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STANTON J. ROWE,

FOUNDER AND CEO OF NXT BIOMEDICAL

Wisdom and encouragement for MedTech innovators:

An interview with Stanton Rowe, whose many innovations have helped transform patient care.

IMMR Accelerating your innovative research

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Nicolas Borenstein, DVM, PhD
Scientific Director - Founding Partner - Board Member.

I was one of the lucky guys who worked with Stanton Rowe along with Alain Cribier, Stan Rabinovich, Assaf Bash and the rest of the great PVT team on what ushered in a true revolution in transcatheter treatment of structural heart disease at the dawn of the 21st century. Stan has always been a visionary leader and I'm very grateful that he spent a bit of his time sharing with us his perspectives on MedTech innovation in general, and amid the COVID-19 pandemic in particular. His words of wisdom provide both inspiration and practical advice for those of us who have the thrill and privilege of working on innovation for better health care.

Stan Rowe is no stranger to innovating and managing the process of innovation. He is currently the CEO of NXT Biomedical, a medical device incubator funded by Deerfield Capital, Johnson & Johnson, and Edwards Lifesciences. His previous roles include Chief Scientific Officer and Corporate Vice President of Technology at Edwards Lifesciences, Co-Founder and CEO of Percutaneous Valve Technologies, which developed the first transcatheter aortic valve replacement, Corporate Vice President for Datascope, and Vice President at Johnson & Johnson's Interventional Systems Division. We had an opportunity to speak with Stan about innovation and his advice for entrepreneurs.

Welcome Stan. Would you begin by telling us about NXT Biomedical and your approach to innovation? How are things going thus far?

SR: Well, there are two different kinds of incubators. One kind incubates companies, getting them prepared for their next round of financing or supporting them operationally. The other kind, and there are only three or four around the world that I can point to, are focused on actually performing early-stage development. That's what we do. We're not investors per se; we do invest in projects, but we're using our funding to do that early-stage development ourselves. Based on this, our objective is to spin out between five and eight series A companies over the next five years. So far, we're meeting that target, and I'm really excited about how things are going.

How do you identify the projects that you decide to pursue, and how do you approach innovation?

SR: Most innovation is somewhat opportunistic. We get exposed to the practice of medicine and ask ourselves, "Why can't we do it better?" I'd estimate that half of our projects arise from intellectual property (IP) that we develop internally, and the other half involve externally sourced IP. Many times, things start off internal, you think you've got a brilliant idea on your own, and you go look in the patent art, and you find that someone else thought of it three years ago...of course. But that's okay, as long as you can license that IP and do your work with it to move it forward. We begin by looking at unmet medical needs and we assess them. We try to quantify them and ask whether the research dollars

necessary are worth spending on them if we can solve the problem. So that's the investment question. Then, do we have an idea that we think will solve the problem, and is it proprietary? And the third question is, can we go about doing feasibility development thoughtfully and efficiently in a way that in a few years could demonstrate whether this idea really has legs? So that's our process. One of the things I talk about frequently is that innovation is a three-legged stool: Firstly, we need a deep understanding of medicine - we have to be able to talk to physicians at their level and understand their practices, and to understand the history and the pathology and the physiology adequately to be able to do our job very well. Secondly, we need to understand the business of innovation, which is patents, investments, development strategy, competition, and markets at a quantitative level. And then thirdly is the biomedical engineering. We have to be creative problem solvers and good engineers who understand the product development process. And I think that only when you do those three well can you truly innovate.

Do you have any particular disease areas in which you focus, or are you agnostic to where opportunity might lie?

SR: It's probably more a function of things we exclude. Most of us came out of Edwards Lifesciences, and so we've done a lot of work in structural heart disease, in transcatheter mitral or aortic valve replacement. Those are wonderful devices and they've impacted hundreds of thousands of lives. I'm really proud of the work we've done there, and now it's time to do new things. Some of our projects are cardiovascular, some are not, and some are pretty far afield from what we've done before. But I think we all like that, we have a team that really enjoys going deep and learning in new areas. That makes innovation really fun because we're being exposed to things we didn't really understand before.

Are there technology platforms that you're particularly excited about, and have you put any boundaries around what approaches you'd consider?

SR: Given that we're backed by Deerfield Capital that manages $11 billion, Johnson & Johnson and Edwards, we're more focused on the big problems to solve. Iterative development is not interesting to me. I'd rather take bigger swings at the bat (to use an American analogy!). We're going to take on bigger problems to solve, maybe with bigger risks, and that's okay. In general we like image-guided, minimally invasive approaches, because we think they're not only better for patients, they're also cost effective. I think sometimes we get it wrong when we do product development. We look at mortality. Mortality is easy to measure, and it is really important, but it doesn't adequately capture the patient experience. What really impacts patients is morbidity. Too often we're focused on mortality, and we don't appreciate the impacts of having surgical complications, for example renal impairment or a minor stroke. Those kinds of things have huge impacts on patients. If we have a patient-centric approach to development, we're thinking long and hard about how to improve morbidity along with all the other requirements that we have. That to me leads to very patient-focused outcomes.

What new solutions are receiving the most attention these days?

SR: One area I'm really interested in and see a lot of work being done in is wearables. Wearables are great because they're both illness- and wellness-focused, and can help keep patients out of hospitals, which improves their lives. Too often our diagnostics have comprised a check-in every six months or once per year. Can we really understand how patients are doing when we have such sporadic feedback? What if when they come in, they happen to be having an especially bad day or good day? We don't really understand how they're doing by looking at them so intermittently. With wearables, we might get novel and continuous views on how patients are doing that are totally objective. I think this offers us unique insights into how to measure outcomes and how to develop devices that improve the true outcomes of patients.

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How would you say the COVID-19 pandemic has impacted the pace of innovation, the investment landscape, and the ability of innovators to advance research and development? For example, conducting clinical trials has been very problematic. What's your observation?

SR: Well, it's certainly distracted us all, although many of us have found that working from home works just fine and we can continue to be productive, which is great. For many of us who have traveled constantly for decades, it's been quite a respite. Clinical trials, as you mentioned, have been severely impacted: International and domestic travel have been restricted and hospitals are focused on treating COVID patients, which rightfully they should be. Their focus on clinical trials has been much diminished, and that's had a big impact on us. Nevertheless, I think that we've been able to do a lot of the academic and thought work around innovation. I think we've been able to do a lot of the benchtop work around innovation. It's slowed us up, but I think that ultimately, we're still going to deliver big.

What about entrepreneurs who are out trying to raise Seed capital? Are deals getting done?

SR: I still interface with a lot of startups and I think Seed and Series A funding probably remain the two hardest to get: It's really hard to find folks that are actively doing that, so there's a lot of attrition. But I think there are some great investors out there, and there are a lot of different forms of investment today. In addition to traditional Angel investors there are now many Angel groups, and there are active family Foundations. So there are places to get funding, but I think still it's very, very difficult. Of course you have to cover the basics: You have to have a great team, a great idea, and as much data as you can to support that it is a great idea and that you can make it work. And telling that story well is really important. I wish all the entrepreneurs out there the best of luck in pursuing their dreams. It's not an easy path, for sure. It takes a lot of perseverance to make it.

I would also encourage people to think about whether you can test your physiology before you have a full device. Something we do frequently is try to use off the shelf products or other components to really validate the physiology or the performance of a product concept as quickly as possible. And doing smart animal studies can also really help, of course, if you think long and hard about what you can replicate and what you can't replicate. What translates from animals to man is really important.

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What advice would you have for an entrepreneur who's thinking about launching a new venture this year and has to garner initial funding?

SR: I frequently call it kissing frogs. You'll never know from the cover of the book whether people are going to invest or not. So you just have to carry your presentation around and get in front of a lot of different people and tell your story. Your story will get better, you'll learn how to tell it better, you'll face really difficult questions, which will make you better at presenting. You just have to go out and beat the bushes to find the funding and it can be really challenging and difficult. But part of the test as to whether you're an entrepreneur or not is facing that 95% rejection to get the 5% acceptance.

Physicians frequently come up with concepts for new therapies and become enamored with the prospect of being entrepreneurs. When you encounter physicians who have those yearnings, how do you counsel them?

SR: Il think several things are really important. It's an incredibly powerful combination to pair great biomedical engineering with great medical talent and insights. The longer someone holds onto an idea without having somebody actually work on developing it, and funding it, the less value it's ever going to have. You have to have a sense of timing and be expeditious about finding really good talent to collaborate with you to take your novel idea through a process of feasibility evaluation, patent filing, animal studies... You have to figure out what works and doesn't work. No idea is ever developed perfectly in its inception. We go through a process of failure and understanding and perfecting a device before it actually is good enough and ready to hit the marketplace. You need great partnerships, and so finding those people is critical. If you're at a university, you can work with your own biomedical engineering groups to get started. Find people in the industry who are friends of yours or befriend them, they have their own networks of people who work on nascent concepts. Talk to venture capitalists who are really keen on doing this, and they will help put together a team. There are a number of different ways that you can go through this process, but if you're just hanging on to an idea, or trying to go it alone, it'll never see the light of day. Find some partners and make it real.

Any last thoughts?

SR: Today, like many other days, is a great day for innovation, and what we do for a living is a privilege. We get to serve patients and have an impact on patients. That is profound, and I think that's the kind of work that we can really be proud of. It takes a lot of teamwork, which makes it really fun - to collaborate with really smart people and with bright physicians to figure out: What are the best test methods? How do we do animal studies? How do we design clinical studies? How do we get approvals? It's really complex and really challenging, but really impactful, and there's nothing like meeting the patients that benefit from our technology. And so every day, I think it's a privilege to do the work that we do. Thank you for giving me this opportunity to share my thoughts with you.

Stan, the pleasure is ours.

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