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Tim Nelson, MD

We Fix Broken Hearts

Longevity Focus Session Presentation

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Tim Nelson | A360 | Longevity Focus Session Presentation

Tim Nelson:

Well, thank you for everybody for coming. Hopefully you got a chance to hear me talk. I went through 45 slides in eight minutes. I've never done that before, so I really have nothing else to talk about. So the point of this was really to do twofold for me. First, my ask to you is anybody that's interested in joining us for dinner tonight, we have a small group joining for dinner and some of you are joining. Thank you. And if anybody wants to join Dan Babs, Beau, Dave's going to be there. Alex is going to be there. Please. You'll have a QR code here and you can sign up. So thank you. But really I wanted to see what you heard and have a dialogue and a conversation around what we heard just as a way to set that up so everybody can start thinking about their questions.

We don't have it figured out. What I showed you today is a start on a mission that is going to be my life long's mission to cure congenital heart disease and heart disease in general. We don't have it figured out. And we need people, we need partners, we need collaborators. We need inspiration. Steal Dan's, not steal, but use Dan what he's taught me, the free zone and build collaborations. We're really not competing with anything other than disease here, and that is what we have to figure out how we can do.

That was the origins of HeartWorks, a clinical stage nonprofit that has been built to have a for-profit arm to scale it and expand it. And that unique structure has gotten a lot of attention of how we can apply and leverage what we do. So the technology is cool. Our purpose and our mission with the kids is very cool and impactful, but I really believe it's the structure that we're creating together that I'm learning from all of you that allows us to actually execute on a vision and actually deliver the cure. And I'll just say that I don't think that this is limited to congenital heart disease. I think rare pediatric disease is a great place to start a model like this, but I think this model is dramatically scalable. So this is really a time to have questions and dialogue. So I'll open it up, Dan.

Dan:

Yeah, I mean including yourself, these five others. For people who haven't been introduced to this before, it's very, very shocking that this is. What I liked about today is that it's kind of like the Steve Jobs model. Steve Jobs never said anything until you could buy it tomorrow. And it's not something that's sitting off five years and we're at stage one clinical, you can do this tomorrow. But what shocked you the most since let's say you go back when you met the couple who asked if you're going to be committed to this, we'll be committed to you. But what has shocked you the most? It could be on the medical side, it could be on the organizational side. It could be-

Tim Nelson:

What shocked me-

Dan:

Shocked, I mean you were not expecting it.

Tim Nelson:
What shocked me the most and surprised me the most in this journey, that's been going on for 12 years right now, I'm a physician, I'm a scientist. I was training to be a cardiothoracic surgeon. I was in the operating room doing the open heart surgeries as a medical student. And I remember a week where we did a two kilo baby. Anybody know how big a two kilo baby is? I know your family's story and some people know how small a two kilo baby is and how fragile they are and being able to get that child through an operation that has a 50% mortality rate, 50% chance of mortality in the operating room when you do it. I was part of that team, we get out of there, we're high-fiving each other. We feel like we just won an Olympic gold medal, right?

Two days, three days, four days later goes by, I'm in the clinic and I'm seeing a four-year-old, very similar to Ava that I told you about today that had the same surgeries and we have no options. She's not a transplant candidate. There's nothing we can do for this four year old child. And I remember feeling this guilt, I don't know how to explain it, but what were we celebrating two days earlier that we got a kid off the table with a complex surgery? And then four days later, I see a patient that's four years old that I say, "There's nothing else we can do for you." I'm not taking anything away from the four years that that family had together with that child. Don't misinterpret what I'm saying. But as a physician celebrating that transient moment made me say, we got to do something different.

We got to do something different. There's technology out there. And so I changed my career path from being a cardiac surgeon to cardiology to do more research. And now I don't see patients anymore because I'm a full-time manager of an operation that has an option of building a cure team that can actually cure these diseases that we palliate in traditional medicine. So I share that story Dan, because I'm a physician scientist, an entrepreneur that is just going along the motions trying to develop a new product. And what has surprised me the most in the last four years is what the Wanek family has taught me. The Wanek family as owner of Ashley Furniture have resources to invest in us unlike most of the world's population. They're affected by this condition with a 27-year-old daughter that has congenital heart disease. They worry about tomorrow.

Tomorrow, they worry about. And so what are the solutions we're building today to make that possible? And when we went through this journey, what surprised me is how grateful they are, how engaged they are, how proud they are of what we are building as a community. I just got the text messages from Todd who's unable to be here today, but people are texting him and he is so proud of what we are creating together. And it's not me, it's just a part of a team that we can do the extraordinary right now. And when you see that we can give hope to families, but we can also give hope to the investment community to actually be part of a cure team, it makes me realize that resources are abundant. The money is not the limitation, it's the partnerships, it's the collaboration and it's the focus to deliver on the products today. And the clinical trials I told you about today are available today for patients that meet those criteria.

Dan:
[inaudible 00:06:49]

Tim Nelson:
Correct.

Dan:
Yeah. Can you share the end of one concept? Because this is, I think where, and you showed it on the slide where HealthWorks is a straight line and then there's the investment community and everything else and they're all over the map. But here's just on the straight line and I got it in when I first met you, I met you in San Francisco and I said, "I think the cure is really interesting. But I think the funding model that you created is the game changer here."

Tim Nelson:

We like to use the line "Where focus goes, energy flows". We love that mentality and we're really building a personalized solution for one patient and perfecting that. And we've done that. I didn't say it today, I intended to, but that room that we were upstairs at the large room, we have manufactured this product on twice. The number of people that are in that room. It would've been an important thing to be able to share. I forgot to share that today. We've manufactured these seeds on twice the number of people that were in that room because we can do it on one, we can do it on 10, we can do it on 100. And it becomes scalable because we've perfected, we have manufactured these stem cells more than anybody else in the world and we've treated more babies with congenital heart disease with stem cells than every other group in the world combined. So that's the momentum that we're building. I'll get back to you, Beau. Sorry.

Speaker 3:

The clarity of focus and the drive and your mission and what you're trying to solve. Can you talk a little bit about the magic around the collaboration and partnerships and how you pull this amazing ecosystem community together, what you've learned in doing that and some of the missteps that maybe set you back because?

Tim Nelson:

That's a lot there. Let me see if I can unpack a little bit of nuggets here. Where my head goes with that question is that we have built this network of 11 pediatric hospitals across North America that work together. Has anybody ever tried to get their hospital to collaborate with another hospital? Anybody been in that world before? It's damn near impossible. These are silos that have been built and getting institutions to collaborate is an act of God. Well, we took a because of, again, Todd and Karen Wanek and the business mindset that taught me as a physician scientist, we said, follow the money. Where's the money? Every pediatric hospital in this country makes money from these open heart surgeries. Say that again. Every pediatric hospital makes profit from doing open heart surgery. Okay, that's a fact. Record it broadcast it. It's a fact. Nobody can dispute it.

Follow the money. And what's happening is there's 120 programs in the United States that do open heart surgery. We need 60, this is my personal opinion, this is debatable. I believe we need 60 programs in the United States, not 120. Why? Because we're spreading out too few patients to too many hospitals, having too low a volume and not having the centers of excellence. So I was giving a talk and Bob Shady, who is chair of pediatric cardiology at Children's Hospital of Philadelphia, which has got the biggest reputation in the business, came up, asked me publicly in front of 400 people, "Have you ever considered collaborating? Could you collaborate?" And I thought, why would they, the world's greatest collaborate with us? I said, you don't say no in front of 400 people to Bob Shady. So I said yes. And afterwards we started talking about it and it turned out he taught me that their volumes are decreasing because there's too many places that are doing more surgeries like them.

They used to be the only shop in town. Everybody traveled to them. Now it's dissipated locally. That's not good. If I was having a son or daughter, I would not go to a low volume program. I would go to a high volume program. We need to maximize the volume to drive centers of excellence. That understanding was the tipping point to saying, oh, I can help the biggest guy in the room. So we define the Crush pad. I'm not going to tell you who the who's on that Crush pad, but there are hospitals that need to be shut down and not doing pediatric open heart surgery. I believe that. So we went to the biggest best players and we said, if we bring the technology to you, you're not going to pay for the technology. We're going to bring the clinical trials to you. More patients are going to travel to you to be part of the cutting edge latest study, CEOs all said yes.

I said, "If it brings more volume to you and you make money on that, how can we share?" And then they thought, "Oh crap, he just got me." And the way we share, he doesn't send me money from chop, but they cover the cost of patient care. So they cover the ECHOs, the MRIs, the blood draws, all the things that we

have to do to collect the data. They agree in our network to cover that cost that has to date saved me about $6 million that I haven't had to pay somebody else. So it's a reverse innovation model that allows us to not pay people to do our trials, but they actually pay to be part of us because we're a world leading dominant focal point. And now hospitals are working together with HeartWorks because it's a nonprofit and hospitals will collaborate with a nonprofit. And so we've turned that collaborative model upside down and that has been the catalyst to allow us to be doing the first trials in the world.

Beau:

So in terms of investment or partnership, what is it that you're looking for, number one and number two, in terms of investment? Is there a specific need that needs that investment or more urgently than anything else?

Tim Nelson:

Great question. So where's the money? No money, no mission, right? So today as a nonprofit clinical stage, we're raising a $100,000 dollars per patient to manufacture the product and do the clinical trial. We just had a virtual fundraiser. We raised $700,000 on one night in a virtual fundraiser. We covered the cost of manufacturing the first seven patients in this clinical trial. That gives us some breathing room. We need to raise the next $2 million to treat the next 20 patients to complete the clinical trial. So we are trying to raise a $100,000 per patient to be able to deliver a product that is the world's first regenerative product and get the clinical data in the ecosystem. But then the other part of the question that you're asking Beau is that's the nonprofit HeartWorks. And underneath that we have a for profit regen that all of our IP is owned within all of our clinical knowledge is within.

And we haven't defined the tipping point yet, where that then allows us to raise capital in an investment model to scale it to non-congenital patients, ischemic heart patients, other countries, other worlds. That's the cycles of learning that we need to maximize to be able to ultimately bring this to a marketplace. So the nonprofit, the collaborations gives us the fast pass with the FDA to get the clinical data to show that it's safe and effective, but we're structured to be able to take investments and we need help figuring that out. I'm a physician scientist, we don't have all of the structure of the deal figured out. And that's where folks like you are going to be really helpful to help us figure out that model. And that's what we're inviting people to be part of the journey with us as we figure that out.

Beau:
The $2 million is contributions, donations?

Tim Nelson:
The $2 million would be a contribution to 503c nonprofit that allows us to do the clinical trial. And we believe that we can scale that and eliminate the need for venture capital money to be able to get the clinical data generated so that we have a better investment when we actually have data. So you've heard people say de-risk the technology, we're de-risking it with a philanthropic contribution today and building the model so we can raise the capital to scale it.

Beau:
And how far away is the for-profit? Is that next year? Is that two years?

Tim Nelson:
We're years away from that. Not months away from that. I'm imagining two years away from that.

Dan:
The manufacturer, I mean the profit making is really the manufacturing. He's got the nonprofit. The nonprofit is the R&D lab. And then you go through the IP process. Because what Mayo did, which I thought was really smart, is that I met Tim on a Wednesday, the previous Friday, the FDA had given him clearance. Okay. Yeah. And then on Monday, Mayo gave him all his IP back with the 3% ongoing like license.

Tim Nelson:
Exactly.

Dan:
Smart on their part.

Tim Nelson:
So now we have it-

Dan:
He's got that IP already and IP now, the whole world of IP has changed just fundamentally over the last three or four years. And every one of his patents starts off by being probably half a million dollars, maybe a million dollars. And that's just what exists. But now his whole process is just going to generate enormous IP, patent IP.

Tim Nelson:
Okay. And let me come back to the timeline because I don't want to mislead people on this. When I say two years, that's a physician scientist mindset of where we're at with our clinical trials, blah, blah, blah. And for full disclosure, I manage a team on $10 million a year budget, is what the Wanek family has contributed to us to build the platform of what we're doing that allows us to do this. My commitment to them is to double our budget to $20 million a year to be able to scale it to more patients and bring it to more clinical trials. And so with $10 million investment, we scale the manufacturing, we fundamentally change the scope and scale of what we do. We change the timeline to when it's investible. So there's things I don't fully see right now. And so my view is managing what we have in the bank right now versus necessarily managing what we're asking for. So timeline can be accelerated dramatically.

Beau:
Can I just give you my thoughts around what my interest might be?

Tim Nelson:
Please.

Beau:
One would be I'd like to contribute charitably for sure, but I'm also interested in investing. And you said it's true that for-profit doesn't need to be two years. It could be, right?

Tim Nelson:
This is the kind of people I love.

Dan:
So funny. I was talking to him all week and I said, "You've got a world changing model." And he said, "What's this program of yours, Strategic Coach?" And I said, "HeartWorks", I said, "It's a nonprofit." And he said, "Yeah. I say, I can't have you in there, the word nonprofit, I just can't have people talk about non-profit. It makes me itch. I've had two near death experiences with non-profit." And then he told me about the IP and I says, "Profit making?" He said, "Yeah." "Okay, you're in the program."

Tim Nelson:
And the beauty of this, it's evolving. And Ken, we've talked about a little bit, Warren, I don't know if you're here, we've talked about a little bit. There's this model of building a philanthropy hybrid model that accelerates all of this and makes the investment even better. And that's what we have, I think the world's greatest opportunity to build with a focus on congenital heart disease.

Mark:
I know they had clinical trials, trials are about congenital heart defects. Help people understand what other conditions, once you are able to go commercial, can or might be addressed.

Tim Nelson:

I won't get personal here, but I'll tell you. So look, people die of heart failure because the motor is too weak. In the congenital heart world, we reconstruct the heart to make the five horsepower engine have to be the motor that does the whole body's work. So by definition, day one of these kids, they're in heart failure. Their motor is too small for their body. So from day one, they need new revascularization, new refurbishing of their heart. One in five of us are going to die of heart disease in this room. That's the facts of today. Hopefully that changes and many of those people will die with a weak heart because of a heart attack, because of a genetic viral infection. Multiple things can weaken the heart muscle and people die of heart failure because their heart muscle is too weak.

What we're fundamentally building here is your heart muscle from your skin that allows us to rebuild, refurbish your heart. My view is that you never need a heart transplant. If we rebuild your heart well enough, we eliminate the need for any sternotomy and heart transplant because we're just rebuilding your heart as you need it to make it bigger, better, and stronger. So the pediatric focus is our fast pass with the FDA, with founders, with funders. But the scale up plan is the hundreds of millions of people that have this condition.

Speaker 6:

May I ask a question?

Tim Nelson:

No, you may not. How old are you?

Speaker 6:

I'm 11.

Tim Nelson:

No, anybody 10 and older is only, so you can, I guess. I'm joking my friend. Of course you can.

Speaker 6:

Anyone ever has here read the House of the Scorpion?

Tim Nelson:

I have not. Tell me about it.

Speaker 6:

So it's basically this guy and he lives in a stretch of land between Mexico and the United States. And that stretch of land is basically the United States and Mexico collaborated and gave land for all the drug lords so that they wouldn't keep on giving drugs to Mexico and United States. And he's the clone of one of the drug woods, but he's grown from a piece of skin.

Tim Nelson:

There you go.

Speaker 6:

That drug lord, is that kind of the same thing?

Tim Nelson:

It's 100% the same thing. That's pretty cool. Y'all get that? 11. 11. No, this is exactly what we were doing. We are taking your skin, rebuilding your stem cell that literally can give rise to any cell in your body. So somebody, I'm trying to find the face here. Maybe had to duck out. Ask me the question about neurons regeneration. And you literally, with these seeds that we make, you can differentiate into any tissue. We're focused on the heart, but you literally can use these cells to give rise to every single cell in your body is theoretically possible. And so imagine the liver, imagine the kidney, imagine the eye, imagine the brain. These cells that we're manufacturing personalized specific to you can be used for this. And we're looking for partners and we are in negotiations with some companies that you would all recognize where we are potentially licensing our world leading experience of manufacturing that stem cell to be able to enable their differentiation that's not heart related. So that's the platform that allows us to build off of fat.

Speaker 7:

So this is just maybe a little bit of a side question, but I just want to understand it better before the dinner tonight.

Tim Nelson:

Yes.

Speaker 7:

When Todd and?

Tim Nelson:

Karen.

Speaker 7:

Karen, committed that a hundred million dollars and they asked for a commitment to until you had a cure. What?

Tim Nelson:

Say that again.

Speaker 7:

That you weren't going to go, was it that you weren't going to go commercial or you were going to stick with this until you had a cure or something like that?

Tim Nelson:

This is Todd and Karen. This is Karen and this is Gabrielle. That's who I work for. And when Todd made the original pledge of $35 million to Mayo Clinic, he brought in a sign that had of her that I signed that said, I'm working for you and that's who I work for. And so how good is that, right?

So my commitment is to her and every kid like her. And how do you do that? If we do philanthropic contributions to do that, I'm going to be very old and gray and we're going to have an incremental conversation about, that's the facts. We can all agree on that if we use philanthropy to launch it and then scale it. So the Wanek family is focused on how do we scale this thing? And if that means we scale it with other things to keep the focus here and allow that possible, that's the path we need to go on.

Speaker 7:

Got it. Sorry. [inaudible 00:23:17]

Speaker 8:

Tim, I've got a related question. There's lots of research that are well funded and not for profit and other than the leadership, what systems and process, because clearly your leadership and the family's leadership's incredible. But I'm sitting here going, why is this working so well? Why are you getting the speed when it shouldn't be going that fast given all the things that stack up against the way that works? I don't know if you've got a few, there's still points from why you work so well.

Tim Nelson:

So I'm trying to get to this slide so I can Next one here. This is the secret. This slide is the secret slide. Okay. The secret here is that the way we are structured has allowed us to incentivize and motivate partners that have never been incentivized and motivated. And at the end of the day, it's about being a priority. A priority to a family, priority to an investor, priority to a hospital. And by launching this as, let me back up here a second. For 10 years, HeartWorks did not exist. This is important. Nobody else would know this except the people in the room here. For 10 years, HeartWorks didn't exist. I was a physician scientist at Mayo Clinic. The Wanek's gave contributions to Mayo Clinic and we ran our research in an academic setting.

Speaker 9:

The bottom line?

Tim Nelson:

The bottom line. That's what we were for 10 years. And we realized in this journey that the market is too small to have an industrial partner because they need a blockbuster drug to be able to scale. You get that, right? It's the rare disease. But we need to scale the funding, to accelerate the timeline of the cure. So I know I'm being recorded, I'll probably get in trouble for this, but Todd Wanek and the CEO of Mayo Clinic and I sat down and Todd Wanek asked the CEO of Mayo Clinic to match his contributions to this effort. CEO of Mayo Clinic, like any institution would, said "No. We've gotten a hundred million dollars into this platform. We can't play favorites. We got a million things. We can't do that." And so that was the conversation. That was the birth of HeartWorks. As HeartWorks, it allowed us to go out and work collaboratively with other institutions and align resources, align people, incentivize people, not have the conflict of interest for me, eliminate it.

And all of those things were really important to get this launched. We have not made a mistake with that. We've been very thoughtful and it's worked as planned because now we have a lower cost of what we do in the manufacturing. It's at cost, right? And we've been able to move faster. There's companies that have spent three times the amount of money we have spent and have gone out of business this year trying to do what we're doing. Three times the amount of money and gone out of business trying to do what we're doing because they haven't had the alignment of the ecosystem. So this has been the perfect playbook to get us to this point of clinical data, but this isn't a perfect playbook for the future. And so as we have HeartWorks as a nonprofit and Re-gen as a for-profit, we now get to figure out the next act of this and figure out how to keep the momentum going. But this is truly the secret that we learned. We didn't design this from the beginning. We learned with the troubles and headaches. Yes.

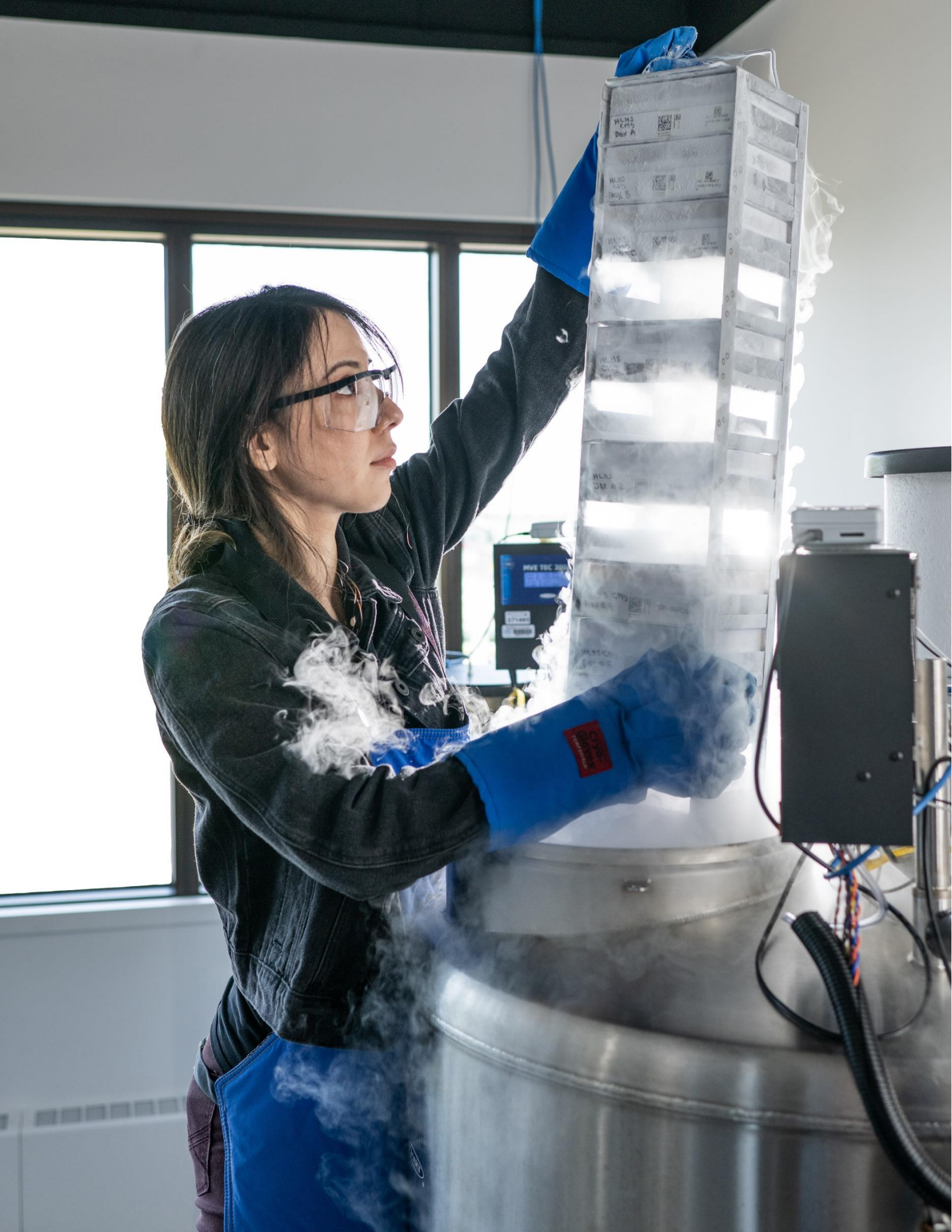
Speaker 9:

To take off of the young man's story here, is there a third company that's for profit just in that borderline or the south of the border that can generate funds? Because if I have a little baby and I can't take them here, I'll go away.

Tim Nelson:

Let me directly address the hub of your question right now. Why can we not do things in the US and we can do things off shores? That's the hub of the question you're asking right now. There's one legal reason in the United States that everybody has to understand in the United States, we have rules to protect our customers, if you will, that you can't pay as an individual for an experimental therapy. You personally cannot pay for an experimental therapy on yourself. That's the rules of the FDA. The consumer won't get in trouble if they violate that guidelines. I as a manufacturer will get in trouble for violating that in the United States. But in the United States, I have the permission from the FDA, the permission from an IRB to do experimental therapies and we have philanthropy that funds it.

But if I take that approval and that product and manufacturing off shores, some countries don't have the same rules and you can allow the person to pay out of their own pocket for an experimental therapy, which is what this is, does that track? And so there is a model that we could reasonably do that blends both together. And whether it's a different entity or how we structure it and whatnot, that's all things we don't have perfectly spelled out. But the answer to your question is yes, there is a pathway to do that and that could increase and accelerate our cycles of learning, which would be transformative.



Speaker 9:
[inaudible 00:28:22]

Tim Nelson:
Correct.

Speaker 9:
[inaudible 00:28:27]

Tim Nelson:
What would people with heart failure pay to have their own heart manufactured and be delivered into their heart? What would people pay? I don't know. Your guess is as good as mine, but that's a reasonable question.

Speaker 12:
How long was it from theory through clinical trials?

Tim Nelson:
We've been doing this for 12 years.

Speaker 12:
Was it theory or was there technology out there that?

Speaker 13:
After Yamanaka.

Tim Nelson:
So Shinya Yamanaka won the Nobel Prize for this induced pluripotent stem cell technology. I was a stem cell biologist that was studying embryonic stem cells, mouse embryonic stem cells. And I cured mouse heart disease with that technology. And I'll tell you, you're right, mouse, right? Who cares?

I'll tell you a story. In the cardiac surgery in Milwaukee, Wisconsin where I was training, I made a proposal as a senior medical student, why don't we treat patients with mouse embryonic stem cells? We do xenotransplants. I can make perfect heart muscles. They beat pretty fast in their mouse cells, but they're still motors. And I got laughed out of the room from the cardiac surgeon and to their credit, they were justified in ridiculing me and laughing at me, because I was stupid enough, naive enough, and brave enough I guess, had enough courage to be able to propose that.

And they laughed at me. But then remarkably, two years later, Shinya Yamanaka discovered induced pluripotent stem cells that allowed the same technology to happen from a patient. And we immediately put all of our energy into that technology. And for 12 years now, we've been scaling the production and manufacturing. Many of you have seen beating heart muscles from this technology for years. What we've done different is we've built the team, the infrastructure, the quality system to do it in a clinical grade way and get it into clinical trials. And so that crazy idea of mouse cells is now today available for patients with their own cells. So that's been a 12-year journey. Mike?

Mike:
Can you talk a little bit about your vision for putting together the group that will help bring this and commercialize it in the vision of just getting kick started tonight at the dinner?

Tim Nelson:
Yeah.

Mike:

[inaudible 00:30:49] Make the explicit app is, I guess, what I was wondering.

Tim Nelson:

Let me get the QR code up here for dinner tonight. Anybody that wants to join us because I'll, here it is. Grab the QR code if you're interested in joining us for dinner. What we are going to do at dinner tonight is begin talking about the things that Beau is challenging us to talk about. The timeline on this, what is it going to take? We're calling it a leadership council. It's going to be an invite only. We got to make sure we have the right group that has the right skills, the right mindset to be part of a leadership council that will allow us to start brainstorming and thinking about and putting, not brainstorming, I hate that word. Putting action into this plan and really putting a plan that we can act on together. And so we're not going to do that as physician scientists.

We're not going to do that with the team we have right now. We are looking for you all or somebody you know, that you think could be a perfect fit for that type of leadership council that wants to be part of a mission that isn't going to happen in three years. We're not going to solve all of what we're dreaming about in three years. This is a mission, this is a purpose. I'm looking at Alex right now, which InfoTrust and what he's doing is unbelievably remarkable for us and getting his company behind it. And so there's a number of ways that that can happen as well. And so it's those type of people that the leadership council is going to be built out of.