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*In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE Magazine meets with Laura Niklason, M.D., Ph.D. Founder, President and CEO, Humacyte.*

**Taren:** Dr. Niklason, welcome to our WoW podcast program.

**Dr. Niklason:** Thank you so much for having me. I'm delighted to be here, and that it's an exciting time for our company and for me personally.

**Taren:** I can't wait to dig in. Laura, it's good to connect with you again. You were a PharmaVOICE 100 back in 2017 and since then the company has just gone crazy bonkers, great stuff that's happening. For those in our audience who aren't familiar with you, you are a star in the field of regenerative medicine and tissue engineering. So talk to me a little bit about your vision and what led you to found Humacyte back in 2004 and then we'll talk about the exciting stuff that's coming up.

**Dr. Niklason:** You're right. I've been working in the field of regenerative medicine for, gosh, about 25 years now. I started working on trying to grow replacement human tissues back when I was still doing my post doc training at MIT in the mid 90s. And back then the thought of growing tissues in the laboratory or in a jar as people used to say was really science fiction. We've been fortunate to be able to keep working on the project long enough that I think we're turning it into science fact now.

So I had worked on methods to grow replacement human arteries in the 1990s and then into the 2000s and after working on it for about 10 years in academia, it just became clear that the amount of push, the amount of manpower, the amount of capital that it was going to take to move this what looked like a good science experiment into human clinical trials and then ultimately into approval that the amount of money in capital and time was just going to be too much for an academic lab. And so we spun out the company in late 2004 Humacyte to do just that.

**Taren:** It's exciting, and I love how you referenced it – turning the science fiction into science fact, very exciting. As a layperson and you touched on a little bit, can you talk me through the company's technology or what it means for patients?

**Dr. Niklason:** So at Humacyte, we like to believe that we've developed category defining innovation. Our innovation uses normal human cells that we obtained from human tissues, but

that we've used to form a cell bank, and the cells from that cell bank are used in our manufacturing process to make replacement human tissues for a patient.

Right now, our approach uses bank cells and grows them in bioreactors, and the size and the shape of the bioreactor dictates the size and the shape of the tissue that we grow. So for example, we can grow tubular tissues in different diameters and length, but ultimately I believe we can also grow from flat tissues and tissues of all sorts of different shapes. Importantly, the tissues that we grow are mechanically very strong and so they function with the mechanical properties that are similar to our native blood vessels or skin or tendons or whatever. But also just as importantly, our biomanufacturing process means that the tissues that we grow are also universally implantable. So these tissues can be implanted into any patient and in the more than 450 patients now who have been implanted with our vessel we've seen no instance of clinical rejection.

**Taren:** Fascinating. So at what stage are you – would you consider yourself in a phase 2, phase 3? How close are you to making this possible for patients across the board, this technology?

**Dr. Niklason:** Yes, so Humacytes, human acellular vessels (or HAV) are not yet approved for use in any country, but we are in phase 3 trials in two indications in using our vessels as implants for patients who need blood vessels for hemodialysis, these are patients who have kidney failure. We're also in a phase 3 trial in patients who have injuries to their blood vessels, like from car accidents or from gunshot wounds. And we're studying the utility of our vessels to repair those injuries in those patients. So we've been in clinical trials now for eight and a half years, but we're not yet approved, but we hope to be approved in the next couple of years.

**Taren:** Wow, really exciting stuff and such a need for what you're doing. And I would imagine that these first two areas are just the tip of the iceberg in terms of how the technology can be used going forward.

**Dr. Niklason:** Yes. We're excited about the different possibilities that are out there. They also have phase 2 trials underway using our vessels to treat patients who have blockages in the arteries in their legs. These patients often suffer painful walking and the artery blockages can be so severe that these patients can undergo amputation because they don't have enough blood flow. So we've used our vessels in dozens of patients who have severe blockages in their leg arteries, and in some cases we believe we've helped some patients avoid amputation.

It's a very exciting place to work because we're providing essentially off the shelf replacement tissues or off the shelf spare parts for patients who need tissue replacements, particularly in vascular disease.

**Taren:** Amazing. Science fact indeed. Since you've taken the helm of Humacyte as CEO back in October 2020, the company has made a number of agreements and you are taking an innovative path to becoming a public company. So tell me what this next part of the journey looks like for Humacyte.

**Dr. Niklason:** Well, in February of this year we announced the intent to perform a merger with a SPAC company (Special Purpose Acquisition Company) called Alpha Healthcare. That was in February and we're actually very close to completing that merger now. In fact, the shareholder vote for Alpha Healthcare to approve the merger is scheduled for the 24<sup>th</sup> of this month, so it's right around the corner. We anticipate that after the completion of the merger it will be traded as a public company. Our ticker will be Huma H-U-M-A and we'll reconstitute a new board of directors which will contain some of our existing board members, but also some new exciting additions to the team.

**Taren:** Really exciting. What are some of those learnings that you've been able to glean over the last couple of months since February? You know taking a company public, your first year as the CEO, what are some of those lessons you've learned?

**Dr. Niklason:** Well, I think in terms of the process of going public particularly with the novel mechanism of doing a reverse merger with a SPAC, frankly it's a lot of people who are going public by this mechanism are doing a lot of learning in real time. We've had to partner closely with some of our investment bank colleagues who are expert at SPAC transactions to understand the SEC requirements and to understand the rules of the road for interacting with investors as well as folks in the two companies.

So I've had to learn a lot about SPAC-related transactions and finance, but I think I've also had to learn a lot about messaging with investors. Certainly as the founder of Humacyte 16 years ago, I've certainly had many, many meetings with investors over the years and prospective investors and with various investment bankers, but in the process of moving from being a private company to being public, the importance of uniformity and consistency of messaging becomes just paramount. And so the importance of being clear and concise and consistent when you deliver statements about the company or the technology or what you think may come in the future is just really critical and that's been a big learning for me.

**Taren:** And you did all this during COVID of course. How did that change some of those conversations|?

**Dr. Niklason:** It did, and the great irony I think of COVID for the finance world is that as we saw in 2020 there were more IPOs done in the US than at any other year previous, and 2021 is continuing to be an incredibly active IPO market. So it's a great irony. I actually think that financial transactions such as ours are actually maybe a little easier if you can talk with people, if you can talk with investors and analysts and bankers in a rapid fire virtual format.

So on the one hand, I think communicating in that setting is just inherently harder, but if you can have six or eight investor meetings in a day without having to travel to six or eight cities, that's a huge boon. It's on the one hand, I think again, the importance of clarity of communication and making the message easy to understand is so important if you're trying to communicate through a computer screen, but boy, you can talk to a lot of people.

**Taren:** Yes. I would imagine, I've talked to CEOs in the past who have done those investment meeting rounds and they're like 25 cities in 40 days and it's just exhausting. So yes, while it's a little bit different, it also seems to have worked very well for you.

**Dr. Niklason:** Yeah. It has enabled us to have multiple meetings again with multiple investors and that was really one of the reasons that we decided to go the SPAC route for taking the company public. As you may know, as I said the IPO market in 2020 and 2021 has been very robust and we had decided to try to take the company public in late 2020, and we were speaking with several banks who were interested in taking us out by a conventional mechanism by the standard IPO route. But we became interested in the SPAC route because, frankly, it gives you more time in advance of the announcement and then post announcement. It gives you more time to interact with investors and have actually multiple meetings to talk about the company and the technology. And I found for Humacyte that turned out to be really important because we are really a first in class type of technology and frankly, it's hard to get the whole message across in a standard 30 or 45-minute investor call. So the ability to stretch it out and have more time and really allow people to dig in, I think, was an advantage for us.

**Taren:** That's awesome. And thank you so much for explaining the difference between the traditional IPO route and the SPAC route and the advantages it's providing to you as an organization. The business combination is expected I understand to provide upwards of \$255 million and expected market cap of over one billion. These are big numbers. How are you planning on using these funds as part of your future growth strategy?

**Dr. Niklason:** Well, I think the funds are going to be deployed in a number of ways. First and foremost, we're going to finish out our phase 3 clinical trials, complete the enrollment and the analysis of the data and then do submissions to the FDA for a biological licensing application probably in two indications in the use of our vessels to treat vascular trauma and also using the vessels to help patients who need hemodialysis for kidney failure. But in addition, we're going to use some of these funds to try to advance our pipeline.

Humacyte has been very fortunate because we have been privately funded for the last 16 years and the total funding that we brought in is just a little bit south of \$500 million and that's allowed us to not just move these main clinical programs forward, but also to start the process of various pipeline opportunities.

So, for example, we have right now going on studies where we're using smaller versions of our vessels to do heart bypass in primates. We're also doing a mock up of pediatric heart surgery and using our vessels to reconstruct pediatric hearts also in primates, and we're looking at developing the use of our vessels for as a delivery vehicle to deliver islets to patients with type 1 diabetes. And we're very excited about all of these pipeline opportunities and certainly some of the funds, some of the use of proceeds is going to go to advancing those through pre-clinical stages.

**Taren:** Sure. That's exciting stuff. I understand you also entered into a recent commercial partnership for one of your lead programs. With all that you have going on, how do you balance

everything between bringing the company forward into the SPAC merger, managing the pipeline, thinking about your employees – it's a lot on a CEO's desk, how do you manage everything? How do you balance it?

**Dr. Niklason:** That's such a good question. I think I'm...

**Taren:** Yes, not really in balance, but I am.

**Dr. Niklason:** I'm helped by a couple of things. One is that because I'm the founder of the company and because I've been involved from the beginning at least on the technological side and certainly also on some of the financing and the fundraising side, I was able to sort of hit the ground running when I took the job as CEO. So I didn't have much of a learning curve in terms of how the operation works. So that helps.

It's also key I think to have as we say all the time at Humacyte, the right people sitting in the right seats on the bus. One thing that we've done is we changed out a couple of people in leadership positions and also we've made some moves on the technical staffing side, which have really mostly put people into the right seats on the bus. We've had actually very low turnover at Humacyte; people enjoy working here and they kind of drink the Kool-Aid, I think, that everybody is excited about the technology and what we can do for patients. We've also grown rapidly. I mean six years ago we were only 30 people and now we're 140 or 150. And sometimes when a company grows rapidly, some groups grow too quickly, some groups grow too slowly, some people wind up sitting in the wrong seats on the bus. And so part of making the CEO's job doable is making sure that the right people are sitting in the right seats and not just one level below you, but even a couple of levels below that just getting the right people installed, can be... just makes your life so much easier.

**Taren:** Absolutely. That is tremendous growth and managing that growth – and you started off as a small company and now you really are becoming a billion dollar organization and with that comes people change because the technology is one thing, but it's also that people management part of it and making sure, as you said, everybody is in the right role and everybody feels comfortable with the changes that are coming their way. And at this pace, they're probably coming up pretty fast and furious too, so all of that requires finesse from the CEO.

**Dr. Niklason:** My approach to communication which often works – although I will say sometimes I over communicate, but as I tell people I'm a big tent kind of girl. And I've learned this from Humacyte, but also frankly from running my academic lab which I did for many years. If you're trying to do something that's very hard and very new, which is what arguably Humacyte has been doing since the inception, if you're doing something very hard and very new you almost always benefit if pretty much everyone knows where you're going and why. And what I found is that particularly as organizations grow and as you get more tiers of management, the communication to the rest of the team about where you're going and why can get lost. And when you're in a very fast paced environment and when things are hard, that can be really damaging.

So we work really, really hard to be very communicative with all members of the team. So we have at the leadership level, at the senior management level we all meet twice a week in person when possible and that's absolutely scheduled and nobody misses that. And we also have monthly town halls where we speak to everybody in the company.

**Taren:** I think those are great pieces of leadership advice. So clear communications, often communications and making sure that you understand that the vision is clearly communicated, so kudos to you for laying out the vision so well that you've been able to grow the company so successfully.

That leads me into my next question set here. I'm going to brag on you a little bit if you don't mind. So keep your blushes to yourself 😊 but from your tremendous contributions in the field, I mean *Time Magazine* named your work and identified the engineering of whole lung tissue that could exchange gas in vivo as one of the top 50 most important inventions in 2010, that's a wow. You've also been inducted into the National Academy of Inventors and Women in Technology Hall of Fame, another wow wow, and named by *Fortune Magazine* as one of the 34 Leaders Who Are Changing Healthcare, wowza. And you have a rare honor of being inducted into both the National Academy of Engineering and the National Academy of Medicine, tremendous. Just tremendous. What do all these accolades mean to you though? I mean that's a big body of work.

**Dr. Niklason:** I think a lot of successful people are successful because they never really feel successful, and so they keep running very hard kind of regardless of what milestones they may hit. I think I'm probably one of those people. So I don't think I dwell on that stuff very much. I will say, I will admit that when I was inducted into the National Academy of Medicine I did have a feeling like wow, maybe I've kind of arrived. That was a nice feeling. And I thought well gee, maybe people will take me seriously. So it's very much of a – but I think a lot of people who have a lot of sort of material external success do feel like that, that they kind of discount those successes in their own heads and they just keep moving along and trying to do the next thing, and I'm certainly sort of, of that ilk. So honestly, I don't think about it very much.

**Taren:** Well, Dr. Niklason, I will say you have arrived. I think you have more than arrived. So congratulations, and I would expect these are not the last of the honors that you are going to see coming your way. Clearly, you are a role model for other women and women scientists, women entrepreneurs, women with vision – what advice do you have for some of us who would like to reach the C-suite that are still charting our own journeys and our own paths? What have been some of the most helpful things for you?

**Dr. Niklason:** That's always a hard question because I think success looks different for everyone, but I think in general, first of all, attending to the job that you're doing, attending to the job that you have rather than auditioning for the next job, I think is vital. And one of the best ways of getting the next job is doing the job that you have incredibly well. Part of that is obviously being competent at whatever it is you're doing, but another part of it is also maintaining composure and being calm, cool and collected even when things are stressful. And

that's actually one thing that I have to admit I haven't done very well for much of my career. I'm a pretty fiery person and so I give that advice to other people, but I'm not sure I've always followed it.

But particularly for women I think that the prospect of upset, angry women in the workplace it doesn't play very well. It doesn't play very well. So doing your job well, being calm, cool and collected I think are very important.

But also another thing that was said to me once by our former CEO Carrie Cox who's another sort of very successful woman in biotech and pharma, she said to me once, "There is no career fairy. There is no fairy who comes along with a magic wand and says shazam, here you go, here's your next role." And that's really true. So I think women, do your job, is paramount, but also knowing when to raise your hand and say I think I deserve the next job, or I would like the next job, or I think I would do great at the next job – and those latter two are probably better ways to approach it. I think you have to do that because men are much more comfortable doing that than women are in general and there is no career fairy. There's no career fairy.

**Taren:** I love that Carrie said that, that's great. And that leads me to one of my next questions is that that female mentorship – and I know that Carrie has sat on the board. She's on the board of Humacyte and you also look to Kathleen Sebelius – did I say her last name correctly?

**Dr. Niklason:** Mm-hmm. Sebelius, Sebelius, yes, mm-hmm.

**Taren:** Kathleen who currently serves on Humacyte's board. So I love the fact that you look at board diversity as well. So what are some of the other ways – because I know that mentorship is important to you – that you're widening the path for other women. Somebody once said, you can blaze a path on your own, but it only leaves one person walking behind. We need to widen the path, right.

**Dr. Niklason:** Mm-hmm. Mm-hmm. Well, you know, since the beginning there's been a big female contingent in leadership in senior positions at Humacyte and even in my academic lab that was also true and still is true. So for example, our co-founder Juliana Blum is our executive vice president of corporate development, and our chief operating officer who runs all of our technical and manufacturing efforts is also a woman and she joined the company. She was employee number 9 or 10 or something. So we have actually a number of women in various senior positions and who are climbing in the organization. In some ways actually it's been a help in terms of recruitment.

Humacyte is located in the Research Triangle Park area. It's a very vibrant and busily growing biotech environment and actually recruiting is hard here. It's gotten a lot harder in the last 5 or 10 years. And frankly, one of the competitive advantages we have is that we are viewed as being a female friendly company, and so it's actually easier for us to poach very high quality female talent. So it tends to reinforce itself.

One thing I will say is that I know I've read articles about boardroom behavior or meeting behavior and about how women tend to get either ignored or talked over or something like that, and one thing I can say proudly is that that absolutely never happens here.

**Taren:** That's awesome. That's awesome. And I also know that you are very much focused too on equity and you've hired two EDI champions, and you're setting a strong example of what a more equitable future of biopharma could look like. Tell me about this work that you're doing.

**Dr. Niklason:** Well, these were not new hires; these were actually existing employees who wanted to take on the role of diversity champions and we're happy to support that. But from my standpoint and honestly, I think this has been a lot of the messaging that I've gotten from some of our employees. So our employee makeup actually mirrors the composition of the population of North Carolina in terms of African-Americans and Asians and Caucasians and men and women. It's actually an almost exact mirror of where we are.

So that makes me feel good because it makes me feel like we're recruiting appropriately. But for me, I think the most important thing here is inclusiveness, and it really also falls under the banner of being sort of hyper-communicator and a big tent girl. If you include everybody at different levels in the company, but also who come from different backgrounds, if you include everybody in what you're trying to do and why you're trying to do it and if you make them all part of the mission and the solution, to me, I think that's the best for the company and it's also the best for the individuals. So that's really what I strive for is inclusiveness.

**Taren:** And that's often the piece that gets left off or left on the sidelines when we talk about equity and diversity. So I'm so glad to hear you say that. That's great and congratulations to you on creating that positive work space for your employees as well as for the community of Research Triangle Park. I don't know that your competitors would be so thrilled with you about poaching, but that's okay. That's a different topic.

**Dr. Niklason:** You know it's a dog eat dog world out there.

**Taren:** And your tent is big enough for everybody. I get it, so I love it. On a more serious note, I'd like for you to tell me about an accomplishment or a wow moment that either changed the trajectory of your career or that has left a lasting impression on you, and with all the accolades we just went through, I am going to challenge you to try to pick one or two that really stand out for you.

**Dr. Niklason:** Well, I'll give you two. I'll give you two. One is when I went to work for Robert Langer at MIT. He's a very famous guy, and he was sort of at the cutting edge of regenerative medicine and tissue engineering in the 80s and 90s. I went to his lab as a post doc actually while I was still a resident at Mass General, and there was some friction at Mass General about whether or not I would be allowed to work at MIT in Dr. Langer's laboratory. And actually the friction was bad enough that it went up to the level of the dean, and I actually almost lost my position as a resident at Mass General because I wanted to do research in this man's lab. And it was eventually resolved, but at the time I had decided that if it – even if it cost me my residency



I was going to work in Langer's lab, and so the ability to make that all work and join his lab I think was really pivotal for what I was able to do since that time.

**Taren:** So brave of you to make that decision. You were young in your career, and that takes a lot of guts.

**Dr. Niklason:** It was very scary. It was nerve wracking. It was nerve wracking. Eventually the administration kind of turned around and said this would be okay, but I was definitely stepping out of the box in a way that they weren't comfortable with. And it was just clear to me that it was the right thing for me to do, but yes it was a difficult time.

The other thing is actually I have to give thanks to my husband, Brady Dougan. He funded Humacyte in the early years at a time when nobody else would, and he had the capital in hand and he just believed in me and in the mission. There were a lot of small tissue engineering companies that flamed out over the last 10, 15 years and we were not one of them because he just supported us. And so clearly we've got a lot of external funding now, but gosh that wasn't the case 15 years ago. So this wouldn't have happened without him.

**Taren:** Well, what a smart man he was (A) to marry you and then to fund the company, too. So he's got vision. That's awesome. Laura, thank you so much. It has been such a delight to speak with you, and I'm so excited for your next step in two weeks. Congratulations on this really significant milestone for you and for Humacyte, and I can't wait to see what you all do coming down the pike. I'll be watching those phase 3 trials, such important work you're doing. And thank you, thank you for being part of our WoW podcast series.

**Dr. Niklason:** Thank you so much. I really enjoyed it.

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