second. What does the process look like from a VC standpoint?

[00:21:24] **Scott Wolf:** So first of all, they are looking for a very large return on their investment, and because they have a portfolio of companies. They know some are gonna work and some aren't, that they the ones that do work they want to be able to get a lot, you know a big return and they're not talking about like 20 percent a year they're talking about that we want ten times our money back. That, that kind of, um, shapes the entire, viewpoint of a venture capitalist for, the way their business works, they, need to get these very large returns.

So

[00:22:03] **Pat Kothe:** they need to, and they need to get it in a certain time frame for the life of the

[00:22:07] **Scott Wolf:** exactly. It has to be in a certain timeframe and depending on where they are in the life cycle of the fund, they're looking for different things. So they might be towards the tail. Let's say the last investment of the fund, they don't want to invest in something that's going to take 10 years.

They want something that's nearer term. so there, there's a lot. You know, that goes into their thinking that relates to how, uh, just how a venture capital fund. it works, but that the first thing is yeah, timeframes and, and return, colors a lot of it.

So it's difficult. And also the size of the funds. So if you have, let's say a $50 million fund, that fund can make million dollar investments, and, and get, let's say they, they can get, a few million dollars into a company over the life time of that investment. That's okay for a 50 million fund, but a 5 billion fund, it, has to be able to invest, a very large amount of money into, into any company, cause they, they can't just have a thousand companies in their portfolio.

[00:23:13] **Pat Kothe:** They're on the boards of these companies. So it's harder for, for really large funds to invest in early stage medical devices, because the investments are smaller, the timeframes are longer, That I guess is, is most of the thinking is around most of those investment portfolio management you know, thoughts. And then weighing the criteria. We went through from an, from an entrepreneur's standpoint, what you're looking for. From a VC standpoint, are they looking for the same things, but in a different order?

[00:23:47] **Scott Wolf:** yeah, I would say so. I'd say they're looking at exactly the same things. and, for instance, patent, they, there's some risks that they, are, they're not willing to take, so they just have, they're not willing to take any intellectual property risk. No market risk. They want these large markets where, you know that if you can develop this product, you It will have a large market and it will, generate a lot of sales.

They're willing to take some technical risk. Okay. Will this technology work? Can this team develop this technology? Those are the kinds of risks that they are very good at, evaluating. Yeah, they'll put a lot of effort into, looking at market and talking to physicians and really trying to, see, see if there's a market there and if, if, if there is then looking at the technology and evaluating whether it's actually gonna, you know, that's, that's the bet they're taking that this technology and this team can develop this.

[00:24:49] **Pat Kothe:** Yeah. A common saying within the industry, and it's common, you know, is, you know, you bet on, bet on the jockey, not on the horse. Is that true?

[00:24:58] **Scott Wolf:** there's not a lot of uh, I've found not a lot of cronyism, you know in venture capital that it's You know pretty hard dollars and cents and technology kind of decision making at least that's been my experience.

[00:25:14] **Pat Kothe:** It's a lot easier to take the meeting to when you've got an experienced entrepreneur. It's a lot easier to get into the conversation, but when it all boils down to it, all of those other criteria that we looked at still have to be met.

[00:25:25] **Scott Wolf:** Yeah, that's right. Especially medical device might be different in other, you know, in health tech or, in health care services. I don't know. But in, yeah, in devices, I don't think, people are, yeah, making more risky decisions on technology or on patents, because it's their favorite CEO.

[00:25:45] **Pat Kothe:** You've been on both sides, uh, of the table when you're making presentations and I'm sure you learned some things early on what to say, what not to say, and then when you're on the VC side, what do entrepreneurs not know that they're doing incorrectly when they're, in a meeting with, with a

[00:26:04] **Scott Wolf:** That's a good question. Um, I actually, I talk to young entrepreneurs about this. I tell them you are the expert, you are going in to share your expertise about this, with these, potential investors. So be confident, be, sure of your answers. if you don't know something, you'll say why you don't know if it's something that you should know and how you're going to find out and how, you're going to, answer that question, but the confidence, is, I think lacking a lot of, first time entrepreneurs. cause yeah, it's can be very intimidating.

There's a lot riding on the outcome. The other is, uh, yeah, know what questions are going to be asked in advance. So you should vet this. do your presentation multiple times, with other people see what questions come up, do it as many times as you can, because the questions are usually the same, between potential investors.

So you shouldn't be surprised by any questions that are being asked and, you should have a plan, a real plan for getting this. Product developed, but also getting, through the FDA, getting reimbursement,and sales marketing, and this should be a real plan. It, it doesn't have to be a fully baked business plan with numbers attached, five years out, but you have to know the life cycle of, of this product.

[00:27:35] **Pat Kothe:** think one of the other things that I've learned through the process too is doing your homework on the person that's across the table from you. you need to know, as we said, you need to know where they are in their fund. Uh, where you are, uh, what other investments they've made, in the space, are they, typically investing in the type of round that you're, that you're in?

Are they a seed investor? Are they a B investor? You know, kind of where, where, you know, what's their sweet spot for it? That's basically sales 101 is you need to understand the other side's motivations before you start

[00:28:08] **Scott Wolf:** That's right. Yeah. Yeah, exactly. Um, yeah. And then, um, uh, you know, and have, your experts ready to answer their questions. Your scientific advisors or medical advisory board, ready to, um, because you've obviously vetted

your idea with these, So You know, experts and they should be willing to talk to, the investors for you to tell them, why they think it's a good idea.

[00:28:38] **Pat Kothe:** Just some great information in the last 30 minutes we put together. A lot of, a lot of hard, hard learned facts

[00:28:48] **Scott Wolf:** Hard, hard learned. Yeah. You know, again, it, they are, yeah, all hard learned, you know, because I had, you know, when I first started I made, you know, yeah, I, I've made, uh, I've made most of the mistakes that the, uh, that new entrepreneurs are going to make.

[00:29:05] **Pat Kothe:** I think that kind of going back to if you're going to spend the next 5, 8, 10 years with an idea, you better know what makes it successful. what makes a successful idea? And you just laid out all of the different criteria. And basically what you're trying to do is mitigate the risks associated with it, with this idea.

Make sure that there's a great opportunity at the tail end of this thing. And as you said, it's also keeping an eye on, is it fundable? can I, can I put the fuel in there to make this happen? Is, because funding is a significant risk, one of the most significant risks that a startup has

[00:29:48] **Scott Wolf:** Yeah, no, it's very, I, and I, at one point I, I got funding from, the government of Singapore, cause they were looking to. experience entrepreneurs, maybe, employ people there and teach people how to build companies. And so they gave me a significant amount of funding and I went out to Singapore quite a bit too.

So you have to explore other avenues. Just do whatever you can to to keep the company going, certain times because, you, yeah, you, so again, you have to really believe in,that the company will have an outcome like Aerin Medical is having, right now that you're able to actually, really positively change the practice of medicine.

[00:30:28] **Pat Kothe:** Well, let's talk about Aerin. Really a fascinating, technology, being applied into, a problem area. So tell us about what the problem is that Aerin is solving.

[00:30:40] **Scott Wolf:** Yeah. So we're developing non invasive solutions, office. friendly treatments, for a host of chronic, nasal airway conditions. And so our first two products are solving, nasal airway obstruction. So just having this feeling or not being able to get enough air through your nose. So that's our first product, VivAer.

Our second product is, RhinAer, which treats chronic rhinitis. So, uh, a chronically runny nose, post nasal drip, just overactive mucus production in your nose that affects, millions of people in, in. it's a very common condition, especially as people age.

[00:31:23] **Pat Kothe:** What is the, you know, kind of go a little bit further into the problem. What happens when somebody has an obstructed nasal passage? what's the, what's that person's life like? How is it,

[00:31:35] **Scott Wolf:** yeah, the patient journey, you know, we call it. And, and, but that, that is actually the question I asked when I first got into, into this, so I was attracted to ENT because, there are physicians that do procedures, in the O. R., they see patients in the office, they can do, you know, and they can do office procedures.

I thought it was ripe for maybe moving some of the things that they did in the O. R. to the office or providing them new things to do, to in the O. R. So I actually looked in the beginning,I went to ENTs and I said, what do your patients complain about, you know, what, and, uh, so nasal obstructionwas number one, and I started to look into what the actual problem was, so if you think of it, In physics terms, the problem is, you know, not getting enough air into into your nose.

So where is the resistance coming from? And I discovered this thing I never heard of called the nasal valve. So it's the area of greatest resistance in your entire nasal airway, and it's, it's really what breathe right strips work on. So those nasal strips that pull the sides of your nose open, that's pulling open this nasal valve area.

It's where like 60 percent of nasal resistance, and just about everybody breathes better if you put on a nasal strip or you pull the sides, of your nose open. So that got me thinking, okay, would everybody then benefit if we could just enlarge that area a little bit? using radiofrequency energy.

That's where this idea came from. We spent a lot of time looking, can you safely treat, you know, use radiofrequency in this area? And you can't, because traditional radiofrequency is really ablative. So we had to develop a way that you could apply um, radiofrequency to shape and open the nasal airway without, really, damaging the, mucosa where you would have a mucosal ulcers or even perforation. So we had to develop a very safe way of, of applying radiofrequency to the, to the mucosa in the nose and that we developed a temperature controlled radiofrequency, um, to, to do it.

[00:33:51] **Pat Kothe:** Scott, one of the... Other issues, I don't know if this is, um, what, how you're applying the technology to is, with, people with apnea, sleep apnea, people who snore, is this something that can, that helps solve those issues as well?

[00:34:08] **Scott Wolf:** I'll take snoring first because we can definitely help a certain population who snores. If you have a nasal airway obstruction, you can snore just from that because you produce, when you breathe in, you produce too much negative, pressure and it causes your palate to to vibrate. And if you open up the nose in a lot of those patients, that snoring will stop. Our studies have shown that people report less snoring after our procedure who snored before. And we have a lot of, really good, uh, data on, improving sleep.

People feel more refreshed when they wake up. It's definitely something that can help, with, sleep disordered breathing. When you talk about sleep apnea, that is, a lot of patients with sleep apnea also have problems with, their tongue. falling back and, it's a multifactorial problem.

So we would never really say that we can treat, sleep apnea, but we can definitely help, some patients with, with snoring and other sleep disorder problems.

[00:35:10] **Pat Kothe:** So from a, a, a, a patient, you know, kind of going back to patient standpoint, they're having difficulty breathing out of one or both nostrils and you open this up. Is there a medical issue that you're solving other than uncomfortable feeling in the patient?

[00:35:28] **Scott Wolf:** Sleep is, is probably the biggest one.Sleep and well being, so it just people are much happier and, feel better when they breathe through their nose.

So those patients, you know, if they go to see their ENT, the ENT will do what's called a caudal maneuver, which is basically opening up this nasal valve area that we talked about. If they can breathe better after having the Caudal maneuver, the VivAer procedure in the office is likely to help they, that those patients don't necessarily have to go to surgery anymore.

That's what we were trying to, um. You know, is, is provide patients who, either aren't surgical candidates or don't want to have surgery, another option, for, for getting better nose breathing.

[00:36:12] **Pat Kothe:** As a father of a, of a woman who had a deviated septum and had surgery and it did not work properly, she's still having problems to, breathing,as an adult. Uh, I think this is an interesting

[00:36:29] **Scott Wolf:** Well, one reason that, that, you know, deviated septum surgeries might not work is because there could be a nasal valve problem. on top of that. And so that is something she might want to check with her ENT about.

[00:36:41] **Pat Kothe:** Yeah. So, uh, you mentioned. Reimbursement. Is this the product that you're, just recently got some positive news on reimbursement?

[00:36:52] **Scott Wolf:** Both of them. So, so, um, so VivAer for nasal obstruction, that code went into effect at the beginning of this year. So that's being, covered by, Medicare and Medicaid and then private insurers are making their own decisions about it. And then our, our RhinAer code goes into effect at the beginning of 2024.

[00:37:12] **Scott Wolf:** Let's talk about RhinAer for a little bit and what problem that's solving.

yeah, so RhinAer solves the problem of,too much mucus, produced in the nose, so chronic rhinitis and these patients are, can have just either just clear fluid dripping from their nose, so you'll, people walk around holding a tissue all the time and sniffling, and it can also be allergic rhinitis, which is associated with, congestion and itching and, and sneezing and both can be associated with post nasal drip.

Millions of people have this, but there's really been nothing to treat it, other than the medication and medication, a lot of people don't either don't respond or, don't tolerate it well, or just don't want to be on medication for the rest of their lives.

What our device does, what RhinAer does, is it goes in and, um, ablates the nerves that control mucus production, and they happen to be in an area of the nose that we can reach with the RhinAer device, and we apply, radio frequency energy over the area of the nerves in multiple areas.

We have a very high success rate in our randomized control trial. So it's been very exciting. And while doing RhinAer, we can also use that same technology to reduce the size of enlarged turbinates and reduce the size of, uh, nasal swell bodies, which are another thing that can cause congestion. So we can also reduce congestion along with reducing the, overproduction of mucus.

[00:38:43] **Pat Kothe:** So you've got two problems. Both patients come to the ENT to get diagnosed and they can get it done at the time, or in the physician's office. And it's, how long is the procedure? Less,

[00:39:00] **Scott Wolf:** It's,

[00:39:00] **Pat Kothe:** than half hour?

[00:39:01] **Scott Wolf:** yeah, it's less than half, less than a half hour, I would say, average of, 20 minutes of actual procedure time. We do, we provide topical anesthetic, topical and some injected anesthetic. So that, that needs to take into

account. So you're, in and out of, the office, much less than an hour, but the actual procedure is about 20 minutes.

[00:39:21] **Pat Kothe:** Tell me about the training, that a physician would need to have for this product or

[00:39:27] **Scott Wolf:** Yeah, no, it's actually pretty great. For VivAer, you really don't, you don't even need to use an endoscope. Everything you're treating is, in the, front of the nose. So, uh, they're, They're really up and running, after seeing a video and, we're, we'll be there with them in the first cases, but it's a very, it's a very short learning curve.

It's working on areas that the ENT physician is very familiar with accessing and, working on in other procedures.

[00:39:58] **Pat Kothe:** As far as the product itself, I'm assuming that there's a power source and then there's wands of some sort as

[00:40:04] **Scott Wolf:** That's right, we have a generator, and then we plug in, uh, two different handpieces and the generator will read the handpiece and, know which procedure, to, to provide.

[00:40:14] **Pat Kothe:** As far as business model, are you selling these devices leasing the power? how do, how? How's this bus, the business model

[00:40:22] **Scott Wolf:** We're selling the, the disposable hand pieces and, and then, giving away a generator with a purchase of a box of handpieces. And then the generator can stay in their office.

[00:40:34] **Pat Kothe:** Is this something that is a new, service? A new, revenue generator, so to speak, for the physician?

[00:40:42] **Scott Wolf:** It definitely is. Yeah, it definitely is. And, it is something they can, incorporate easily in their practice. The generator, needs a very small place to sit, you know, a countertop and, and it's very small footprint. The prevalence of, nasal airway obstruction is about 30 percent in the U. S. And of the patients that. actually, walk into the ENT's office, it's a lot higher, even if they're coming in for something else. So this allows them to offer, a pretty, low, no doubt time way in the office of treating those patients that they wouldn't normally be able to offer anything to.

[00:41:22] **Pat Kothe:** Up until just recently when you received your reimbursement, was this an out of pocket cost for patients?

[00:41:30] **Scott Wolf:** It was, yes. It was out of pocket for,treating the lateral wall of the nose, but there were some codes available for other, uses of the device.

[00:41:41] **Pat Kothe:** So the regulatory pathway for these devices were 510ks?

That's right. 510(k)s,. Yes With or without clinical data?

[00:41:49] **Scott Wolf:** with our clinical data

[00:41:49] **Pat Kothe:** With clinicals.

[00:41:51] **Scott Wolf:** into the FDA, we did a, a meeting with them and told them what we plan to do So worked it out in advance. what clinical data we'd be providing with them.

So sometimes when we do our clinical studies for regulatory, it's a more of a finite group of patients, but when we take it out into the marketplace, we need additional data. was your data for the regulatory, submission sufficient for the market or do you, did you need to do additional clinical studies once you hit the

Yeah, no, that's a, it's a great question because it is a different, um, you know, there's a different goal for different clinical data. We had the goal of getting FDA clearance of our 510k, but then also getting new codes. So we, we did many more studies after because to get a new code needs, a randomized control study plus, and, really about five peer reviewed journals with different studies.

So we did,many more studies after the FDA study, including a randomized, sham controlled study for each product.

[00:43:00] **Pat Kothe:** How are you distributing the product? Do you have a direct sales force or is it a distributor

[00:43:04] **Scott Wolf:** have a direct

[00:43:04] **Pat Kothe:** or a combo? and available in the U. S. are you available outside the U.

[00:43:08] **Scott Wolf:** U. S. only right now.

[00:43:11] **Pat Kothe:** What is the next couple of years look like? really hitting the market hard and getting market adoption, new products. what does it look

[00:43:18] **Scott Wolf:** we want to, really, just, there's tremendous opportunity in both of our current products. We're really focusing on giving our physician users the

best possible experience. So there'll be, updates to those existing. products. So that, that's really our main focus for the couple, for the next couple of years, but there are also additional opportunities in ENT that we want to develop products for. We're working hard on our, pipeline and, have some things in the hopper and you know, things that we're looking at. So we want to really continue to, to offer as much innovation as we can in the field of ENT medicine. It's a field that, that everybody needs good nasal breathing and, good function in their nose and there's a lot of conditions that, I think that we can help with.

we're gonna devote a lot of energy to doing that.

[00:44:11] **Pat Kothe:** Well, Scott, it's a very interesting problem, uh, two problems that, that you're solving. And I think most of us know someone who has one or both of these issues. And, knowing about this, I think would be, very interesting for our listeners. And then finding the clinicians who can perform these procedures or be able to talk them through to see if they're eligible for these procedures is gonna be something I think, will be very, interesting, again, for our listeners to, to evaluate whether it, it can help them or someone, that they're related to.

[00:44:45] **Scott Wolf:** Our website has, has a physician finder and information on both of our products. Aerin Medical, A E R I N. Aaronmedical. com,

[00:44:54] **Pat Kothe:** How'd you come up with the name, Aerin?

[00:44:57] **Scott Wolf:** Cause air goes in your nose and I want more air in, and then I spelled it in a, I thought it was a fancy way of spelling it. I got both spellings as a URL, but, um, so Aerin, and then, uh, I, I was able to buy the, the URL, um, just, uh, the website Aerin. com. So just A E R I N. They wanted, um, 850 for it.

I said, Oh, you're, what are you're dreaming. And I offered them like 500 bucks for it. They said no. And they sold it to like Estee Lauder company. so I probably could have, uh, funded Aerin by just selling the, buying that URL and selling it. So

[00:45:38] **Pat Kothe:** Scott, thanks so much for a great conversation. I do have another question and going back to where we, you know, where we kind of started in that it's a entrepreneur VC side of things. Companies can't function without money, and money can't do anything without great ideas and great people to, to be able to implement something and build something.

But sometimes, some of these investment decisions are kind of outside of the control of an entrepreneur. You could get hit with COVID. You could get hit with a down cycle. In addition to what you have as a product. There are a lot of great ideas that for whatever reason, don't hit the funding cycle and aren't able to, to be realized, even

though they're, they're a good idea. Is our current system for investing in medical device working properly? and are there some ways that we can make it better than what it is?

[00:46:45] **Scott Wolf:** I think you're. You know, you've correctly pointed out, the issues. I think that the system of bringing ideas to market and, is flawed. And it's, there, it's a lot based, it's really cyclical. There are times when, you know, early stage money just dries up. There's the very early stage money that, is, friends and family and angels. If you don't know people, it's very difficult to tap into, there's this mid stage where, traditionally smaller VCs might have, might play and, that's an ever changing universe where, uh, smaller funds make those earlier stage investments in medical devices, but those firms might get bigger and not want to make those investments, or they might be at the wrong fund cycle. And then there's later stage investment, which they're, the universe is perfectly set for, there's large VCs and private equity investors.

So once you get past this early, earlier stages, you can start, if you survive, you know, that long, you can act there, there, that, that world works. But this earlier stage world is, is chaotic and is is a little hit or miss, and that's why it has required passionate entrepreneurs who are, You know, who are willing to, turn over every stone to, to get, to get this financing, done, cause that's really the only way that it, it happens.

So there's, groups like Fogarty Innovation, that are trying to bridge that and help entrepreneurs. There's, incubators like Y Combinator that has funded a lot of, early stage, healthcare companies, and I think that's what's, really needed is a, a sustaining universe of that kind of funding.

But in my long career, I just haven't. really seen a huge change, in it. I don't have any good answers, except to say that it still is possible for, one person with an idea. if they're willing to, knock on a lot of doors and kiss a lot of frogs, to get it done.

and it's still fun and, and rewarding. And if I have any, any good ideas for changing the, uh, the infrastructure, I'll let you know.

[00:49:14] **Pat Kothe:** Entrepreneurs are important in bringing innovations to healthcare. But they're not the only ones that do it. We need investment to make our visions come to life. I appreciated that Scott could look at things more holistically based on his experience as a VC, as well as an operator. A few of my takeaways. First of all being a serial entrepreneur. It's a lot like riding a wild roller coaster, uh, with it's share crazy ups and downs.

You're constantly facing challenges like the pressure to keep innovating the fear of failing. Uh, which is always lurking around. And the whole whirlwind of managing multiple projects at once. But Hey, uh, In the midst of all that chaos. Uh, there's this incredible chance to learn and grow like never before. Each new venture teaches you things you'd never learn otherwise. And that makes you more adaptable, tougher. And given you a, a real killer instrument instinct for sniffing out opportunities. And then let's not forget the thrill of chasing different passions and the potential for massive success. Yeah, it's a wild ride, but for a serial entrepreneur, it's the thrill that keeps us going.

The second is know your operating thesis. And he talked, you know, really, um, in depth on what the profile is of the type of opportunity that he wants to work on. It's gotta be something with a big idea, big market. It's a new idea. Reasonable regulatory pathway, a path to reimbursement fundable. He's open to, to, you know, different types of regulatory, um, pathways, uh, but he wants to, he wants to de-risk the deal as much as possible. And make sure that there's a big opportunity there because it's a lot of time and effort that's going to go into building this company. So what he's done and what I suggest that all of us do is look for patterns and continue to hone the criteria of the things that you look to do get involved with.

If you're a serial entrepreneur, stakes are big, make sure that you know, what is inside and what's outside of the opportunities that, that, uh, that, that, uh, take on. The last thing was advice to entrepreneurs when pitching to investors. And this kind of goes across all pitches, whether we're, or we're pitching to investors or a pitching idea within a company. Be confident you're the expert in this area. Make sure that, that you're confident when you're, when you're talking to people. Predict the questions that are coming. Most of the questions that are coming are things that you can predict and having conversations with with others. So make sure that you prepare. And then if you don't know, say so. And what I liked, what Scott said is, say why you don't know. Uh, if you've got a good explanation of why you don't know. Uh, it will go a long way and, and, uh, making sure that they know that you're confident that you're going to be able to get it. And the final thing was have a real plan.

They expect you, they expect you to have thought through the product. But they also expect you to think through regulatory reimbursement, sales, marketing, everything else about, about your business.

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