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Pelvital USA, Inc. – Bringing to market Flyte® a Mechanotherapy Treatment for Stress Urinary Incontinence

Dale Wahlstrom
CEO /Co-Founder

Pelvital USA, Inc.
www.flytetherapy.com

Contact:
Dale Wahlstrom, CEO
C: 612 804 1319
E: dale.wahlstrom@pelvital.com
Ryan Willemsen, COO
C: 651 492 3910
E: ryan.willemsen@pelvital.com

Interview conducted by:
Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: ***Mr. Wahlstrom, what is the vision behind Pelvital USA, Inc?***
Mr. Wahlstrom: The genesis of our name Pelvital was developed by the original Norwegian founders of the technology, and it is intended to inspire people to focus attention on pelvic health. The physicians and engineers in Norway who developed the technology understood that the human skeletal muscle cell is designed to respond to pressure through a process called mechanotransduction and developed the product to take advantage of this capability. The Pelvital mission is to apply the principles of mechanotransduction to generate cell repair and healing via a process called mechanotherapy to improve the lives of people living with debilitating musculoskeletal disorders. Physical Therapists use mechanotherapy every day in their practice, our vision is to be a global leader in device-based mechanotherapy solutions.

The focus of our first product line is to treat one of the most, if not the most undertreated conditions in the world, which is pelvic floor dysfunction. The device, branded Flyte™, uses a mechanotransduction response to heal and to regenerate the pelvic floor muscle. We are focused at first on stress urinary incontinence (SUI) in women, but the plan is to expand to other forms of pelvic floor dysfunction. We chose SUI as our first product because in the United States, about one in three women either have or will suffer from some form of incontinence, and about half of that number will have SUI. Once you get to the age of 50, that number is more like 50 percent of women, so it is a major issue. The problem with SUI is that it is a silent problem. Most women have been told and believe that it is just part of getting old and having babies, and they should learn to live with it. Therefore, the idea of having an at home treatment that works when used 5 minutes per day over 6 weeks and can actually help women to regain their normal quality of life is new, and for some, hard to believe.

CEOCFO: ***Are you surprised that women are just letting that go by and not being more vocal?***
Mr. Wahlstrom: It is a very personal issue and women are hesitant to talk about it, and society has "normalized living silently and suffering with the issue". The biggest hurdle we have as a company is getting women to realize there is hope for them to maintain, or regain, their normal lifestyle and "normalizing the treatment of the condition". It is not only women, but the women have a much higher rate of incontinence than men do. Sometimes, it is just a small leakage where you cough or sneeze and you have some leakage, but as you get older it can and often does get worse. Therefore, if it is not treated when you are at a younger age it may be harder to treat the older that you get. A statistic that is not well known, is that about 35 to 40 percent of the people living in nursing homes are admitted at an older age because of

some form of incontinence. Incontinence is a major driver of healthcare issues and major driver of women losing the ability to live an independent life.

CEOCFO: *What is Flyte® and how does it work?*
Mr. Wahlstrom: That is a great question. There are many devices out there, and if you go to Amazon and search for products to manage incontinence, you will find about 20 pages of products. However, most of them are pads, diapers and gadgets that are not backed by clinical data. There were a number of physicians at the Arctic University of Norway that were involved in developing the Flyte™ product. The physicians were treating women using different devices, as well as using standard pelvic floor muscle treatment, but were having unacceptable results. This prompted them to try to look for something that would yield a better outcome for their patients. Therefore, they combined forces with a company called, Ergotest, which is a company in Norway that develops equipment and training protocols to help professional athletes achieve 5 to 15 percent performance improvement out of a highly trained muscle. The physicians and the engineers combined their knowledge and skill sets and developed a device which became known as Flyte™.

The Flyte wand is vaginally inserted and is sized to make contact with the pelvic floor muscles and provide a gentle, therapeutic stretch while inserted. The wand's internal electronic components measure the tone of the muscle and deliver mechanical pulses to stimulate the pelvic floor, delivering biofeedback while the patients complete pelvic floor muscle contractions (Kegels). The pulses work together with the therapeutic stretch and contractions to deliver an effective mechanotherapy-based treatment for incontinence.

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The designers chose this approach because they understood that every muscle cell in the body has a predefined shape and pressure. That shape and pressure is called the state of tensegrity and if you disrupt that state of tensegrity, you create the mechanotransduction response. The disruption causes the nucleus of the cell to generate a protein response, and that protein response is the basis of cell repair and regeneration. The intentional deformation of the cell to trigger this response is called mechanotherapy. These doctors understood this biophysical response well, and the device was built around that mechanism. The clinical data demonstrated in two studies including 179 women that the treatment works extremely well when done at home for 5 minutes a day for 6 weeks. Treatment time to achieve dry or near dry results in the U.S. clinical ranged from 2 weeks to 12 weeks with the majority achieving this goal within 6 weeks.

CEOCFO: *What has changed in the device over the years? What have you learned as more and more women have used it? Have there been changes?*
Mr. Wahlstrom: Yes, we learned a lot. We learned that different components of the therapy are more important than we thought they were. Therefore, we have enhanced the ability of the device to deliver certain aspects of the therapy to enhance the outcomes. At a result we currently have a second-generation device in development and the concept for a third-generation device for expanded applications being framed. The design of the second-generation device incorporates these learnings, which we are confident will have at least a 30+ percent increase in clinical benefits over what the first-generation device has achieved, which already provides the best independently validated clinical outcome on the market today.

CEOCFO: *Would a woman use this continually?*
Mr. Wahlstrom: Another great question! First, those 60 women that were part of the study in Norway had been incontinent for an average of 9.3 years and were referred to the university medical center for surgery as a last resort. They had already gone through pelvic floor muscle training with a physical therapist and most of them, if not all of them, had used some form of electrical stimulation or some other type of device and were not successful. They were referred for surgery as a last resort. However, they were offered the opportunity to try the Flyte device, and if it did not work then they would then have the option of coming back and doing the surgery.

What we know is that 2 years post the completion of the clinical study the clinical team in Norway reached out to the patients to try to understand their condition at that time. Out of the 60 patients they were able to contact 36 women. Out of 36 women, none of them had had surgery and 77% of them still claim to be continent.

For the study we did in the United States with 119 women, which was completed in December of 2019, we are doing a 2-year follow up. This is being conducted through the University of Minnesota. The 2-year follow up will end in December of this year, 2021. Therefore, by January 2022 we will know the results. Based on what we have observed in the U.S. and experienced in Norway, we believe we will find that some patients are dry or near dry and are continent with little or no continued treatment, and others will need periodic retreatment, but we do not have a definitive answer at this moment in time.

CEOCFO: ***Does it depend on the woman's age? Does it depend on the level of incontinence? Does it depend on a woman's size, shape, ethnicity, or is it somewhat one size fits all?***
Mr. Wahlstrom: Out of the 179 women that were involved with the clinical studies we know all about 10 percent of the women did not respond to the treatment at all. They have something that interferes with the treatment, such as a torn ligament, or a nerve that has been damaged; something is unusual and requires more aggressive therapy, in some cases surgery.

In the case of severe leakage, like 70 grams (~5 tablespoons) to 530 grams (~2 cups) of leakage per day, we saw dramatic decrease. These were mostly women who were leaking in the range of 300 to 500 grams per day who achieved reductions to 45 to 60 grams per day. They are still not dry, but their lives are much improved. This group accounts for about another 15 - 20 percent of the clinical population.

About 70 percent were dry or near dry with minor levels of leakage. People in this group had mild, moderate and severe leakage and started with leakage weights ranging from 10.3 grams (~2 teaspoons) to ~250 grams (~1 cup) at baseline, but all of them achieved a final leakage of 10 grams or less within 2 to 12 weeks after 5 minutes of at home treatment per day.

It is reasonable to think that it will be more challenging for older people, which is why we are encouraging people to proactively treat a weakened pelvic floor muscle after a traumatic pelvic floor event like childbirth. The condition most deteriorates and is harder to treat with the onset of age, more child births, and obesity. However, I cannot tell you based on our clinical data that the response rate of older women was measurably less than the middle age or younger women. It was not that clear even though you would expect that to be the case. We also did not have any indication that ethnicity had any impact.

However, we are so confident in the safety, ease of use, and performance of the Flyte that we offer a performance guarantee. Regardless of age, ethnicity, or parity, if Flyte doesn't work for the you after doing the 5 minute per day treatment for 6 weeks, we will refund the full purchase price. We are so proud of what our Norwegian partners invented, and the clinical proof compiled by our university healthcare professionals in both Norway and Minnesota, that we will stand behind the performance guarantee assuming the patients do their part for 5 minutes per day for 6 weeks.

CEOCFO: ***Where are you today with getting the word out and making people aware of what you have developed?***
Mr. Wahlstrom: We received board approval on January 7th to engage in U.S market release so we began rollout almost immediately. The FDA gave us clearance for both direct to consumer (DTC) sales as well as prescription sales, so we can sell either way. We have been looking at both approaches, working with clinicians and working online. Today, most of the sales are coming from direct-to-consumer online sales, where women are just buying the product and using it at home. Another interesting statistic that I should have mentioned earlier is that, as we said, the vast majority of women are dealing with their condition alone and in silence. The number is actually about 75 to 85 percent of the women that have this condition have not even talked to their doctor about it and have not been formally diagnosed. However, they are online, looking for help. They make up the majority of the market.

As a company, we are committed to helping women get help even if Flyte is not the product for them. If they prove to be one of that 10 percent that do not respond, or the 10 to 15 percent that respond but are not satisfied with the level of

dryness achieved and want to go on for more aggressive therapy, we want to have established relationships with medical professionals around the country who are experts in the area of pelvic floor issues to refer them too. Right now we are building that network of clinicians, and if there are any physical therapists or physicians reading this interview who are interested, we would love to talk with you.

We are also expanding our online presence. For example, we recently employed two PhD level physical therapists who are specialists in pelvic floor disorders. They will be available online to answer questions and help women who are struggling, or uncertain about their options, to get advice. We are not healthcare services, but advice on what to do and how to get started and who to talk to if it seems Flyte may not be right for them.

That is where we are. We are market launched, we are selling products, but we are really trying to build a presence and to help women to realize that there is a solution. Our biggest competitor is lack of awareness among patients that there are solutions to help them with their condition and they are not alone. Just reach out (Ask a PT | Flyte by Pelvital USA (flytetherapy.com).

CEOCFO: *Would you tell us about manufacturing and maintaining inventory?*
Mr. Wahlstrom: Our manufacturing is done in Minnesota, which is where we are housed, but of course, we buy components from all over the world. We have inventory on hand here and we ship directly to the customers that order. We have capacity to grow dramatically more than where we are right now. Supply line will not be an issue.

CEOCFO: *Is there any maintenance required for Flyte?*
Mr. Wahlstrom: I am glad you asked. There is a performance guarantee both clinically and from a device reliability perspective. There is no secondary follow-on activity or maintenance, or anything required other than cleaning the device after each use with soap and water. If the device fails for some reason before the one-year guarantee, we will just replace the device at no charge.

CEOCFO: *Why pay attention to Pelvital and Flyte?*
Mr. Wahlstrom: Flyte is a new therapeutic platform that leverages a well-known and understood biophysical response to the human body to create healing, repair, and strengthening. The first-generation device has demonstrated its capability in the treatment of SUI, and that is only a start.

Most of the readers are likely aware that the most commonly accepted treatment platform used today is electrical stimulation for almost everything. I worked at Medtronic for 25 years bringing new products to market using electrical stimulation. Electrical stimulation is extremely useful and works well for the treatment where *conscious control* is not necessary, such as cardiac muscles, or control of pain by blocking nerve signals. It was not until I started working with these doctors and engineers in Norway that I realized there are certain things that you should not use electrical stimulation to treat. *Conscious control* is where the mind and the muscle are interacting with each other, and the individual can control the muscle voluntarily. That voluntary or conscious control is required to create the potential for sustainable results. Physical therapists and muscle rehab physicians know this well. Electrical stimulation takes over the muscle and causes the muscle to do what the device wants it to do, not what the mind or nervous system wants the muscle to do. Therefore, the natural mechanotransduction response that is so important to healing and so important to sustainable outcomes is minimized or eliminated during electrical stimulation therapy. The doctors and engineers in Norway understood that, and they educated me as to why that is important.

So why pay attention? Flyte is the starting point for delivery of a **new treatment platform** delivering mechanotherapy via a medical device for the treatment of SUI, but it is only the beginning. Pelvital will be a leader in delivering a **mechanotherapy treatment platform** for many conditions requiring **conscious control** of a muscle. New approaches create opportunities to make a difference.

Flyte™ by PELVITAL