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In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE magazine meets with Gail McIntyre, CEO, Aravive Inc.

Taren: Dr. McIntyre, welcome to the WoW podcast program.

Gail: Thank you for having me. I really appreciate it, Taren.

Taren: I'm so looking forward to reconnecting with you after your 2020 PharmaVOICE 100 recognition. Congratulations again, and we're thrilled to have you part of the program. I got to know you a little bit through that process, and I'd love to be able to have you share with our podcast audience your story a little bit. If you could let me know, you started thinking about the life sciences when you were actually in grade school and you did a project about leukemia. And this incited your interest to drive a cure for cancer. Talk to me about how this has evolved and framed your career of more than 25 years.

Gail: I think I've been lucky. My parents used to say I was lucky because I knew what I wanted to do from an early age. I love science and I always wanted to do something in science. And for me this started with trying to figure out what I could I that I really want to do.

But everything I've done, from that 7th grade project through to choosing classes in high school, deciding on what majors and classes to take in college, and then what to do after college, it's really been focused on trying to learn more science and figure out exactly what I want to do with my science degree. Between undergrad and graduate school I had the luxury of being able to work at the Dana-Farber Cancer Institute for a couple of years, and I actually worked on drugs with a company that's now called ImmunoGen. I worked on what they called ADC, the antibody drug conjugate. They were supposed to be a magic bullet for cancer. They're still out there being developed. That's really what got me even more excited and realizing that's what I want to do. I want to go and work on drugs to help patients. I've had a passion for understanding disease and then how to cure it. At a young age I wanted to cure it. Now I know. I want to be able to at least treat it.

Taren: I think that's fascinating that in a sense your parents are right, that you were lucky. Everybody who has that clear vision of what they want to do with their life's

passion and pursuits are at such a young age. However, along the way you've made a lot of luck for yourself in getting to the position in which you now find yourself as CEO, where you were named in April of 2020. Talk to me about how you would define your first year as head of the company.

Gail: It's been really quite exciting and it's been a great growth opportunity for me because I've been able to grow with the company. I've been with the company for over four and a half years. Obviously, I'm very comfortable with the science, and then very involved obviously in driving the strategy of development. So moving with the company into that CEO role felt very natural with a nice, natural evolution.

My first priority was to actually move the lead compound, which is a protein called AVB-500 into phase 3 pivotal platinum-resistant ovarian cancer trial. And that requires first and foremost building a team and coming up with a solid development plan that we could discuss with the US as well as the EU regulators. And to come up with a clever adoptive phase 2 pivotal trial that in my opinion I think we have. We needed a very talented and seasoned teams. We need an experienced chief medical officer. And we've brought one in recently, a seasoned biostatistician who has brilliant ideas about adaptive design. And of course all the hardworking scientists in the clinical and non-clinical arena.

That's been my number one priority to get a real clear plan for our phase 3 platinum-resistant ovarian program, and then also get another study up and running in renal cell carcinoma because I think we have a great asset and we really need to move quickly and make sure that we really exploit all of the potential that this drug has.

Taren: It's fascinating. And with that scientific background it does give you that leg up in terms of setting the direction for the company from that science perspective. You must have thought about with a successful phase 3 program that leads you to that next pivotal milestone and thinking about commercializing the product. What are some of your plans around that? Would you develop a separate commercial team? Have you started to think about it?

Gail: We have to quite honestly. The team we have now is really focused on development, so when companies move in to the commercial arena you would need to bring in at least consultants or a partner, if not a full commercial team to actually take that program on to the market.

Taren: Sad to say but even today there are still very few women sitting in CEO roles at biopharma companies, and coming from a scientific background even fewer of you. Do you consider yourself to be a role model?

Gail: I'd love to be considered a role model, because I would love to be able to instill competence and inspire women to think about careers in science and push themselves.

Do things that they might otherwise do. Maybe they don't have quite the confidence or they think they're not as good as someone else, which is surprising. There are a lot of people out there that have that attitude, and I am a firm believer that if you do your homework, you use data to drive your decision, that drive and the passion and all the hard work, and a very objective scientific approach will get you actually farther than even talent.

Taren: Did you have some metrics along the way that helped prep you, or help you define your roadmap to the C-suite?

Gail: I've been lucky. I've had a lot of people that have taken chances on me, believed in me, and put me in positions that maybe someone might say "I'm not sure she's ready for and she might not have the experience. Right now the chairman of our board, Fred Eshelman, has served as a mentor for me for a couple of decades now. He was my boss at PPD and he put me over a compound partnering group, in which we licensed in programs early on and used the PPD resources to actually advance those programs.

And then when we built up a great pipeline within the CRO environment we actually spun out into a company called Furiex, and we had a 4-year tenure out there. And then that company got bought by Forest, and now he's actually working with me now as chairman of the board of Aravive.

And even before then now, working at Dana-Farber Cancer Institute I had the luxury of working with some really talented scientists who are associated with ImmunoGen and with the Dana-Farber Cancer Institute. And before that I had a professor at Merrimack College who believed me enough to actually allow me to be one of four students to do hardcore cell culture work, which is really what gave me the opportunity to get that job at Dana-Farber Cancer Institute. All along the way I've had people that just really worked closely with me and given me opportunities that I'm not sure I would've known how to get those opportunities on my own.

Taren: How can we as women emulate that for the next generation, and making other women understand that those opportunities are available to them? What needs to be done to change that perspective or remove some of those barriers?

Gail: I think what I would encourage anyone to do, especially women, push yourself beyond the comfort zone. Take advantage of every opportunity. Trust yourself. Do your homework. And stick to data facts. You do your homework and you stick to the data and the facts. Have confidence, because a lot of people will walk into a room saying, "I'm nervous about presenting or bringing this up in front of the team." But if you really know your data you're going to be the expert. And you need to have confidence that you are going to be the expert in that. That's the main piece of advice I'd give, is to have confidence and do your homework, and believe in yourself.

Taren: Just a minute ago you talked about PPD, and you spent quite some time at that large CRO. Let's talk about how that experience helped frame your journey, which included the full development process of three drugs, which is unusual in itself as well, Nesina, Priligy, and Viberzi, if I'm pronouncing those correctly. That's quite an accomplishment. Talk to me about what made those programs so successful?

Gail: Yeah, and you do pronounce those correctly. Spot on. They try to intentionally make a difficult name to pronounce. I can't pronounce a lot of drug names. First, in and of itself working in a CRO is a huge education on its own in drug development, because you're exposed to a lot of different ways of doing things. You're working for a number of different sponsors. That's number one.

Two, I was fortunate enough to be on those three programs that were actually developed through the PPD compound partnering pipeline that we've built. And again, that was with Fred Eshelman's vision of using the CRO resources to actually develop our own drugs. And then those compounds were actually spun out into Furiex, the public biotech company. And because of Viberzi Forest came along and then bought us within a four-year period.

It's just was a rare opportunity to work, first, with the CRO, and get exposed to all that drug development experience. And then be able to apply that to your own pipeline and then spin that pipeline out and show that within a four-year period you can add such value.

I do want to say though, the secret is the team. It's not one person. You can have a great vision, but if you don't have a team, and if you don't have a team that respects one another and works really closely together you're not going to get anywhere.

And we had a very small team. I think we were a company less than 25, and we were able to move five through the phase 2 program, and then take that on program Viberzi through phase 3. The only way a small group like that could do that, it was a just huge amount of trust and respect across the team.

Taren: Those are such important lessons. And I love that point when you said working for a CRO it gives you different perspectives because of the different sponsors that you get to work with. As you move through that piece of your career, if you are involved in a CRO, you can really take that to that next level if you decide to go to a company side because you've seen what works and what doesn't work from so many different perspectives. Really interesting.

I also understand that you have some strong feelings about making those go, no-go decisions in terms of drug development, which is also quite unusual because these drugs are very personal to the developers. It's really hard to tell a scientist, your drug is just not going to make it to that next level.

Can you share why you think it's important to recognize when a drug should not proceed? And what are some of those factors that you look at?

Gail: This is a tough one as you because it's a catch-22, right? You want your drug to succeed but... I think it's hard. I think if someone honestly looks at their drugs and they know when to stop development, that person should be rewarded.

And maybe that's part of the problem. I'm not sure that in an industry people who recognize that we're done with this drug. We shouldn't move it on. I'm not sure people reward it. There's a lot of reward for drugs moving forward. That's one thing.

I think I like most scientists look at the drug and think about the patients. If I had a family member with that disease would I want that family member to take that drug? Because you're concerned. The irony in oncology is that while we desperately need new oncology agents they can be very challenging to conduct oncology studies as there are a lot of competing trials.

You hear about this shortage of oncology patients and yet we need new oncology drugs. You can't help but wonder do we need to think more closely about which drug should go into which patient. And it would be nice and I would hope that people would look very critically at their data, pre-clinical data included. And if there's anything in there that says, "Hey, maybe we should take a different direction or clinical, or maybe we shouldn't go in to the clinical arena that they would really look and think twice about taking that drug into that patient population.

I do like the targeted therapies because by definition it should ensure that the right drug is given to the right patient. It's again about patient safety and these patients, especially oncology patients, sometimes they have one more shot at a trial, so you'd like to give them the best chance.

Taren: When we think about the history of drug development it has changed so radically over the last 20 years in so many ways, and yet it hasn't changed at all. And we're looking at targeted therapies as you said, and because of the underlying scientific and the technology we're able to more closely match a patient with a trial, rather than it being a scattershot approach. But at the same time we're still seeing so many of those barriers for patient recruitment and patient retention.

Gail: Definite. And patients, it's probably hard for them trying to figure out what is the best study to go into.

Taren: And they're scared. That's part of the process too. Do you address that at all when you're looking at your drug development programs?

Gail: I'd like to think we do address it. The current company I'm in has one drug, and it's proven to have a very nice safety profile. And it's not a drug that you would give on its own for cancer. We're able to go into healthy volunteers because the safety profile has been so benign.

But when you give it in combination with say paclitaxel, which is what we did in our phase 1B study we see a really nice at least additive clinical activity, such that patients have longer median progression free survival, times we're seeing more response. We even had two complete responders in our trial.

So far (*knock on wood*), it's showing somewhat of a, for a lack of a better expression, ideal profile, because it's adding to the clinical activity without adding to the tox burden. I think again I've lucked out, because if you wanted to develop an oncology drug that's exactly what you'd want to do.

Taren: Even with all that success though drug development is fraught with a number of pitfalls and disappointments because of a drug not meeting an endpoint, or it misses its mark in a clinical trial. And as a leader how do you keep those teams buoyed and ever optimistic, because drug development is hard?

Gail: It is. We had a saying in our little team, and that is it's okay if the drug fails us, but we don't want to fail the drug. We take a scientific approach. Again, if you really are critical about your data and you think about the signs you should be able to come up with a really good development plan. It's very specific to your drug and your science. And again, it's about just making sure you do the right study with the right patients, for the right science. And as long as we do that, then if the drug fails then we can say, okay, we gave it our best shot and it was the scientific approach, and the drug doesn't work.

Taren: I love that. It takes the personal out of it and yet that's such a great saying. Keeping in mind that you're leading a whole organization now, and you led some pretty significant teams in the past, how would you describe your leadership style? And then how do you think your teams would describe you as a leader?

Gail: I would consider myself as more of a mentor. And because of my experience I do get in the trenches. I work alongside my colleagues. I've written all three IND that have gone in at Aravive. I know every piece of data in here, and that's been one of the luxuries. Because I've been exposed to the founders at Aravive. They've been really great in terms of training me on this program.

I would like to think that I'm down there in the trenches working with them. And I think that I need to exhibit the behavior that I want to see in others. I don't think you could ask other people to do something that you yourself would not do. Let me put it this way. I've worked with some people for over a decade now and they continue to work with me, so I think that's a good sign.

Taren: Yes, it's a good sign. Your colleagues consider you to be very thoughtful, very passionate, compassionate, very fair, very forthright, which are all those great characteristics that we look to for in our leaders, smart, all of that stuff, just to get that back to you.

We've talked a little bit about mentoring through our conversation and I know that it's so important to you as you have mentioned. Tell me about your involvement with your Alma matter, UNC Chapel Hill, and what you're doing there to mentor folks.

Gail: I'm really proud of my UNC Chapel Hill colleagues. I think there's been some great clients from there. I had a great education there. I've loved my years there. I stay in touch with a lot of my colleagues. I've consulted with a number of spin out companies because I would love to see some of those companies do really well.

My interactions with UNC have been a little more informal. I will say though that the mentoring is really important to me, and recently I've reconnected with my undergrad, Merrimack College up in the North Andover, Massachusetts. I've done some online mentoring for them through LinkedIn. But they've asked me recently if I'd like to come back, visit and talk with the students up there once things return to a little bit more normal.

I would love to do that because I would love to be able to talk to some college students, especially women, and encourage them in their science careers. Because I know that when I was a college undergrad, and especially with a small undergrad school like that, UNC just has a wealth of opportunity, and there's a lot of really high profile people there. But in some of these other colleges, although Merrimack has gotten a lot bigger, the students I know, well when I was, were craving information about what they can do with a science background. What can they do and can they make a difference?

I do have to acknowledge that I went to college before the internet, so maybe things are a little bit different right now. But I've really struggled with what can I do. Because it's either you go to med school or you teach in a university. I didn't know there was anything else that you could do. And I didn't know how to acquire the knowledge and experience to actually get to where I am now, so I would love to be able to be a resource for people to help guide them.

Taren: As a pre-internet collegian I understand. You talked about when we get back to whatever this next phase of our reality is, some call it the new normal, the next normal, whatever that is, what do you see for your company, how are you all adjusting to being not together as much as you used to be in person. I'm assuming that is still true for you. It makes it a little bit different. Hasn't changed your leadership style at all?

Gail: That's another lucky thing. For the past 10 years I've been working virtually. So even at Furiex, the company before, we were virtual. And our headquarters were in North Carolina, but really, less than 50% of the company was actually working from the North Carolina office. A lot of us were spread throughout the US. There's people in Texas, D.C., Colorado, Wisconsin, California, everywhere.

When COVID hit it really didn't make a lot of difference to us because Aravive is a virtual company. And we have learned to work virtually. And there is a trick to working virtually. You probably know that as well as I do. You have to know to pick up the phone and call people every day because you don't have those hallway interactions or coffee break interactions. It is a trip to pick up the phone and talk to people, and you have to realize not to take emails so seriously because that can be a tough forum.

We did have the luxury as a company when we had to work from our home offices, a lot of us were already doing that. So it was a pretty easy transition. But I do have to say that we do miss getting together periodically because there are some team interactions and socialization that really I think helped build the team in the collegial atmosphere.

Taren: You hit upon a point that I wanted to delve a little bit deeper into if you don't mind, and that's talking about working differently in virtual from the beginning. That's unusual too for a biopharma company to be a virtual type of company. Did that pose any challenges for you all in terms of fund raising or venture capital, or even the perception of the organization out there in the financial world?

Gail: I haven't really seen that quite honestly because I think in the financial world they really judge you by whether or not you meet your milestones. So I think as long as you are honest and say this is what we planned to do over the next year or two years, and if you deliver on those you're fine. I've never seen that.

Some people aren't used to working in the virtual arena, but I think now after a year of doing it it'll be interesting to see how many companies now change indefinitely to be a little more virtual moving forward.

Taren: And there's this whole movement towards decentralized clinical trials, which is also a piece of virtuality and being more online, and taking advantage of those technology options that are coming online in greater number every day it seems like.

Gail: Yeah, and you hit actually an interesting point. If you think about clinical trials, at one time there were these CROs and they had all the clinical research associates in one building. And they go out on planes to all over the country to do the monitoring. But years ago, decades ago maybe even, the CROs realized, "We should reach out to the CRA that reside in the different states and actually have them be part of the company and have them work from home because they need to be closer to the sites that they're going to monitor." There has been total a move to decentralized even decades ago.

Taren: Agreed. And it just makes so much sense that whenever that light bulb went off, for that first CRO to say, hey. And then everybody kind of followed suit quickly afterwards. Throughout your very successful career you have no doubt had a number of milestones and a number of highs. But I'm going to challenge you to pick out one career move that either has left a lasting impression on you, or changed the trajectory of your career. What is that wow moment for you?

Gail: I know, that's my problem. I can think of four right off the bat. You want me to go through all four and then do the runner up?

Taren: I'll let you do the three runner ups and then you can give me the biggie.

Gail: Okay. Maybe you can help me with the biggie then. As you mentioned, in 7th grade, doing a project on leukemia, writing away to the St. Jude Hospital and realizing there were hospitals that focused on cancer therapy and understanding leukemia and what it was, and that there are drugs. That was a wow moment, because that told me I wanted to go into science.

But then number two, and this is I think a bigger wow moment than I appreciate. My second job at age 18, I worked 3-11 as a phlebotomist in a local hospital. And when there was some downtime the med techs there, and this is an example of people who would really help me in my career. They taught me how to do the hematology and the chemistry and the coag test. And they actually trained me in a blood bank, so I was transfusing patients.

And so there was an opt for a two-year med tech opening to go full-time when I was in college. I went up to the managing pathologist and I argued that because I think I was a junior at that time in college that I had the equivalent of the two-year med tech degree. And because the hospital was a teaching hospital, and I had been trained by the med techs of the hospital, that I would like to apply for that med tech degree and move from a phlebotomist into med tech and he said okay, and he put me through additional training. And then that put me into a full-time medical technology career, which I use to this day, assessing patient safety, clinical chemistry, hematology. That's 50% of the safety data and application. That I think was a really big wow moment.

And then, as I mentioned before, because I had a college teacher, I'll never forget her, Dr. Welsh, she picked me to be one of four students, the only female I might add, to actually culture cells. And I worked with cancer cells in that lab. Because of that experience I had as an undergrad at Merrimack I got a position as a lab tech at Dana-Farber with a group now known as ImmunoGen, and that's where I made one of the first ADCs B4 block and that actually went into cancer trials right when I left ImmunoGen and went down to UNC Chapel Hill.

And then again, I mentioned all the different people in my post-graduate careers that have taken chances on me and put me into leadership roles, and then guided me along the way such that I am where I am now. I think I've had a lot of wow moments.

And maybe the turning point was that junior year in college where that pathologist took a chance on a junior in college to actually be a full-time med tech, which opened the window to all of clinical science.

Taren: Not only did he take a chance but you were bold enough to ask for it. And that doesn't always happen. So that's kudos to you as well as to him for recognizing your potential. But that is a wow.

Gail: I think that's an example of what we're talking about before, you have to push yourself beyond your comfort level. I was nervous. When I started there I hated 7 a.m. draws or 11 o'clock draws. But by the time I've spent many years there I was very comfortable. If I had done what I wanted to after the first month of 7 a.m. draws I wouldn't have stayed there, but I kept pushing myself and it paid off.

Taren: That's the culmination, the reward of persistence and resiliency. And being pretty smart too. Dr. McIntyre, I can't tell you how much I've enjoyed our conversation today. Thank you so much. Thank you for sharing your career journey. Thank you for sharing some terrific insights on how women can plot their career paths more productively.

And thank you for sharing those couple of tips of working virtually right now, picking up the phone. Especially not taking email too seriously, I think that's a great point that we often overlook because people are quick to respond. It doesn't mean that it's a quick response. It just means what it is. It doesn't mean that there's any more intention to it. All great thoughts and great insights. Thank you so much.

Gail: I've really enjoyed this. It was really nice talking with you.

Taren: Likewise. And I want to wish you and your entire team continued great success.

Gail: Thank you very much.

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