

Viveve and its New CEO are Pioneering Women's Intimate Health



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"Today we believe the Viveve treatment represents the most clinically studied, safe and effective non-invasive procedure to address the vaginal laxity condition and improve sexual function"- Scott Durbin

CEOCFO: *Mr. Durbin, you have been with Viveve since early 2013 as CFO and became CEO in 2018. In your previous role did you play a part in developing the company's growth strategy?*

Mr. Durbin: The short answer is yes. As a part of the executive leadership team, beginning as CFO in 2013, I have been integral to the company's growth strategy and commercialization efforts. When I started, we were only a five-person organization with no sales, minimal manufacturing capacity, little funding, and limited clinical data, so we certainly have come a long way since then.

CEOCFO: *Will there be a change in direction under your leadership or will the product emphasis be the same?*

Mr. Durbin: Our vision from very early on has been to be THE leader in women's intimate health, and we have remained committed to and made tremendous progress towards realizing that vision. Therefore, I would not say that we have changed or intend to change direction. My focus when I assumed the CEO position from the CFO role was to help the company accelerate its clinical development programs towards label expansion for sexual function and urinary incontinence indications, to lower our cost of goods, and to accelerate the ramp of sales. We have made tremendous progress towards these goals. To that end, we recently transitioned commercially from a capital sales model to a recurring revenue model in the U.S., which is designed to reduce financial barriers to entry and lower customers' risk of adopting our system. This change was initiated in June and has quickly shown positive traction including a significant increase in customer adoption rates. We believe the new commercial model has the potential for improved profitability based on lower selling costs.

To support this model, we also introduced an expanded suite of customer services including a new dedicated customer care team designed to enhance the success of our customers and to help optimize the benefits of our CMRF (cryogen-cooled monopolar radiofrequency) technology for patients. Secondly, we improved our clinical and commercial training to support this program through an initiative we call Viveve University, which is an onsite comprehensive program that offers clinical training, expert demonstrations, marketing resources, patient selection guidelines, and communication tips for use in consultations with prospective patients. The third initiative which we launched as a part of the shift to a recurring revenue model was an enhanced customer portal and marketing support programs. Overall, we believe this new model will scale placements faster and lead us to greater profitability in the long-run. For our customers, they do not have a huge cash outlay for capital equipment or have to finance the purchase through third-parties.

CEOCFO: *Viveve is focused on women's health and wellness products. What are some of the qualities that you bring to the position that made you the right fit at this time?*

Mr. Durbin: I have spent my entire company career in the life science space in C-level roles including CFO and COO, and I think I bring a tremendous amount of strategic development experience to what Viveve is trying to accomplish right

now. I have always been attracted to the challenges represented by significant unmet medical needs. In particular, women's health is one of the areas of medicine that has been historically under-funded and lacked development. The fact that in the 21st century one in three women do not have an effective non-invasive therapeutic solution for urinary leakage or that vaginal laxity impacts a significant percentage of the female population post-childbirth, is incredibly unfortunate, but on the flipside, it has also provided us with a unique and compelling opportunity.

CEOCFO: *Would you tell us what vaginal laxity is, how it was addressed in the past, and what makes the Viveve device unique?*

Mr. Durbin: Vaginal laxity is the overstretching of the vaginal introitus, or the vaginal opening. This condition can cause decreased sensation during intercourse and reduced sexual function for women. It has mainly been addressed in the past with Kegel exercises or exercises designed effectively to strengthen the muscles of the pelvic floor. Kegel exercises while good are not directly addressing the fundamental issue of the over-stretching of the soft tissues of the vagina post-childbirth. There are surgical procedures that have shown to be effective, but they are highly invasive and costly because they are paid out-of-pocket and there are potential side-effects as well as surgical downtime. Today we believe the Viveve treatment represents the most clinically studied, safe and effective non-invasive procedure to address the vaginal laxity condition and improve sexual function, as evidenced by international regulatory approvals and clearances for these indications in over 50 countries.

CEOCFO: *What is cryogen-cooled monopolar radiofrequency (CMRF) and how does it and your device help to rebuild collagen?*

Mr. Durbin: Cryogen-cooled monopolar radiofrequency is actually a very unique, safe and patented, dual-energy technology that has been clinically proven in multiple indications such as vaginal laxity and sexual function as well as urinary incontinence. It has been proven to improve and restore vaginal and pelvic-floor tissues which results in improving the symptoms of these conditions and quality of life for women who receive our treatment.

Our device, the CMRF device, is the only energy-based technology that can safely deliver a consistent level of RF energy or heat to the vaginal tissues to the depth required to activate Heat Shock Proteins (HSP) and fibroblasts at the cellular level to initiate the collagen regeneration process. It is the unique incorporation and dual-energy source of cryogen, which actually cools the sensitive vaginal surface tissue, both before and after the delivery of the RF energy, that allows the treatment to maintain time on tissue and therefore achieve the depths of penetration of that energy necessary for collagen activation comfortably and without the potential to burn a patient.

Every other RF or laser energy-based device on the market in this category treats only the surface tissue because they cannot maintain time on sensitive tissue required for the energy to reach deeply enough without the potential risk for patient pain or possible burns. In sexual function we believe that our RF is stimulating the Heat Shock Proteins, leading to a neocollagenesis cascade or the creation of new collagen that restores the soft tissue around the vaginal opening or introitus and thereby improves sexual function. Importantly we have proven this mechanism of action in animal tissue studies, multiple clinical trials, and are preparing to read out the largest and most important of our trials in April of next year which could lead to the first ever medical device sexual function indication for women in the U.S.

CEOCFO: *What are some of the things you are addressing in your clinical trials and efforts with the FDA?*

Mr. Durbin: In stress urinary incontinence (SUI), we have produced strong clinical evidence of the technology in two different single-arm studies. In our recently completed LIBERATE-International Trial, the results for the treated group across all the different end points and patient reported outcomes were excellent and actually surpassed the regulatory requirements for an indication in this area by a substantial margin. For example, at the end of six months, the treated patients experienced a 77% reduction in leakage as measured by the 1-hour Pad Weight Test, a standard urodynamic objective outcome measure, and an 83% reduction in incontinence episodes as measured on a 3-day bladder voiding diary. Unfortunately, and surprisingly however, the sham group in the trial performed equally as well and far above what would be expected in terms of both the magnitude and the duration of effect. As a result, there was insufficient statistical separation between the two arms to meet the primary end-point. While the results are scientifically interesting, and we are learning from analyzing the data, we cannot use that study for regulatory filing. However, the data demonstrates a consistent benefit for patients.

The sham tip used in the LIBERATE International trial was not entirely inert. It delivered an amount of cryogen cooling that was similar to the treatment tip in the active group, but without the therapeutic amount of RF. Given the magnitude and consistency of effects for both groups in the studies, the current hypothesis is that something other than a placebo effect occurred. We are optimistic that there continues to be a path forward for our SUI clinical development program and in fact

are intending to pursue a small international feasibility study utilizing a new fully inert sham tip. We believe the study will show that the LIBERATE International results were not a placebo effect but perhaps a different mechanism of action effect in this particular indication.

CEOCFO: *Where are you today with the Viveve System. Have there been any upgrades or updates to the system over the past year?*

Mr. Durbin: I am pleased to say that earlier this year we unveiled what we call Viveve 2.0, our second-generation device. Importantly while it is functionally the same, our new system provides a better user interface, enhanced consistency and performance and reliability, all while reducing the company's manufacturing cost. We are very excited about the launch of the new system and have had positive physician customer responses.

CEOCFO: *Viveve offers an In-the-Clinic, as well as an In-Home device. What is the difference in the two products, and why two devices?*

Mr. Durbin: Our in-clinic device is the system that we have been talking about and just discussed. This is our main CMRF technology platform. However, several years ago, we entered into a distribution partnership for the professional sector with a company called InControl Medical, which manufactures several at-home devices for various types of incontinence. These are take-home low-cost products that helped us add products to our sales force.

CEOCFO: *What is the market size for this particular women's health issue, which is vaginal laxity? Does it continue to grow annually?*

Mr. Durbin: In the U.S. we have done extensive market research in this area and estimate nearly five million women suffer from symptoms of vaginal laxity and diminished sexual function. These are post-partum women. Based on the consumable market alone, just the total available market for our consumable treatment tips, it represents \$2 billion total. Worldwide that total available market is much larger, and we have estimates that double its size to approximately \$4 billion.

The SUI indication is even larger, and we estimate that nearly eleven million women in the U.S., who are pre-menopausal, suffer from symptoms caused by mild to moderate SUI. We think that represents about a \$6 billion total available market for consumables. Globally this number is even higher, and we believe it could be double or \$12 billion. That does not take into account the opportunity in urinary incontinence to gain insurance reimbursement in this indication, which doubles the market opportunity again.

CEOCFO: *Are your products sold worldwide? If sold globally, would that be through distributors?*

Mr. Durbin: Today our CMRF product is sold globally through a mix of direct sales, under the new recurring revenue model in the US, and through distribution partners worldwide. In fact, we began our commercial efforts outside the U.S. through distributors. We recently initiated and announced via press release two new distribution partnerships in Canada and China. Both are well regarded medical device distributor in their respective regions and the latter was the partner of Zeltiq, which manufactures CoolSculpting, a medical technology that has had great success being adopted globally.

CEOCFO: *How are you reaching out? Do you advertise much in traditional media? Do you attend conferences?*

Mr. Durbin: For the last several years we have focused on developing the market in the U.S. and globally. Today we market Viveve in many countries outside the United States, as the only proven, safe, clinically effective treatment option for vaginal laxity and/or sexual function. We leverage many different marketing efforts and tactics including physician opinion leader outreach, presentations, and attendance at various medical conferences in the U.S. and abroad.

We utilize scientific publications as well as promotions through targeted social media programs. In the U.S. we are currently only approved for general surgical procedures for electrocoagulation and hemostasis, so we carefully avoid promoting the device or the procedure off-label. This takes us full circle back to the rationale and the importance of our U.S. clinical programs, which may lead us to labels in the United States for these indications. New labels would allow us to significantly expand or tap into the vaginal laxity/sexual function and SUI market opportunities and further enable our promotional abilities.

CEOCFO: *Where are your products manufactured?*

Mr. Durbin: Our CMRF technology is manufactured in the United States. We have various large-scale contract manufacturing partners. The InControl products that we distribute are also manufactured in the U.S. by InControl Medical.

CEOCFO: Do you currently have the funds needed to continue to grow your business or will you be looking to partnerships and to bringing more investors?

Mr. Durbin: We are frequently in discussions with potential partners as well as investors about continuing to help fund the company. Recently, we filed an S-1 Registration Statement with the SEC for a public offering to raise additional equity capital from investors in the near future.

CEOCFO: Final thoughts. If we were to talk a year from now, what would the future look like for Viveve?

Mr. Durbin: I believe the future for Viveve is brighter than ever and I have been a part of an incredible team at Viveve for the last seven years. That future is currently not reflected in our public market valuation. While we have a lot of work to do over the next year, we have an extraordinary and dedicated team within Viveve that have contributed immensely.

We have made tremendous progress towards advancing our clinical development programs. Our pivotal U.S. sexual function trial, VIVEVE II will read out in eight months. We have lowered our cost to manufacture our system and consumable treatment tips with the launch of the Viveve 2.0 system. We have realigned the business around a brand-new sales model which we believe will accelerate the revenue growth and profitability of the company in the near future and I think that puts us in a place today where the future is extraordinarily bright.

The logo for VIVEVE, featuring the word "VIVEVE" in a bold, sans-serif font. The letters are a light green color. The 'V' and 'E' at the end are slightly larger than the other letters.