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In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE Magazine, meets with Dr. Maria Fardis, President and CEO, Iovance Biotherapeutics, Inc.

Taren: Dr. Fardis, you have literally moved from the lab to the C-Suite, which is very rare for women. During this time, you have had an incredibly interesting career journey. You're a scientist and expert in medicinal chemistry. You have led multiple clinical programs and you were Chief of Oncology Operations and Alliances and then a Chief Operating Officer. And now, you are CEO and President of Iovance.

You have said career paths are to be defined by you and not others. I'd love to know what factors you considered when you were defining your career path.

Maria: Thank you for that question. Yes, you're correct. I have made that statement. My general goal always at a position is to do my absolute best at a job. I make it my personal business every detail along the way. I try to stay positive and work and focus on the task and trying to do the right thing for the patients and the product. I'm not particularly focused on my career per se, but I do believe that once one does their best at a position, it is noticed, and the outcome is very favorable.

Just focusing on what I want would not necessarily be sufficient, I think we have to earn what comes and once we do, because it comes with a background of having learned the position, having learned about the job and having learned about the product, we are on a stronger platform for our next stage of growth. So it's not that the career is specifically per se my focus, but I think it's more of an outcome of the focus being on doing your absolute best at what we have in terms of training and expanding our knowledge at the job and about the product.

Taren: That's wonderful. In addition to that, what are some of the other lessons you learned along the way that might benefit other women scientists who aspire to be executive leaders, who may not see that career path or even that ability to move forward as clearly as you did.

Maria: I always encourage my colleagues, female or male, to make sure that early on they get well-educated. The knowledge we gain through an undergraduate or graduate program is something that is incredibly immense and at the early stages of life, it's a lot easier to do that. It's the advice I give my own children as well. That doesn't mean that's all there is. That's just one of the platforms that we build for ourselves.

Beyond that, integrity, sincerity, hard work, positive attitude will go a long way. Those get noticed. We spend a lot of time with our coworkers in a very enclosed environment and ultimately, everybody wants to be around somebody who is sincere and has integrity at work. So I don't think there is any shortcuts. They are the same good old values that will come to work and again they are valued by any employer.

I think it is important that we consider as female executives that we create opportunities for our younger generation. And from my perspective, the opportunity doesn't need to be gender-specific, but to think about other people's careers and making sure that we give a lending hand. It is our responsibility as executives to assure that other people's careers are watched after, the same way that they might have watched after our careers. So I want to be sure that our peers think about, as management, we have a responsibility to develop our key members and our next-generation drug developers.

Taren: Fantastic. I also know from reading your bio and having got to know you a little bit through your PharmaVOICE 100 Honor, you are incredibly passionate about science and you have a true love for science. How has this passion fueled your approach to drug development?

Maria: I put the goals before me and the effort in perspective. When I am focused in accomplishing something, for me the long hours are not long hours. They're not torturous. I enjoy every minute of it. This is exactly what I want to be doing with my day. This is exactly what I want to see. I want to see the patient's letter or the response from a patient or a family of a patient sending me a letter saying how the patient is doing.

So to some degree, this has to come within. So do what you like to do, I think is the advice that comes out of it. Because ultimately at the end of the day, if you don't enjoy every minute of what you're doing, the days are going to be long and difficult. If you are doing what you're enjoying to do, it doesn't feel like a chore. It doesn't feel like a job. It feels like you're on point... you're executing your passion, and it's just absolutely utter fun.

So the approach to drug development, it does come from... we briefly talked about being well-educated, understanding the landscape, making sure that we understand every nook and cranny of drug development, this is just for me, as well as being passionate about it. And I think those coupled with each other makes for a very easy day job. It's not a long day job whatsoever.

Taren: That's an incredibly optimistic point of view. But we all know that drug development is fought with a lot of complications, and things don't always go the way you hope they'll go. How do you keep yourself and your teams buoyed during those times of not-so-successful outcomes?

Maria: That's correct. Drug development definitely is not for the faint in heart. There is a lot of failures along the way. And in bringing not only ourselves to work every day but a team of employees to work every day, it requires a number of factors. We have to start with the goal in mind. The goal always in any drug development program is to bring the product to the patients.

So when we think that endpoint, that vision of how we're going to go from today to that endpoint needs to be very clear to the team. So I make it very clear what our vision is, how we are going to accomplish it and then everyday we correct towards that goal. And I think as a leader, it's my job to make sure a few things are done on a daily basis, that we don't deviate from that vision. It takes a minute of peace during the day to sit back and think, 'Did we get a step closer to that goal today or did we not?' It's very easy to lose focus and become distracted with other items that come up in the course of drug development. It's incredibly difficult to make sure that every step is towards that right goal.

It's also very important to assure that my team is well-staffed, they have all the resources they need, they're all well-educated, that they have all that they could use at work. Then of course through the huge component of financial support in the company, but there's also a huge component of keeping their motivation and mental health and focus going.

On the financial end, of course the company has to be well-resourced, are well-staffed. It's wonderful to have a very strong group of shareholders who believe in the mission of the company and support the company with their financial backing, that allows for proper hiring, that allows for proper resources to be available for employees, and of course the team member has to be comfortable at work. This is what they do on a daily basis.

So all of those aspects are something that a leader has to think about in order to make sure that the company is successful. It goes from a strategic perspective and view to stay in focus on a day-to-day basis, assuring that the morale of the team stays high, to assuring that they have the financial backing that they need, and then on a day-to-day basis, administering to their health, their well-being, and whatever else their needs may be. All of that is the responsibility of the leader.

Taren: That's fantastic. And let's talk a little bit about your approach to the strategic vision of the organization as well as your involvement with the investment community. So upon taking the helm of Iovance, you started to make some pretty big changes. Furthermore, Iovance is involved in one of the hottest areas of science right now, cancer immunotherapies. And you were instrumental in turning the company's tumor-infiltrating lymphocytes or TIL-manufacturing process into a viable commercial model. Tell us about how you arrived at that strategic vision and your direction for the company going forward.

Maria: Well, thank you for that question. You're correct. It does go back to thinking... to start anything with the goal in mind. We have to know where we are going in order to be able to define how we are going to get there.

So I started at the same points. Before joining the company, I was thinking 'how would I take this ultimately very, very personal product,' this is very much the example of personalized medicine in today's landscape into market. A product that is so unique in the case that every batch is a patient and every patient is a batch has to be handled with great care and there needs to be ultra-sophisticated manufacturing capacity available and a lot of that to allow for patient's flexibility. Ultimately, our focus needs to be patient flexibility and patient care.

So where I started thinking about our development program was manufacturing. I realized that there was two things that we need to address. The duration of manufacturing of our products was approximately six weeks long. This was a product we have licensed from National Cancer Institute, from Dr. Steve Rosenberg, and I felt that if we can shorten that, that would be hugely beneficial for the patient. And at the same time I wanted to increase our capacity in working with commercial manufacturing organizations or CMOs and we started talking to a number of CMOs in collaborating for them to provide us manufacturing capacity.

In the first six months, we optimized the manufacturing process. We had increased our manufacturing capacity. We had gained some momentum in terms of internal team members. And we had a manufacturing process that then restarted implementing in our CMOs and started dosing patients. In the course of the subsequent year, we dosed enough patients to assure that our modifications in our manufacturing process did not change the product in a meaningful way or at least it made it even better. Once we saw responses with this new manufacturing method, which we call Generation 2 or Gen2, we then expanded that manufacturing method to our multiple indications.

In a clinical setting, we are looking at a pill, as you noted, tumor-infiltrating lymphocytes, and treatment for metastatic melanoma, cervical and head and neck cancers and we are now starting our program in non-small cell lung cancer. Once we had sufficient data regarding this Gen2, we implemented this particular manufacturing method for all of our studies and started investigating the data for all of these indications.

In metastatic melanoma, we gathered sufficient information during the course of 2018 to bring this to FDA and started dialogue about the path of registration for our TIL product. In the case of melanoma, this is called Lifileucel and we wanted to find out from the FDA if they have agreement on an accelerated path for Lifileucel for registration. The agency agreed that a fast-to-market approach is reasonable for this particular product and for melanoma we are now executing to this fast-to-market strategy.

In addition to that, we have continued our studies in cervical and head and neck. As part of that, we conducted around the financing. It has been wonderful to see our shareholder participation to allow for further development of this product in clinic. We also work very closely with our partners, specifically a lot of hospitals, our close partners including Moffitt Cancer Center and MD Anderson and a few others that we work closely with in investigation of pills further. And we are very pleased with the collaborations that we've had in further investigating the power of pill in the newer and rare indications.

So when we step back, the whole of the strategy was to think about solving manufacturing problems first, then generating clinical data, then talking to regulators to assure that there's agreement in our registration path and then executing to all of them to bring the product to the market.

As a next phase, what my focus is is on commercialization of the product and we are building our commercial facility that would allow us, Iovance ourselves, to be able to manufacture pills in support and collaboration with CMOs and independently when into the marketplace. So that's our next phase of growth and development.

Taren: Well, congratulations. That's very exciting. I find it interesting that you are going to take on the commercialization aspect of this product as well. That's pretty unusual for a biotech company. What led you to that decision?

Maria: That's an excellent topic and I had taken some time to think it through because a partnership with a CMO certainly is an option and we have been very fortunate to have wonderful CMOs who have been truly our partners in drug development. I think in long-term there's two aspects that has sort of allowed me to think about should we be thinking our own manufacturing versus a partnership in manufacturing.

And this specific item comes back to cost, of course. We have to assure that at some point that we return the value to our shareholders who have been so generous with their support of the company and we want to make sure that our cost of manufacturing allows for a net that is more favorable to our bottom line to come back to the company and shareholders.

At the same time, there is a degree of flexibility that is for self-therapies that is required, and while the CMOs have been wonderful in accommodating our need for flexibility and timing, we think that's very well-accommodated by our internal team who is able to touch the product and understand the patient needs.

So those two factors had allowed us to think about it. The reason for timing, this is something a lot of companies decide at various stages of development to go after commercial manufacturing, we are later compared to some of our peers in self-therapy landscape, and the reason for me was I did not want to tie up fixed assets of the company

and commercial manufacturing until we fully understood the power of our assets at these few indications.

I also wanted to make sure that we have agreement with FDA in terms of the patient population, so the capacity of such manufacturing facility is appropriately adjusted so that patients that they think would be our first initial indications. Since both of those needs have been met now, we think it's a very good time to go out and build our commercial manufacturing facility.

Taren: Can't wait to see what happens next, and we'll follow up to make sure we're on top of how things develop in that area. Because I think it's very exciting what you all are doing.

I want to touch on a little bit about the market cap of the company, and you're accredited for increasing it six-fold. I'd love to know what your experience has been in dealing with that investment community. You stated that shareholders are very important and that the company is well-financed and resourced. So how did you get to achieve that market cap?

Maria: It's twofold and you're correct. The support from shareholders and investors, existing and new ones is incredibly important in any drug development program. We are very fortunate to have the support of our existing and new investors in the process, and I think it is very much a two-way collaboration. Our job as management team as well as employees of the company is to do the right thing for the product and the patients.

When we develop the product, we create value for the product and that value creation ultimately is very much tied to the shareholder interest as well as value of the company. So we have to remember every day that we have to take the product further along in development and by that we not only do the patients and the product good, but also, we create value and shareholders return our investment.

Taren: Excellent. Is there one tip you can provide to other CEOs who are working with investment communities, something that you learned along the way that you had wished you knew before you started down that path?

Maria: Something I learned along the way was that investors are partners. Instead of thinking that I'm just reporting, a lot of them have become true friends and partners in our drug development program and journey. And I think that that it took me a little bit of time to figure that out, that although they ask me questions and they hold me accountable and responsible, that doesn't mean we're not partners.

We're very much truly partners in this process, and I think that would have done me well if I had figured that out a little sooner. It took me a few months, but I'm good with what we are right now. I'm very pleased with the relationship that I have with our investors in general.

Taren: Thanks for sharing. That's a great tip. As one of the few women CEOs in the industry and unfortunately that is the case right now when you look at the numbers across all the pharma and biotech, there are other women who would like to send to the C-Suite, I'd like to know how you gauge success for yourself and how do you celebrate those successes?

Maria: I genuinely believe success is when you bring a therapy to patients. I don't know if that necessarily has anything to do with being a woman CEO. I think that one of the best joys of anybody's life in drug development is to see that label, that FDA issued at the end when a product gets approved. It's quite unparalleled. That excitement of... that accomplishment of bringing a therapy to patients is quite unparalleled.

To be honest, I don't do anything specific besides that in terms of celebrating success. I don't do anything else that is besides just keep that goal in mind. Really, our job is to serve the patients and the community and the families that go with it. To me, that's celebration of success.

At the end of the day when a product comes to market, whether I was there, or I wasn't there, but I worked in the product, that's a moment to sit back and say, 'Okay, this was all worth it. It was absolutely worth it.'

Taren: Well, I can't thank you enough for being part of our podcast program and for sharing your insights with us.

Maria: Absolutely. Well, thank you so much. I really appreciate your time.

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