EP.132 - MedTech Innovator Cohort

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis. I'm your host for *BioTalk*. We're doing something a little unusual today. I have corralled three dynamic female entrepreneurs from the state of Maryland who are all going to be on the same podcast today. We're going to see who trips over each other first today. But I guarantee it, this isn't orchestrated, so we're going to play this by ear. It's the first time triple podcast, but I think all the listeners are going to enjoy this. They have a special designation, and that's why they're on this podcast together. They have all participated in the world's largest medtech accelerator program, which is called the MedTech Innovator, which just completed within the last two weeks.

0:01:07 1,150 companies apply to be in this 2023 cohort, and only 61 out of 1,150 were selected. Out of that, there were 21 states represented, and 16 countries. But guess what? Maryland, out of the 21 states, got three MedTech winners. All three of them are *female* entrepreneurs which is exciting. I'm sure the listeners are going to be glad to see this representation from the state of Maryland, which will even go further into California later this year, which we'll talk about. Let me introduce them. After I introduce them, they're going to do self-introductions, because no one can introduce them better than themselves.

0:01:57 The three winners we have, from Maryland, of the MedTech Innovator contest, are Ellington West, who is the CEO and Co-Founder of Sonavi Labs. Hi, Ellington.

Ellington West: Hello!

Rich Bendis: Welcome back to *BioTalk*. We did one with Ellington a little while ago, if you want to go back and listen to that, and then she's going to tell you how she has progressed today, since we did the last *BioTalk*. Then we also have Samantha Scott, which goes by Sam, who is the Founder and CEO of JuneBrain. Sam, welcome to *BioTalk*.

Sam Scott: Thank you. Hello.

Rich Bendis: Hi. Then Michelle Crawley, President of Xcision Medical Systems. Michelle, welcome to *BioTalk*.

Michelle Crawley: Thank you very much.

Rich Bendis: By the way, Ellington and Sam are from Baltimore, and Michelle is from Columbia, Maryland. So, three Maryland Terps here, companies. I think Michelle actually does have a tie to the University of Maryland which she can talk about. Let's start with some introductions. We're going to start with Ellington first. Ellington, let's give a little background on yourself and your company.

0:03:05

Ellington West: Yes. Thank you so much for having me. It's always wonderful participating and also being an active listener of this podcast. So, Ellington West, CEO and Co-Founder of Sonavi Labs here. I had the pleasure of licensing our technology out of Hopkins back in 2017. We have developed a device named Feelix, so it's a hardware/software solution. Feelix listens to the sound of a patient's lung, analyzes those sounds, and then shares that actionable data with care teams anywhere in the world. Our goal, our aim, and our focus is to be predictive of asthma attacks and COPD exacerbation. On the acute side, we can actually diagnose pneumonia in less than 40 seconds without an x-ray or provider present. We started with a real focus on global health, partnering with the Gates Foundation, because there was one child under the age of five dying every 36 seconds from pneumonia, which is detectable and treatable.

0:04:04 So we ran full steam ahead to really create a global and accessible solution there. Then we looked in our own backyard, here in Maryland, and recognized that African American children were three times more likely to die from an asthma attack than any other patient population right here in Baltimore, and so we wanted to create another, again, accessible and easy-to-use device. Our software runs different algorithms, but it's all processed through one singular device and platform. We love the opportunity we have to now build into different indications. Again, I'm thrilled to be here today and to be with these wonderful women.

Rich Bendis: Thank you, Ellington. You told us a little bit about the company, but you didn't say anything about your own personal background and how you became an entrepreneur. They'd like to learn that, too, if you could do that briefly.

Ellington West: That's a great question, and thank you. I always talk about my company first; it's like my baby. I forget my identity in the process. [laughs] I actually come from a sales background. I was the director of sales for a national healthcare company prior to jumping off of the entrepreneurial diving board.

0:05:06 Actually, I did so because my father, Dr. Jim West, was actually the principal inventor of this technology, a professor at Hopkins with 250 patents. He actually invented the electret microphone, so the microphone in all cell phones, the microphones that I'm speaking to you on right now. So when he said, "Listen, we have an opportunity to change the world and transform the way that respiratory care is delivered," I decided to go full steam ahead. I also, through this process, have had the honor of being appointed by our former governor to sit on the Maryland Life Sciences Advisory Board. So, really being able to pull in that expertise from not only my sales and commercialization background, but to really be able to apply that to getting this device really out and commercialized is kind of the intersection of where my leadership I think plays a key role in our organization.

Rich Bendis: Thank you for your personal background. And we'll see you tomorrow at the Life Science Advisory Board meeting in Baltimore.

Ellington West: Can't wait! [laughs]

0:06:01

Rich Bendis: Next, we have Samantha Scott, founder and CEO, JuneBrain. Sam?

Sam Scott: Hi, everyone. I'm Dr. Samantha Scott, but I go by Sam. I started JuneBrain a few years ago—2017, a few years ago now. My background is a combination of neuroengineer—my PhD is in biomedical engineering, and I really focused heavily on understanding patients who have retinal disease from a brain point of view. So, how does loss of vision impact the

brain? How does sight restoration with a medical device impact the brain? That is my happy place. It's the intersection between neurological understanding of the body versus the retina, so the eye-brain interface. I started the company soon after I was diagnosed with a neuromuscular disease, so I switched from being a scientist to a patient. It was really the experience of being challenged with my physicians understanding how disease is progressing only based on my subjective input, not based on any objective measures.

0:07:09 That's the challenge that inspired me to start JuneBrain. Right now, we're developing a device called the Neuro-i. It's a telehealth eye-scanning technology that automatically understands how your disease is progressing via eye measures. That's whether you have active retinal disease or active neurological disease. The nice thing about what we're developing is that it combines AI with accessibility. So our goal is to bring OCT—it's called optical coherence tomography; it's a technology used to scan the eye—our goal is to bring this into more accessible settings so that it can be accessed by people who are severely disabled, or in rural communities that don't typically have access to these specialized technologies. That's it, in a nutshell.

Rich Bendis: Thanks for the intro. The name is interesting—JuneBrain.

Sam Scott: Yes.

Rich Bendis: How did you come up with JuneBrain?

0:08:01

Sam Scott: I'm a military brat, Army and Air Force brat. My mom likes guys in uniforms. But [laughs] one of the places I loved to live the most was in the South, and I loved the name junebug. It just stuck on me. JuneBrain, we were founded in June, June is one of the brain awareness months; it just worked. [laughs]

Rich Bendis: It just so happens we're doing this podcast in June, so everything is aligned around June for you, right?

Sam Scott: Yes.

Rich Bendis: Thank you. Our third guest is Michelle Crowley, President, Xcision Medical Systems in Columbia. Michelle, a little background?

Michelle Crawley: Just like Ellington, I actually was totally prepared to just talk about my company. I really wasn't even thinking about me. The company is based in Columbia, Maryland. We are a technology transfer out of the University of Maryland. Our founder and CEO is a medical physicist who was the chair of Medical Physics at University of Maryland. I have taken over being the president, but our founder and CEO is still with us, Dr. Cedric Yu.

0:09:04 We make a stereotactic radiation therapy device that treats breast cancer in as little as one single treatment. We are looking to prove the patient population for which surgery could be obviated. It would be a massive change from the way that breast cancer is currently being treated. There's about 20 million women that actually get affected by breast cancer over a ten-year period, almost 2 million women a year, and in many places in the world there's a massive shortage of radiation therapy treatment devices. Breast cancer represents about 25% to 50% of all cancer patients that are in radiation oncology centers around the world. So, being able to improve the efficiency with which you're treating these patients, you can actually improve the overall healthcare paradigm in many places in the world. Obviously it's also great for the patient, too. In our country, we take for granted that if you get breast cancer and you need to be treated, you can just get in. In many places in the world, the wait times are measured in months, so waiting six months is not an unusual thing.

0:10:14 That's what we do, and that's where we're at. We've been in business since 2006 when the development started. We got our 510(k) at the end of 2017, and so we are commercial. We have four treating centers around the world. My background, I actually have been in radiation oncology for about 25 years. I've been here at Xcision for 12 years. Before that I was with a really big company that is in this space. Before that, I worked on the space shuttle program. I have more of an engineering background. I came out of aerospace. I love this business. And radiation oncology is actually medicine that works. It really does what it's supposed to do. So it's a fabulous business working with clinicians that are really helping people treat serious diseases, and giving them the tools that they need is just a real pleasure. Thank you for having me.

0:11:06

Rich Bendis: You're welcome. Congratulations, all three of you. I'm going to deviate from the script, which my producer Andy Eckert knows I do that all the time. I'm going to come back to each of you with a different question than what you were prepared for. What would you consider to be the latest major milestone that you have achieved, and what is the next major milestone that you're searching to achieve? Go back to Ellington to answer those, and then we're going to get a little more into the company and the technology after these questions.

Ellington West: Wonderful. I love this question because I think that as leaders we often forget to remind ourselves of the wins, because we're always chasing the next thing, and getting to that ultimate finish line. Everyone's is also defined a little bit differently. When I think about the most recent wins that we've truly been celebrating, it is along the regulatory path. We are 510(k) cleared for our hardware, and we just completed our submission for our software as a medical device designation, so we should hear back in the next couple weeks—up to 90 days, but hopefully in the next few weeks, because we've had a lot of engagement. So, thrilled by that, and very proud of our team and what we've done on that front.

0:12:18 Then what I have on the horizon is closing a financing round that we have. We have soft circled a very large majority of it already, and hope to close in the next few weeks if not months. So, thrilled by that, and knowing that that's going to also give us the horsepower that we need to keep going as fast as we can.

Rich Bendis: Great, thank you. I think all three of you are going to be doing ABR, right? Always Be Racing. Right?

Ellington West: Always.

[all laugh]

Rich Bendis: Always, okay.

Ellington West: I didn't know what that was. [laughs]

Rich Bendis: There we go. But ABR, you're going to be all in the ABR mode, and I think

Sam was talking about that. Samantha Scott, Sam, with JuneBrain, latest major milestone you achieved, and what's the next one to conquer?

0:13:03

Sam Scott: That is a great, question. I agree, Ellington, we do need to recognize the wins! I would say our latest accomplishment on the device side is redefining our headset in a way that is more usable and accessible. We have a prototype that works well, but what we've done is translate that a bit further to make sure that it's comfortable for patients with a variety of disability. That was a huge milestone. Our next upcoming milestone, which is related to fundraising—we're always fundraising [laughs]—we're aiming to reach a million dollars raised, and we've reached $815,000 so far. So, hoping to close that last portion of the first million, as well as submit to the FDA next month for our software.

Rich Bendis: Great. So if anybody has $185,000 that is just sitting there that they would like to invest, JuneBrain and Samantha Scott is willing to talk to you.

Sam Scott: Yes. I take pennies. [laughs]

0:14:02

Rich Bendis: You take pennies. [laughs] Okay!

Sam Scott: After all, I probably shouldn't say that. [laughs]

Person: You shouldn't! [laughs]

Rich Bendis: If anybody has 10,850,000 pennies, then she'll take that as well. Lastly, Michelle, major milestone and goal?

Michelle Crawley: The last major milestone was the closing of a Series A, for $7 million which was—thrilled about that. Of course the next one will be closing a Series B before the end of the calendar year, for $18 to $20 million. Actually we have a lot of intellectual property at Xcision. As I mentioned, our CEO is definitely a scientist and he is an inventor. We have a lot of patents. We're going to be developing—GammaPod is our first product, but we have intellectual property to develop our other projects, and so we're going to start—we've actually started it a few years ago, but now

we're going to be starting it, in earnest, with a team, and we're looking to fundraise to do that, and to commercialize the technology in the United States.

0:15:01 I would also say that we have sold our first European system and got it installed, and got it clinical, and got the customer happy. We actually sold our next two machines in Italy, and so our next thing is delivering those machines, and getting those customers happy. Because happy customers is what sells your equipment, too.

Rich Bendis: Great. Good luck to all three of you in your next fundraising efforts. Let's go back a little bit about the companies. For Ellington, your Feelix hardware harnesses the power of AI, and that really helps to identify and track respiratory abnormalities. How do you see AI technology, which everybody is talking about, but really—and there's the good and the bad of it. You're hearing what's good about AI, and what's some of the challenges with AI. But how do you see that evolving in the future, and how will it impact the way diseases are diagnosed and managed, especially related to your technology?

Ellington West: I think it's such a great question, and it's obviously at the forefront of everyone's mind.

0:16:02 It's funny, when I first cofounded the company, it was really hard to get people's minds wrapped around really trusting AI, right? We will always be working towards not just providers feeling comfortable with utilizing it, but more importantly patients, being able to trust the personalization that can be achieved through AI when it comes to diagnosing and managing clinical challenges, diseases, and different disease states. I think that there are two different conversations. I think that when we look at AI and the ethics outside of healthcare, that is a wild, wild west. I think that in healthcare, we have regulatory bodies that are currently trying to really navigate and understand and set the appropriate parameters that will allow us all to be successful, and for all of us to really benefit from the existence of these models. Now, where I think that there are huge opportunities is that—and I'll use osculation, which is utilizing a stethoscope, and a physician listening through a stethoscope is the act of osculation.

0:17:11 When a physician is using their stethoscope, they only agree 70% of the time on what it is that they heard. But when you have Feelix, our device, there's a 98% accuracy in our ability to identify the presence of those abnormalities. Even more specifically when it comes to something like pneumonia, we also have a 98% accuracy in our ability to diagnose, and that's because we trained the device on x-ray data as well as an adjudication panel of some of the best pulmonologists in the world. But then came the issue of the FDA, who says, "Well, what's really the gold standard? And how do we know, and how do we train these models?" And those are real questions, but still we have to work towards really creating a strong base and foundation for.

0:18:00 But the reality is that when we see this shortage of physicians across the globe, and we even think about burnout and we think about the challenges that we're seeing in rural America today, going back and citing exactly what Michelle said in terms of wait times for all of our patients, what we have to do is think about creative ways to extend and augment the ability of our providers. And here's what I know for sure, is that there will never be a world where physicians are not in the loop. They are essential. There is a human factor in empathy, a bedside manner, and an understanding that a machine can never duplicate. But what we *can* do is create a higher level of confidence in point of care decision-making, and again, getting even deeper into the personalization of solutions for our patients. So I'm very optimistic about what this world is going to look like as we continue to layer in AI, but we have to do it at a pace that is ensuring inclusivity of all of our patients, so that the data sets that we're training are reflective of the true populations that we are serving.

0:19:07 That is something that has been at the forefront of my mind for our company from the very beginning, was, how can we ensure that our data is inclusive, that we're clear about who it is that we serve, and then we reverse-engineer that to make sure that they're reflected in our patient population. I think that there are so many applications of AI, whether it is imaging, from a radiologist standpoint, where we're seeing that AI, when layered in, is actually more accurate, again, than radiologists. In the case of osculation, we're seeing the same. But where it excites me the most is in early detection. That's where I get very excited in terms of oncology,

and really being able to nip something in the bud before it springs. And even in our case of respiratory diseases, being predictive of an asthma attack or a COPD exacerbation. The opportunities are really endless.

0:20:01 We just have to make sure that we are coming together as a community to ensure that we understand the risks, and that we can respond to them with the right parameters that ensure that our patients are well taken care of.

Rich Bendis: Thank you, Ellington. I think what's interesting, when I listen to all three of you, and I looked at some of the backgrounds, there may be some synergies for your companies to work together and collaborate. Also, when I was looking at Samantha, you're interested in inclusion, too. Basically you're developing tools to remotely and quantitatively evaluate the progression of diseases like MS using retinal image data. But can you share, how do you think these tools will change the patient experience, particularly in some of these underserved communities, which also Ellington was talking about?

Sam Scott: Sure. It's so important. One of the first things we did was extensive customer discovery, and that included speaking with as many patients as possible to understand their current experience, and to inform how we design our device.

0:21:07 The experience that they shared with us, and it's an experience that I have personally been challenged with, is many patients, especially with neurological disease or retinal disease, the way that providers currently track their disease is through self-report. It's very subjective. It's a result of providers having limited bandwidth in their clinics for patients to come in more frequently. So patients are asked to call into the clinic when they have a new symptom, or if anything has changed to let the provider know, and the provider may use that subjective information to make a change to their treatment regimen. The problem with that is that, one, when it comes to symptoms, it is not always reflective of subclinical disease activity. If you have MS, for example, you could possibly have an increase in your lesion load or something going on in the cortex that doesn't immediately translate into a change in symptoms.

0:22:05 We really want to catch that new disease sooner, treat it sooner. Even with retinal disease. For example, many patients are asked to report if they're—they use an Amsler grid, with AMD, for example. "If you see any distortions in the grid, call into the office. It's most likely time for you to have a new treatment or injection, anti-VEGF injection sooner than later." But again it's very subjective. Many patients shared with us that they will keep track of their symptoms on a napkin, or on their latest snail mail envelope. And generally it's hard to understand, "What do I report? What is significant enough to share with a doctor?" What we're doing is changing that experience by providing patients and providers with objective data. From a patient point of view, this can help give peace of mind. And increased stress is tied to increased relapses, so there's a clinical benefit to reducing patient stress.

0:23:04 Being able to understand if a patient is feeling a symptom, is that connected with disease that should be treated. When it comes to underserved communities, we define that as—examples—rural communities who are outside of a specialty clinic zone. They can't quickly access something like OCT. It also includes people who are low mobility. It's difficult for them to get to a clinic. Or individuals who are in assisted living homes or nursing homes. One example, with MS, some patients are so severely disabled that they can't complete traditional imaging, so MRI or OCT is not possible. With our device, it's wearable. It can be worn on someone who is disabled, has limited upper body mobility, who has a difficult time being in set positions for prolonged periods of time. It's also mobile, so we can take it to rural communities, and it's directly connected back to their provider.

0:24:00 A provider can be in one location, and they can now serve a much broader range of patients. It's also important for clinical trials. Many clinical trials rely on the patients that they can directly access, and for OCT, that's people who live within some margin area of a specialty clinic. But now, by having a device like this that's accessible, you can now broaden the diversity of patients who are included in these trials. That is critical for developing treatments and understanding disease progression and whatnot.

Rich Bendis: Thank you for that explanation. I think that you've got really a great cause

there, that you're trying to address with your technology, Sam. Michelle, Xcision's GammaPod system separates itself by delivering higher doses of radiation in one or several large fractions, which you're going to explain to us. How does this change the traditional treatment model for breast cancer, and how does the patient benefit from this treatment?

0:25:03

Michelle Crawley: The standard of care treatment model consists of a lumpectomy that is followed by wound healing, and then a course of 15 to 40 daily treatments of radiation for the entire breast, each with a very small amount of—dose of radiation that is delivered while the patient is lying on their back. The GammaPod treats a small fraction of the breast tissue, and it focuses on the area where the tumor or the tumor bed is located, in one to as many as five treatments, with a much higher dose, and the patient is lying face down. The incredibly short treatment and healthy tissue sparing technology provides obvious benefits as it relates to the time out of a patient's life that they have to spend accomplishing a curative treatment. But it also does this with less toxicity to the skin, the heart, the lungs, and the chest wall. We can now do *that*, without a clinical trial.

0:26:03 We know that this works. You can go in and get treated in any one of our treating sites, not on a clinical trial, and have that done. You can do that today. We have clinical trials that are underway now at almost all of our centers with our device to treat *prior* to surgery. So while the lump is actually in there, rather than doing a lumpectomy first and then having to wound-heal and wait to get your treatments, you can actually do it immediately. Then they're waiting a particular period of time, taking the lump out and doing pathology, so that they can determine, when do you have a pathological complete response. Because in many other places in the body—the spine, the brain, the lungs, lots of places—they do these treatments on the tumor, and they don't take them out, because your body just reabsorbs the tissue. Especially very tiny, early stage breast cancer is typically one to maybe one and a half cm big, so these are tiny little tumors that could be easily treated, with very little radiation—it's so tiny—rather than coming in and cutting it out, wound healing, dealing with going to the hospital, having surgery, having all these things.

0:27:14 Then of course you're dealing with applying radiation to a much larger target because you've taken the lump out, so you have bigger and bigger and bigger targets; you're having to deliver more radiation to the patients. Obviously the benefits are, you're only having to go a few times. There are many places, even in the United States, *many places*, especially the flyover states, where people are 500 miles from where they have to go to get radiation oncology. Can you imagine having to do that, just, okay, I'm going to take a three- to eight-week time out, and just go live somewhere else, pay for all of those expenses, because I can't travel all that way back and forth. This is ridiculous, right? So there's a huge problem with patient compliance, not only here in the United States but definitely across the world.

0:28:07 If you're in Africa, and you are traveling by foot to get to a center where you could be treated, you can just see how traveling one time, getting one treatment that leaves you not needing surgery, would be *amazingly* beneficial, to not only the patients, but to the healthcare system trying to support their population with really inadequate resources.

Rich Bendis: The benefits are obvious.

Michelle Crawley: Obvious.

Rich Bendis: Michelle, hurry up and get your technology global, because it's going to help a lot of people.

Michelle Crawley: I am working with that. I am building a global distribution network right now, and that's one of the things that I'm actually going to be doing through the MedTech Innovator program, is leveraging some of the contacts and stuff, to—I have a couple of different areas where I've already got regulatory clearance, and I'm looking for a distributor in that area that is the right one.

0:29:03 Your partners are really important, in this way. They really have to be able to—this is not like it's a $10.99 product that's off the shelf and just needs to be stocked. It's a bit more complicated than that.

Rich Bendis: You're a perfect lead-in, because we're going to go back to the MedTech Innovator program. You set the stage for what I'm going to ask next. What

does being a part of this program do for you, and what opportunities do you think the MedTech Innovator program opens up for—Sam, with JuneBrain, what opportunities has the MedTech Innovator program opened up for you?

Sam Scott: A lot. [laughs] Just the summit, it was three days with this awesome group of people. They're all medtech nerds. I keep saying that, but that's how I saw them. It was wonderful. I think for this it means access to new partnership opportunities and strategic investors in the space.

0:30:02 It's a different level of not having to explain the regulatory hurdles or the barriers to entry. It's well known. It's understood. These are challenges others in the cohort have already faced. That's very nice. The community also is awesome, so it's a network that I think we'll be able to lean on and grow with. I was very—not surprised, just it was nice to see how open people were with swapping their war stories during the summit. Like, "Oh, I failed at this. It sucked! But I learned from it this way, and you should not make the same mistake." It was great. That's something I think we've needed, my team has needed, I have needed as the CEO. This is my first startup, and there's so much that I don't know I don't know. So, yeah, it's great.

Rich Bendis: Thank you. That was great. Ellington, talk about the benefits of being involved with that MedTech Innovator program.

Ellington West: It has been tremendous.

0:31:00 Piggybacking off of what Sam said, first I have to pause, because she's being entirely too humble. Sam actually was nominated for the Vision Award while we were at this conference, which is she was selected by her peers to present at the Wilson and Sonsini conference in front of a *packed* room of investors, and she stood there and moved all of us in telling and sharing her story. I think that for her, it wasn't just the summit; it was the ability to really tell her story among so many powerful investors, colleagues and peers. Everyone left I think with a big place for JuneBrain in their hearts, and investors I think opportunity on her cap table. Bravo there, Sam, on that.

Sam Scott: Thank you! That's very kind.

Rich Bendis: By the way, if you're going to raise a million bucks, or another $185,000, and you have this opportunity, don't stop there. You need to have a bigger ask, okay? Because it takes as much time to raise $5 million as it does $100,000. So, go for a bigger close, there, Sam!

0:32:03

Ellington West: Well said! I agree. Encouraging her to do the exact same. I think this will be an oversubscribed round, for sure. But, the experience was dynamic. It is in that trading of war stories. I think that there were 17 women in the whole cohort, so being able to also find your people is also so important. But I think that for us, Paul Grand, the CEO, said one third of all of health medtech funding that was achieved last year, a *third* of those companies were actually MedTech Innovator companies. So, we have essentially gone through what I like to consider we're in the Harvard of accelerators. And just being associated and affiliated—

Rich Bendis: How about the Johns Hopkins of accelerators?

[all laugh]

Ellington West: Thank you, Rich! A standing ovation is needed for that. Christy Wyskiel will also appreciate that, and President Daniels. I agree with you; it is the *Hopkins* of healthcare accelerators.

Rich Bendis: We have Harvard in our backyard, with Johns Hopkins and the University of Maryland, so why talk about somebody outside of our region?

0:33:08

Ellington West: Yeah. Boston, where is that again? So, yeah. [laughs] It has been dynamic. Just again to build these relationships, to get the guidance that we need. And also when it comes to hardware. Hardware is hard, guys, right? And so having really great resources that are used to running this gauntlet and being there and prepared to receive you has also been an absolute blessing. I feel personally very fortunate to be a part of this cohort.

Rich Bendis: Great, thank you. Michelle, you talked briefly about some of the benefits of the MedTech Innovator program for you and what you're looking for. Maybe you might expound on that a little bit?

Michelle Crawley: For anybody who is actually not familiar with what this thing is—we call it MTI, MedTech Innovator—MTI incubator program—it's very beneficial to Xcision in that we are involved in this ecosystem of medtech company CEOs, presidents, leaders of their organizations, mentors, partners, investors, and providers of services—CRO services, design-build services, all kinds of different kinds of services, who are focused on helping us, these people in the program, grow.

0:34:17 So, the learning from each other, from them; the access to resources, to knowledge, to just things that you can do; connections to people, key opinion people leaders, people in your space—"Oh, I know this person can do marketing for you. This person can do market access for you. I had such great success with this thing." That kind of thing. Funding. Funding is super key. Nothing happens without funding, right? And visibility. Look at this podcast, you know? They're really key to a small company. We don't have millions of dollars to market ourselves or to pay for certain information. You just have limited resources. And your products have to be *fantastic* to even get to this point, right?

0:35:05 Even then, it's *hard* to do what you need to do without all of these resources. Not just money, but the resources and connections. So it's super beneficial. I'm so, so happy, so blessed to have been chosen.

Rich Bendis: We have probably a lot of listeners that never knew about the MedTech Innovator program and might be interested in applying next year for the program. From each of you, talk a little bit about the application and selection process that you had to go through and what kind of an experience it was. Sam, why don't we start with you this time?

Sam Scott: Sure. This was my third time applying, so, if you do apply and you get rejected, just keep trying. We applied the first year of JuneBrain and second year, and then this past year I applied to the main accelerator and the MedTech Color spinoff, and we got into MedTech Color. It was a pitch competition.

0:36:00 We placed second, which allowed us to go into the road show in Baltimore. Then from there, we were invited to do the big accelerator. The selection process, they're very thorough. [laughs] I think they even

shared—they are very thoughtful about each cohort, so they evaluate each company thoroughly and they try their best to really choose the best of the best. “The cream of the cream” is what they kept saying. I hadn’t heard that before. [laughs] But it’s a straightforward process. Just keep trying if you don’t get it the first time.

Rich Bendis: Great. Thank you. Congratulations on the third try! Ellington, how many times did you try?

Ellington West: We applied twice. I think ultimately it’s like 60 people involved in evaluating not only your pitch but your full application. They are from all elements of our industry, whether that’s regulatory, reimbursement, manufacturing, R&D and development, and of course the clinical component.

0:37:00 What’s so great is when you are accepted, you really get that just feeling of, “Wow, this has been vetted by some of the best in the world, and they chose *us*.” That’s what’s so exciting. This was my second time. The first time, I was pitching—and I’ll never forget—I’m in like one of those roundtable discussions, and this woman like *annihilated* my reimbursement strategy. She was like, “None of this makes sense. How could this be successful?” I was sitting there and I’m like, “Oh my gosh!” Like she did not hold any punches. And she says, “But call me after this.” So I called her afterwards. She’s now actually one of my board members. Because I said, “Help me!” What I do know is that I’m coachable and I’m always ready to learn. I’m a forever student. So let’s roll up our sleeves.” Together, as we redefined our reimbursement strategy, I really think that’s what allowed us to be then accepted this year. Now I’m excited for all the other things that I’m going to learn along the way, because I’m sure there’s a lot to come.

0:38:00

Rich Bendis: I hate to ask, but that’s not one of my entrepreneurs in residence, was it?

Ellington West: No. [laughs] But I want to meet all of your entrepreneurs in residence.

Rich Bendis: Oh, okay. We have 18 of them now. But that sounds like one that would ask that kind of question. I’m sorry.

Ellington West: I love that.

Rich Bendis: Then, Michelle, talk about your experience in the application process.

Michelle Crawley: The application process was really easy. We did only do it this one time. I never even heard of MedTech Innovator, but I got an email that said, "Oh, here's this thing, and you have this opportunity." I looked at it, and I said, "Oh, we have the opportunity to get non-dilutive funding. Great. I'm applying." [laughs] So I did. I had no idea what I was getting into. At all. None whatsoever. But what a happy accident. It was just fantastic. They're incredibly thorough; I will say that. I did the virtual pitches. I didn't do the one in Baltimore. I did a virtual pitch. And now I'm so glad that I did [laughs]. It was a very different type of environment. I had never done a pitch in my life, for money.

0:39:01 Our CEO just deals with that, and I sort of run the company and stuff. I do sales to customers, and I know the product, and those kinds of things, but I had never pitched for money before. So for me, it was a fantastic growing opportunity. I thought to myself, "Well, we're looking for $7 million or $18 million"—so I'm like, "Okay, $300,000, how bad can it be if I screw up?" Right? [laughs]

Rich Bendis: [laughs]

Michelle Crawley: Turns out it was like one of the best things that ever happened. The potential for non-dilutive funding—sure, that's great, that's wonderful. But that's not really the *value* that you get out of this kind of a program. Everybody is a winner. I went into it thinking that it was really just a competition, constant competitions, like *Shark Tank* or something. I had no idea what to expect. It was just a real surprisingly collegiate curation of people together that are supporting one another, and it was just a fantastic experience.

0:40:01 I felt like I was drinking out of a fire hose for three days, trying to take in as much information as I could out of these people who were fantastic and had so much to share and to give, over the program. I'm really looking forward to the next year as we go through the—I would encourage *anybody*—definitely go through the process. Because going through the process and really having to detail out your strategy and

what you're doing and where you are with each thing—reimbursement, product development, regulatory strategy—having to really think that through, if you haven't really put a lot of detail into it, you need to if you're going to be successful, and this gives you that sort of focus, and getting good feedback in the process. Fantastic.

Rich Bendis: Thank you. I guess the key is for those who have not applied yet, if you have a medical device diagnostic or digital health company and are looking for feedback as well as potentially non-dilutive funding, and an ongoing process, the MedTech Innovator program is a great program to get engaged with.

0:41:08 I know we're getting close to an end here, and I want to close by focusing on something close to my heart, and that is that you're all part of what we call the BioHealth Capital Region, which is fourth leading BioHealth cluster in the United States. Just found out through another study we're the top three in talent in the United States. There's a new study that just came out and said that we are the third highest ranked talent region in the BioHealth industry in the United States. Our goal of being a top three by 2023 has at least been achieved in the talent area. And you all know how important that is. But I want to ask each of you what the benefits are of being headquartered in Columbia and Baltimore, in the BioHealth Capital Region, and what this region has done for you to help grow your companies. Ellington, we'll let you start off.

0:42:05

Ellington West: I feel so fortunate to have headquartered and founded by company here in Baltimore. The support that has been wrapped around our success is unmatched, and I know that because I've met so many other founders in other states that have struggled to just have their voice amplified and to have resources intentionally made available for them. Whether it has been working with Colin from the Baltimore Development Corporation, or Christy Wyskiel at Johns Hopkins Tech Transfer, there has just been so much support of companies, private partnerships, and folks who just say, "We are so committed to creating innovative solutions in life sciences that we will stop at nothing to ensure your success." I think that that's kind of that small-town, small state—throw a little—I think it's like Charm City

with a little southern charm, but also this extreme precision and focus on competition and success that makes us so unique and so special.

0:43:15 And then, don't even get me started on clinical trials, and the access that I have to hospital systems. For us to have three trials in three Maryland state hospitals is *huge* to me, and again, comes from a willingness from our community to support our success. And *then*, I have CMS right here in Baltimore, so if I have a question, if I need resources, these folks are here, and they're ready and willing to help us. Then I'm a hop, skip, jump away from D.C. when it comes to advocating for policy that impacts the trajectory of our technology and success. If all of these things are less than 30 minutes away from me, and there are people coming out of the woodwork to support me, but then on top of it, based on basically what Rich just said, the fact that we are now on everyone's radar, that means that we are on investors' radars as well.

0:44:09 Those limiting factors that used to exist based on capital structure and limitation based on geography, is completely out of the window. And I forgot—sorry, I'm almost done; I just clearly love where we are—is that talent acquisition. It's not just that we have some of the best talent; it's that they can afford to live here. They can afford to grow their families here. Then I have great employee retention. I just feel incredibly lucky. I'm not going anywhere. I swear to you, I was in Austin two weeks ago, and someone said, "Oh my god, you're from Baltimore?" I was like, "Well, what's next, *The Wire*?" They were like, "No, this is like this incredible medtech hub!" I just felt so great. I think about Bob Storey over at LaunchPort, who will stop at *nothing* to make sure that Baltimore stays in that top three.

0:45:00 And Rich, we were so lucky in getting you from Philly. It was probably the best thing that ever happened to this region. So I'm just thrilled across the board. And—I'm done, I'm off my soapbox, but I'm just so thrilled to be here. [laughs]

Rich Bendis: That was a paid testimonial from Ellington West, the Cofounder and CEO of Sonavi Labs. Sam, how can you top that? What do you want to add to that, about the benefits of being in the BioHealth Capital Region?

Sam Scott: I cannot top that. I'll just say ditto. [laughs]

Rich Bendis: [laughs]

Sam Scott: Ditto to everything Ellington just said, and the people she name-dropped. Yes, they have been awesome. I'd say for us, again, all of the above. Proximity to our primary collaborators has been awesome. Because we work with Hopkins. We license software from Hopkins. We're working with UMB on clinical studies. It's nice to have everyone so close. We can literally just take our latest prototype, hop across the street, show it to our collaborator. It's nice. Then also, what Ellington mentioned about D.C. advocacy. One of my favorite groups in this area is 2GI, 2Gether-International.

0:46:03 They're a group for disabled founders, led by Diego Mariscal. He's awesome. For example, one of the initiatives they have is to get better access to startup resources and funding for disabled founders, who are often not considered, or there's still a stigma attached, and erasing all of that. It's very unique to be in a place where I can do JuneBrain but also participate or help out with those types of efforts that are very impactful. So, yes, this is a great place.

Rich Bendis: Thank you, Sam. Michelle, what's left to be said about our region?

Michelle Crawley: Oh, there's actually quite a bit! We are really in great debt to—and if you have not taken advantage of this, pay attention—the Maryland Biotechnology Investment Tax Credit program. We wouldn't be here if it wasn't for that. I would also name the FDA, and for us, the NRC, and the Maryland Department of Environment, not to mention the University of Maryland.

0:47:05 The proximity made frequent personal communication available. These agencies, people in these agencies—I was so surprised; I heard a lot of people like, "Oh, I'm so afraid of going and talking to the FDA." I'm like, "Are you kidding?" Like, those are the best conversations, right? You don't go in there and be adversarial. These people have seen—everything, right? They know. They want you to be successful. They're there to service the American population and to make sure that they're protected. And so anything that they are asking you for is typically in your best

interest to do it, because if you have a mistake or you don't do something properly, you can hurt somebody, in this business. That's the last thing any of us want to do, right? You learn, and you grow, through these conversations, through these dialogues. I would also say the University of Maryland Technology Transfer Office has just been *fantastic* to work with.

0:48:05 As everybody was saying, there's *so* much infrastructure here. I would also say, for us, Howard County has the largest population of PhDs in the nation. We have the number one school system in all of the nation. Maryland has got the top schools. We've got the number one library system. We have *amazing* parks. You think about just the natural beauty of our area here, too. Attracting and retaining people to come to this area—they don't have to send their kids to private schools and stuff. They can just be in their communities. It's just a really wonderful place. I've only been in Maryland for 12 years, but—I think we were talking about this before the podcast even started—I love it here. This is really an amazing place. And just for medtech companies, it's fantastic. The ecosystem is here to really help you be successful.

0:49:01

Rich Bendis: What a great way to close a podcast, talking about the great attributes we have, and assets, within our region. I want to thank all three of you for being here on a very unique podcast. All three are winners, and part of the MedTech Innovator competition. Three female successful entrepreneurs from the state of Maryland. You're going to represent us when you all go to California later in this year. Congratulations to all of you. We've had Ellington West, CEO and Co-Founder of Sonavi Labs. Ellington, thank you for being on. Any last words from you?

Ellington West: No, thank you just so much for having me and sharing our story.

Rich Bendis: You're welcome. Samantha Scott, Sam, founder and CEO of JuneBrain. Thank you for being on *BioTalk*. Any last words, Sam?

Sam Scott: No. Thank you as well. This is awesome. It's great that you're highlighting what we're about to experience over the next few months.

Rich Bendis: Great, thank you! Michelle Crowley, President, Xcision Medical Systems.

Michelle, thank you for being on *BioTalk*. Any last words from you?

0:50:02

Michelle Crawley: No. Thank you again. The visibility is fantastic, and if anybody is interested, they can go to our website, www.xcision.com and find out more about us, if you're looking for the closest place to get treated, if you're a patient or you know somebody is, with early stage breast cancer, or investment [laughs], or to purchase a system. [laughs] Contact me!

Rich Bendis: I think each of you would basically refer everybody to your websites if they want to learn more information. Somebody mentioned *Shark Tank*, but I would be remiss if I didn't say that we have Crab Trap; we don't have *Shark Tank* in Maryland. The eighth edition of Crab Trap is going to be on September 20th. We're going to be calling for applications for you to apply for it. Basically you'll get a chance to present, if you are selected, at U.S. Pharmacopeia on September 20th at 10:00 in the morning, and there are cash prizes as well as CRO services and other things that will be available.

0:51:02 That information will be coming out soon. And, the 9th Annual BioHealth Capital Region Forum will also be on the 19th and 20th at U.S. Pharmacopeia. All of you *should* attend, because it's a great place to network, meet other contacts. And the Crab Trap competition on the 20th is a way to get in front of some world-class judges and get some prizes. I hope you all have a chance to apply for that. Thank you all for being on this edition of *BioTalk*. It has been really different and really enlightening to see the energy and enthusiasm all of you bring to your companies and to our region. Thank you very much.

Ellington West: Thank you.

Michelle Crawley: Thank you.

Sam Scott: Thank you.

Narrator: Thanks for listening to *BioTalk*, with Rich Bendis.

End of recording