

## EP.59 - Darryl Sampey FINAL

**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, your host of *BioTalk*. We're continuing this series on a virtual mode, just like everybody else is virtual these days. And we really have an interesting guest today. It's the first time we've had someone from the Frederick part of the BioHealth Capital Region, and a rapidly growing company up there. And we're happy to have Darryl Sampey, who is the Co-founder, President, and CEO of BioFactura, joining us on *BioTalk* today. Darryl, welcome to *BioTalk*.

**Darryl Sampey:** Thanks, Rich. Glad to be here. Virtually.

**Rich Bendis:** This virtual world we're all trying to survive. And as you and I were talking before we went live, you've got some pretty exciting things happening with BioFactura these days.

0:01:01 We're going to give the listeners a little bit about some of this excitement that you're encountering. And the other thing that's exciting is BARDA seems to be a member of the family in the BioHealth Capital Region, as we have multiple companies who have partnered with BARDA, and you have been one of those. And we're going to go into the details a little bit about that later. But first, I think the listeners really want to know more about who Darryl Sampey is. And in order to do that, Darryl, just give us a little bit of your background, what you've done historically, and then maybe a little bit about your academic background here in Maryland.

**Darryl Sampey:** Definitely a Maryland hometown boy. I went to University of Maryland for my chemical engineering degree, my undergraduate degree, back in the early nineties, and ended up going into industry right after getting my bachelor degree of engineering, at a company called North American Vaccine, which was in Beltsville.

0:02:00 It was acquired by Baxter eventually, but for a couple of years, I worked on process development for vaccines for meningitis and some other infectious diseases. And in '98, I hopped over to Human Genome Sciences in Rockville, which at the time was pretty small, maybe a little over 200 people at the time I joined, but rapidly growing. And through kind of the

dot-com bubble times in 2000, we saw that company go from 200 to over 1,200, so it was an amazing growth. And I was from pretty early to 2004, when myself and three other scientists and engineers started BioFactura. So during those early years in Maryland biotech industry, learned a lot about the technical side of what we do in process development and scale-up for manufacturing these kinds of products.

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And, pretty much got tired of working for other people, as things went along, and had some ideas of our own, and got three other engineers and scientists of like mind to join up and form BioFactura. We were all at-the-bench, on-the-floor type engineers and scientists. Nobody was a director level. Nobody had a million dollars saved in the bank so they could go start a company and not take salaries. So it was really a grassroots effort. We said, "We think we have a good idea and a good plan" and basically just busted out a company on our own, and had about two months' worth of runway to start making money or go bankrupt. It was a true startup in that respect. No investors, just a great plan. And we started doing contract work for other people right out of the gate to bring in revenue and make the company happen.

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So it was an exciting time. Still is. But risk-takers, for sure.

**Rich Bendis:**

It's exciting to hear about some of those adventures that some of the early entrepreneurs have had. But one of the things, before we get more into BioFactura, you continued your education after you got your undergraduate degree at Maryland, didn't you, Darryl?

**Darryl Sampey:**

That's correct.

**Rich Bendis:**

What else did you do there?

**Darryl Sampey:**

After leaving Human Genome Sciences, and about a year into starting BioFactura, at the time we didn't even have our own lab, so we had like one office. But I had maintained really close connection with the University of Maryland in College Park, specifically the Bioprocess Scale-Up Facility which was there. And we were able to basically rent time on the bench on a weekly basis to do work and earn money. And that was through my undergrad advisor, Bill Bentley, who's still at the University of Maryland.

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**Rich Bendis:** He's a super guy.

**Darryl Sampey:** Yep! At the time, he was starting up the bioengineering department, which became the Fischell Department of Bioengineering with Bob Fischell's investment into that. And I was one of his first grad students. Because he said, "Hey, you started your own thing? Why don't you come back and get your PhD with my new endeavor here?" And crazy as I was, I was like, "Sure, why not?" So I went back, and over a bit of a long stretch, did finish and get my PhD from University of Maryland in bioengineering, just a few years ago, right when I hit about 50 years old.

**Rich Bendis:** [laugh]

**Darryl Sampey:** So it's never too late!

**Rich Bendis:** It's never too late. And to be honest with you, having Bill as a mentor, actually, is not a bad person, because they've developed that into a national and globally recognized center, the Fischell Institute, right now. So you came up with some great entrepreneurial mentors, I would say.

**Darryl Sampey:** Absolutely. No, Bill was critical, not only with the company, but myself and he's a great guy.

**Rich Bendis:** And your academic education shows patience and persistence, just like an entrepreneur has to have when they're growing a business.

0:06:05 So you mentioned you four created the company without a lot of capital, had a couple months runway. And so what was your business plan initially with BioFactura? And did you have to pivot at all, or did you stick to your knitting, and just basically it worked exactly the way you thought it was going to, Darryl?

**Darryl Sampey:** Oh, lots of pivoting. Lots of pivoting there. We began—at the time, we had read that there would be a large market for contract service, like CMO type business, and that there was going to be a big gap in capability and capacity. So that was the original business plan, was to get into contract manufacturing. Which we did, for about a year, at a pretty small scale. But where a pivot happened was—it's interesting, because it led to a big deal, many, many years later—is we had a personal connection with a scientist at Fort Detrick, and that person led us to begin a collaboration with them to develop a smallpox therapeutic for DoD, for the Army.

0:07:13 And that led us to some grant funding that we won, in about the second year out. So in 2005, we got our first grant.

**Rich Bendis:** Were those SBIR grants?

**Darryl Sampey:** It was. Correct. It was a Phase I SBIR from the Army that started everything. We got a Phase 2. There were some additional ones. We even learned—I learned in defending the SBIR program when it was reauthorized in Congress—I learned how to lobby Congress myself. And so at the time, there were earmarks. There aren't anymore, but at the time, there were. So I put in—and back then, we had Barbara Mikulski who was running the Defense Appropriations Subcommittee. So I put some requests for earmarks for this program in the Appropriations, and actually got a couple earmarks directly from the Maryland delegation, which again helped to advance the program through that initial five-year contract through 2010.

0:08:12 So that really was a change from doing contract service work for other companies to really developing eventually our own products. Before the end of that time, we ended up exclusively licensing all of the components for that drug, from both Fort Detrick and NIH labs. And in 2010, we presented that program and the initial data to BARDA and to the DoD Advanced Development organization. And unfortunately for us, they had already two antiviral drugs that were a bit further along in the pathway. So they said, "We only need two. We don't need three. Go do something else." And we did. But about eight years later—so persistence, persistence—we ended up reengaging with BARDA because one of the two drugs they were developing failed and wasn't going to make it.

0:09:09 And we ended up being the backup plan for that. And it led us to eventually the award last year of a \$67 million contract to continue working on this project, that again was started in 2005, about a year out of starting a company. So time horizons are really long with the government, sometimes.

**Rich Bendis:** You're right. And a lot of people are hearing the BARDA name these days, so talk a little bit about how it is to work with them, and what's the process that you had to go through in order to get this major \$67 million contract with them.

**Darryl Sampey:** I had been engaged in biodefense work, again, since 2005 with Fort Detrick, and from then expanded my network along the way during those years and did and do have a pretty broad network in biodefense, not only with smallpox but with some other threats that we developed countermeasures against.

0:10:05 And so I was pretty much always in some contact with BARDA along the way, and would reach out periodically and say, “Hey, any interest?” And usually, I’d get, “No, no, no.” But I got a different answer about two and a half years ago. And when they decided that they may need this as the second product in their countermeasures for smallpox, they eventually asked us to manufacture a small amount of the drug for a non-human primate study, which they sponsored in order to basically test it and see if it worked in the gold standard model. We did that. It worked well. And then in the very beginning of 2019, they came in and said, “Look, this looks good to us. Put a proposal in to take it all the way through phase 1 clinical trials.” So we did that. They were very collaborative in the writing of that proposal, which they can be, up until submission.

0:11:06 So they were very helpful in crafting it so that we could time the options and the structure as best to fit their needs. And we submitted it, and we got the award. So it has been great!

**Rich Bendis:** So that was more of a direct contract solicitation rather than a competitive RFP. I mean, one, they knew you as a contractor. They knew the business. Helped you try to form the proposal in a way that it would meet what their needs are. Which different agencies can do. And so I think a lot of that probably led to them having the trust in you that had been built up over a number of years, which probably would not occur with someone right out of the box they had never met before.

**Darryl Sampey:** Definitely. Agree with all points. And we did have a track record, and a very good relationship with our collaborators. Again, Fort Detrick being up here in Frederick, we do a lot of work with them. So I think yes, that’s very important.

0:12:02 And I think the trust to award—at the time, we were only ten people. To award a \$67 million contract to that small a company, I didn’t expect it, to be honest. I really didn’t. But they believed that we had the capability to execute, as did we. And so far, almost a year into it, we’re doing quite

well. I think they're very happy. We speak with them every other week on the telephone for about an hour. It has been a great contract and a great partnership with them. I have no complaints whatsoever. And I think they're happy with how we've progressed.

**Rich Bendis:** So congratulations. But tell our listeners a little bit about how it has changed your life. Having that award, it's sort of—not that BioFactura wasn't known before, but a small company, as you say, with ten people, getting a \$67 million award is a pretty big deal. So what has this done to change operations for BioFactura, growth for BioFactura, and sort of what has it done positively for you?

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**Darryl Sampey:** So, you're right. It was an absolute game-changer for us, to get that kind of an award, and non-dilutive but very helpful in allowing the company to expand very rapidly. In fact we've basically tripled the company in a year. Now we're almost 30 people and hiring currently, to meet the needs of that contract, but we also do things outside of that particular program. Specifically we, over the last several years, have been developing biosimilars, which are generic biologics. And having that foundation of BARDA has really allowed us to accelerate the internal programs as well, because we're building out a very similar capability, as these are all the same class of drugs.

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They're all IgG antibodies. So we manufacture an antibody for smallpox very similarly to how we would manufacture an antibody for psoriasis, for instance. As far as manufacturing, testing, all of these things, there's a lot of overlap and a lot of similarities. So the BARDA awards allowed us to much more rapidly build out our capability and our ability to take a product to market. Which we are doing, now, in parallel with BARDA.

**Rich Bendis:** You also, I think, mentioned that you're actually going to end up going into clinical trials with this product you're taking to market. Correct?

**Darryl Sampey:** Yeah.

**Rich Bendis:** Tell us a little bit about the status of the product and this whole regulatory process you have to go through.

- Darryl Sampey:** Another interesting fact is back when we started the company in early days, we ended up inventing a platform, a novel biomanufacturing platform, which we used for the smallpox program and for other things we were doing in the early days.
- 0:15:00 But later on in the company's history, we saw the biosimilars thing take off and found a really interesting niche for our platform to manufacture biosimilars to certain innovator products that were manufactured in a similar platform, host cell, if you will. So we were able to make a very close match in product quality to the innovator with our platform which gave us a big advantage in biosimilars development and manufacturing. And that really is where we decided to make the foray into building these products internally. We actually started it in working with another company, a company called Momenta we got a contract with, and a licensing deal with, early on. So the initial thought was to just license the platform out in biosimilars, but we realized to keep the value and capture more value, it would be better to develop our own products.
- 0:16:00 And that's when I decided to turn and start raising initially angel investor money, and then eventually some small institutional money that we've brought in to develop these biosimilar products that have—our lead product is a biosimilar with a market of over a billion dollars, *for us*. So it's a big deal for us, and a big deal for investors, obviously.
- Rich Bendis:** Two things I want to follow up on. One is your investment strategy, but before you said that, you mentioned you had grown from ten to 30 people in the last year. Over the last four or five months, we've had some challenging times. So I would imagine other entrepreneurs are interested in how are you doing with your recruiting during the pandemic, and what has changed in your recruiting process as you're trying to recruit people to your company?
- Darryl Sampey:** Well, lots of video meetings in lieu of personal and in-person meetings, of course. And we're all getting used to that, and I think probably getting better and better at that.
- 0:17:01 So we typically screen people by video call initially, and then sometimes we'll have them on site and do one-on-ones there. We have very careful controls of our facility. Everybody has been wearing masks since way before that was mandated by anyone. And so we've had no issues thus

far in the facility with our personnel. Everything has been very careful. And so we do bring people in occasionally. But we've hired people directly just by video. We do use recruiters to find people. It's a tight job market for employers, especially in Maryland right now. There's a lot of companies hiring, especially companies involved in the pandemic product development space, like Emergent and Paragon—or, well, Catalent now—and others. So there's a lot of demand for these people, and it's hard to find good people anyway.

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So it is very hard to find the right people for the jobs we have, but we're doing well. We're doing well. It just takes a little longer.

**Rich Bendis:**

When you sell—tell us a little bit about how you sell your differential advantage to people. So I mean, you have Altimunne, Novavax, Emergent you mentioned, GSK, AstraZeneca. All these people are competing for talent. And as you know, there's a limited source of people available. So what's your sales pitch?

**Darryl Sampey:**

We definitely bring in a certain type of person. And even at this stage—I mean, we're at 30 people; to me that's big because we were only up to ten a year ago—but we bring in those with that entrepreneurial spirit, that may have worked at the larger companies in the past and has found that that's not as fulfilling to them. They don't feel like they're contributing to the big picture. And at a company like BioFactura, they certainly can—and are required to—I mean, everybody pitches in with a company this small.

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And we're taking things through clinical trials and down the road just like the big companies as well. So we do with 30 people what a lot of people do with 200-plus people. It definitely is a certain type of person that wants this challenge. And we find them. And we've been able to, kind of through the interview process, weed out those crazy people that join the company and do really well with us.

**Rich Bendis:**

They have similar profiles to the founder, right?

**Darryl Sampey:**

They certainly can. And do. [laugh]

**Rich Bendis:**

[laugh] Some of those crazy people! You mentioned your investment strategy, and initially, you had contract manufacturing for some contracts. Then you had some non-dilutive funding. You've been



fortunate to get the BARDA contract. But then when you decided to go into your own product, which you're going to commercialize, that required some additional financing strategies. So let's talk to the listeners about your financing strategy and how it has progressed.

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And just to let everybody know again, this is Darryl Sampey we're talking to, who is the Co-Founder and President of BioFactura in Frederick, Maryland. So Darryl, tell us about your financing success.

**Darryl Sampey:**

As I mentioned, when we identified biosimilars as a big opportunity for the company, my first target was to get a license and a deal with a larger company involved with biosimilars to prove that we could get market acceptance and validation of the platform that we had. And we were able to do that without investors, and that was with, as I mentioned, Momenta, a company up in Cambridge, Mass, which we did some good work with over several years. What I realized after we got that moving along was that we would do better if we developed our own products in-house versus just licensing the technology to other companies who do that.

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And in order to do that, we needed to raise some private capital. And at the time, with that buy-in from industry, from Momenta, I thought we were at a point where I could convince non friends and family, more sophisticated angel investors, that this was a valuable opportunity that they should invest in. And so I put together—ramped up the business plan for that strategy, and then got into some angel pitches, local ones mainly, different conferences. I ended up pitching a group of people, probably 50 people, at an angel event, and met somebody that was absolutely key to the success of where I am, and that's Dr. Jeffrey Hausfeld. Dr. Hausfeld I hadn't known personally until he saw my pitch at this angel event. And it really struck a chord with him. I was talking about basically the new wave of generics.

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He is a retired surgeon and actually lived during the first generic—small molecule generics wave back in the seventies and eighties. So he really knew—he kind of connected that with, "Hey, this is just biological. We have this advantage." And so that really attracted him to the opportunity. And we met a few times, and there was a great chemistry there. So he ended up investing in the company, but also joining the company, eventually, as the Chairman of the Board, and full-time as our Chief

Medical Officer. And in that initial round of angels, we were targeting a million and a half, and he basically said, “Look, I'm going to go into this with my money, and I've got a network.” And he was able to raise more than a million and a half. So we oversubscribed that round with his leadership on that.

**Rich Bendis:** Cool!

**Darryl Sampey:** And since then, he has been the principal fundraiser as far as our equity fundraising goes, and my absolute fully connected business partner.

0:23:06 We've actually raised—we did a second raise about two years after that for—the target was \$6 million. We oversubscribed that round as well. And importantly, in that round, we were able to bring in some non-angel smaller institutional investors. Although I would say they were still non-traditional. And that was an absolute testament to Dr. H's creativity in finding investors, and most likely due to his connection to the medical field. We were able to bring in a hospital venture fund, which was very interesting. University of Vermont Health Investment Venture Fund, who manages I think eight hospitals up in Vermont. They invested a million in that six-million-dollar round. And then we were able to get a hedge fund, again, that had some personal connections with Dr. H., to pull the trigger and invest.

0:24:02 So we really transitioned over into at least some initial non-angel funds, which are setting us up for the next round, which we're probably going to be getting into this fall.

**Rich Bendis:** What's nice is—what's complementary is you were probably able to focus on the business, and Dr. Hausfeld, who everybody knows in the region with a lot of the investor conferences he puts on, he's omnipresent. But he, I assume, could tee things up for you to come and talk, too, but yet could take the lead and let you continue to focus on the business.

**Darryl Sampey:** Absolutely. But I will step back and say Dr. Hausfeld is one of the smartest people I've ever known. And even the first two years or so that he was with me, he's so inquisitive, down to “How do you run a mass spectrometer?” He wants to know everything about how what we do is done, to the point where he doesn't even need me to pitch investors at this point.

**Rich Bendis:** OK. [laugh]

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**Darryl Sampey:** He can answer technical questions. He can answer manufacturing questions, GMP questions. You name it; he has pretty much got the answer, because he knows it, cold. And that's a rarity, that not only does he know it, but he really enjoys learning about it, and he wants to be able to present it as well as I do. And he can, which is fantastic.

**Rich Bendis:** It sounds like a great relationship, and you got an active investor rather than a passive investor, definitely.

**Darryl Sampey:** Incredibly so.

**Rich Bendis:** That's super. So let's talk about the future now. Tell us a little bit about what some of your personal and corporate goals are for Darryl Sampey as well as BioFactura.

**Darryl Sampey:** We are currently continuing to ramp up our manufacturing capability at the facility in Frederick that we have. We're actually starting a GMP phase I production run, in this case for a client. We still do a little bit of contract work, although that is phasing down, given the demands with the BARDA contract and with our internal programs.

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But that said, we have a few things to kind of finish up, and one of them is a GMP run that starts this week, in our facility. So continuing to expand the personnel and the capability to successfully manufacture product for human use, for phase I trials, is always a big challenge. It's not an easy thing to do, and we've spent the last several years getting that capability into place and doing manufacturing for these kinds of trials. So once that immediate run is done, we're going to be shifting to our biosimilar that we're going to be taking into phase I in the first half of next year. So we're hoping by the end of the year, that phase I manufacturing is completed. We're actually going to be doing that study in Australia. There are some government tax programs there that really help with the phase I trials, and a lot of people leverage that, and we are.

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And fortunately, they've been less impacted by the pandemic, which is also a good thing for clinical trials, which can be severely disrupted by this

pandemic, so it's another risk that we have to keep our eyes open for in the future. Hopefully things will get figured out next year.

**Rich Bendis:** Well, we're all hoping. Definitely we hope to have a vaccine in 2021. I think 2020 is a little optimistic, as you know, since you're in the business. But we hope next year, we'll be there. Earlier, we mentioned Frederick, and you're my first guest I've ever had from the Frederick area of the BioHealth Capital Region. Talk a little bit about the Frederick ecosystem, for people who aren't familiar with it.

**Darryl Sampey:** So Frederick is a great town. I've lived here almost 12 years now, personally lived here. And we brought BioFactura here about eight years ago, I think. We brought the company when it was very small up to the incubator facility here called FITC, which is the Frederick Innovative Technology Center, Incorporated. FITC.

0:28:11 And we were at FITC for about three years, and graduated from there, and built our own facility here also in Frederick about five years ago. And we found it has been a great place to start a company. The local county governments are very supportive of expanding biotech up here in Frederick. I mean, obviously we have AstraZeneca's manufacturing facility here, which is a big deal. But there are other companies, both small and medium—and large; we have Lonza up here in Walkersville, right outside of Frederick. It's got a big footprint up here as well. And of course Fort Detrick with a lot of work in biodefense as well. So we found it's a great place to get a company started, and I think it has become more and more attractive to employees to live and work up here.

0:29:02 In fact, we've been able to snag some great employees that were just so fed up with the commute down 270 that they'd rather work here in Frederick. And that was a big deal for them, in leaving a company and coming up here and staying and working locally. So no, it's great. I've got all the kudos in the world for the area and for the people that run the place up here.

**Rich Bendis:** You also have a federal lab up there in NCI. Do you do any collaboration with them at all?

**Darryl Sampey:** We haven't yet, but you're right. In fact our facility is basically in the shadow of the very large NCI lab up here in Frederick. We've been focused mainly on biodefense, and then into these biosimilars, so we

haven't done a lot of work in cancer, to date. But it's still a fantastic resource, obviously, for companies looking to start up here in Frederick.

**Rich Bendis:** Yeah, it's a nice anchor for your cluster there.

**Darryl Sampey:** Yes.

**Rich Bendis:** Let's talk a little bit about other people who might be with large companies or just getting started and want to go the entrepreneurial journey.

0:30:05 What are your words of wisdom to those that might want to embark on it, or are just entering it right now?

**Darryl Sampey:** For me, it was a necessity, personally, for me, to do this. There was a point in time where I knew that I would not do well at a large company. It was just not working out for me. I am the kind of person that likes to question authority. I'm the kind of person that doesn't like to take an answer at its face value. I want to learn more. And sometimes that doesn't work so well in a large organization, and slowly climbing a corporate ladder. So for me, and I think for most entrepreneurs, you've gotta have that fire in your heart to want to work for yourself, to want to create something that's your own. And that takes a certain type of person to do that. So I think that's step one. If you're driven to do that, if you feel that way, and maybe you're dissatisfied with where you are, then it's a good place to start.

0:31:07 I think the other thing is you need to find likeminded people to begin something with. It's hard enough to start something. I certainly couldn't have done this company alone in the beginning. I ended up recruiting in my personal network other likeminded people, and I think that's a great next step, is if you have this idea—actually, one of my cofounders, Alexandre DeSeabra, actually came up with the idea to start with, and he brought me into his office and said, "Hey, I got this idea! We should start our own company!" And I'm thinking, "What, are you crazy?" But I started looking at it, and I started writing the business plan, and it just hooked me. And I thought, "Yeah, this is doable. We can do this." And then we started pulling in other people and getting this nucleus of momentum to get things started. I think that's important—to surround yourself with the right people.

0:32:00 And, once you start things, is collaboration. So we continue constantly to collaborate with others. I mentioned we started a collaboration with Fort Detrick very quickly after we started the company. That has led to a lot of great things including eventually this BARDA contract. There have been many other collaborations between then and now, both with universities, with federal labs, and with other companies, small and large, along the way, that we've done. And I think collaboration is absolutely essential in bringing whatever your idea is down the road, and making it happen. So that's another big—you have to be collaborative, get out there, meet people, get them excited about what you're doing, and light a fire under them to help you get it done.

**Rich Bendis:** It's clear you still have a fire in your belly for doing this.

**Darryl Sampey:** Sixteen years later! [laugh]

**Rich Bendis:** Yeah, 16 years later. Overnight success, right?

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**Darryl Sampey:** Right!

**Rich Bendis:** Just like they always say. But it seems like you're on a great path right now. And whatever we can do to help you, we'd be glad to. And by the way, if you're doing your next round, we're going to have the third annual BioHealth Capital Investment Conference coming up in October.

**Darryl Sampey:** We'll be there!

**Rich Bendis:** You will be invited. We'll have 100 companies and 50 investors, and hopefully some of them will take a look at you. We just had one, AsclepiX, from Baltimore—I don't know if you know Wendy Perrow, but she met somebody in October last year, and three weeks ago, they just did their \$35 million Series A with a brand-new contact they had never met before.

**Darryl Sampey:** Wow.

**Rich Bendis:** So we hope you run into that person in October for your Series C or whatever you're phrasing this round as.

**Darryl Sampey:** it is Series C, and we hope the same. Yes! [laugh]

**Rich Bendis:** [laugh] But I want to congratulate you on the progress you've made. You're a great contributor to the BioHealth Capital Region. Look forward to following up with you on your future successes, and thank you very much for being a guest on *BioTalk*.

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**Darryl Sampey:** Thanks, Rich, and you keep up the good work, too!

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

**End of recording**