Dr. Carol Nacy

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on

the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis. I'm your host of *BioTalk*, and, as you know, we

interview leaders within the BioHealth industry within our region,

nationally, and internationally, and we have a special guest this week. We have someone who has been one of the original biotech entrepreneurs in Montgomery County, Maryland, I think. And we're going to learn more about that as we get into this discussion with Dr. Carol Nacy, who is the CEO and founder of Sequella, and someone who was one of the first biotech entrepreneurs I met when I got involved in Montgomery County, Maryland with BioHealth Innovation. And I want to welcome Carol to

BioTalk, Carol.

0:01:00

Carol Nacy: I'm very pleased to actually be able to see you, Rich. It's been a long time

since we've clinked wine glasses at the CEO dinners, and I really miss that

contact.

Rich Bendis: Yeah, I do too and, you know, unfortunately, our virtual BioForum in

October was a little different than being at AstraZeneca with all of those

people that we all knew and would love—

Carol Nacy: Right.

Rich Bendis: —to have a chat with and a drink, Carol. But maybe 2021 sometime—

Carol Nacy: Yes.

Rich Bendis: —we will get to a new norm, which will include some personal

interaction.

Carol Nacy: That will be very exciting.

Rich Bendis: Yes, I can't wait for it. So, but, in the meantime, while I've got you, and

we can look at each other, which is nice, we'd like to introduce you to our listeners, and the best way to do that is for you to talk a little bit about

your personal background and history.

Carol Nacy: My first foray into industry was actually at EntreMed. EntreMed was

started by several different people, some of whom were from Walter

Reed Army Institute of Research.

0:02:01 And I was actually running a department there, and they asked if I would

help them design their science. And I took a three-year sabbatical from Walter Reed to do that, came to build EntreMed out, and liked it so much

that I actually left Walter Reed altogether, and became a serial

entrepreneur. So my background is in microbiology and immunology. My

most favorite thing in the entire world is bacteria so [laugh]—

Rich Bendis: [laugh]

Carol Nacy: —yeah, I know this is—

Rich Bendis: Which we're trying to avoid these days.

Carol Nacy: Yes, we're trying to avoid viruses.

Rich Bendis: Yes.

Carol Nacy: Well, I've never had a fondness for viruses. But, nonetheless, I left

EntreMed a little bit after the public offering. I was lucky that the chair of the board, and the president of the corporation brought me along with the public offering, so I was able to experience that, and then we went public. And we truncated our infectious diseases, and became something

quite different in the oncology company.

0:03:02 So I left to start Sequella, and then I actually loaned myself out for two

years to a company in California, commuted from D.C. every week. My job there was to revamp the science, and get that company acquired, which we did in a little less than two years when I came back to begin

building out Sequella.

Rich Bendis: And where did you get the idea for Sequella, and what was the base

technology that you founded the company on?

Carol Nacy: It actually came from the National Institutes of Health. When I left Walter

Reed to go to EntreMed, about two years in, the National Institutes of Health asked me to be on a panel to review the previous five years granting program for tuberculosis, and to forecast what they should be funding in the future. That was such an interesting meeting for me

because I'd been at Walter Reed at that time about 17 years, I guess, and I'd never heard the word 'tuberculosis'.

0:04:03

So I thought this would be like a half-day meeting, right? Then they scheduled a three-day meeting, and I was completely shocked. And then the statistics started rolling out on the first day of that meeting, and I realized there were 10 million cases of TB every year with two million deaths. It was the number one killer of women of childbearing age, the number one killer of HIV-infected people. I was shocked. So I left there with the idea that I should think about tuberculosis as a global health menace that had no one paying attention to it, clearly. The drugs were 40 years old. The vaccine was 100 years old. The diagnostic was even older than that. That was sort of the genesis of how I got the idea for Sequella. And then it was just a question of persuading people that, even though TB is not a particular problem in the US, we have now learned with COVID, if you don't cure the problem everywhere, you have a problem whether you think you have it or not.

0:05:07

So then we went out and created some founders, and created the company, and we've been off and running for the last, as you kindly mentioned to me, 23 years.

Rich Bendis:

Twenty-three years, 23 years as a bioentrepreneur and a serial entrepreneur because, as you mentioned, EntreMed was the first as—

Carol Nacy:

Right.

Rich Bendis:

—you were involved in the founding team there, which is now CASI or however they pronounce it, but it survived. But that's the route that a lot of the companies in our region have gone is they've been acquired. They've been rebranded. They've pivoted. They've become something else other than what they began. But Sequella has not changed its name. It's had the same CEO for 23 years. And, so, what do you attribute the longevity to for Sequella at this point, Carol?

0:05:55

Carol Nacy:

I think really the mission of the company is so important on a global basis that we've been able to bring in incredibly bright people to put their minds to finding solutions to the problems that the world is facing, specifically with TB but also with other bacteria that we work on. We've

been able to discover—I have two fabulous women chemists who came up with several drugs, one of which has finished a registration trial in Russia. And we're bringing that to the FDA hopefully to have accelerated registration. And that was a drug that we discovered in-house, and brought all the way through to a phase III study. We've had other compounds that are now in phase II in Africa, starting a clinical trial in about two weeks, a dose-escalation trial of our second compound, which is a new antibiotic also focused on TB. And we have a third drug that works on diarrheal disease that's the number one infectious disease in the United States.

0:07:02

Rich Bendis: So you founded the company around tuberculosis, you're still there

today, but you mentioned other bacteria. So there's other things that you've increased in your pipeline of research that's Sequella's focused on.

What are some of those other areas?

Carol Nacy: We're still very focused on diseases of the developing countries, so we

have drugs that will work on a parasitic infection that I happened, by the

way, to work on at Walter Reed—

Rich Bendis: Wow.

Carol Nacy: and also a bacteria that causes ulcers in people. And you will be surprised

to know that 50% of the world is infected at the moment, so it's a huge

problem. But it's a major problem in Asia because it is one of the necessary factors for gastric cancer. So it's an inducer of gastric cancer

with, I think, a genetic background and an environmental onset.

0:08:00 So we're working on a drug that's in phase II for Heliobacter pylori also,

so.

Rich Bendis: Wow, and, as you look at the history of the company, if you'd look at

what you would consider your major success to point, at this point, what

are you most proud about?

Carol Nacy: I'm thrilled that our drug that we discovered in-house, SQ109, has been

so successful in clinical trials, and is so safe by comparison to the other TB drugs that are out there. Literally, no serious adverse events in any of the

clinical trials that we've done. We've also worked in partnership with a

number of groups globally. It really does take a village to raise a TB drug, I have to say. Without the assistance of the National Institutes of Health, the European Union EDCTP program, our colleagues in South Africa, Tanzania, Mozambique, we probably could not have done what we've done on the small amount of cash that we've raised.

0:09:03

Rich Bendis: And how do you find that you can get attention for something when you

have so many other competing interests today like CAR T and cell therapy, immunotherapy, and oncology, and you're still trying to focus on some third-world diseases in third-world countries? How do you get the attention you need to keep the spirit going with this company, and then

how do you find the strategic partners you need to grow?

Carol Nacy: It's not simple. Antibiotics are a huge problem worldwide. We are having

an antibiotic resistance crisis globally. There have been at least four bankruptcies of public antibiotics companies here in the United States. So funding is very, very difficult for companies doing what we do. But the need is so great that there are other ways in which we can bring together

people to get the job done.

0:10:04 So we've worked with a corporate partner in Russia. We've worked with

clinical trial groups in the European Union to move these drugs forward. We have partnerships in South Africa. And with all of that, we're able to do what we need to do to move the drugs forward. Unfortunately, it takes longer if you do it this way than it would if someone came along

and gave you, you know, \$150 million, oh, my God.

Rich Bendis: Yeah, right [laugh]. So you're still really at a clinical stage and—

Carol Nacy: Correct.

Rich Bendis: —you're getting closer to commercialization than you've ever been, so—

Carol Nacy: That's true.

Rich Bendis: —how close are you, and what is going to—what's it going to take get

over this last major hurdle?

Carol Nacy: What we're looking for now is the funding to bring our drug SQ109 to the

FDA in an end-of-phase II meeting.

0:10:59

All of the TB drugs that have been registered in the US to date have been accelerated registrations where you are allowed to market and sell your product while you complete your phase III clinical trial. It's essentially a phase IV program. So I believe we have sufficient safety data and efficacy data for this drug to bring it to the FDA. But it does take a fair amount of money to sort through all of the data, get it ready in a briefing package, and do all the work that you need to do to bring a drug to the FDA. And that's what we're raising capital for at the moment. We raise capital privately. We don't—there's not a big—we're not a public company, so—

Rich Bendis:

Right.

Carol Nacy:

—we don't have restrictions on discussing things. So that's where we are now. We're in the middle of clinical trials for our second drug. That also I have enough grant support for that to bring it through to an accelerated phase IIb registration trial, and we're just pushing forward on all fronts.

0:12:00

Rich Bendis:

So, at the end of the day, the non-dilutive funding that you're getting from the grants has been extremely important to Sequella's history?

Carol Nacy:

Absolutely, and the relationship with investigators at the National Institutes of Health, and then academic centers all over this country, has just been incredibly important. And I feel like there has been literally hundreds of scientists who've been working with us to make sure that these drugs actually—because they're safe and they're effective—to make sure that they actually get to the patients that need them.

Rich Bendis:

Has your NIH relationship been distracted at all because of all the attention everybody is focused on COVID-19 at this time?

Carol Nacy:

It's really interesting because a lot of the program managers are actually grateful to have something besides COVID to read, so [laugh]—

Rich Bendis:

[laugh]

Carol Nacy:

—they've been very helpful, encouraging about getting grants in to do other things as well. But there has been a huge emphasis on COVID.

0:12:56

Rich Bendis: Right, and then when you talk about the FDA, you know, the FDA is very

mysterious to a lot of people that don't happen to be within 30 minutes of it. But you're very close to them. Is the proximity to the FDA and your business, is there any advantage to that versus someone who's in

California trying to do the same thing you're doing?

Carol Nacy: I think the only real advantage is that you can go in person to the

meetings that they have on other drugs. You can see them in action. And, also, there are some people that were postdocs in my lab that are now at

the FDA, so I know that they're actually people-people.

Rich Bendis: Yeah, [laugh] real people [laugh].

Carol Nacy: Real people, yes.

Rich Bendis: Yes, and right now, I would imagine though all of that interaction is

virtual rather than in person, correct?

Carol Nacy: Yeah, it's frustrating in that sense. And I feel very bad for them that

they've had such an influx of things that they've had to look at critically in

such a short period of time.

0:13:57 The good news is that everybody came together to try to figure out

solutions to COVID. The bad news is that it all lands on their lap in the

end.

Rich Bendis: Right.

Carol Nacy: So they've been very, very busy, and God bless them.

Rich Bendis: And what I've asked other CEOs of pharma and bio companies is that

what impact has COVID had on your operations directly?

Carol Nacy: I spent from March until July in Delaware, hiding from COVID because I

am not young, interestingly, and nor is my husband [laugh].

Rich Bendis: Right [laugh], right, I think we share that trait.

Carol Nacy: We might share that trait.

Rich Bendis: Right.

Carol Nacy: But, in any case, we basically shut down to make sure that our staff was

protected from getting the virus, and that they were going to remain

healthy. We reopened in July, and so one of the things that has impacted us is that the clinical trial of our second drug, which will start in the next, oh, before December—we just had a call this morning.

0:15:00

Everything's on track for first patient in, and I'm very excited about that. But that was supposed to start in April in South Africa and Tanzania, and it's been postponed at least three times so far. And to keep the grant support going, keep the people funded in order to be able to start this clinical trial has been an interesting tour de force by the grant holder, which is a wonderful clinician out of Ludwig Maximilian University at—in Munich. So I give him so much credit for having spent all of this time keeping everybody's head above water while we wait for the clinical trial to start, and we just spend money, money, money, money—

Rich Bendis: [laugh]

Carol Nacy: —just sitting.

Rich Bendis: Right, I—

Carol Nacy: In that sense, it has certainly impacted our business because we can't

make the same kind of headway when everything is shut down

worldwide.

0:15:55 On the other hand, I'm working with someone who you know who has a

new diagnostics company, and is making a very novel antibody detection system, and I'm excited about that. And I also am on the board of a company that was an immuno-oncology company that had pivoted to COVID, and now has a vaccine that's starting clinical trials. So I've been fortunate to have a peripheral role in COVID, and I'm very pleased I didn't have a major role because it really is a difficult disease to have to deal

with.

Rich Bendis: It sure is. But in one of the things that you've mentioned to me is the

impact that COVID has on other infectious diseases, including

tuberculosis, which a lot of people don't know about. So maybe you

could expand on that?

Carol Nacy: Well, I mean, the problem with sequestration and people not being able

to see their physicians one-on-one means that diagnosis lags. And for

every person who has TB, it's very much like COVID.

0:17:01

It's aerosol transmitted. It's a lung disorder. Many of the symptoms that people go through are the same. So to distinguish between COVID and TB or flu is difficult. And if you can't bring the person into the clinic, then they don't also get the appropriate care. For every infected individual who goes untreated, they infect 15 additional people for a year that they—

Rich Bendis:

Wow.

Carol Nacy:

—go untreated. So we've had now nine months of people not being diagnosed correctly, people who are unable to get their medications. We are seeing an upswing in both infections worldwide. We now have over 10 million—see, when I started Sequella, there were eight million new patients every year. Now we're up to 10.5 million new cases.

0:18:02

In part, that's because of this phenomenon of if you don't treat the person, they, by aerosol, transmit their disease to others, and so there's kind of an exponential creep. And we don't have enough diagnostics like COVID. We don't have enough drugs that work, and work efficiently, and so we are seeing a huge upswing right now. And the World Health Organization's very concerned about that.

Rich Bendis:

We're fortunate to have people like you that are not just chasing the almighty dollar but also understand that there's a need to address things in the world, especially in a lot of the emerging countries that people in America don't have to contend with on a day-to-day basis to the same extent.

Carol Nacy:

Right, so let me give you some statistics in the US for TB, which I think should be eye-opening. So we have about 10,000 cases in a year.

0:19:00

About 70% of those are in people who are US citizens who were born elsewhere—

Rich Bendis:

OK.

Carol Nacy:

—acquire their infection outside the country. But we test somewhere between 300,000 to 450,000 people every year for latent TB, that is TB where, just like those people who got it elsewhere and weren't sick for years, now came down with it. These people have latent TB. We test everybody in prison systems, in nursing homes, in hospitals once a year

for latent tuberculosis. And we find 300 to 400,000 people with latent TB never been treated prophylactically. We're one of the few countries in the world that has what's called a TB elimination program where we go out and do contact tracing, like they're trying to do for COVID.

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The whole system for contact tracing is for STDs and tuberculosis here in the United States. So we identify people who have been exposed, and we treat them early, which is why we're under control. Outside the US, they have TB control programs, which means you have to self-identify with symptoms, and then they test you and then treat you. So, in the meantime, you've been busily spreading your infection to everybody you talk to or sit in an elevator with or sit on a bus with, so.

Rich Bendis:

Yeah, what's amazing though is if you have this history, and you know how to control in the United States, and it's very similar to COVID, how come that parallel wasn't incorporated in the way we were going to attack COVID?

Carol Nacy:

Well, those of us who know anything about TB were surprised that it wasn't. I mean, we have—CDC has contact tracing capability. If we had done this in the very beginning, I think we would've been in much better shape.

0:21:00

Rich Bendis: Maybe things might change in 2021, I hope.

Carol Nacy: I hope.

Rich Bendis: Yeah, yeah, we have two promising vaccines, and maybe two or three

more on the horizon, some coming right from our companies right here

in Montgomery County.

Carol Nacy: I know. Isn't that exciting?

Rich Bendis: That's really exciting, and to see that about \$6 billion worth of warp-

speed money come into AZ and GSK and Novavax and Emergent right in our own backyard is actually giving more attention to our region, and making people aware of how important our region is to the world in the

BioHealth industry.

Carol Nacy: Oh, this is probably the best place in the entire world to be, Montgomery

County, Prince George's County, I mean, Maryland is a great place to

work, as you know.

Rich Bendis: Yes, I know, yes, and we're trying to educate more people about that, so.

> And then one of the other things is you sent me a report, talking about recent findings that one in seven patients hospitalized with COVID has acquired a secondary infection, and those that acquired that infection,

50% of them have died.

Carol Nacy: That's correct.

0:21:58

Rich Bendis: That's another fact which is not well-known by people.

Well, and, you know, I think any time you have people in intensive care, **Carol Nacy:**

> they are in such dire straits that any infectious pathogen is going to be a problem for them. So, yes, it is very clear for those of us who are in the anti-infective space that the misuse of antibiotics early on to prevent that from happening is now resulting in some—a resistance development that we did not expect. So some of our antibiotics that we really rely on in hospital are going to be less effective going forward simply because of COVID and because of the necessity of making sure that people who are so ill, especially when they can't breathe, making sure that they don't also pick up a secondary infection that is more lethal even than the virus

itself.

0:22:55

Rich Bendis: Well, it seems with your experience that you've had over the few years

> that you've been working in this industry that that expertise would be appreciated by other people that could take advantage of it. So how do you share your knowledge and this wealth of experience you have, Carol, that can address some of the other underlying problems we have in

America and around the world?

Carol Nacy: How would you like me to share that?

Rich Bendis: Well, I don't know, I mean, how can we get the word out that you have

some wisdom that could be shared with other people? I don't know if

people are aware of that.

Carol Nacy:

Well, I don't know if they're aware of it either. I do lecture. I do mentor people, and we have actually—once we brought both of our lead drugs into the clinic, we had to slow down the R&D. We actually incubate a lot of little companies. We have five little companies in Sequella, and it's fun to have them because they're all working on very different things. Nobody's working on infectious diseases but us, and so we learn a lot. It's—part of science is having a critical mass of people, and they don't have to be all in the same field.

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In fact, it's better if they're not, because it's the ideas back and forth just asking a question that you might not have thought of yourself because you're so familiar with your discipline.

Rich Bendis:

A lot of people don't understand the mentoring and the incubation aspects of it because there aren't as many companies doing what you're doing that have the capability to do it, so, you know, within our region. And I became aware of your mentoring when one of the companies BHI took on originally, which maybe you might've introduced us to back in the day, was Matt Mulvey and Katie, who you gave some incubation space or a bench at Sequella when they moved down from NYU in New York City.

Carol Nacy:

Matt actually knew my son, who's a documentary filmmaker, who was living in New York City. And when Matt was getting his PhD, he wasn't quite sure what he wanted to do. So he actually came down to work at Sequella, and I had him work with Katie.

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She came from Johns Hopkins right out of her PhD, wasn't sure she wanted to do bench science, was very sure she wanted to do something in science. And she actually came to me many years back, and primarily to write, as part of what we do as scientists is write, and she's very good at it. So Katie and Matt worked at Sequella for a while. But, like all companies where there are serial entrepreneurs that are working in the company, you breed more serial entrepreneurs. And Matt had the idea that his PhD thesis might become something important, and we encouraged him to move in that direction. Part of what we need to do as scientists is make sure that other scientists have their day in the sun, have their opportunity to find something really important. And so he got the entrepreneurial bug, as did Katie, and they took off and built their company, and, lo and behold, they did a great job.

0:26:01

Rich Bendis: So, I mean, we're talking about BeneVir, which was—

Carol Nacy: Yes.

Rich Bendis: —acquired by the Janssen Division of J&J.

Carol Nacy: Absolutely.

Rich Bendis: But I didn't realize you were a matchmaker too, so you actually—

Carol Nacy: [laugh]

Rich Bendis: —introduced the two of them. They ended up getting married—

Carol Nacy: Had—

Rich Bendis: —formed the comp...

Carol Nacy: —two children.

Rich Bendis: Had two children—

Carol Nacy: I think of them as my grandchildren [laugh].

Rich Bendis: Yeah, I'm sure you do. You should be a proud grandmother. But, you

know-

Carol Nacy: I am. I am so proud of them. They're both terrific people, to begin with,

great scientists, good thinkers. They've just done such a great job. And I'm still in contact with Matt. We work on a project that he had when he was here, which we call B-SMART, and so we have a grant for that, and he's working with me. So I get to talk to him. I get to see pictures of the

kids.

Rich Bendis: Well, that's cool, I mean, and a lot of people wish that they had met Matt

when you did, and could've been investors in his company.

Carol Nacy: [laugh] Yes—

Rich Bendis: [laugh] But so—

Carol Nacy: —I'm sure.

Rich Bendis: And if you'd have five more of them you're incubating now, I'd like to

meet them because who knows whether they're going to be the next

Matt Mulvey?

0:27:00

Carol Nacy: Yeah, it's true.

Rich Bendis: Yeah.

Carol Nacy: There are some really spectacular people in there.

Rich Bendis: Well, let's find a way that we get to know them because most people

don't know that your incubating to the extent that you are with five entrepreneurial companies, and maybe they could get some more exposure. We could do a—maybe we could do a little panel discussion

with your incubators and you—

Carol Nacy: [laugh]

Rich Bendis: —on *BioTalk*, and give them exposure, right?

Carol Nacy: Yeah, sure, they would love it.

Rich Bendis: If they're ready for prime time, I'd love to do that, so let's....

Carol Nacy: I have a couple that are really amazing, and they are—they're growing in

leaps and bounds. One I think is probably going to leave in February or

March because they got a DOD grant that's huge and—

Rich Bendis: Oh, super.

Carol Nacy: —they're an engineering company. So they'll probably leave and, God

bless, this is how we do this—

Rich Bendis: Oh, that's right.

Carol Nacy: —right?

Rich Bendis: Graduation is the key to success and incubation, so—

Carol Nacy: Yeah.

Rich Bendis: —yeah, that means it opens up a space for someone else to come into

your fold.

Carol Nacy: Right.

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Rich Bendis: So, anyway, that's really neat, and I think the listeners would be glad to

know that you're probably one of the original mentoring incubation

facilities—

Carol Nacy: [laugh]

Rich Bendis: —before we actually had incubators in Montgomery County for people to

go to. So congratulations on that, and thank you for giving back to

people.

Carol Nacy: No, thanks. This is, you know, this is all part of science. This is how we do

business—

Rich Bendis: Yeah, and so—

Carol Nacy: —the business of science.

Rich Bendis: —you mentioned Maryland a little bit, and Montgomery County and

Prince George's and the whole region. So how has this region been for you to, you know, grow your career, try to grow your business, compared to you work with people around the world and other parts of the United

States—

Carol Nacy: Yes.

Rich Bendis: —that you get to compare the BioHealth Capital Region to those regions.

So how does this region rank for you?

Carol Nacy: So I love Montgomery County. I love being there. They're so supportive,

and the state of Maryland has been incredibly support of Sequella and every company that has come out of Sequella. So I always tell people,

"Come to Maryland."

0:28:57 My California company was in Redwood City just south of San Francisco,

and what I can say is that there is a very different view of life there. I don't ever stop thinking of science. I think probably I spend at least 16

hours a day either thinking, doing, or writing. In California, I was

completely shocked because people would sort of tootle in around 9:30,

10 o'clock in the morning, having already done yoga, and sailed their sailboat—

Rich Bendis:

Carol Nacy: —for several hours [laugh]. And I'd be like, "What?" [laugh]

Rich Bendis: Yeah, [laugh].

Right.

Carol Nacy: [laugh] I mean, they—and they would leave at 4:30 to play tennis, and I'd

be like, "What?" [laugh]

Rich Bendis: Yeah.

Carol Nacy: So we have a very East Coast attitude here in Maryland. And what I have

tried to explain to my children and to all of the scientists that work for me, and the ones that have gone on to be entrepreneurs is you can

always sleep when you retire. By the way, I'm never retiring.

0:30:00

Rich Bendis: Yeah, I understand that, yeah.

Carol Nacy: [laugh] If your science is part of your life, there is no work-life balance.

You don't have to worry about it that way. I have five children. They all made it through their teenage years. They're married. They have children of their own. It is possible to do just about everything that you need to do, and still be a devoted scientist, and really enjoy your life. I've spent

my enti...

Rich Bendis: Well, you're living proof of that, Carol, so—

Carol Nacy: Oh [laugh]—

Rich Bendis: —yeah, yeah.

Carol Nacy: —I'm old proof of that. [laugh]

Rich Bendis: Yeah, we're talking with Carol Nacy, who's the CEO and founder of

Sequella, and a serial entrepreneur here in the BioHealth Capital Region, and also a mentor of emerging hopefully successful entrepreneurs in our industry. So tell us a little bit about your vision. What's your long-term vision for your personal life and Sequella, since they sort of blend

together?

Carol Nacy: They do, they do.

Rich Bendis: Yeah.

0:30:53

Carol Nacy: My long-term vision for Sequella is that we will get our drugs to the

patients that need them, we will build a following for those drugs, and then I think someone with global distribution should pick us up. But we are lucky in that TB is a very different kind of antibiotic than the normal. TB antibiotics are—you can find about 70% of all patients with two distribution centers. One is the Global Fund for the World Health Organization, and the other is the CDC. There are TB control programs in every single country of the world, and those TB control programs report to the World Health Organization. Our TB elimination program is run out of the CDC. So between those two distribution centers, we can get our drugs to the majority of patients that need them, especially in developing countries. But I think if we were going to widely distribute our drug, we

would want to work with a larger pharmaceutical company.

0:31:59 What we're really good at is interesting science, and we know what we're

good at. What we don't know anything about is marketing and sales because that's not our strength. And I think in our industry, we need to begin to think about segregating our industry into those people who do the high-risk R&D, which is like Sequella, those who transform that into products with late-stage clinical trials, and then those that do marketing and sales. There are lots of little companies out there that do incredible science. And what we need to do is find a way to pass that science

upstream.

Rich Bendis: I understand. It seems to be one of the biggest gaps is finding

commercialization partners because, you're right, we're rich with science in our region, and then the commercialization lags because we haven't had as many commercial products get out of the good science and

research that we have in the region.

0:32:58 And, you know, MedImmune has been one that's been extremely

successful, and Supernus and, you know, there's a number of companies that are emerging now where they've achieved that success. But there are so many more like yourself that are on the cusp but just need the

right partner or the right breakthrough or the right resources or the right network to get to the next step.

Carol Nacy: Absolutely, absolutely.

Rich Bendis: Well, and so I guess the—I'm going to close with what can we do to help

you get to your ultimate goal, Carol?

Carol Nacy: My ask is always that you consider antibiotics and the antibiotic

resistance issues going forward. If we lose our antibiotics, which we are currently doing one-by-one, we are not going to be able to do surgery. We are not going to be able to treat oncology. We can't do any of our modern medicines without antibiotics. And we need to pay attention to antibiotic resistance as it is developing worldwide because once it develops someplace else, it is just a matter of time before it comes here and spreads.

0:34:06 Antibiotic resistance is not a game, it's not fun, and it's really critical. So,

on that ask side, I ask people to think about when you go to your

pediatrician with your child who has a cold, don't ask for an antibiotic. It doesn't work against a virus. So you need to pay attention to the use of antibiotics in your own home, use of antibiotics in feed animals, and recognize that we create the environment that enables antibiotic resistance to develop, and we are in control. We can fix this problem.

And, in the meantime, if you can, invest in Sequella or invest in

antibiotics—

Rich Bendis: Yeah, OK, there we go [laugh].

Carol Nacy: —please, yes.

Rich Bendis: I was going to say you have an unselfish answer, as you typically do from

your scientific background. But, finally, you had an ask.

Carol Nacy: Yeah [laugh], right.

0:35:00

Rich Bendis: You have to ask for the order sometimes, Carol, so.

Carol Nacy: Well, yeah, you know.

Rich Bendis: So the key is you are open for investment, I guess.

Carol Nacy: Absolutely.

Rich Bendis: I mean, you would look for some private investors.

Carol Nacy: We have about 200 private investors now. We've raised about \$108

million-

Rich Bendis: Right.

Carol Nacy: —about 2:1 grants to investment. And \$108 million is not a lot to bring

two drugs through to phase II from scratch.

Rich Bendis: No, and then from an equity standpoint, leveraging equity dollars 2:1

with non-dilutive money is very good for your investors.

Carol Nacy: Right, exactly, and my investors all have essentially double bottom lines.

They believe in the science. They believe in me as a scientist, and I do have a good scientific background. And they want to make money. I want

to make money.

Rich Bendis: [laugh] Yeah, right.

Carol Nacy: But we want to make money by doing something really important for the

world.

Rich Bendis: Yeah, you want to make money by doing good.

Carol Nacy: Yes—

Rich Bendis: Yep.

Carol Nacy: —that's true.

Rich Bendis: OK, so not a bad mission.

0:36:01 So, at the end of the day, hopefully, if there's anybody listening—

Carol Nacy: [laugh]

Rich Bendis: —to this great story and the great science and passion that Carol Nacy

has to help the world, how would they get ahold of you, Carol?

Carol Nacy: CarolNacy@Sequella.com or my cell phone, which is on my emails, so.

Rich Bendis: OK, so easily accessible, so.

Carol Nacy: Easy. I am always available.

Rich Bendis: Yes, yes, you are, especially when you're working 18 hours a day, 24

days—

Carol Nacy: [laugh]

Rich Bendis: -24/7.

Carol Nacy: Yeah.

Rich Bendis: So I want to thank you for chatting with us. I've learned a lot. I thought I

knew you but I didn't really know you until we went into in-depth here about some of the things you're involved with. And, also, I love what you're trying to do to give back with your mentoring and incubation of emerging life science and biotech entrepreneurs in our region. So we'd like to give them some notoriety as well as yourself, so we'll follow up

with that as an action item.

Carol Nacy: That sounds great.

Rich Bendis: I wish you the best of luck, and hopefully we'll come back next year, do

this again, and talk about how you've achieved some of your critical

milestones that are your goals.

0:37:03

Carol Nacy: Thank you for having me. I really appreciate it.

Rich Bendis: You're welcome.

Carol Nacy: It is so good to see you.

Rich Bendis: It's great to see you too, and we've been visiting with Carol Nacy, who's

the CEO and founder of Sequella, and wish her the best of luck in the

future. Carol, thank you.

Carol Nacy: Thank you.

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

End of recording