The Innovators
Conversations
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Interview with Austin Duke

VP Emerging Therapies
Rosellini Scientific

Austin is a passionate developer of medical devices, refusing to accept the idea that medical device development must follow the pathways established in decades past. Instead, Austin is applying Lean Startup and agile development methodology to reform how medical technology is brought to market. He is focused on analyzing the scientific merit of potential investments, developing/executing non-dilutive funding strategies, and translating innovative early-stage ideas through preclinical testing to pilot clinical studies.

His background is in the development of novel methods of neuro stimulation. He is published in diverse journals and has presented at domestic and international conferences. His work was highlighted in Nature Photonics, and was also named a Highlight of 2012 by Journal of Neural Engineering. He received his PhD. from Vanderbilt University. Austin can be reached at Austin@rosselliniscientific.com

Interview conducted by Doug Berger, Managing Director, INNOVATE doug@innovate1st.com

Doug: Please provide our readers with some background on Rosellini Scientific.

Austin: We work primarily in medical devices, point of care medicine, and tele-health. We like to think of ourselves as a bridge between anyone who has a good idea and the ultimate commercialization of that idea. Rosellini Scientific got its start with neurostimulation and active implanted medical devices.

We partner with inventors or academic researchers who have an early proof of concept. Then we will provide expertise in science and engineering, fundraising, legal and accounting, and go-to-market strategy. Once we reach an inflection point, we will then spin that out into a new company along with the principal people involved, leverage a larger partner, and raise additional funding to accelerate that technology on its own, independent of Rosellini Scientific.

At the time of our inception we acquired, and continue to manage, two operating entities. One involves servicing post-market equipment in hospitals, such as hospital beds and anesthesia equipment. The other is a remote dental company that sends dentists and hygienists to nursing homes where patients have trouble getting out to dental offices. Both of those operating entities produce profits that allow us to reinvest in emerging therapies, which is really exciting.

Another advantage is that hospitals and nursing homes are a great hotbed for new ideas and idea testing. It's a nice marriage of operations and R&D in the medical device, remote health care, and point of healthcare spaces.

Doug: You have been very deliberate about applying the lean, agile methodology in the arena of regulated devices. I am particularly interested in how the lean startup is influencing the early stage evolution and go-to-market of medical devices.

Austin: Our team is among a group of innovators and entrepreneurs in the healthcare space that looks back over the decades of how medical devices are being developed; we refuse to accept that we have to follow that paradigm. There is a more efficient and faster way to get devices into the clinic, into the hands of doctors, and to the people who need them without sacrificing essentials like device integrity and safety.

Being a small team, we are more agile just by nature. However, we stumbled across business model innovators like Eric Ries and Steve Blank who were pushing customer discovery and development at a very early stage in the project development cycle. We found their lean approach for high technology to be applicable to healthcare ventures.

We recently participated in a National Institutes of Health pilot program called the Innovation Corps, or I-Corps. The program, to train young companies, was led by Steve Blank, but also brought in folks like Paul Yock from Stanford, and leading life science VCs and entrepreneurs, all of whom have taken companies from the ground up. The program sought to train entrepreneurs, as well as the NIH, on how to incorporate customer discovery and development in a way that allows rapid iteration to a successful business model. Essentially, you get immediate feedback from potential customers as to whether your assumptions are true, which allows you to pivot as needed before too much capital and energy is invested.

The lean startup method allows companies like ours to take a scientific hypothesis validation approach to commercialization. While on the one hand, scientists and our engineers may be in the lab doing technical development, we also have a team able to de-risk commercialization concerns. So you avoid this long standing tradition of going down in the lab, building something really cool, coming up for air three years later only to find out that nobody wanted it.

It's relatively easy for medical innovators to do really impressive things like building an advanced widget or software. It's difficult to match that with an unmet clinical need. It's even more difficult to match that with a regulatory strategy and a reimbursement strategy, especially early on. I would wager that less than 10 percent of companies ever even think about the hospital or the ultimate payer in their value proposition. It seems like you can say, "Well, I'll cross that bridge when I get there." But what you find is that your development right now will often directly influence value to those at the other end of the chain.

I was talking to someone about a drug that showed remarkable clinical efficacy. It received FDA approval, went to market, and the company just filed for bankruptcy - they priced themselves out of hospital and health care adoption. We need to be thinking about that early.

Doug: So getting out of the building and talking to the entire value chain is a crucial lesson.

Austin: We have learned a ton of lessons by directly talking with patients, with doctors, with providers, and with people throughout health care system. We took one of our projects into the NIH program; it was a neuro stimulator to treat a specific cardiac

disease caused by an electrical malfunction. At the outset we thought, “Yes, it’s a problem, but maybe it’s not that big of a market.” We went out and talked to patients, specialists, and regulatory people and found that it was a huge market and unmet need. There are challenges that nobody has yet been able to solve. If we can overcome these challenges, then we will be extremely successful and have a big clinical impact.

One of the really important things that we understood through this process was the clinical endpoints that we needed to assess in a study in order to prove that our device was successful. Before we got into this process, I did not appreciate that the medical specialists fall into two different camps. One type cares most about symptoms; another type cares most about the amount of time that you are in an episode. The FDA requires a different set of endpoints. Reimbursements require a different set of endpoints. Then you have the guideline committees, which dictate how the therapy should be treated. We found that we potentially need to consider all of these different endpoints, but not necessarily at the same time. Addressing them in the correct order is critical.

In addition, if you are a young company and you are ultimately looking to leverage the capabilities of a larger company, the Medtronics, the Boston Scientifics of the world, you have to think, "What is the value proposition we need to show them in our clinical data?"

Doug: These inputs came prior to a prototype.

Austin: When we talked to the specialist we asked, "If I can do X for you is that a big deal?” If they ask, "What about the mechanism?" I will deflect that early on and say, "Just assume that we can do this. Will it matter?" As we validate that we are working on an important problem it starts to get into a bit more detail, "Well, to deliver that value proposition what does it need to look like? How should I go about doing that? What is the best way for me to reach you three years from now when I do have a device that I want to distribute to you?" So, yes, you learn a lot by just getting out of the building and talking to people.

Doug: What other parts of the lean startup have you found particularly useful?

Austin: The concept of a Minimum Viable Product, or MVP, meaning, what is the least that you need to do in order to be viable in the market? You don’t want to waste time on development of features before you prove that the primary value of the technology addresses a customer need. For devices that can get a little tricky. We found that in initial clinical studies, to the extent that it is possible, we want to use off the shelf technology. If our innovation is on a variation of a method, or if it is on an indication for use but the actual technology exists, then we want to find a way to mitigate the amount of time spent in development. This allows us to collect very meaningful clinical data earlier and at a lower cost than if we build out technology ourselves. On one of our projects, we have the technology, but it is going to take at least 12 months and cost at least a million dollars to get the supply chain up to run a study. Whereas, we can buy a comparable device off the shelf and immediately get into the clinical case for our use.

When we went out on this customer discovery process, I talked to people from big medical device companies. I said, "If I show up to your door with early clinical data paired with IP do you even blink, or do you need to see the development and the technology that supports this?” The answer came back unanimously, "Don't spend a dollar on development until you have answered your clinical question." That was strong validation for using the Minimum Viable Product.

Doug: Then once you start thinking about MVP, you start thinking of original ways to create an MVP clinical for those first 20 people, meeting the safety requirements because you're using a device that is already proven.

Austin: As another example of an MVP, we developed a new technology that has an implanted counterpart and external component. We will create quick prototypes that we can then go put in the hands of potential end users and get immediate feedback. We can do that with some of our implanted components. Take a lead that we have developed, for instance, we go to the surgeon who is familiar with it and get feedback on it as part of an iterative design process. That is important.

Doug: How does regulatory approval fit into the early stage?

Austin: In in the U.S., you have several different regulatory pathways. For Class 1 devices, there are already substantial equivalents and approval is usually going to be a letter. Class 2 is a 510K, where you may need some amount of clinical data. Then class 3 is the most rigorous, where you're going to have to have substantial clinical data supporting your approach. In the U.S., you have to show efficacy data and safety data.

Another way, and this is typically how we go about it, is to go to Europe where you can go for the CE mark. The CE mark is based only on safety, the indication for use and efficacy is not as important. A CE mark allows you to go to market and start selling, which now gives you easier access to collect the early clinical data that you need through post-market surveillance.

Here's a real life example; a company has a device that looks a like a tiara. You wear it on the front of your head and it stimulates the nerves to control for migraine. In the U.S., the FDA would say that it's a non-significant risk device. However, there are no predicate devices, so it is automatically classified as a class 3 device. This company ran clinical trials with 60 to 70 patients in Belgium and showed the safety and efficacy of their device. They used that data in the U.S. to go through a regulatory pathway and were just granted approval for sale in the U.S.

Another company just IPO'd in the neuro stimulation market. They went to Europe and got the CE mark and started selling in Germany. Then they went to Australia, which is a surrogate for the U.S. market because it acts more like our health care reimbursement system, and proved revenues there. They did all of that in parallel to their FDA pivotal study to get Class 3 approval, and they IPO'd at the completion of that pivotal study.

Doug: Let's shift to the topic of non-dilutive funding.

Austin: A lot of people do not appreciate what this is, but it is something that has been incredibly important to what we do. Non-dilutive funding is any funding that does not give up equity and it typically comes from grants. We are able to use grant money to answer a lot of the early questions without raising expensive capital. That allows us to hunt for a signal or inflection point that we are onto a good commercial idea. Grant funding can be thought of as the fire starter. Once that spark is lit, then equity capital pours fuel on it. Therefore we increase the valuation of a company without diluting equity.

There are challenges to getting that money. It is generally slow. The small business innovation research (SBIR) program at the NIH or the NSF takes about nine months. They will offer an initial amount of money to prove your concept and your team. Then you have to go back and apply for more. One of the advantages to Europe is that there is generally fewer restrictions on the timing of grants. There

are also challenges once you receive the money. You can be tied to spending that money in certain places. The U.S. obviously wants you to spend your money in the U.S.

Doug: How does this approach effect the valuation differently from the traditional ways that people have developed medical devices?

Austin: The non-dilutive funding is essential for our business model. Generally, companies are going to get their pre-money valuation at a clinical milestone of around 10-30 patients. De-risking, getting the early clinical data, and especially doing a non-dilutive funding, makes you an incredibly attractive investment.

Historical data for the neurostimulation market, which is one of our primary areas of interest, says that the pre-money valuation at 10-30 patients is in the range of $60 to $100 million. In VC pitch decks we have started to see companies citing the amount of customer interviews they've done. "We have talked to this many doctors, this many patients, this many nurses. If we build it, they have told us that they will come." That adds a lot of value.

When you're looking at market size, it is harder to tease out the valuation because you are dependent on many variables. We are looking for a patient population of 50,000 to 100,000 per year. Pursuing non-dilutive funding, de-risking commercialization activity, and improving your clinical data are three things that are going to be immensely important for achieving a high valuation.