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MIKE KOENIGS

CAPABILITYAMPLIFIER

Tim Nelson, MD

Interviewed by Mike Koenigs

Fixing Broken Hearts

to Prevent Broken Hearts

Capability Amplifier Podcast

Tim Nelson, MD, PhD Interviewed By Mike Koenigs

Mike Koenigs:

Hey, welcome to an episode of Capability Amplifier. This is Mike Koenigs. And across from me is Dr. Tim Nelson from HeartWorks. Nice to have you here, my friend.

Dr. Tim Nelson, MD, PhD:

Great to be here. Thank you.

Mike Koenigs:

All right, so first of all, before I get this thing rolling, I am going to tell you a little bit about Tim and what his team has been doing. So I want you to imagine that you're in the hospital and you and your spouse are about to welcome a baby girl into the world. Now, it's a normal birth, but immediately there's a problem and she's rushed away. You have no idea what's happening, but hours later, the doctor comes to you and your spouse and gives you the bad news. Your baby girl has congenital heart disease, that's CHD. She only has half a heart. Three months later, she dies of heart failure. So your baby girl dies of a broken heart, you and your spouse live the rest of your lives with a broken heart.

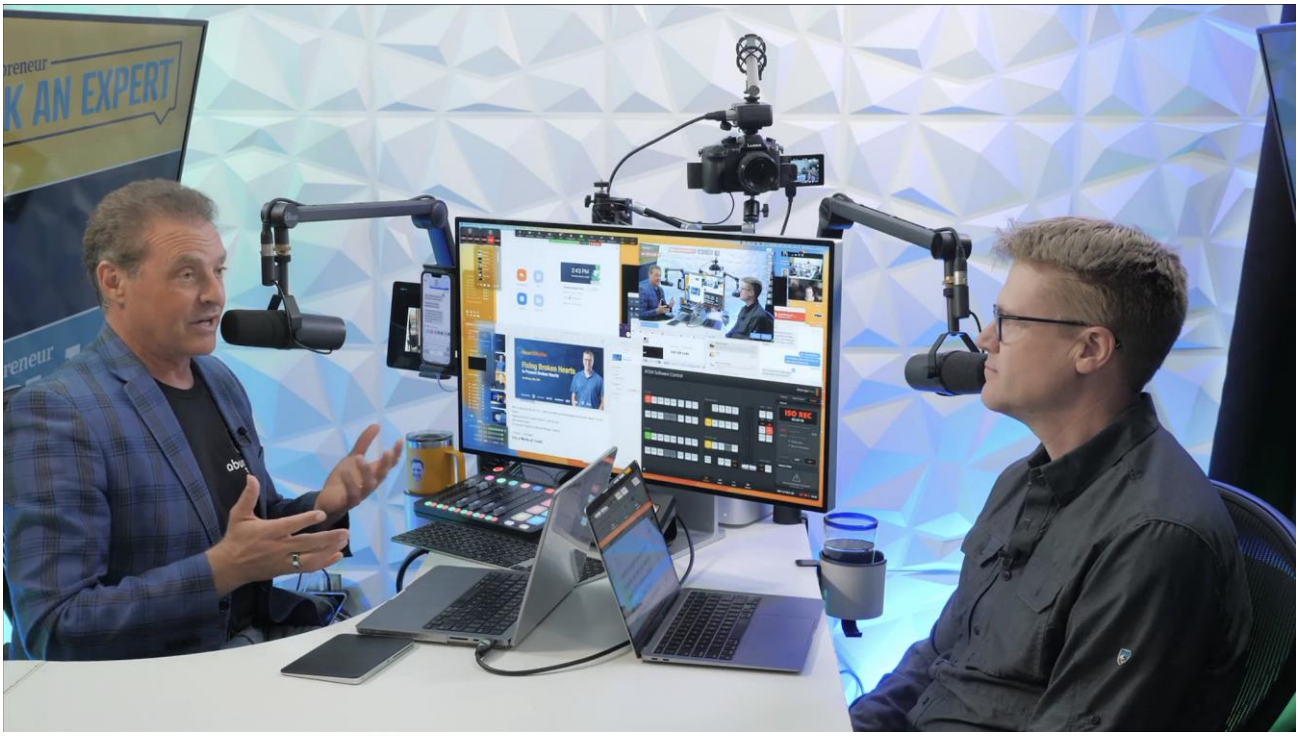
As I said earlier, my guest today is Dr. Tim Nelson, PhD. Founder of HeartWorks in partnership with the Mayo Clinic in Rochester, Minnesota, and he's raised over $100 million to date to help save the lives of children with CHD with stem cells. Now, before I bring on Dr. Nelson, I have Peter Diamandis from Abundance 360 and Bill Weir from ABC News Nightline, who will frame this in ways that I can't. So here you go with Peter Diamandis first.

Mike Koenigs:

Well, Dr. Tim, it's great for you to be here today. I'm really excited about this. This is groundbreaking work and it's nice to have endorsements like those two on your side. But I'd like you to just talk a little bit about Ryles, a three-month infant and what you did there and the promise of this technology.

Dr. Tim Nelson, MD, PhD:

Yeah, thank you. So Baby Ryles was one of these thousand kids born every year in the United States with half a heart. And what we started with him when he and his family learned about this complex disease of congenital heart disease, is they wanted to be part of these new clinical trials using cell-based therapies to try to strengthen and rebuild the heart. And so what we did at Mayo Clinic is we brought our products that we manufactured to Children's Hospital of Philadelphia, and it was the first time in his case that we did it at Children's Hospital of Philadelphia. We thaw the product in the operating room, we loaded it into the needle delivery device, and we literally injected his own stem cells into the baby's heart, when Baby Ryles was about three months old. It was a remarkable day. We traveled out from Rochester, Minnesota, did it, and was able to be with the family and give them hope that we can do more than just the standard surgeries that lead to the outcomes that none of us are proud of.



Dr. Tim Nelson, MD, PhD:

Yeah, thank you. So Baby Ryles was one of these thousand kids born every year in the United States with half a heart. And what we started with him when he and his family learned about this complex disease of congenital heart disease, is they wanted to be part of these new clinical trials using cell-based therapies to try to strengthen and rebuild the heart. And so what we did at Mayo Clinic is we brought our products that we manufactured to Children's Hospital of Philadelphia, and it was the first time in his case that we did it at Children's Hospital of Philadelphia. We thaw the product in the operating room, we loaded it into the needle delivery device, and we literally injected his own stem cells into the baby's heart, when Baby Ryles was about three months old. It was a remarkable day. We traveled out from Rochester, Minnesota, did it, and was able to be with the family and give them hope that we can do more than just the standard surgeries that lead to the outcomes that none of us are proud of.

Mike Koenigs:

All right, and one of the things that... I'm a big crier, so we've had lots of time to prepare and talk and think about this. And when I saw the parents as you came in and greeted them to give them the news that the surgery had been successful, I lost it. But you get to see this all the time, both the ugliest sides, but also the happiest sides as well. So this is super, super emotional. I just can't imagine going through this like you do and watching it over and over again.

Dr. Tim Nelson, MD, PhD:

Yeah, no, these families go through a lot. We can't even really understand what these families go through. And I'll tell you, as a provider doing these first in man clinical trials, there's a lot of anxiety on my end as well, doing something for the first time when you don't really know what's going to happen. But they trust us. We go for it. We do something to give them a better hope. And when it does work out, it's quite a relief and joy for all of us in the room.

Mike Koenigs:

Yeah, it's remarkable. So I think I have so many questions for you today. Some of it has to do with just the size of this market. The fact is the market for anything heart related when you think about both children, adults, the sick care system we have today, lost time due to sick hearts just in the United States alone represents close to a trillion dollars a year. And then moving forward, obviously it's been getting worse, not necessarily better, but some of the things that we're going to talk about are the technology itself, how it works, the opportunity that you have, the move from being a pure nonprofit to moving into and bringing this to the world in partnership with businesses. But I want to go backwards to the industry itself that you've been dealing with, which are children. And I know there's a little story about Ava who's 10 years old who can't get a transplant. So we'll go backwards first before we move forward. So tell me a little bit about that, which will lead us to talking a little bit about the transplant industry?

Dr. Tim Nelson, MD, PhD:

Well, Ava is a great story for us to always remember. Ava is a girl that was born with half a heart. She had other complicating features that prevented her from being able to have all the standard care surgeries. And now today she's developed other complications that even prevents her from being a candidate for our heart transplant. So the challenges of all that she's been through, we literally at 10 years of age, she's outlived all options that we've created for, and how do we not have better options for girls like Ava? Well, there's lots of reasons for it, but what we at HeartWorks are aiming to do is to make new options available to rebuild the hearts, to allow her heart to be stronger, and we got to move faster than we are today. For people like Ava, we're literally have outlived all of their options.

Mike Koenigs:

And we'll talk more about adults, but what are the numbers right now about the number of newborns that are born, just the death rate, I guess you could say, and how many people are living with CHD right now?

Dr. Tim Nelson, MD, PhD:

So one in a hundred babies born today roughly are born with congenital heart disease, one in a hundred, right.

Mike Koenigs:

It's unbelievable.

Dr. Tim Nelson, MD, PhD:

So it's not as rare as some people might realize, 25% of them will require an open heart surgery in the first year of life just to survive. And even in the best case, with the best surgeons, best medicines, best institutions, the sickest of the sick have a 50% chance of living till their fifth birthday. All of these statistics are not generally recognized and none of them make any of us proud in the healthcare world. And we simply have to find a better way of doing better.

Mike Koenigs:

Well, and so for the ones that make it to their fifth birthday and get a transplant, talk a little bit about the statistics there, because I did not know what they're like. And this goes for not just children, but for adults as well. So what's the reality of the transplant business?

Dr. Tim Nelson, MD, PhD:

Transplant is a remarkable thing for the families or the individuals that do get it's remarkable. It's lifesaving for them at that moment. However, the statistics are very humbling. There's only 3000 heart transplants for all ages, for all indications done in the United States annually, roughly. 3000. That's it. There's a hundred thousand people that need that. But even if you do get the transplant, you're destined to taking drugs that prevent the immune system from attacking that foreign tissue. And when you take those drugs kills the immune system, it also causes your body to develop cancers. Beyond that, the heart doesn't last forever that you got transplanted. We've got kids that even Bill Weir showed in his Nightline piece and the full version of it that is on his third heart and he's 10 years old.

Mike Koenigs:

It's unbelievable. Yeah.

Dr. Tim Nelson, MD, PhD:

So the average heart only lasts 10 years at most. So the whole idea of transplant being a cure is not true. It's a remarkable life-saving measure that only the desperate will do. We fundamentally have to have better options than transplant to cure this disease.

Mike Koenigs:

So the bottom line when you look at the stats are 3% actually get the transplants. That's for hearts alone. I would imagine that other organs are probably fairly similar. It's a million bucks for the transplant. Average is seven years before you either need, need a new one or the amino suppressant drugs basically cause cancer. So it's really just prolonging the circumstance versus your technology. So why don't you bottom line the technology? Peter did a great job in the very beginning and then what we saw with the ABC Newsline piece that also did a good job. But why don't you frame it in terms of what's available now and what your

Dr. Tim Nelson, MD, PhD:

The big moonshot is to fix broken hearts here with your own cells. The ability of the technology available to us today is to literally take your skin, bioengineer it into your heart, and be able to transplant your heart muscle back into your heart. That's the money shot. If we can take your cells and make your heart bigger, better, and stronger, we've essentially cured congenital heart disease and other heart diseases. So that technology has been primetime today. And we are launching the world's first clinical trial at Mayo Clinic in Rochester, Minnesota to be able to treat patients with their own heart muscle cells. That technology can be scaled to many, many other conditions when the time is right, when it's safe, when it's proven and all of those things. But this is the moonshot that we are going after and it's real.

Mike Koenigs:

Yeah. Now, where I get super excited because we've had lots of time to chat. The notion that if you had a heart attack in the very near future, hopefully you'd be able to essentially cultivate the cells, inject them, and rebuild as much as 25% of a heart in a year. That's phenomenal. And also, if we fast-forward this even further, as Bill Weir said in the clip, the idea that we could start growing organ tissues that would be available on ice in the event that we had some sort of a disease, all of it using our cells. And it doesn't require umbilical cord stem cells. It's basically from our skin, which is amazing. And somehow with some magic that you guys have figured out turning skin into a beating heart like we saw in the video in the beginning. Is just, as Peter said it perfectly, nothing short of miraculous.

So why don't we talk a little bit about the decision you made to get into going to the Mayo Clinic and the incredible gift from the Wanek Family that springboarded and got this thing going and just their philanthropic vision, their gratitude minded interest in this work, but also what was the domino, the tipping point for them?

Dr. Tim Nelson, MD, PhD:

So look, I started out training to be a cardiothoracic surgeon. I was planning on being the surgeon that would do the open heart surgeries, because I didn't think there was anything more remarkable that you could do with one's life than to be able to reconstruct somebody's heart. And I remember being in medical school while I was doing my PhD in molecular biology and studying stem cells, I was training with the surgeons. And there was a clear week when I was training that we did these amazing surgeries and we were super excited about our ability to do the reconstructive surgeries, the Gabrielle, that Ava, that all the Baby Ryles, all of them have had. When we did that, we celebrated. We thought we really had done something. But the hard reality is same day, same week, you'll see a four-year-old like Ava that has no options, and you realize that we really aren't curing this disease.

We're really palliating it. And so in my training and in my medical school at Medical College of Wisconsin, during the embryonic stem cell era of all the ethical concerns on that, there's this magical belief we can use stem cells. But then Shinya Yamanaka won the Nobel Prize with induced pluripotent stem cells, which means we can eliminate the need for embryonic stem cells and we can bioengineer those types of cells from your body. That's what happened, and that's what we immediately started applying our energy, our research and our time, and it was just fortuitous at many levels that we met the Wanek Family, they came to Mayo Clinic, they said, what's new in cardiac regeneration? And we had just done this in mice and proved that we could do it in mice. And we said, "Why not do it in humans?" And they said, "Okay." And we went on a journey together for the last 12 years where we took that idea and that simple conversation. And now as we sit here today, we have launched the FDA's first clinical trial to start doing that technology in humans rebuilding hearts.

Mike Koenigs:

It's unbelievable. And the donation they made, the commitment they've made, talk about that because without that incredible level of a commitment, it's astonishing. The fact that you started nonprofit first, and I've been around that for a long time with Vivian. For 17 years she's been raising money and doing work in Uganda and India and with Native American tribes. And I know how hard it is to run a nonprofit and how hard it is to go out and ask for money, but talk about the money commitment side.

Dr. Tim Nelson, MD, PhD:

Well, what would any parent do if they were faced with this situation of a child with a half a heart? What the Wanek family did is they got in the driver's seat from day one, they found the world's best care that they could get. They went to Switzerland where Gabrielle was born and had the Norwood operation from Dr. Extraordinaire, Bill Norwood himself at that time. And they've always been at the forefront of getting the best care, doing the best that they can do, which every family would do. So the opportunity is for the Wanek Family to say, now what's next ? After all the standard of care, all the surgical, what's next? Can we build the care team that can develop the new therapy? And that level of philanthropic support of a hundred million dollars to date has been extraordinary. That has allowed us to do what isn't possible with grant money or institutional money. That's what has set this platform up, and that's what makes us all really excited that this can really go to the next level.

Mike Koenigs:

It's astonishing. So let's go and talk a little bit about the potential future. And that is the fact that this is adaptable. And we were jokingly comparing this to you've built a platform which is the iPhone of the medical industry. So use that metaphor, and then let's go on and talk about how many different uses there are potentially for this technology.

Dr. Tim Nelson, MD, PhD:

So this idea of being able to create a pluripotent stem cell in the lab, what that pluripotent means is those cells are capable of giving rise to every single cell in your body, head to toe. A hundred trillion cells are in your body as it sits here today. Every single cell can come from a pluripotent stem cell. We now can bio-engineer that from an ordinary piece of skin. So we literally have a platform of cells that can be trained to become anything we need for replacement parts. That's the reality of this technology. We just happen to make it into the heart muscle, which is a big deal. And there's a lot of congenital heart patients, and there's 150 million people living in the planet that have heart disease. So this is a big, big opportunity to now take that type of technology. If we can treat one patient with their own cells, why can't we treat every patient with their own cells?

Mike Koenigs:

Okay, so I'm going to ask the direct question and this'll be the back and forth part of the show. Let's pick organs that this could potentially work with, because again, I want it to be super explicit. That's why I asked the question. So I had asked you before we rolled, like if you had to pick another organ and another organ and another organ to do this with, what would they be?

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Dr. Tim Nelson, MD, PhD:

And diabetes in the pancreas is the first one that jumps to mind, right? Yeah. It's a single cell. It makes the insulin. There's absolutely efforts that are going on in this world that are going to win that race and be able to make your pancreas produce your insulin. And that's an effective cure for diabetes. There's no doubt that that's going to happen. Kidneys, lungs, livers, all of these tissues are capable of being derived from this platform of pluripotent cells. What we do that's different is that we do it from your own body and we make one product for one patient. This is called autologous. It comes from your own body and eliminates the need for any immunosuppression drugs from a foreign tissue being introduced in your body. It's a long road, it's an expensive road, but we in a few others in this community are totally committed that if we can do it with an autologous approach, we can do it for everybody anywhere. And that's the mission in the moonshot that we're committed to.

Mike Koenigs:

It's mind-boggling. And it just goes to show that you're genuinely a category of one brand because you've got this patented, you're on the brink of being able to now bring this to market and commercialize it. And so you're the only in the world that does what you do. You're the best in the world at what you do. You've got an incredible team. You've got the benefit of a Nobel license. I mean, you're perfectly positioned to literally rock the entire medical world. And that goes to every aspect of medicine, which again could begin with. We could say, well, helping children, being able to change the world of transplants, which is a huge business, but also, again, it's seriously flawed. And then the amount of medical care that goes into just about anything related to organ replacement or whatever. So, before we move on to the next segment, again, I'm talking from a very layman's point of view here, but is there anything else you want to add on before we talk about some of the partnerships and relationships you have that have enabled this to happen in the first place and continue to?

Dr. Tim Nelson, MD, PhD:

Yeah. No, and we're just so grateful to the families that have trusted us to be part of these pioneering efforts, and we're so grateful to the Wanek Family and what they've allowed us to do and the trust that they put into this team. I mean, it really does start with a philanthropic mission aligned, purpose-built team of people, which the Waneks founded. That's what it requires to be able to take this disruptive technology, get it out of the lab, get it through the clinical trials. It's a long expensive road that typical investors are not going to be able and willing to invest in at this earliest stage. But that's what the Wanek family did 12 years ago. And now that is what has catapulted us to be at a point where we now can start dreaming about what's next. How are we going to bring this to more patients more quickly? And if it wasn't for the last 12 years and the Wanek Trust and the investment of the team and the families that have been involved, we wouldn't be having this conversation today.

Mike Koenigs:

And then talk a little bit about some of your institutional partners. So clearly you've got the Mayo Clinic. They've been massive relationship builders, partnerships, but also legitimizers. Anytime you got the Mayo Clinic sticker next to you, that's a good thing. But talk about some of the other big partners and institutions that you have behind you?

Dr. Tim Nelson, MD, PhD:

We've got 11 of the best pediatric hospitals in North America that are combined forces. And these hospitals that are partnering with us are not just passive participants. They're actively involved. They're financially contributing to the product developments and the clinical trials that we're doing. It's a fundamentally different relationship. Because HeartWorks is a nonprofit that's working across institutional boundaries. It gives us a relationship and a structure that allows us to move at the speed of trust and to do so much more quickly because of these relationships. So we're so grateful for these surgeons, these families, these institutions that have banded together in ways that are just unique. You don't typically see institutions working in such a collaborative model.

Mike Koenigs:

Astonishing. So you got Children's Hospital of LA, Children's Hospital of Colorado, Ashner Hospital for Children, Anne and Robert H. Lurie Children's Hospital, Chicago, Cincinnati Children's Hospital, Philadelphia, Sick Kids, Children's Minnesota. Those partnerships are complicated, I know. And now we're going to talk about the most complicated partnership imaginable, the FDA. You're the first to be selected to do clinicals. You're rolling right now. What does it typically cost? How long does it typically take to get a product approved? Let's talk about the impossible barrier.

Dr. Tim Nelson, MD, PhD:

Look, the FDA has an impossible task to do, right? To make sure patients are safe and make sure things move as quickly as possible. I can tell you the FDA has been nothing but constructive and helpful for moving forward what we do. And that's been really important and we've built the trust over the last 12 years that we're going to do it the right way. We're going to do it the safe way, and we're going to move this forward as a partnership of hospitals. And the FDA has been really critical. It typically takes 17 plus years, 3 billion to develop a product that gets full approval with the FDA. That's when you have a big market, a big need, and big investors that can get behind it. In a rare disease market like congenital heart disease, those dollars just simply don't exist. Therefore, how long does it take to develop a product with the FDA and the regulatory environment in that traditional model?

It's probably an infinite amount of time because the dollars are just not there. The HeartWorks model is created to really blend that together and to create a pathway where we can go from an idea in the lab to a clinical trial and ultimately to commercialize the product using the partnerships of academia, using the partnerships of philanthropy. And I like to say that philanthropy can be expected to develop the cure as long as philanthropy is not expected to deliver the cure. And what I mean by that is we can develop the cure with philanthropic dollars, but we have to build a sustainable business model to be able to deliver it. And that really becomes a core essence, a core commitment of what HeartWorks model represents.

Mike Koenigs:

And you and I are going to do a second video about the business model. I really want to go super deep with you on that. But let's just go through a scenario and talk briefly about what it might look like. So right now, you've got the FDA and go through the approval process and we'll call it playing by the rules in the United States. And there are ways to commercialize this in a way that's ethical, moral, and legal outside of the US, but also to bring this to market. So I want to play out a scenario. Let's say for example, you're someone who couldn't get a transplant for whatever reason, and you had the means. And I also want to go through like let's say we did this for an adult.

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So let's say I came to you and I had the ability to pay the bill to invest, to have this done privately, let's say, and what would the process or procedure look like? How long would it take from the time I made the decision, I provided a piece of my skin, you grew it, and then it was put inside my body and we would see some kind of results. What are the possibilities and potentials based on what right now?

Dr. Tim Nelson, MD, PhD:

Yeah. First from the technology standpoint, that skin to your heart muscle is a nine-month process. So we have to be able to anticipate it, we have to build it, we have to have it in storage, if you will. And then it probably takes multiple months for that product to integrate into your heart and really have a functional benefit. So let's say a two-year period of time from when you have a functional benefit, it's a long road from that standpoint. The opportunity with this technology is to identify patients as early as possible, get into the process where we can rebuild somebody's heart before it becomes a crisis mode. There's absolutely, absolutely no way that we don't do that at some point in the near future. The question is where, how, and when. And all of those questions are solvable questions.

And you're right that there's different regulations and different environments that we have to be respectful of. However, there's multiple ways to put together an ecosystem, an industry to be able to get the data, prove it can be done safely, and find ways of funding it so we can scale it and bring this disruptive technology to as many patients as possible. That's what we all have to be committed to.

Mike Koenigs:

And one of the things that we have, I'm looking at on my screen right now, and if you look at it on your side, it's slide 27. I'm going to display that right now, which shows a graft. So this is a one month, four month, nine month graft. And we'll describe that for anyone who's listening to us right now. But why don't you describe what the images that we're looking at at this moment, and this is in this particular case with a child. It was specifically with one of your patients. So this was from their cord versus a skin graft. Is that correct?

Dr. Tim Nelson, MD, PhD:

Actually not.

Mike Koenigs:

Oh, it isn't? Okay. So tell me what I need to say there. Let's do a break. How do I make this? So my goal is to be able to tell a story about an adult, which we just did. I want to make sure. So that might take, basically you're saying two to three year, or should we just not do a visual and move on to the notion of commercializing this?

Dr. Tim Nelson, MD, PhD:

Well, I think what you're looking at slide 27, what this actually is human heart tissue and a primate.

Mike Koenigs:

Oh, and a primate. Oh, okay.

Dr. Tim Nelson, MD, PhD:

So what this is showing us actually is that we can engraft and we can rebuild tissue. And that image I think is powerful because that's exactly what adult patients need to happen. So this is proof in the pudding right here.

Mike Koenigs:

So I want to do a hypothetical with you, which should be, again, from a commercialization point of view, and we've got a visual that I want to bring up right now. So this notion again, of we've taken a skin sample, basically produced the material, this heart material in the lab that might take nine months to do. It gets injected through a surgical procedure, and it's a fairly minor one. It's not like full on open heart surgery. And then from there, it starts doing its work, which can be anywhere from, you've basically said a year or two, we'll say. So, but we've got a visual, and for anyone listening, we're going to describe it. For anyone watching, if you're watching the video, we'll talk about what this is. So can you just describe to us what we're looking at on screen?

Dr. Tim Nelson, MD, PhD:

Yeah, so what you're looking on screen here is the green cells labeled with red nuclei are human cells. So these were one of our patients that we bio-engineered their heart muscle, and we put it into an animal model system that's required by the FDA to show its safety and efficacy. And as you can see, these green cells looking at a histology cross-section of tissue here, you can see at one month to four month to nine month that this tissue is not only surviving, it's growing, it's expanding, and it's incorporating into the heart muscle of the host. This literally is rebuilding the heart muscle from the inside out. This isn't fertilizer. These are seeds of your own heart muscle that's growing.

And the idea here is that we can take a five horsepower engine that's failing. We can plant the seeds of your heart muscle cells, and we can grow and expand that to make it a 50 horsepower motor that's bigger, better, and stronger. So this is proof in the pudding here that you're looking at, that these cells actually can do what we hope that they can do and extrapolate that out for who can benefit from this. And we're talking hundreds of millions of patients that could benefit from having your own heart transplanted into your own heart muscle.

Mike Koenigs:

And what I was blown away with, so I'd asked you, so if someone has a massive heart attack, how much of the heart is effectively destroyed? And based on the models and the data you have right now, how much time would it take to regenerate that with this technology?

Dr. Tim Nelson, MD, PhD:

So you can lose about a quarter of your heart muscle in having a heart attack, as we all know. We all know somebody that's had that happen to them, and they can go from normal heart function to completely abnormal heart function with one heart attack. With this technology, over the course of nine months span, we can literally regrow enough heart muscle cells to replace tha cell for cell. The goal now is to how to transplant that into the heart, get it to survive, and be able to function as the 25% of the heart that was lost. So the summary of that is in the nine-month period of time, we can regenerate your heart in the lab sufficiently to replace what you were lost during a heart attack. And that's a game changing technology that has simply never existed before this.

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Mike Koenigs:

So let's talk a little bit about any potential downsides, because I know for any skeptics out there, other people who are worried about stem cell technologies beyond just getting past any legal hurdles, one of the things that this does is gets past the ethical and moral hurdles that people, if they're concerned about, I like to jokingly say baby juice, if there's infant, any kind of donor tissue that comes up all the time. In this case, it's your material, but what are the potential risks that you've got to test against and be wary of? What could be some of the potential downsides?

Dr. Tim Nelson, MD, PhD:

Yeah. First to double click on what you just said, that this technology does eliminate the ethical concerns of embryonic stem cell. And I think that's really important for everybody to know because sometimes we hear the word stem cell and we immediately think embryos are being made or destroyed. That's not true here. We literally are eliminating that process by using your cells. So I think that's a really important point for everybody to appreciate. There are risk. Everything new has some level of risk. And so the risk that these cells could have is could they grow abnormal tissue? Could they grow into tissue that we don't want? Could they cause any arrhythmia because they're electrically active cells? And could that cause an abnormal beating pattern in the heart that it gets transplanted? These are things that we've studied very carefully over the last couple of years.

The FDA has guided us through that process. And it's also important to realize that we'll never have a definitive answer to those things. So we're going to have to start at some point in patients that are high risk, that have no other options and that are able and willing to participate in pioneering efforts like this. That's the data that will allow us to determine how safe, effective this could be, and that's what will allow us to scale it to more patients that are healthier, that are maybe younger. All of those next steps come out of the data that we collect in the clinical trials. So it's not without risk, but it's also important to realize that we're applying this to patients, that there's a lot of risk of doing nothing as well.

Mike Koenigs:

And I think just to create some clarity, so the earlier versions were using young people's cells, which were umbilical. The future is again, using the skin, and you've proven the model in primates. You're about to begin the FDA trials. What's the timeline here? Let's do a worst case, best case, not including some sort of total failure you didn't anticipate from the time this can be commercialized, available to people in need.

Dr. Tim Nelson, MD, PhD:

So the clinical trials, we're going to treat nine patients in the next two years with this bio-engineered cells. That's what we're going to do to make sure that we can do it safely and effectively in the first time it's ever been done in patients in humans. The results of that in the next two years is going to determine the trajectory. Best case scenario, it engrafts, it does everything that it has happened in the lab, and we have functional benefit. We'd be doing larger studies and bringing it to more patients as rapidly as we possibly can in two years and beyond.

Worst case scenario is we find something that is harmful, that slows us down, that we got to go back to the drawing board and that could put a hold on it. So we're very carefully trying to bring this forward at the right time at the right pace in the right patients, because ultimately all of us want the same thing, which is to know what is the right cell to make the biggest impact. So we're optimistic. We think that this technology has game-changing capabilities and we are the right team at the right time to begin testing improving that.

Mike Koenigs:

And then I'm going to put on my major speculator hat because I'm an eternal optimist and I like looking at the potential which should be, is it theoretically possible to start the commercialization, make it available to adults who understand the risk in a, let's call it an opt-in paid program and be running that in parallel fairly soon? Is that ethical? Is it moral? Is it possible?

Dr. Tim Nelson, MD, PhD:

Yeah. What people need to understand what the FDA guidance in the United States is that we have a regulatory system that prevents patients from paying out of their own pocket to be part of clinical trials. That's the rules and regulations that we have in the United States. There are other countries that don't have those rules. They do allow people to pay out of pocket to be part of clinical trials. And many of those trials are being done around the globe in many settings. Some are not such safe environments, in not safe ways. So there's a hundred percent reason to be skeptical and concerned about that. But there's also ways to do it, as you said, in an ethical, moral responsible way that could help us accelerate the knowledge that this technology has to be able to bring it to patients more quickly. So those are things that we constantly are evaluating and trying to figure out what does make sense at this time, at this stage of technology development.

Mike Koenigs:

And that leads us to some of the big ask that you have right now, which have to do with one of the things that we're talking about, for example, at Abundance 360 this year. So you have the great opportunity to speak on stage, speak in front of groups, and you've organized some remarkable opportunities for partners to learn more about collaborating with you, getting involved in the discussions about bringing this to market and commercializing it as well. And then we've also got some extra goodies that we've put together that we're giving away for everyone who's listening and is interested in this technology. So why don't you talk a little bit about the partners you're looking for, what you need next besides true believers who want to support you and support the nonprofit, which is a 501(c)(3), a fully legitimate nonprofit, and there's lots of ways to provide funding to that.

But talk about what you need, what you're looking for, what some of the offers are that we're giving away today, which by the way, I'm just going to tell the everyone right now you can learn more about and get all these goodies that we're about to talk about at webuildhearts.org/free. Let's start there. So I'm going to let you just tear into it and talk about what do you need.

Dr. Tim Nelson, MD, PhD:

So Todd and Karen Wanek and their entire family have been extraordinary partners. They have been the perfect partners to be able to launch what we have done. Because they've been committed to the mission. They've com been committed to the future. They've been committed to not accepting the status quo of our current treatment plan for congenital heart disease. Those people are out there. One in a hundred are affected by this. There are many other families like the Wanek Family that are affected by this. Those are perfect partners for us to be together on this mission because the road is long and we do need to have that philanthropic support to be able to do the clinical trials and move this as quickly as possible. In addition to that, we're now starting to dream about building a legitimate, robust leadership council that can help advise us with their connections, their wisdom, their business savvy to create the platforms of the future, take this technology out of the congenital heart world and bring it to a larger market.

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Those are conversations that we need to find the right partners to be part of it at this ground level stage so that we can build it the right way and not make the mistakes that may be predictable to some, and really build upon a trillion-dollar industry here that really cures congenital heart disease and beyond. So we're really excited. We know those people are listening to you right now. We know those people will be in the room at A 360, and we're extremely excited to learn from these folks and create a future together. I mean, imagine Mike. People that have the capacity, have the desire, but have never had a team of people to do biomedical innovation. We can bring that team of biomedical innovators to that ecosystem. And when you find the perfect fit, it really is catalytic for everybody.

Mike Koenigs:

Yeah, it's the more I've spent time with you... And I think this is a good time if it's okay with you. One thing I learned about you in our discussions was you're sitting on a multi-trillion dollar business opportunity here and you've given up an enormous amount of your time as a doctor, and you haven't taken any money from the organization. You're actually paid elsewhere. Why don't you just talk about that relationship? I know I'm putting you on the spot here, but I think it's really important for someone who wants to potentially put skin in the game, get involved, needs to understand the character of the person behind this and what you've frankly given up as well as what you've provided. And I know you don't think about it that way, but the truth is, you haven't gotten rich from this technology. You're really a steward of game changing, life changing, history changing, humanity changing technology. So now that I put you on the spot, why don't you tell everyone a little bit about the money?

Dr. Tim Nelson, MD, PhD:

Well, Todd Wanek, the day he made the first pledge, he had me sign a picture of his daughter, Gabrielle, that said, I'm working for you. And from that day forward, I committed myself, my career and everything that I do to be working for Gabrielle and all the other kids that are like that. This is what I do, and I get the privilege to do this at Mayo Clinic. As a physician scientist, I get the privilege of doing this across platforms and institutions, and this is a privilege to do what I do. And we're excited about what the future can do because of the culture of the team, because of the people we have, and because of the ability to amplify on top of what we have. So this hasn't been about building a business. It's truly been about patience over profits.

However, for this to truly be about patience, we have to have profits that can sustain it and build it. And so we will get there when it makes sense, but we'll never forget who I work for. I work for Gabrielle and all the other kids, and it's patience over profits as our primary mission and finding people that are aligned with that can be catalytic.

Mike Koenigs:

Yeah. So I'm going to help make the ask with you for you. Because again, now that I've been immersed in this, I'm committed to the vision. I love everything I've seen. And just for everyone watching listening right now, I'm just like, and my wife who's been sitting here is watching me. I'm crying my eyeballs out, looking at the kids and the parents when they see the kids come out of surgery, it's really, really touching. It's hard to keep a dry eye. And if you ever get a chance to see Tim speak live, definitely do it. But where I want to help make the ask with and for Tim is what he needs right now are these relationships and connections to people who've commercialized this medicine and not only have the pockets, but the relationships with the deep pockets who are aligned with the values of this organization.

I think that's first and foremost. So he's building this leadership council. The first opportunity to participate

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in this is actually at Abundance 360 with Peter Diamandis, because there's some real amazing people there. And Tim has organized a dinner, for example, with Dan Sullivan, Joe Polish from Genius Network, Bab Smith, who's Dan's wife and business partner, Todd Wanek, who, he and his family have funded this work to the tune of a hundred million commitment already. And now the next step is what is the most effective way to commercialize this technology and get in front of a multi-trillion dollar opportunity, not just for hearts, but everything beyond that. So if you're the kind of person with the relationships, connections, both to the technology and people and money, head on over to webuildhearts.org/collaborate. That is the link to learn more about that. And then there's something that we put together as a gift for everyone who's watching and listening to this podcast right now.

I'm going to go through these at first, Tim, and then why don't you double pitch with me. So you can go to webuildhearts.org/free. And there you're going to get a download of the complete walkthrough of the HeartWorks model, which includes case studies, an overview of their stem cell technology that's being used right now for overcoming congenital heart disease and infants and adults. And then there's multiple videos which include a history of HeartWorks, the relationship with the Mayo Clinic, a deep dive with Tim about the technology, and then an opportunity to schedule a virtual lab tour and learn more about the mission, which is incredible. I can't believe you're doing that.

And then the other thing that's really, really good is the full news segment from Bill Weir from ABC Nightline. Now there's one from 10 years ago, and then there's the updated version because he is checked in. There's a relationship there. And then there's also a journey with Ryles and his family where you really get to watch and see how this works, plus again, that application to become a member of the Leadership Council and learn more. So is there anything else that you want to add there, Tim, that I forgot to add? And also any other asks beyond this?

Dr. Tim Nelson, MD, PhD:

Now, this is great. I appreciate you highlighting all of this. And I would really encourage anybody that has any interest to join us on a virtual lab tour. Because there's nothing more interesting in my opinion and powerful to actually come see the team of 60 people in action daily doing the work and see that we are actually manufacturing products that get delivered into the hearts of children and adults. This is really happening today. And because of that, we have an opportunity to find the right leaders, partners, collaborators, to take this to a whole nother level. So come start with the lab tour, come see us in action, ask your questions, and we're eager to find the right partners that can be motivated to be part of today's plan and to be part of creating the plan for tomorrow.

Mike Koenigs:

Unbelievable. I was blown away when I first heard about you, then when I met you, and then when I got to have the good fortune, being able to announce you at Genius Network and now working with you is frankly a dream come true. I have not seen anything so groundbreaking and real in this space. That's what's so astonishing is the level of care, the detail, just doing things in the most ethical, moral, straightforward way. And plus, you're a nice boy from Minnesota like me, so we have that in common. That's actually why they asked me to announce you in the first place. They're like, he's a nice Minnesota boy. You guys will get along. And you feel like a relative to me from the moment we've met. I'm like, you're just like my cousins. So this has been an absolute joy. And any other final words before we wrap this up?

Dr. Tim Nelson, MD, PhD:

Well, can you imagine a better podcast to be part of Capabilities Amplifier, and what you do and what Dan does, what Joe has done. I mean, this is a remarkable community, and we have all the resources abundantly in front of us to do everything we're talking about today and more. So thank you for the opportunity to be part of your world.

Mike Koenigs:

Yeah, it is absolutely my pleasure. So the way we'll wrap this up, this is Capability Amplifier. Right now I'm going to make the other ask, which is share this with anyone who could benefit from first of all, learning about this breakthrough technology. Anyone who's been affected with anything related to CHD or that's congenital heart disease, anything related to heart disease in general, or is interested in breakthrough stem cell research and wants to learn more, but also take advantage of the goodies. And as usual, your five star review on iTunes. Your comments mean the world to Dan Sullivan and I. So with that, here's what we're going to do. We're going to wrap this up. I want to say thank you for listening. Thank you for watching Goodbye from Dr. Tim Nelson and myself. This is Capability Amplifier.