ceocfointerviews.com

Issue: May 7, 2018

**CEOCFO Magazine**

# Utilizing Clinically Proven Cryogen-Cooled Monopolar Radiofrequency Technology to treat Vaginal Laxity, the Viveve® System is enabling Women to Reclaim Intimate Sensation lost through Childbirth or the Aging Process

**Ms. Patricia Scheller**
**CEO and Director**

**Viveve (NASDAQ: VIVE)**
**www.viveve.com**

**Contact:**
**Patricia Scheller**
**720-696-8101**
**pscheller@viveve.com**

**Interview conducted by:**
**Bud Wayne, Editorial Executive**
**CEOCFO Magazine**

**"We want to make sure that when people hear about vaginal rejuvenation they think of Viveve and the scientific and clinical evidence we provide that supports the use of our device to treat women's intimate health conditions."- Ms. Patricia Scheller**

**CEOCFO:** ***Ms. Scheller, you have over 25 years in the healthcare industry with quite an impressive resume. How long have you been with Viveve and what attracted you to the company? Was it the chance to focus on women's health and wellness products?***
**Ms. Scheller:** Thank you, Mr. Wayne, for the opportunity to talk with you about Viveve. I joined the company in 2012 when the company was essentially a VC backed shell with what I would call a very checkered past. There had been several management issues and strategic missteps and the Board of Directors made the decision to make one last attempt to bring the technology to market. It was kind of the ugly step child. My first reaction was "wow" there is a lot of baggage here, but upon reflection and after much due diligence I realized the company had huge potential. There was a proven technology, promising clinical data and most importantly there was a huge untapped market.

I believe that the women's health market has been underserved for a very long time. That is especially true in the women's intimate health space, where there is a real dearth of proven products and, as a result, women suffer needlessly. Viagra and other products for men's sexual health have been available for over a decade, however bringing products to market to address women's sexual health issues has been a real struggle. So, once I came to the conclusion that the products Viveve had developed could tap into a very large market with limited effective competition, there was no looking back. I could not wait to join and develop both the market and build the company.

**CEOCFO:** ***Where does the name of the company, Viveve, come from?***
**Ms. Scheller:** The name Viveve is actually a compilation of several different linguistic roots. If you look at the spelling Viveve, there is a Latin

term Viv, which is meant to signify life. If you look at the first four letters Vive, that is a French word which means long life. The company's patented technology has the proven ability to naturally bring to life or activate the neocollagenesis process – the rebuilding of collagen within vaginal tissue, that can help restore intimate sensation, sexual health, and improve a woman's quality of life. And finally, the suffix Eve is a women's name which links the name back to women. The name was meant to convey that the company is focused on improving women's lives over the course of their lifetime. As a company founded to address women's needs, I believe the name is reflective of what the company actually does.

**CEOCFO:** ***What is driving the trend towards women's health and wellness and nonsurgical gynecological procedures?***
***Ms. Scheller:*** Overall the healthcare community is moving in the direction of less invasive procedures and the women's intimate health space is no exception. Everyone would prefer to have a clinically efficacious result with minimal downtime and that means not having a full-blown surgical procedure, and not exposing yourself to systemic side-effects with pharmaceutical products. Patients seem to be much more educated about their treatment options. We have seen that in many cases patients are approaching the clinician about new treatments rather than the other way around. Historically physicians would advertise the availability of a particular technology or procedure, educate patients on the benefits and then sell them on that procedure. We are now seeing that paradigm being turned on its head. Woman are doing a significant amount of research about their intimate health issues and then seeking out physicians who offer the procedures that they have learned about, typically on the internet.

We're also starting to see cross-pollination among medical specialties with doctors in one specialty area, for example, the aesthetics market, influencing the marketing practices of doctors in other specialties, such as the gynecology market. We are seeing physicians starting to incorporate new types of treatments and marketing programs based on what they are learning from other specialties.

**CEOCFO:** ***Would you tell us about sustained tissue tightening, the condition or conditions it addresses and about your product to treat the condition or conditions?***
**Ms. Scheller:** The Viveve system is based upon the use of cryogen cooled monopolar radiofrequency energy and this technology has a well-documented mechanism of action. It has been used for over a decade in the dermatology space to reduce wrinkles in skin tissue. The technology upon which the Viveve system is based was actually the first technology of its kind to offer non-surgical treatment for wrinkles. Viveve was founded by an OBGYN who in partnership with the inventor of the RF technology, saw the potential to use the technology to address a very prevalent condition that he saw in his practice and which he called vaginal laxity.

Vaginal laxity occurs when tissue at the opening of the vaginal canal becomes stretched. Typically, this happens after childbirth but it can be due to other reasons such as aging, trauma, smoking, hormonal changes and other reasons. In approximately 50% of the women who have delivered vaginally, the tissue becomes stretched beyond its ability to return to its normal condition; it remains lax and results in a significant decrease in quality of life for women. The sensitivity of the tissue is decreased, and often they do not feel the same response from sexual

encounters that they did prior to experiencing childbirth. What doctors have found is that vaginal laxity frequently leads to a decrease in sexual function.

By applying radiofrequency energy to the tissue, we deliver deep heating of the tissue which stimulates cells called fibroblasts. These fibroblast cells are throughout everyone's body and their function is to produce collagen. What we are doing is essentially allowing the body to naturally ramp-up collagen production in a very specific location. The new collagen that these fibroblast cells produce are deposited over time and most patients will see that within thirty days the treated tissue will undergo a restoration of elasticity and sensitivity. The collagen production and remodeling continues for up to ninety days and women typically see continued improvement through that time period before it levels off.

We have demonstrated that a single, comfortable treatment, delivered in thirty minutes in an out-patient setting, can have a profound impact on vaginal laxity and sexual function. We have conducted a large multinational, randomized, blinded and sham-controlled study, the only one ever done in the area of vaginal laxity and sexual function. We are not only unique in having done rigorous clinical testing, but the incorporation of cryogen cooling into our procedure is also unique. The cryogen helps protect the sensitive vaginal tissue and allows for deep tissue penetration and maximal collagen production in a single procedure. We have published the results from this landmark clinical trial in two peer-reviewed journal articles. Both articles demonstrated that a single Viveve treatment provided a clinically meaningful improvement for patients suffering from vaginal laxity and sexual dysfunction.

The clinical trial was also submitted to regulatory authorities around the world to gain regulatory clearance in almost sixty countries for the treatment of vaginal laxity and/or sexual function. Here in the US, we have a general surgical indication, but recently we received FDA approval of an Investigational Device Exemption (IDE) to conduct a large-scale study here in the US to obtain an indication for the treatment of sexual dysfunction. We are hoping to announce shortly that enrollment in that IDE study has started.

**CEOCFO:** ***How big is the market? Is this something that affects women worldwide with a need to address it in a humanitarian way in developing countries?***

**Ms. Scheller:** This is a huge market! We estimate that treating vaginal laxity and sexual function opens up a $7 billion global market opportunity for the company. It is something that our market research shows impacts women around the world. In some markets, such as China or Brazil, a sizeable majority of women seek to have Caesarian sections to avoid experiencing vaginal laxity. These women willingly undergo surgical procedures that have a certain amount of risk, and a recovery period that tends to be lengthier than a vaginal birth just so they can avoid this condition.

We recently have seen data from pilot studies that have been undertaken in Canada that suggests that our procedure, done in a slightly modified way, could provide a profound benefit for women who are suffering from stress urinary incontinence. The incontinence market is even larger than the vaginal laxity and sexual function market - possibly as big as $10 to $12 billion worldwide. We are very fortunate to have a platform technology that could potentially treat multiple disease states. In addition to sexual function and stress incontinence, there may

be other conditions, such as vaginal atrophy a post-menopausal condition, which is a market as large as the vaginal laxity and sexual function market. We are looking at a number of different applications, many of which open up multi-billion-dollar markets, that we believe our platform will be uniquely positioned to treat.

**CEOCFO:** ***Who are you selling to? What is your strategy for addressing the market?***
**Ms. Scheller:** Outside the United States where we have been selling since the third quarter of 2015, we use a distribution network. We have over twenty-five distribution partners that cover sixty-seven different countries. These partners have started to build out a robust business. If you look at the end of 2015 we launched in the third quarter, posting about four months of sales. That year we sold about $1.4 million of product, all of it internationally. In 2016, our first full year of sales, we had just over $7 million in revenues, all generated internationally. Then in February 2017, we launched the technology in the US, with a direct sales force that sells into multiple physician specialty areas. The US differs from most of the rest of the world not only in that we sell direct, but because we have a general surgical indication, NOT a sexual function or vaginal laxity indication. Despite that, last year the US represented about 70% of our sales in 2017 and we registered total revenue of about $15.3 million. In just one short year we saw 114% year-over-year growth in revenue. We have seen the technology being embraced in countries around the world.

**CEOCFO:** ***What is involved in putting this all together?***
**Ms. Scheller:** We have a great team at Viveve. I am the most fortunate person in the world to have been able to work with a really fabulous group of people. Our strategy has been to hire seasoned professionals with a proven track record. Across the organization, our employees are all very passionate about the technology. We have strong representation of women at all levels within the company and I think the chance to present women's voices in the area of women's intimate health is critically important.

**CEOCFO:** ***Would you tell us about your clinical trials and some of the results?***
**Ms. Scheller:** We have done a significant number of studies to prove the safety and efficacy of the technology. It all starts with pre-clinical and bench testing. I mentioned earlier that the Viveve System was an outgrowth of technology that was originally invented to reduce wrinkles in dermal tissue. This earlier technology was the subject of dozens of peer review articles that documented the efficacy and safety of using radio frequency energy to reduce wrinkles in skin tissue. We built on these foundational studies to prove that the mechanism of action – the stimulation of fibroblasts to produce new collagen - remains the same whether you are dealing with dermal tissue or vaginal tissue.

We then conducted pilot studies to assess and prove that we were stimulating fibroblasts, but not ablating or burning the tissue which would cause damage that would result in a wound-healing cascade. We demonstrated, by conducting temperature-time history profiles in the sheep model, that the temperature settings of our device do not ablate tissue. These safety studies have all been submitted to the FDA and, we believe, were instrumental in assuring the FDA that our product was safe and could be used in a clinical study setting in the US.

Once we completed our pre-clinical studies, we conducted pilot studies in the US and Japan that proved the concept worked in human subjects. These pilot studies showed that the technology delivered statistically significant results.

We then conducted a large-scale clinical trial, which we called the VIVEVE I study, that demonstrated that with a single 30-minute treatment in a doctor's office, a patient could experience a significant improvement not only in their vaginal laxity scores but also in their scores for sexual function.

Upon completion of the VIVEVE I study we began working with the FDA to conduct a similar study which we call VIVEVE II to obtain a claim for the treatment of sexual dysfunction here in the US.
We also started two pilot studies in the area of stress incontinence. These pilot studies, one which we have completed and one which is still ongoing, have provided us with sufficient data to submit a protocol to the Canadian health authorities to conduct a Registry study in Canada. The protocol contemplates enrolling 100 patients in ten clinical sites for the treatment of stress incontinence. We are hopeful that approval to start that study will be granted soon. We are also planning to submit another IDE to the FDA in order to conduct a 200-patient study here in the US to treat women for stress incontinence.

The company is completely devoted to providing our clinicians and patients with clinical data based upon sound protocol that provides clinically meaningful outcomes.

**CEOCFO:** ***What has been response from the medical community?***
**Ms. Scheller:** We have been gratified to see a very positive response from the medical community. There are numerous medical specialties that are natural outlets for our technology. The obvious ones are OBGYNs, urogynecologists and female urologists. The other medical specialists who are now offering the procedure include plastic surgeons, dermatologists, general practitioners and medi-spas. If you look at the areas in which we are seeing an uptake in the technology it is evenly split between the medical community, consisting of OBGYNs and urogyns/urologists and the aesthetic community which is comprised of plastic surgeons and dermatologists and medi-spas. I would say at this point, the universe of physicians that we can tap into is huge. It has been remarkable to see how the early adopters have embraced the technology.

**CEOCFO:** ***What are you doing to get the word out? Do you attend conferences, both medical and investor conferences?***
**Ms. Scheller:** Absolutely! Historically I have spent about 90% of my time on the road and a great deal of that time has been attending both medical and investor conferences. We spend a lot of time speaking to the medical community on both the aesthetic and medical side and we have physicians who present their own investigator-sponsored studies in areas of interest to them. Our presence at medical conferences is continuing to expand.

On the investor side, we are covered now by nine different financial analysts which I think is a remarkable testament to the company's ability to get the message out. For an approximate $100 million market cap company to secure nine different analysts to cover the story is remarkable and we are thankful for the thoughtful assessment of the technology and its opportunity in the marketplace that they provide.

Getting to that point entailed attending a lot of investor conferences and not only being involved at the conferences but working with the various financial groups with whom we are affiliated to do road shows, to meet with investors. This has been a critically important outreach program, especially because we are in a new market space that not many people talk about. We want to make sure that when people hear about vaginal rejuvenation they think of Viveve and the scientific and clinical evidence we provide that supports the use of our device to treat women's intimate health conditions.

**CEOCFO:** ***How are you positioned with funding to continue product development and growth? Are you reaching out to potential investors or partners at this time?***
**Ms. Scheller:** We recently completed a financing in March and that financing provided the company with the capital that should take us through the back half of 2019. However, we are always trying to keep the story in front of investors. As a publicly traded company on Nasdaq, we feel that we need to raise awareness of the company and, equally important, build awareness of the market we are building. We are always out there talking about it and looking for new opportunities to get in front of people and educate them on women's intimate health.

**CEOCFO:** ***Final thoughts. Address our readers in the business, investment and healthcare communities. Why is Viveve an important company?***
**Ms. Scheller:** In my opinion, Viveve is an important company because we are addressing a large market that is underserved. Women deserve to be able to access procedures that can address intimate health conditions that significantly diminish their quality of life. We believe our product can provide clinically meaningful outcomes for women. We have a significant patent estate, unique features and benefits, and we hope with the Viveve treatment, women may be able to reclaim what they may have lost either through childbirth or the aging process, be it a diminution in their sexual function or stress incontinence. It is our hope that we can help improve women's overall quality of life. We believe our technology represents the gold standard in the industry and I am proud of the team that has persevered to bring this technology to women.