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In this episode, Taren Grom, Editor-in-chief of PharmaVOICE magazine meets with Sandy Solmon, CEO, Celavie.

Taren: Sandy, welcome to the PharmaVOICE WoW podcast program.

Sandy: Thank you for inviting me, Taren. I'm really looking forward to talking. I so enjoyed our talk at JP Morgan.

Taren: It was great to see you at JP Morgan, and I loved being able to hear a little bit about your story. I'm thrilled to share your story with our listeners. Your background is really unique. You wear several hats. You lead a private emergency medical technology company, and you're the CEO, chief innovator and founder of Sweet Street Desserts, which I understand is the world's largest manufacturer of frozen gourmet desserts, and you are in 70 countries with more than 700 employees. Let's talk about how your world converged.

You started Sweet Street Desserts first and then you entered into the biosciences industry. Is that correct?

Sandy: It is. Actually I started Sweet Street forty years ago. We have been in existence for 40 years. Celavie, in the scheme of things, is relatively new, but I had been CEO for 13 years. Honestly, I'm still trying to assimilate how if these two worlds have converged. But it's become clearer as I move out into speaking to the industry. I think what I've noticed is that as leaders we always bring ourselves and our ways of thinking to the game.

I've always thought big picture and had an instinct or an intuition so strong that I had no choice to follow it. Be it Sweet Street or Celavie, big ideas I found need nurturing along the way, and I've always had the patience to see those ideas I believe in to fruition.

Taren: That's excellent. Tell me how you got involved with Celavie.

Sandy: First of all, I'll start with the fact that when I was first introduced to Celavie by a scientist, I immediately saw the elegance... actually it was unnamed – when I first got introduced to the technology, I immediately saw the elegance and power of this disruptive stem cell technology. I actually saw that we had a chance to change the paradigm of healing. I felt compelled – truly compelled – to help out. I had no idea I would become angel investor,

cofounder and CEO. It actually was one of those opportunities that I talked about initially and that you were awake, you grab hold of.

So thirteen years ago I was asked to do a favor and help online patents recently filed by a brilliant scientist neurosurgeon. Why did they ask me? Because at Sweet Street I owned 15 design copyrights and three patents and they thought I'd know how to do it functionally. It was my stepfather who asked me, so how could I turn him down.

Taren: Family first, right?

Sandy: Family first. He said it would be easy, but it wasn't. It took almost a year and a half, and by the time it was done, several hundred thousand dollars later, I ended up with patents, a scientist and a lab needing a home. It was sort of a moment. Then I thought how could I abandon this nascent and exciting technology and thus, I started supporting it financially and leading it.

So it's sort of crazy when I think of it in retrospect.

Taren: I was going to say, those early days had to be really interesting.

Sandy: They were. I'll just add this. I understood that there was a great need because I had just coincidentally watched my father-in-law die of Parkinson's disease, and it was horrible to watch. I'll describe him as he was essentially encased in concrete, unable to speak or move at the end. He was once a really voluble New York City dentist to celebrities, like comedian Jerry Lewis. It was a horrible death to watch.

Taren: So it was sort of a perfect storm for you. You had the expertise, you had the personal wherewithal, and you had the financial acumen to be able to bring this all together. It was the right time and the right place for you.

Sandy: It was. I've always thought to live a life with meaning, to have an impact. And I've done that from the start within my company and within Sweet Street. I saw a paradigm shifting technology that would change how people were healed, and I felt that this was something that I needed to put my energy behind.

I sometimes tease 'there goes the house in Aspen,' and it's just how do we choose to spend our money and our resources to make a difference. I honestly felt I had the right skills intuitively.

Taren: Let's talk about some of those skills and how you're translating running that multimillion dollar company to Celavie. As you said, it is a nascent company... well, it's 13 years old now, but it has a groundbreaking technology. How are you kind of using your global skills of running that bigger company and running this technology company in the life sciences?

Sandy: First of all, most important is patients and patient leadership, and sort of the vision to see where it might go. I've never had a turnaround attitude obviously 40 years running Sweet Street. But what I've learned in these 13 years is that yes, my skills are incredibly translatable. One of the reasons is R&D and manufacturing are essentially the same, whether it's stem cells or luscious chocolate cakes.

At Sweet Street, I oversee a team of 15 QA managers, I follow the FDA guidelines who inspects us and also the USDA department of agriculture, and has an industry self-governing body, so we adhere to stacks of regulations from FISMA to SQF.

Both industries have SOPs, GMPs, statistical process control. I directly manage our R&D team of 10 and have since the start of the company. That's the driver of our company's success is the innovators in our industry. So you can see it sounds very much like the biotech industry.

The other flip side of that food, gene and cells, they can all harm if safety systems are, in any way, short circuited. And so I understand through 40 years of manufacturing desserts with fresh dairy and eggs how true this is and what a responsibility we have to protect our consumers, our patients.

I don't want to keep on running on, but the other aspect that I learned at Sweet Street is that it is incredibly important to control one's own proprietary manufacturing system. Speed to market, confidence in the safety and quality of the end product, control of ramp up... all those aspects I bring to bear at Celavie, which is why we invested in our own manufacturing capability early on.

Taren: That's interesting. So there are so many overlaps and similarities. Really, I don't want to minimize it, but it wasn't such a big leap then to think about how to run or organize Celavie because you had already done it for so many years with another company.

Sandy: Yeah, it took discovery though. If you know what I mean. I didn't realize how similar it was. I started seeing how the complicated nature of dealing with the FDA was at Celavie and the requirements, I was going through the same aspects at Sweet Street. We started out with the USDA but over the past seven years, we've been very much involved with the FDA. There are facility inspections and there are regulations. They've sort of merged as the food industry has gotten far more regulated.

Taren: Sure, it makes total sense. You touched on it a second ago about R&D. I know at Sweet Street you talk about how that piece of the organization R&D catalyzes everything from production to market. How are you applying that same philosophy to Celavie?

Sandy: I think it translates totally but with a bit of a difference. In the time since I've started and founded Celavie with our CSO Oleg Kopyov who is the inventor of our technology – let's look at timeframes.

Celavie – we worked for 15 years... or Oleg worked for 15 years to develop his stem cell technology that he originally applied for patent list. And that technology was to utilize undifferentiated and unmodified pure potent stem cells – allogeneic stem cells – to be used in neurodegenerative diseases. And his goal all along was to create cells that had the biologic intelligence to treat a disease in its entirety but had no tumorigenicity or immune response after transplantation.

So if you put the 15 years before I met him and you add 13 years post establishment, where we've been testing and proving out that theory in pre-clinical and clinical trials, we created multiple cell banks utilizing specie specific cells as well. I don't know if you know, we also have an equine stem cell bank and we've applied to the CVM for soft tissue injuries. So it's quite diverse in that respect.

At Sweet Street, at the same time, we come out with 20 plus different product lines. We've got big cakes, to non-GMO wrapped cookies and bars, to vegan lines. It's very diverse and hundreds of different products for the chains we do business with. And I think being able to get so much done at Sweet Street probably supports part of my personality that needs tangible results. And it allows me to apply that patience that I talked about in the beginning to the trials through and to wait for results that will be meaningful to investors and the public.

For instance, we performed our clinical trial in Mexico City over five years ago. We got some incredible early on results. But in talking to KOLs we realized that because of the kind of technology and the concerns and we would have to get longer term results to ensure that it stuck. So five years later, our clinical trial in Mexico City with the University of Mexico has shown that 4 out of the 7 patients have shown great promise in terms of the restorative treatment – actually restoring function and turning back some of the ravages of the disease.

Taren: That's fascinating. Wow.

Sandy: Yes, and of course it's been safe for all seven people. In a fifth it has stabilized and seen no deterioration pre-implementation. So the results, of course, it's a very small population but once I felt assured – I'm a product person. So I'm used to producing a product that works towards a function. So once I felt assured that we had a product, I felt really comfortable going out to the market and talking to people.

Taren: That's awesome. And those results have to feel so affirming that you all are on the right track.

Sandy: Honestly, it was certainly one of the great moments for me when we saw at five years that two patients, in particular, had gotten far better. Now it seems was there a deterioration, where was this treatment going, had they gotten far better at the beginning and was it now declining? No, it took a big move forward and that was exciting to me to show the possibilities.

Obviously, this is in early stage and it's a study with seven humans, but it's exciting to acknowledge that the cells possibly are working the way we expected. It's with those billions of connections that have to be made in our complex frames years later, more connections and clearly seem to be occurring. So yes, it's very exciting.

Taren: That's awesome. Just to tap back into your food services experience, it's a very competitive gain. I think everybody can understand that. And after almost 40 years, you're still at the top of your game. What do you attribute your success to? What makes you so successful?

Sandy: Thank you. At this point in time, I'd say it's all about the strength of our culture, of collaboration, our brand that incorporates the deliciousness and product innovation as key attributes. But most important – our team. I have an amazing complementary expert team around me. Many of us have been together over decades and all of us believe in what the Sweet Street brand stands for and work collaboratively each and every day to move quickly in the marketplace to ensure we are first to market with innovative and delicious new product lines.

We're sort of like a wheel, and the spokes go out and it turns right at the right moments. We keep on expanding our brands based on what the market plays. So when we started out, it was desserts and a slice of cake or pie, and now we've incorporated savories and grab and go and small bites. So we keep on expanding the brand to various other day parts. I see that possibility existing for our stem cells because Celavie cells are part of a platform technology. It's the same cell and the same manufacturing system regardless of the indication – for the same kind of cell for soft tissue injuries. So we believe we have a really broad canvas to paint on with these cells.

Taren: That's awesome. I hear how everything is just relatable from switching seamlessly between one hat and another hat. And at the same time, I'd love to hear about your leadership style. You're very modest about the culture and the team, but how is it that you lead a global operation and then translating that to a smaller team over at Celavie? What is it about your leadership style that incites such success and loyalty?

Sandy: I'm an intuitive instinctive leader. Sometimes people say, "You're a witch, Sandy." I'm able to see opportunities that are less than obvious, and I always have been – to support our direction. And at Celavie, even though I'm not a trained neuroscientist, it could be a novel direction in research, I sort of see it and then suggest that we do something and it provides the clue or a substantiation of some underlying principle we have. And it builds trust. I always lead with purpose and mission. I always come back, what's our goal, how do we stay focused?

I'm also a collaborator, even though I can make a decision, and I do not have a hard time in making a decision at the end, I coalesce the team to decide strategy and resolve problems. I ask a lot of questions of a lot of people, always, but at the end, I know how to make a decision. And I can really rally a team around because I work as hard as anybody else or everybody else.

Although big picture, I'm very granular on a day-to-day basis, and I expect managers to know the details and control for those that are really crucial to success, so I can become a subject matter expert, although briefly.

I like to swim in and out of particular areas of expertise, as needed, and you know what it's like when you keep too much in your brain all simultaneously. Does that answer it?

Taren: Yes, it's great. Absolutely. I love the swim in and out of subject matter expertise. I think that it's a testament to leadership, that curiosity and that willingness to learn and yet not have to get into the weeds. So it's that agility and flexibility that allows you to really oversee a multitude of different areas of operation.

And at the same time, how do you keep your teams motivated—specifically in the life sciences industry, where so much of research and discovery is fraught with disappointment and non-positive results, but yet the work still has to continue on, how do you keep your teams uplifted?

Sandy: Well, we're in the midst of the greatest existential moments at Sweet Street or Celavie. I am always at my calmest, strongest, and most strategic. So, honestly, I rarely look back. I work to find solutions. I never blame. And I believe it builds confidence among team members to stretch, to take risks. That trust can particularly be harvested when the stars align and opportunities present themselves. So it's creating a moment that I will always be there to help find the way at a difficult moment.

I'm great at finding new ideas and resources to develop our team and keep us growing. Although I'm not an expert in the biosciences, I think I'm a good learner and of course when I brought LaVoie Group in to help me understand about getting out into the financial world and introducing me to you, people like you, Taren, who want to help nascent businesses and leaders like myself.

Finding those new ideas and resources helped the team keep growing. And as you know, you've talked to enough scientists by now, they tend to get very cloistered and tunnel-vision. So, I'm there to follow through. I'm willing to spend the money to research a good idea. And I know how to get in the weeds with people to solve a problem. And as I said earlier, I didn't know how to quickly back out and let them run with it.

Taren: Excellent. At the risk of making you look back even though you said that something that you don't tend to do, if you had to think about a piece of advice you would give to your younger self, what would that be?

Sandy: It's really simple. Prioritize more time to make personal life.

Taren: Creative advice for everybody.

Sandy: Yeah, exactly. You don't know how important that is until later on when you have to pull together pieces so— and I do that now.

Taren: So better late than never, right?

Sandy: Better late than never. Yes.

Taren: Excellent. And then finally, we ask all of our podcasters to describe a wow moment of your career, a pivotal moment that maybe changed the trajectory of your career or something that has left you with a lasting feeling or sentiment. Can you pick out one wow moment from your very successful career?

Sandy: It's so hard for me to pick out one moment. I could give you a few. I won the Innovator Award at the Cornell Business School, in specific at the hospitality school, and I was the first woman to win this award. And it's given out at a dinner, 800 people in the industry attend. It was one of those moments, where I really didn't want to even begin to accept the award originally. And it took me some time to understand that, yes, what we created at Sweet Street — what I created, was deserving.

It helped me explain, not just to myself, but then share with the world what my leadership style was and how crucial it was to the success, not just of the company, but of the individuals around me. And it was thrilling moment to be able to speak and see myself as a leader and a mentor for others. So yes, I enjoyed it.

A parallel moment was when we received their five-year follow up in our Human PV trial. I just felt that calm, pure, thrill of staying with something that would make a huge difference in the world and seeing the clue that it could come to fruition. So, those are two great moments.

Taren: Those are two great moments. And I love that you chose one from each piece of your life. So thank you so much for sharing those personal insights with us. And thank you so much for sharing your story of— it's quite unusual, and I find it to be inspirational and how you can have a foot in two different worlds, yet you're making such a significant impact in both. And that's not typical. Really fascinating to speak with you. And thank you so much for being part of our WoW podcast program.

Sandy: Thank you so much, Taren. I really appreciate what you're doing for women and demonstrating our leadership ability. So thanks. Thanks again.

Taren: Well, it's our pleasure, and I feel like it's part of our duty as a woman-owned business. So thank you so much for being part of the program and for sharing your insights.



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