EP.139 - Theresa Podrebarac

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 for *BioTalk*. And we are a special guest this week, and it's really special because she just finished participating in our 9th Annual BioHealth Capital Region Forum, did a TED Talk, and really brought the house down. It's really one of the best discussions and talks we've had in nine years, and everybody commented on that at the end of our forum and at this panel. We're going to talk more about this during the podcast. But I have Dr. Theresa Podrebarac, Senior Vice President Clinical Development, Horizon Therapeutics that we're doing the podcast with today. So, Dr. Podrebarac, thank you for joining *BioTalk*.

Theresa Podrebarac: Yeah. Well, thank you, Rich for inviting me.

0:01:00 It was a terrific experience to come to Maryland. At Horizon Therapeutics, we do have facilities in Maryland, and dedicated scientists and researchers, and so we are very committed to advancing research in the area.

Rich Bendis: Yes, we know that Horizon is extremely important to our ecosystem and growing, and we look forward to much more collaboration with the organization and people, wherever you have them throughout the world. We know you're a global organization. But before we get into Horizon, let's talk about you. And I think the best way to do that is rather than me read from your bio or résumé or vitae, it would be best for you to discuss with our audience your background. So go for it.

Theresa Podrebarac: I started out in a small- to medium-sized mining town in Northern Ontario called Sudbury, Ontario. And I do a little bit of a shout-out because Alex Trebek was actually born in Sudbury, Ontario, and he's obviously more famous than I am.

0:01:59 He was actually a contemporary of my mother's. They went to two different high schools though. So shout-out to the region. And then I went to university in London, Ontario, at the University of Western Ontario. It's now called Western. And that's where I started some undergrad work. At that time, you could fast track into medical school, so

I don't have an undergraduate degree. That's a little bit of trivia. I went into medical school, and I also stayed in that area to study internal medicine. Along the way, I was trying to determine what type of specialty I wanted to go into. And what's very common at that time is every time you're doing a certain rotation, you think, oh gee, I'd like to be a pulmonologist, or at one point I was fascinated with liver disease, and I thought about being a liver specialist. And then I did a clinic in rheumatology, and that's where we see patients who often present with arthritis and pain and autoimmune disease.

0:02:57 Many of the patients were similar age as myself at the time, in their 20s, because autoimmune disease quite often affects more women than men. And I was fascinated at the time about how the immune system could really turn on itself. And it was through this exploration that I decided to become a rheumatologist. So off I went for a fellowship in Ottawa, Ontario. The fellowships at that time—so Canadian training's a little bit different in that internal medicine is a full three years, and then you do two years of specialty. We also had oral exams at the time, not just written, and my rheumatology exam was actually essay and short answer, not multiple choice. So this is going back a ways. But, again, it was just fascinating to me to see the range of diseases that were the result of how the immune system was activated improperly, or there were certain normal pathways of wound healing that went awry.

0:04:02 And then I also saw patients, again, where the treatments I had were so inadequate. We had steroids, which was given the Nobel Prize in the 1950s for curing rheumatoid arthritis. But they can have a terrible toxicity associated with high doses or long-term use. And then we had other treatments that we borrowed from our cancer colleagues, you know, like cyclophosphamide. And I remember very clearly this one patient I had who had lupus, which is a disease that can affect essentially every organ system. And I was explaining to her that her kidneys were failing, and I had to try this medicine, cyclophosphamide, to see if we could save her kidneys. And during this time, she's in her 20s. Her whole life is in front of her. And I'm letting her know that I'm increasing her risk for ovarian failure—at that time, it wasn't as common to be able to bank your eggs, etc.—that I was increasing her risk for bladder cancer and leukemia, and these infusions would likely cause a lot of bladder bleeding and inflammation.

0:05:07 And I kept saying to myself, we have to be able to do better than this for our patients. And it was at this time that there were other individuals that I worked with, with my mentor, who were studying immunology, and they were working with other scientists to do basic research. Now, the reason I brought up that I hadn't got an undergraduate degree, the last time I was at the bench in chemistry was many years before. And my mentor said, "Would you consider doing some basic research?" I like clinical trials, but why don't I give this a go? And at that time, I thought I would be a better rheumatologist if I actually understood the immune system better. So when I was still in Canada, I did some lupus research. I looked at genetics of Canadian women who had lupus, and we were able to contrast French-Canadian women to other women of other origins, because that's a founder effect of all these about seven or eight thousand families that came from France that settled in Quebec.

0:06:05 And they had used this population previously to find some other genes related to high cholesterol. So in the course of these studies, my mentor said, "If you'd like to come back to faculty, you know, you really have to go and get yourself some additional training." So then I interviewed to do postdocs in immunology and, again, I really had no intention when I was doing my training that I would be coming to the United States, and then I was interviewing at these various labs, and I came to Harvard. The individual I interviewed with was the head of rheumatology at the Brigham, and Brigham's associated with MGH in the Harvard system. And what really impressed me was he had a very robust [muffled], they were with a lab with allergy and immunology, but very different disciplines in terms of how they were looking at different parts of the immune system and cell biology.

0:06:58 My mentor was publishing in highly reputable scientific journals like *Science* and *Nature*. And my thought was, I'll get really good training here at Harvard. So I remember one day being in the quad, taking a lunch break, and I said, "Can you believe it? This [muffled] from Northern Ontario, is sitting here now at Harvard to sort this out?" And from there, I was trying to decide what are the next steps? Should I go back to Canada? Will I do more clinical medicine? I saw patients, again, not only in Canada, but when I was in the United States doing my training, I'm fortunate that they recognized all of my training in [muffled]. I just had to do [laugh] more exams, so I had to do the American exams. And then one

of my former colleagues from the lab was recruiting for physician scientists to join industry. And we met at a mutual friend's 40th birthday party, so really serendipity. And what he mentioned to me was that he was looking for someone who could do some first-in-human studies in rheumatoid arthritis and inflammatory bowel disease.

0:07:59 And I felt this was really right up my alley with my rheumatology training, and he was also a rheumatologist. And so I took the plunge, and I said, well, this will be another experiment. You'll now be able to take your clinical training with your scientific training, and then also marry that to having a business sense. When I grew up, I worked in the family business. So my family had a business that was seven days a week, as it often is, and I worked in various jobs. It was a hotel, and I would waitress. And I'm still in a really good short order cook, Rich, by the way.

Rich Bendis: [laugh]

Theresa Podrebarac: I can put a meal together in 20 minutes. [laugh]

Rich Bendis: [laugh] Well, that's great.

Theresa Podrebarac: And that over time then, my parents had me more involved on the business side in terms of keeping the books, and preparing things for taxes, and various things, and having a sense of what it was like to manage a business and manage staff. So that's how I ended up joining industry, so a little bit by serendipity. And now when I look back, it's been 22 years.

0:09:00 The time flies, it really does. And I think I've been truly fortunate to work on many medicines now that for those of us who maybe watch television and see some of those direct-to-consumer advertisements, right, as my family will be with me. "Yes, I worked on that one and—

Rich Bendis: [laugh] Right.

Theresa Podrebarac: —I worked on this one over here." And it's a different way of practicing medicine in that I feel I have an impact beyond my individual interactions that I've had with patients, which I still miss that laying on of hands, and taking away the fear and pain and concern. But I'm greedy. I want more medicines. I want to I say that we can still do more for our patients.

Rich Bendis: Well, it's okay to be greedy. We do have something in common though, because I come from sort of an entrepreneurial background. My parents had a mom-and-pop grocery store. We lived above it. And then they sold that, and they bought a motel, so they were in the motel business. You were in the hotel business. And I know how hard that is.

0:09:59 And actually, we got the benefit by going there at the Jersey Shore every year to the motels, what they had. But they were working the whole time, and you know how that is. You don't really have a lot of time to spend with your family and your kids. But maybe that's what's grounded us to understand better the entrepreneurial values, regardless of what industry you work in. But your evolution was not totally traditional in the manner in which you ended up in industry, but you have stayed there for 22 years. And one of the things that, for the listeners, what's interesting is the evolution to Horizon, because MedImmune was one of the founders of our BioHealth Innovation, our for-profit to help bring the region together. And then, of course, MedImmune was acquired by AstraZeneca. And while MedImmune was going on, there was sort of an internal entrepreneurial culture, and some of the people there spun out a company called Viela Bio. And then Viela Bio spun out, and was acquired by Horizon.

0:11:00 So that's how we're talking to you today because of that evolution, and I'd love to get your feelings on that transition that occurred, and when did you actually enter Horizon during this whole progression that occurred, all the way from the MedImmune to Viela to the Horizon acquisition and merger.

Theresa Podrebarac: During the pandemic, I was working for a very small biotech company. So I have worked for small, medium, and large organizations. And at the small biotech company, at the beginning of the pandemic, we were working on a rare disease called recessive dystrophic epidermolysis bullosa, which is a mouthful, or RDEB.

Rich Bendis: Right. Say that three times.

Theresa Podrebarac: Say that three times. And, again, this is a genetic disease where they lack collagen VII, and are unable then to have these anchoring fibrils to attach the epidermis to the dermis. So it's very severe. These children essentially

develop almost the effect of having third-degree burns. With minimal trauma, they'll slough their skin, and what have you.

0:12:01 So at the beginning of the pandemic, we were enrolling this trial. But, again, these children are—and adults, we are enrolling adults, but the disease starts in childhood. They can be immunocompromised. And our trial was an IV, and they had to come to hospital or clinic. So we were essentially having to pause where the trial was. And the company I was with at the time then essentially said, "Well, we don't really need you at this point in time." And they were consolidating some of the other companies. So I began consulting. I had done a little bit of consulting in 2015. And this is where it helps to have connections, right? And so I had several—I call them the friends and family who, Rich, [muffled] previous work we had worked together. And I had a few consulting projects where I was helping them either understand their transition into the clinic, review indication selection.

0:12:57 I also had a couple of clients who were venture capitalists who would like to have technical diligence done before they enter into a transaction. And in the Horizon case, specifically, one of the individuals who used to work for someone who worked for me at AbbVie reached out and said that they were doing a technical diligence for this company called Viela Bio, and would I be interested in helping them on the technical side, because many of the drugs that Viela had, vis-à-vis MedImmune, were mechanisms I was extremely familiar with, along with the diseases. So I went through the technical diligence for all of the Viela products. And at the end, they made the decision to acquire Viela, I think, for about $3 billion. And that transaction closed, I believe, March of 2021, in that timeframe. And then the individual who's our head of R&D now, Elizabeth Thompson, said--we were also friends, and she reached out and said, "Do you have a few minutes?"

0:13:59 And I thought she was going to ask me about career advice or some such things because I had been in industry a bit longer. And she said, "Well, I have a proposal for you. Would you consider coming now to help us at Horizon integrate Viela, and really lead the clinical development function because we're still building R&D?" Horizon was really much more of a commercial organization that had several rare disease products for cystinosis and urea cyclic disorders, etc., and some other products. So

they were really trying to build R&D. And she said, "Will you come and help me build this function with leading clinical development, and helping with the integration of Viela Bio?" So that's how I came to Horizon. But one of the main reasons that—there were several reasons why I decided, you know, because I said, "Oh, let me think about this." [laugh] I also was interviewing for other chief medical officer roles, and I had had already two offers. So I was deliberating what I should do.

0:14:57 The one thing I will say is that during that process, when you interview for a position, it's a very artificial state. You have these interactions with various individuals. You're trying to understand how the organization works and operates, what the culture is like, etc. Whereas here, because I had consulted for them over several months, I saw the organization in its natural state. I would attend meetings and even meetings with the CEO and other individuals who were important in making the decision about whether to move ahead. And I was left with the sense that these are really nice people. And that does sound trivial, but I've been in many organizations where you don't always have nice people. They were very collaborative, super bright, very collaborative, motivated, really trying to do what was best for patients, but very careful how they did their analyses. And so the other point was they had other things in their portfolio for diseases that I was particularly interested in, such as scleroderma and idiopathic pulmonary fibrosis diseases that still have either no or not that effective approved therapies.

0:16:06 So it was that combination of getting to know the individuals, getting to know the culture of people who really go above and beyond, the pace of the work, the nature of the diseases. So that's why I was drawn to this, and I said, well, I started earlier saying it's an experiment. Well, why don't we give this a shot, and see how well we can bring Horizon forward and also the medicines.

Rich Bendis: And here you are today, and we're glad out of those three opportunities you had that you selected Horizon, because we're going to be the beneficiary of all of your wisdom, which you can bring to the company as well as to our region. So thank you for making that decision. And when we talk about your role as Senior Vice President for Clinical Development at Horizon, that really means a lot in different things in companies. So let's talk a little bit about what that role means for you within Horizon.

0:17:00

Theresa Podrebarac: I have a group now that we grew over the last few years. I've been with Horizon a little over almost two and a half years. I have now about 25 physicians, scientists. I have PhDs, MDs. I also have a nurse, a PharmD. Our chief goal is that we design the clinical development plans for each of the medicines, and we also determine the strategy for how we will develop these medicines. And, again, we're also accountable for the clinical trials. We do have a mission statement which says that we are the chief advocates for our patients, and we see our mission really as to how do we best understand what the medicine can do, both from an effectiveness perspective along with potential safety risks, and how do we choose the best patients who can benefit from the medicine, and really interrogate and understand how that medicine works so we can make good decisions about which medicines to progress and which ones maybe are not going to be successful?

0:18:08 So on my team, I have all of the medicines that we are developing. The individuals who report to me are also, for most of the teams, called a co-asset leader. And so we have someone who comes either from the new product planning function or commercial function, if it's an approved medicine, as we're doing additional indications that we're pursuing, along with one of my individuals. So that's what I mean that we are the co-leaders of the architecture of the program about how will we do this across indications. And that's important because we are not only the medical function in Horizon, and so sometimes—and, you know, Horizon's now an organization of about 2,000—we have a more expansive role than you might see in some other companies, where my team might work on the clinical trials, and do medical monitoring, but may have less of a role in terms of that overall design and understanding.

0:19:04 If you are thinking about, for example, subcutaneous medicine, there's a device. Well, how do you develop those hand in hand? So that's essentially our role. And, like I said, I'm incredibly [muffled].

Rich Bendis: Yeah, I love the mission statement because that's something you're passionate about, chief advocates for our patients. And when we came and asked you to speak, and you graciously accepted, we said, "Well, what would you like to speak about?" And so you came up with a topic, and the topic was underscoring the patient perspective. How patients can

help guide scientific innovation, so totally related to the mission of Horizon, and something you're passionate about as well. So please talk a little bit about how your background as a rheumatologist in treating patients has impacted you to feel about the patient's voice in how they can impact the development of medicines based on what would be best for them.

0:20:01

Theresa Podrebarac: Even though I don't see patients one-to-one anymore, sometimes I'm tempted—be on the public transit or what have you, and so I will be standing there, and I'll notice that they maybe have psoriasis or psoriatic arthritis. And I'm tempted to say, "You know, there are treatments for that." [laugh] Then I realize—

Rich Bendis: [laugh]

Theresa Podrebarac: —you're not in the office anymore.

Rich Bendis: [laugh] Right.

Theresa Podrebarac: But you can't take the physician out of the physician. And rheumatologists, we are really pattern observers. We're observers. And along the way, you appreciate that your role really is to listen and to try and understand what the patients are truly going through, and to help problem-solve. How can we make things better for our patients? And the reason I bring that up is that even though I don't see patients anymore, they live in here. I carry those stories with me, as I mentioned earlier on, about the young patient with lupus [muffled] kidneys, and the treatments that we had to offer versus what we can do today.

0:21:04 And I encourage all of my folks, especially those who are physicians, you know, to carry those patients with you. What are their needs? What are their concerns? It's not just about mortality. It's not just about the quantity of life. It's also about the quality of your life. And this is what we refer to quite often as the unmet need that we see for our patients. And in several diseases, we don't even ask the patients how they feel when we're doing some of our trials. We don't say, "How important is this to you that we are able to ameliorate or fix some of these problems that you have?" And I think that's so vital is to be able to understand what the patient needs, not just the patient but the caregivers too, or parents, the

struggles that they have. The other day, I was sitting next to someone in a salon, and she was telling me about her husband who recently died of ALS.

0:21:58 And she said, "Well, they told us it would be slowly progressive and," she said, "that was fine for the first couple of years, and then things really accelerated." And she was still numb with all the trials and everything that was ongoing. And she said as soon as he died, she realized she had this horrible back pain that she said, "I didn't have time to pay attention to." So we chatted a little bit about that. But I think the other point I wanted to make is not only is that the patient voice something that motivates us, and one of the real treats we have is at least once a year, if not more often, is we invite patients with the diseases we're trying to address to speak to us in R&D, in our research and development, so those who maybe are not as directly involved with patients are able to understand the impact this has on their lives. And that's terribly motivating. You can't [muffled] we're all crying [laugh] by the end of the session, and not just for their struggle but also for hope, right?

0:23:02 And so in terms of how it impacts clinical trials and what we do is we try to make sure that we have good instruments to measure what's important to patients. I know one of our panelists Annie Kennedy was saying that it's not enough to go to the FDA, for example, for an advisory committee, and have these emotional tributes, and that. You're more empowered if you have data. Show us the data of how this improvement is impactful for you. And there are these guidelines in terms of developing instruments, or we often will do is we repurpose an instrument. It worked over here in this disease. There's something similar here. It's a little bit different. But you need sometimes a starting point. And one of the things I really like about Horizon is we're not afraid to take risks. The measurement tool may not be perfect, but am I going to wait for perfection before I start trying things for patients, right?

0:24:02 So part of that is sometimes we negotiate with regulators to say, you know, here's our starting point on the instrument. Here's how we're showing that this instrument really resonates with what we're trying to measure in this specific disease. And then there's a process to have that instrument recognized as having the measurement sensitivity that it needs to measure what we're supposed to be measuring, like I said, to

detect and measure change, and then to understand the magnitude of the change that is meaningful for the patient. I'll give you an example. We could look at the time for patients to develop a flare. Okay. So a flare is usually a worsening disease, and I use flare generally because we can see that in lupus. We can see it in rheumatoid. We can see it in neurologic diseases. And so let's say I can show something that is statistically significant, that is not by chance alone. And I could ask you, Rich, "Rich, in terms of your flare of your arthritis"—let's use something simple, your flare of your arthritis—

0:25:02

Rich Bendis: Which I probably have in both of my knees, you know.

Theresa Podrebarac: [laugh]

Rich Bendis: That's okay.

Theresa Podrebarac: Well, I do as well. And if I said like for a really bad flare, or let's say gout—so gout is a disease that we also treat, which is caused by too much uric acid in your system, that it's not cleared, and then it precipitates, and it can cause joint inflammation. Now, what if I said, "I can show statistically significant that, Rich, before your next flare, I can delay it by 30 days"? And you might be saying, "Gee, you know, 30 days? But I'm still going to get the same flare, or the same intensity of the flare, etc.?" Versus you can ask about, "Well, what would the number of days be between flares that would be important?" So maybe 30 days is too short. But I said, "Look, I could delay it by a year," especially if it was a significant organ-threatening flare, right? Or I could ask the question another way.

0:25:56 Well, what if I asked you, "What is the likelihood that I can put your disease into remission versus just stretching out the period by which you don't have certain symptoms?" But what if I said about the time I could put you into remission, right?

Rich Bendis: I prefer that option.

Theresa Podrebarac: Yep? And then I could say, "Well, steroids and [muffled] often what we use as the—Rich, what if I could get you to remission, and off all your steroids?" So the thing is, we will see that as, oh gee, that's a meaningful outcome. But, at the same time, I would want to [muffled] say, "But I

want to understand your arthritis, or I want to understand how much pain you're having, how much improvement you've had." And it could be that you and I have a different pain tolerance, right? It could be that I feel that if I have a one-point change in a 10-point scale, hey, that's—I'm good. But you could say, "Well, you know what, I really would like to be pain-free. So if I'm up here at an 8 out of 10, I really would like to be at a 1 or a 2 or a zero, preferably." So what we do is in our studies is that in many of those, we ask the patient, "Tell us what's impactful for you."

0:27:02 And then we look at the population to try and say that we, as trial designers, we can design something that's statistically significant to a one-point change. But, Rich, to the average patient, they would say, "So what? That's my day-to-day variability of point change. Today I could be an 8 back pain, you know, I decided to help my friends move the piano last weekend" [laugh]—

Rich Bendis: [laugh]

Theresa Podrebarac: --"so now I'm in more pain," and things of that nature.

Rich Bendis: Theresa, basically, you mentioned Annie Kennedy, who's with the Ever Living Foundation for Rare Diseases. And that was one of the things that I think the audience enjoyed was the back and forth between Annie and you. And I think what would be interesting, Theresa, for the audience right now, or the listeners, is you have a major role in working with patient advocacy groups, and you stated that when you were speaking. What is the role between Horizon, for example, and pharma and bio companies in working with patient advocacy groups, and how do you collaborate, and what is the differentiation between what you do and what they do on behalf of the patient?

0:28:04

Theresa Podrebarac: In terms of collaboration, sometimes it's even a challenge to identify who to collaborate with, right? So for some diseases, there are some prominent advocacy organizations that have been established for several years, right? And so it's to identify those. And then, as you said earlier, you know, we are a global company. And the way advocacy organizations and that work in Europe, there's also that to sort through in terms of what we have in the United States. And I've worked in some diseases when I was working in a smaller organization where it was started by one

person, for example, the Birthmark Foundation, started by this one individual that grew over time, but really was an individual with their laptop trying to find something for their child or for something that then grew into an organization.

0:28:52 And so quite often, the patient advocates, they're often trying to, let's say, find treatments or find what's available so that they, for their membership, can steer individuals to, you know, "Here's something over here. Here's some other organizations that are good to partner with. Here's how we can get some funding." And then if they also need, you know, the one I was mentioning about the Birthmark Foundation, if you need special garments, they have pressure garments, about where to get them, how to get funding if families are in need and they don't have the resources. So there's a lot that is to support the membership. And then some advocacy organizations also support the science behind them. And then others are more politically active, where they are funding various initiatives that try to get Congress, for example, in the United States to either sponsor certain legislation in terms of recognizing their disease space so that, let's say, NIH may have more funds that they can apply to the disease. So it's really multifactorial.

0:29:57 And coming forward, I think what Annie also mentioned, as I talked a little bit about AIDS, was really, again, not only a turning point in terms of understanding immunology, but really a turning point for patients truly advocating to say that we need these medicines. We know there's risk, but please stop being so paternalistic and telling us what we can and cannot choose. Give us choices, right? And so a lot of this is discussion. It's understanding how we can best work together and, like I said, infuse that patient voice into our studies. Also, I can design a terrific study, Rich, but if no one enrolls, it doesn't [laugh] help me very much. [laugh]

Rich Bendis: Right. [laugh]

Theresa Podrebarac: Right. And so part of it is also to get the word out that we are doing studies. And what I think our industry is doing much more in a systematic way is when we are designing, let's say, protocols or endpoints, is to get that patient perspective.

0:30:59 Well, is this, like I said, meaningful to you in having panels either review the protocol or give us input? And then also, as I mentioned, as we're

trying to develop some of these measurement tools about the patient's expectations for treatment, what they think is important, that they would participate, not to help one company but to help the disease state. And so we, at Horizon, for example, as we are working on some of the tools, if we find that the tool works, it will be available for everyone. So it's that collaboration to say that if we're fortunate enough to find a therapy that works or a way of measuring things, we're not going to keep it just to ourselves. [laugh] We're going to share it. And so I think there's many ways that we do collaborate, and I've only touched on a few. But hopefully that gives the audience more of a sense of how the interests of the advocacy groups often meld with what our interests are and how we have to work because I have to work in a highly regulated environment and that, so it's just respecting how we can each work together and hear each other.

0:32:04

Rich Bendis: I think that's a great explanation. And the other thing is Horizon has a really major focus on autoimmune diseases. And if we really look at your pipeline and portfolio that you have today, where would you say the greatest emphasis is at the current state that is closest to market, and some of the things that are further down the road that may take many more years to get to market as you go through this clinical process? So how do you look at the priorities within your clinical pipeline right now?

Theresa Podrebarac: For our approved medicines, we still develop either in other indications, and so we do have a medication that was approved for rare disease called neuromyelitis optica spectrum disorder, which we shorten to NMOSD. And it's a mechanism that can be used in several other types of autoimmune diseases.

0:32:58 So this is more in the neurologic system where patients can present with blindness and paralysis and so—

Rich Bendis: So more of a platform?

Theresa Podrebarac: Correct. So what's cool, I would say, about some of the medicines we have in immunology is that they can work across disease states, so not just in, let's say, arthritis, but they can work in bowel disease. They can work in lung disease, heart disease, various things. And so we continue to develop those indications. Then, on the other hand, for some of our

other more mature products, there's still also an emphasis of can we make this easier for the patient? I mentioned our gout medicine. Well, it's a medicine that's taken usually for at least six months. You can take it longer. But you have to come into the clinic every two weeks, and the infusion takes two hours. So I don't know about you, but I don't necessarily want to see my doctor every two weeks and, you know, let alone fight to get a parking spot, and take time off work.

0:33:55 So the thing is, we continue to look to find out can we change the interval, how often you need to come in, because maybe if I only could do this once a month, maybe that would be easier for me, right? Or can you make this now instead of an infusion that I have to take by IV, that I could have it by injection, and potentially do it at home, right? Because not everyone lives in a center that's easy to come to center. So there is this major emphasis with our approved products of where else can I use them? And then how can I make it easier on patients and also the providers to do that, because it takes quite a bit of staff time, you know, to prepare the infusions, and I'm going to run for two hours. If that can shorten their time, it means that they have more time to look after more patients, right? And then the other part of the portfolio is, like you said, in autoimmune. We also have rare and inflammatory diseases, and then you have the trifecta of a rare autoimmune disease that has a lot of [muffled] and that.

0:34:58 And so we have a lot of emphasis now in the pipeline which, as I mentioned, is at maturation with really the Viela assets that are looking at some diseases where, again, very few companies have gone forward or are going into phase 3. One example we have is IgG4-related disease only became recognized as a disease in 2013. And it's something that I'm sure I probably saw at some point but didn't know what it was exactly, where individuals will have these inflammatory lesions, and they can grow and also have fibrosis or scarring within them. They can affect similar things to another disease called Sjogren's, where it affects the lacrimal glands, salivary glands. But you can also have an involvement of the pancreas. You can also get masses in the back. And this is the one disease that came to mind is that we don't have an ICD-10 code even for this disease in the United States. So it's very difficult for us to understand, you know, what is the true prevalence?

0:36:01 How many individuals are impacted by this? And they can present very differently, as you can imagine. So if I have something affecting my pancreas, and you have something affecting your salivary glands and that, we can present quite differently. So it's trying to, again, we often look to professional organizations who have disease criteria to say, you know, we now codify what this disease is, because you also need that for ICD-10 code. This is what the disease is. Here's what we think the first, second, and third line of treatment is currently available. And then how do we move forward with testing things? And, again, if you're the first, you have to take what you know out of your playbook and say, "Hey, I think this could work as an endpoint, or this might work. But let's go ahead." And that's the part of taking what I call smart risks of saying we can do this. I think I've gone a little off on tangent but—

Rich Bendis: No, that's okay. [laugh]

Theresa Podrebarac: [laugh]

Rich Bendis: I think it demonstrates your passion for everything that you're engaged with, Theresa, so you can go on tangents as much as you want, really.

Theresa Podrebarac: [laugh] Right.

0:36:59

Rich Bendis: I think the listeners are enjoying. So let's talk a little bit. And we're talking with Dr. Theresa Podrebarac, who's the Senior Vice President Clinical Development for Horizon Therapeutics. And since we have a lot of listeners in the BioHealth Capital Region, I want to bring it back to home here, and we're going to get ready to close pretty soon. And back to home means that Horizon has a presence in Montgomery County, Maryland. So what is the role that Horizon has set forth for your operations in Maryland, and what do you see the future growth potential here?

Theresa Podrebarac: We have been fortunate, as I mentioned, with Viela of having an earlier part of that R&D engine, that early pipeline in research, and that has really now become a focus in terms of—Horizon in the past developed medicines that they acquired from other companies. But now we have the ability to really design our own medicines and come first in human.

0:37:58 So what I see is the potential now to really grow part of that early part of the research and development functions here in Maryland, because we've been very fortunate. I myself hired individuals from NIH or those that worked at NIH for many years and come in to industry. We have a collaboration with Johns Hopkins who, again, are one of our neighbors, about how we can work together to find either new targets or new ways of treating different diseases. So I see that this region—I'm in the Boston area. We have Cambridge and, you know, with Harvard and MIT and all these other organizations. But I see this as really a rich area of talent to continue to grow and, as I said, really foster the research and development process overall. But I see this particular emphasis in being able to do maybe some of the earlier parts here particularly well in Montgomery County.

Rich Bendis: Well, we know you're in Boston, which is the second-leading biopharma cluster in the United States.

0:39:01 And we're third now, Theresa, so we've grown. But we're coming after Boston, even though both of them—

Theresa Podrebarac: [laugh]

Rich Bendis: --are important to Horizon. You know that we have a lot of pride in our region here in how we've grown. So we're glad that you're a part of it. Is there anything that we haven't talked about, before we close, that you'd like to impart on our listeners, Theresa?

Theresa Podrebarac: One of the things I mentioned earlier is for some of us, we see a lot of targeted advertisements for medicines to try to patients, so this is the direct-to-consumer advertising. And I can imagine to some people, you know, they'll think, oh, you know, let me just turn the page or silence the commercial, or what have you. And this is unique in terms of what we can do here in the United States. But instead I maybe would like people to think about, well, the reason we have direct-to-consumer outreach is that for some individuals who are still struggling to find a diagnosis, maybe something resonates, something turns a corner for them in terms of being able to find appropriate readers or appropriate therapies.

0:40:06 And the other thing I'd like people to pause and think about is that, in our industry, I think sometimes we get a bad rap, that it's all about the finances and that. And as I said before, my team, we are the advocates

for our patients. And I'd like your listeners to think about there are several dedicated, I mean, thousands of us dedicated professionals who've dedicated their working lives to bring new medicines to patients. And I'll always carry those patients here, Rich.

Rich Bendis: Well, I don't think our listeners have any question as to what your primary role is, is to be the chief patient advocate within Horizon, and you represent that very well, Theresa. So I want to thank you for being on *BioTalk*. And we've had the pleasure of talking with Dr. Theresa Podrebarac, Senior Vice President Clinical Development at Horizon Therapeutics.

0:41:00 And we hope we have the chance to interact with you many more times here in the BioHealth Capital Region. So thank you for being on *BioTalk* today.

Theresa Podrebarac: Thank you, Rich.

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

End of recording