

**EP.118 – BHI Executives in Residence**

**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 breakdown the biggest topics happening today in BioHealth.

**Rich Bendis:** Hi, this Rich Bendis your host for *BioTalk*. We have an unusual show today. We basically have people that most of you should be familiar with in the BioHealth Capital Region, but the other unusual element is that they're all affiliated with BioHealth Innovation, and generally we talk about emerging entrepreneurs and resources within the region, but we have three great resources that are supporting a lot of entrepreneurs in our region with us today to talk about what we offer. A couple of them are new. One, a reentry back into the ecosystem with us. But we have Sarah Miller, who's the Vice President for Economic Development, for BioHealth Innovation.

0:01:00 We have Luis Gutierrez, who is a new Montgomery County part-time Executive-in-Residence. And Jen Butler, another new part-time Montgomery County Executive-in-Residence, who are all on this podcast today. So, we're going to do a four way, which is something that is not normally done, so if we trip over each other, you'd forgive us. But we have very distinguished and experience podcasters with us, so we should have no problem today. I think the first thing we always do is let each person introduce themselves, and I'm going to let Sarah Miller, our Vice President for Economic Development, introduce herself. Sarah?

**Sarah Miller:** Good morning Rich, Luis, and Jen. Thanks for having me today. I'm Sarah Miller, Vice President of Economic Development for BHI. I've worked with economic development and community development in Pennsylvania and Maryland for almost 25 years, so I'm excited to be here at BHI.

0:01:58 I've been here about 18 months and looking forward to discussing this new project with everyone.

**Rich Bendis:** Thank you, Sarah. Next we have Jen Butler, who was our first part-time Executive-in-Residence in Montgomery County, which we're going to explain that program to everybody later. But, Jen?

**Jennifer Butler:** Thanks, Rich. I've been here in the Montgomery County area for almost 20 years. When I talk about my experience over the last 20-plus years, I really talk about three major buckets, and I think most relevant to the Executive-in-Residence is I started my early career in capital markets and strategic consulting. Then, my next major season of my career was working within MedImmune and AstraZeneca, getting that very rich pharmaceutical development working across infectious disease, oncology, and inflammation, autoimmune. Five years ago, I decided to go back to a bit of the origin story, working with small companies, biotechnology companies, and over the last five years, have been able to work inside those organizations, helping them either come to the US, start a US commercial operation, or working with a company going from pre-clinical to clinical stage.

0:03:07 This program is just fantastic, because it really allows me to work with many, many different companies in the ecosystem, really understanding what their needs are to a whole host of things, and I know we're going to get into that. So, thanks for having me.

**Rich Bendis:** Thanks, Jen. Welcome to BHI and the entrepreneurial ecosystem in the BioHealth Capital Region. Our next guest is Luis Gutierrez, and Luis and I go back several years, because he was an Entrepreneur-in-Residence, not an Executive-in-Residence. There's a differentiation there. Sarah will explain that with NIH. Luis is rejoining both organizations. How about that? Luis, welcome back.

**Luis Gutierrez:** Thank you, Rich. I've been here in Montgomery County 30-some years, all working in life sciences and biotech in a variety of roles, some of which were local in scope, some were national and even global in scope.

0:04:00 The skill set I bring is helping companies develop their product development and commercialization strategies to ultimately get to the marketplace. Great science is cool, but to have an impact on patients' lives, you've got to commercialize it. And that requires, as Jen noted, addressing the needs of capital markets and a lot of other stakeholders, and I'm just delighted to see companies make that progression.

**Rich Bendis:** Thank you, Luis. Welcome back. We wouldn't be talking on this podcast

today if we really didn't have the vision of County Executive Mark Elrich and Jake Weissman with the county, who said, "We really need to engage with emerging entrepreneurial companies in the BioHealth area." Sarah, who is very experienced in working with county government, and prior to BHI, with Montgomery County Economic Development Corporation, interacted closely with the county exec's office and co-developed this program on the Executive-in-Residence need together.

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So Sarah, please give us a little more background on the evolution of this new program.

**Sarah Miller:**

Sure. And that's right; this project is in existence because of the leadership and the financial resources that are coming to us from the county government, so we thank them for that. One of the things that we're doing here—there are a lot of services that are available to BioHealth companies around the region and in Montgomery County, and because of those resources and that support—for decades, really—we were able to be a leader during the pandemic with cures and diagnostics and things of that nature. Obviously, you've heard the stories of our companies receiving a lot of funding, both private funding and federal funding, during the pandemic. One of the things that we don't want to forget is the importance of cultivating the startup companies in the BioHealth Capital Region. One of the things that's interesting to me since I've been at BHI, we have a wide scope of services, but also a wide scope of folks that we work with, so we can work with people from around the region, but also we work internationally and across the country.

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So, as a Rockville resident specifically, I was really excited to be able to bring all these great resources back to our community, specifically, and happy that the county is willing to help us fund that. So, what does this mean? This means that we have experienced, seasoned professionals and executives like Luis and Jen out in the trenches, so to speak, with our startups, helping them with all kinds of business issues related to commercialization, as Luis said, but also connecting them with our network and also expanding their own networks; connecting them with certain subject matter experts that we know, whether it's IP attorneys or regulatory; and really giving them an opportunity to sit and kind of vent and their technologies and their business challenges with our executives

in residence. They can each talk to you a little bit more about what they've done so far to give you kind of a flavor of the types of companies, but also the types of challenges that they're helping them to work through.

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**Rich Bendis:** Thanks, Sarah. Again, we thank Montgomery County for the opportunity to partner with them on this program as well. Now, I think Luis and Jen can give us an idea of what are some of the basic needs that entrepreneurs need that are in the BioHealth industry that we think that we will be able to provide some support to them. Jen, let's start with you. What do you think are some of those needs that these entrepreneurs need?

**Jennifer Butler:** Based on my early discussions, just in these last few weeks, having the program start November 1<sup>st</sup>, what I've seen is that often they need additional support as it relates to market data. They understand the technology; they understand their science; and as a very, very tangible example, they may be looking for data that they may not be able to purchase. Market data can sometimes be expensive for the entrepreneurs. Cash is very precious. Even \$5-, \$10-, \$15,000, which is the market data can go for, is expensive. It can sometimes put an experiment behind the market data acquisition.

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And also knowing which questions to ask—what are the relevant market data that would help move a business development or investment decision to that entrepreneur? So, a very specific example: I've been working with one of the companies to really think about scoping that, and we can leverage my background, and Luis talked about this as well, which is understanding, what are the type of data that really can compel and really articulate where commercialization of the asset will go? Or the technology? We can use the market data that's available through BHI and through other things, so that's a very, very specific thing it allows those entrepreneurs to have. I think that's one example that I'm seeing.

**Rich Bendis:** Great. Luis has been helping companies, not only in the region, but nationally, with the National Institutes of Health, in their programs for

many years. What do you see as the typical things that entrepreneurs need, Luis?

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**Luis Gutierrez:** To build on Jen's, that data about where the market is, what they really need is the coaching to then how to present a coaching business plan to both prospective partners, perspective collaborators, and perspective funders. A lot of early stage companies need advice on how to secure funding, be it non-dilutive funding, which is wonderful, as well as going out and getting equity financing. We do spend a lot of our time helping entrepreneurs hone that pitch with a more data driven level, and also a strategic level: Where the holes in the marketplace? What's that pathway for getting to market and balancing the length and cost of that pathway with the size of the return on the back end? We're just delighted to help people do that.

**Rich Bendis:** Yeah, pitching is critical to all of them, and most of them have a lot of scientific background, but don't have some of the business acumen that is necessary in order to interact with investors and partners. The other thing, and I forgot to mention this, is that BHI's had been involved with the NIH for almost 10 years now, with the Entrepreneur-in-Residence Program.

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In addition to Jen and Luis as executives in residence, we have 12 entrepreneurs in residence located throughout the United States supporting small BioHealth companies, so not only is it access to what BHI has, when you put the 14 of you together, it's amazing! You know, I was just talking to my wife about this. I said, "We're one degree of separation from getting to almost any resource that anybody in the United States would need because of the vast network that all of you entrepreneurs and executives in residence have." It's really an amazing environment which really is unique, and Montgomery County is going to be a beneficiary on that. Sarah, when we talk about these services and the needs of these entrepreneurs, what kind of services will BHI be able to provide through the executives in residence to these companies?

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**Sarah Miller:** In addition to the network connections and their own personal expertise that they have, if there is, as I said before, a need for some specialized services, whether that be regulatory, IP, and others, the county also provided us with a small pot of money where we can actually pay for some of those services for companies. I think that we haven't used those yet, because we're still in the early stages of seeing what everyone needs, and the fact is, it takes a little bit of time for executives in residence to develop those relationships, develop those strategies, and then figure out where the gaps are that we can help to fill. But that is an extra benefit that the county had the foresight to provide to us.

**Rich Bendis:** Yeah, I think some of those areas in that incremental budget that we have might relate to intellectual property, and since we're not lawyers, that might be something which the EIRs can talk a little bit more. Maybe it's regulatory strategy. Maybe it's reimbursement strategies, or other areas. Jen, Luis, talk a little bit about some of these other areas and the resources that are available to entrepreneurs within the BioHealth Cap Region that may be in your network or somebody else's network, which we may also be able to attract to support some of these businesses. So, Luis?

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**Luis Gutierrez:** Sure. One of the real attractions of this program is that the county is structured it in a way that it's a lot less bureaucratic and a lot less rules and regs and category driven than a lot of the other economic development programs that are available out there. So, what really distinguishes us well is that Jen and I can really do an in-depth consultation with an entrepreneur, figure out what they really need, whether we collectively—meaning not only her and I, but as you say, Rich, the entire BHI team—are we well suited? And/or do they need to target some specific expertise in regulatory and clinical science, et cetera? And there are funds available for that. So, I'd say that the hallmark of this program that the county's made available is the ease, the speed, and then the ongoing depth that Jen and I can stay involved with them over months.

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It's a very different kind of program that is highly customized and get you

to help you need, whether it's in our heads, or it's in somebody else's head that we need to access.

**Rich Bendis:** Before I go to Jen, one of the things of your area of expertise would be in regulatory, since you had a lot of years with Covance as CRO, so talk a little bit about how you would see regulatory needs and when an early stage company should get involved in the regulatory process.

**Luis Gutierrez:** Certainly. Some of our fellow EIRs have even deeper regulatory expertise than I do, but getting that regulatory read, not only for the US market, but also major ex-US markets, because developing your technology here, most medical technologies are developed for multinational and global application. Early on, that totally defines: How long is it going to take, and how much is it going to cost before you can bring this thing successfully to market? So, getting that regulatory read early on is crucial.

14:00 Of course, we're here in the shadow, literally, of the US FDA, so there's no shortage of folks who have that expertise at a specific therapeutic category level, which is so critical when you're looking at precedence and predicates of what's going before you.

**Rich Bendis:** You bring up an interesting point about we're the shadow of the FDA, but where the shadow of the NIH, and what actually brought me to Montgomery County is about 11-12 years ago, the county executives said, "We have all of these resources in our backyard. How come we don't get a greater return out of the resources that are here?" That's really why BHI was created, and here we are, almost 12 years later, still trying to assist. But some of those needs have never gone away, and they remain the same for entrepreneurs today as they were many years ago, or decades ago. Jen, what's your experience? What are some of these other areas where you think that we can help benefit them?

**Jennifer Butler:** I've been building on this idea of a real customized interaction with all these companies. I will say that the shared thing that you see across these small companies is that they have to rely very heavily on outsourced model.

0:15:03 Some of them, actually, it's embedded in their strategy, for example, with CROs, but when you are a small company and maybe you're scaling from

3 to 10, or 10 to 20, 20 to 30, you still need to have a fully operational company. So, being able to talk with folks like ourselves who understand how to get to that scale, when to leverage the third party—they may not be thinking about outsourcing. Or maybe their operations—HR, legal, IT—when do they begin to think about bringing certain functions in house versus maintaining them out of house? There's experience and there are signs to it. Being able to really sit down with folks who can really be, I'd say, an operational sounding board, in addition to, to your point, the pitch and the strategic—I think that's also a really distinguishing element to having the executives in residence who can really sit there and do that and network.

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I agree. I can't talk enough about this incredible network that you can get into. Just speaking with some of the other EIRs—people, because they have so many years' experience—30-40, they've done lots of different spinouts—you may be able to talk to someone who has an incredible ability to focus on angel, seed, and series A. Then you may be talking to folks who maybe have series B, series C. You may be talking to folks who've gone from 0 to 10 folks. Maybe they've gone from 100 to 200, but that's why you need to sit down with the companies and really understand what are your specific needs where they are at that time? So that, again, with this idea, but also, it's this ease that we're talking to. The program is set up so we can have a conversation quick. We can get the work done, and we can really have that discussion.

**Rich Bendis:**

I think both of you are talking about the ability to go deep. This program isn't designed to help hundreds of companies. It's really to look at promising companies that have significant potential, don't have access to all the resources they need to grow, and basically give them access to that: knowledge, networks, and potential funding resources, which all of us have some of those in our corner, really.

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Jen and Luis, let's talk a little bit about personal successes you've had in working deeply with an individual company. What was the situation when you got involved? And where did you help them evolve? What was really the success point at the end, to where you felt that they didn't need you anymore—they actually graduated? Let's talk about personal experiences each of you have had. So, Jen we'll start with you.



**Jennifer Butler:** Sure. I will say that since school just officially open November 1<sup>st</sup>, I think we're not yet ready for graduation, but I will tell you that already we have had some success in that. So, I'll just talk very personally, a company that just four or five weeks ago I began to work with. My experience was oncology and autoimmune, so from a therapeutic area standpoint, I was able to very quickly get up to speed, and they had got an opportunity to have a business development.

0:18:05 It was that meeting; the meeting that you want. The right people in the room who can make a decision, very large pharma partner, and being able to sit with them and really work on the slides, think very, very succinctly and crisply. Like Luis said, you really have to hit that. You got to stick that landing and be able to do that. That was within the first four weeks of that interaction. In addition, they had to submit a one-page funding summary to a potential ability to get in front of a full consortium of venture capitals that was just this past Monday. I'm really working out, what does a one-page get you in front in order to be selected? So these are very, very tangible. It's another consultation. It's really me putting pen to paper, really doing that, and also adding in one or two key market context setting things, so that investors can understand and the BD can understand, what is the opportunity?

19:00 What's the market we think we're going to disrupt or enhance specific to oncology? So, it's a very specific example of doing that. And I'll continue my conversations with that company going forward as we have some things headed toward the end of the year.

**Rich Bendis:** Yeah, that's a great example of something that almost every company needs. So, Luis, this doesn't have to be within last week since this is brand new with you, but the question is in your career, talk about a deep dive where you really helped somebody and what you brought to the party.

**Luis Gutierrez:** Certainly, although it is what I'm working with now, a company that I engaged with that is local.

**Rich Bendis:** Local in Montgomery County?

**Luis Gutierrez:** Yes, indeed—has a drug candidate that they're developing, and the entrepreneur was really struggling with, “What's the pitch?” I helped

them dive deeper into, “What's the series of indications?”—because he had too many of them, and, “What's the right priority from the perspective of pathway and payback, so that you can get that lead indication to fund the others?”

20:00 Again, in a matter of weeks, we read it as pitch, and he's now in potential M&A discussions. We'll see where it needs. It may lead nowhere. It may link us up with another company who is interested; we have a vehicle to funding, lead indication.

**Rich Bendis:** Great, super. Great example. And it's one you're going to continue to work with as you progress.

**Luis Gutierrez:** Exactly. It's an ongoing relationship. It's not just, “Here's a one hour. Here's my advice. Have a good life. Let us know how it works out.” We'll stay involved every month.

**Rich Bendis:** Super. These are some of the things that we see as the needs. Sarah, as you interact with county government and talk to them about what their expectations are that we're going to do with this program, what is it that you think that they're looking for BHI and the executive in residence to bring to these companies in Montgomery County? And what would be success in their minds?

**Sarah Miller:** These stories are success, I think, in their minds. I mean, this is what they want. They want to have one on one expert consultations and help and strategy with these companies.

21:00 As I said before, there are a lot of different organizations that have teams that work with BioHealth companies, but they're in different ways. They have to do with leasing space, or they have to do with maybe tax credits and things like that. But this kind of one-on-one deep dive into the business and the business plan is something that's really unique to BHI, so I think they'll be very, very happy that they can be able to provide that to their companies. I would say the other thing that's interesting from their perspective is, in many ways, this is a fact-finding mission for them as well as policymakers. It's not every day—unless you have maybe a business roundtable when you hear from people—it's not every day that you get this inside view of the inner workings. Not to say that we're giving them

proprietary information or anything like that, but you can begin to track the types of businesses and the startups that are in Montgomery County now. You can begin to see all of the work that the county and others have put in over the past decades.

22:00

What we have now to show for that—how things have evolved, how bioinformatics, certainly—the county just announced that program with the University of Maryland—and how really our BioHealth cluster is evolving. I think that you can't underestimate the importance of knowing that as a policymaker. The county has a long history of making good decisions about helping the investor tax-credit supplement, right? Helping with the SBIR-matching fund, helping with zoning issues related to BioHealth. So, this is just another example of them really putting their money where their mouth is and trying to find out how to help companies.

**Rich Bendis:**

Super. I think that's fantastic. And I think it's all something that's very attainable in meeting the county's goals. I'm just going to basically talk about three minor success stories—or actually major success stories—BHI had, which we hope we can replicate with this program. First one is Benevere, which was a company that actually got incubated in Carol Macy's company in Sequella.

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It was an oncology company. The technology came out of NYU. Basically, they were looking as to how to take their science to market. One of our EIR's back then, many years ago—this was maybe eight years ago—got involved, helped them pivot the company, and over time, Benevere ended up selling to the Jansen Division of J&J. The total potential valuation of that deal was over a billion dollars, but they attribute the entrepreneur in residence from BHI, helping assess the science, the technology, and the direction that they should go as one of the major reasons for their success. Another one which I think is really emblematic of what we're trying to replicate in the region is a company called miReculé. Anthony Saleh started out as a research scientist at the National Cancer Institute, working on head and neck cancer with his research.

24:00

Spent several years with one of the top scientists at NCI on this

technology, approached his PI and said, "I'd like to learn about entrepreneurship," and interacted with one of our EIRs who was actually working at the National Institute of health. As a result of that, he ended up spending 50% of his time with BHI and 50% of his time with NCI. He interacted with our EIRs and analysts to learn about entrepreneurship, and what we did with Anthony is let him lead the international soft landing of an organ-on-a-chip company from the Netherlands, Mimetas, to enter the United States. He actually ended up being the managing director of Mimetas in the first two years to get them established here in the US. While he was doing that, a scientist at the NCI has a conflict of interest policy, which, you cannot actually work on the science that you have been researching at a federal laboratory for a year.

25:03

So, he actually had to leave NCI to look at commercializing technology that he had been working on, head and neck cancer, at the National Cancer Institute. He finally left full-time, went to work for BHI on a full-time basis after. After his year, actually a couple of years being gone from NCI, he licensed the technology on the head and neck cancer, formed a new company called miRecale, and basically got the assistance—BHI was a co-founder in that company with him. Our EIRs, analysts, and team helped him start up that company, and over time, has been very successful in applying for non-dilutive funding, and has received probably about over \$4 million of non-dilutive of funding, has taken advantage of both the Maryland and Montgomery County investor tax-credit programs that were in existence. He took advantage of the matching SBIR program that was in existence at Montgomery County.

26:02

Also what's happened is one of our analysts, Ashwin Kulkarni has now gone to join Anthony at miRecale. So, another resource which was educated in the BHI Network is now working for him—started off as a COO, but is more migrating to the financial world right now. And they've added another technology around muscular dystrophy to their pipeline, so they have a dual path with their science and technology. What was just released in the last month and a half has been a major deal with Sanofi, which involves a significant upfront payment and over \$400 million of milestones that can be achieved for this company that has less than 10 employees, and all of this growth has evolved in Montgomery County,

Maryland, with all of the resources, all of their expansion, has gone within Alexandria real estate facilities.

27:00

Alexandria Real Estate Ventures was one of the investors in miRecule. Some of the board members of BHI have been angel investors within miRecule. So basically, this is an example, and a poster job for Montgomery County, how a scientist at NCI, which is located in Montgomery County, left NCI, started up a company, took advantage of all of the Montgomery County, state of Maryland programs and all the resources BHI has. We're hoping Jen and Luis can identify other Anthony Salehs that exist within Montgomery County that we can help them, lead them down that same pathway that they have. We know that Anthony's not done yet, because the Sanofi deal only involves half of his pipeline. The oncology is still sitting there, which is untapped related to doing strategic partnership. We're very excited about his success. It's not fully achieved yet, but it would not have been able to have been progressed to the stage it is, if it didn't have access to all of the resources that exist, the network and funding within Montgomery County, as well as some of the BHI team members.

28:07

Jen and Luis, you have identified somebody just like Anthony, right?

**Luis Gutierrez:**

They roll in daily.

**Jennifer Butler:**

Of course.

**Rich Bendis:**

[laughs]

**Luis Gutierrez:**

That's why we're doing this podcast. Jen's email and mine are both posted on the BHI, BioHealthInnovation.org website, and we welcome inbound inquiries from companies that think may qualify.

**Rich Bendis:**

Yeah, I think the key is—Sarah, let's talk about if somebody wants to get access to Jen and Luis. Give me a typical profile of the company that we would engage with, and how do they come in contact with us so that we could make those introductions?

**Sarah Miller:**

Well, I know that they are not going to like this, but I would say that anyone should come in contact with us, and I think that's what makes this project a little bit different. It is not someone who has this idea of an SBIR

that they need help with, or some idea of some specific thing that they want to come to BHI for to get our well known services.

29:04

This is, in fact, a way that we can triage people's needs and talk to them and see what happens. And, frankly, in some cases, we might not be able to help people. I think that's okay too, but we will give our best recommendations and our best effort to assist people however we can. With that being said, certainly the companies can go onto the website and touch base with Luis or Jen. They can certainly email me directly at [SMiller@biohealthinnovation.org](mailto:SMiller@biohealthinnovation.org). We also are in an outreach period right now where we are connecting with some better known incubators and shared workspaces, but we're also connecting with some of the newer, small lab areas that have been built, and also some of those companies that sub-lease their space, or their benches, as the case may be, to some really small startups, so we're really looking at those well-established facilities, but also within our network.

29:57

**Rich Bendis:**

Thank you, Sarah. I like to always close the *BioTalk* podcast with sort of an open mic where all the participants can have the last words, and where you heard last words from Sarah Miller, our vice president for economic development at BioHealth Innovation on how to get in touch with this program and the executives in residence. Now let me turn it over to Luis Gutierrez, executive resident. Luis, last words on this new role you have.

**Luis Gutierrez:**

Delighted to be back with the BioHealth Innovation team, and we're locally focused here in the BioHealth Capital Region. I welcome companies looking for help to get in touch.

**Rich Bendis:**

Great. Thank you, Luis. Welcome back. And Jen?

**Jennifer Butler:**

I just can't reiterate enough about, I think, the ease and the access and the depth of the program. Please reach out to us, at least for initial talk, as Sarah had mentioned, about triaging. This is a different program. This really is something to really have a great engagement. I'm very, very enthusiastic about being able to support Montgomery County and the region through this program.

0:31:04 So, this is just incredibly important to really see this ecosystem thrive.

**Rich Bendis:** Thank you very much, Jen. I want to thank Sarah Miller, Jen Butler, and Luis Gutierrez for being on *BioTalk* today. Also as a follow up—and you guys can tell me the timeline—we'll bring on some of your success stories with you for some of those companies that you've been mentoring or working with over time, and will circle back and do this on a regular basis to give updates so that people can see the progress that's being made with the Executive-in-Residence Program at Montgomery County. So, thank you all, and good luck and good hunting for those newly emerging BioHealth entrepreneurs in Montgomery County.

**Luis Gutierrez:** Thanks, Rich.

**Sarah Miller:** Thank you.

**Jennifer Butler:** Thank you.

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

**End of recording.**