Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Viveve Medical (VIVMF-OTC)

VIVMF: Q2 Revenue Underwhelming, But Operational Progress

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	11/18/2014
Current Price (08/19/15)	$0.81
Target Price	**$1.10**

OUTLOOK

Viveve's flagship product, the Viveve System, is used to treat vaginal laxity, a condition which is often caused by vaginal childbirth and one in which about 50% of women that have undergone normal vaginal delivery hold as a concern. Other methods exist to address vaginal laxity although they suffer from certain drawbacks.

Clinical trial data has shown that the Viveve treatment was able to restore vaginal tightness to pre-childbirth levels in 100% of patients with statistically significant efficacy. A sham-controlled study could have full results in Q1 2016. This marketing study, along with data from previous studies and the recent significantly beefed-up distribution is expected to help accelerate the roll-out of the Viveve System.
Our DCF-based valuation values the company at $1.10/share.

SUMMARY DATA

52-Week High	**$4.00**
52-Week Low	**$0.30**
One-Year Return (%)	**43.33**
Beta	**1.05**
Average Daily Volume (sh)	**62,795**
Shares Outstanding (mil)	**51**
Market Capitalization ($mil)	**$44**
Short Interest Ratio (days)	**1.07**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**39**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					90 A
2015	38 A	73 A	145 E	290 E	547 E
2016					4036 E
2017					8369 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					-$1.27 A
2015	-$0.14 A	-$0.08 A	-$0.06 E	-$0.05 E	-$0.29 E
2016					-$0.15 E
2017					-$0.10 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 2015 Financial Results / Operational Update

Viveve filed their 10-Q for the second quarter ending June 30. Financial results were underwhelming. While we had not expected meaningful amounts of revenue in the quarter, results still came in well below what we had forecast. Management had indicated that almost immediately following getting financing in place, that an initial roll-out of a first wave of systems was likely. VIVMF raised $11M net in mid-May and received another $1.5M from their term loan during the first half of 2015 yet placed only 5 systems between mid-May and mid-August. Given the underperformance in system placements we have made some significant downward revisions to our current year placement rates and consumables sales, and resultant revenue estimates. We have also, again, upwardly revised our OpEx estimates as clearly our numbers have been too low.

Q2 revenue came in at $73k, well below our $157k estimate. While VIVMF did not disclose system or consumable unit sales related specifically to Q1, the first and second quarter 10-Qs indicate that five consoles and 430 treatment tips were sold between the middle of May and the middle of August. And while disappointing relative to our expectations - we were looking for 5 system placements in Q2, which we think was closer to 2 – we still expect a steepening in the placement and utilization curve as a result of sales through the new distributors and further facilitated by the sales/marketing infrastructure build-out made possible by the significantly beef-up cash balance.

OpEx was $2.9M, significantly higher than our $2.5M estimate. With OpEx now coming in well ahead of our forecasts for two straight quarters, it's clear we have underestimated the near-term spend. We have again made upward adjustments. Net loss was $3.0M, compared to our $2.6M estimate.

Cash used in operating activities was $3.4M in Q2, which is double that of Q1. Viveve exited the quarter with $8.4M in cash and equivalents. Subsequent to quarter end they drew the final $1M left on the term loan. The company notes in the Q2 10-Q that they believe the current cash balance will be sufficient to fund the company for the next twelve months – which implies the burn rate will moderate from the level of the most recent quarter.

But while financials have not been a highlight in 1H, VIVMF has made meaningful strides on the operational front. The most notable operational progress relates to advancing the OUS clinical study and a significant beefing up of their third-party distribution capabilities and footprints.

In mid-July the company announced that an evaluation had been done on 62 patients (of an expected total enrollment of 113) in the VIVEVE 1 study which reported no serious adverse events and that no changes to the study protocol were planned. Also that, "The company believes, based on this prospective unblinded analysis, that the study is on track to meet its primary efficacy and safety outcomes". While the company did not provide any efficacy data, the interim analysis was enough to satisfy the milestone in the loan indenture required to draw the $1 million third tranche. That requirement is to have provided "positive 3-month interim results" with respect to this VIVEVE 1 trial.

From what we can gather, expected timelines related to this study remain mostly intact, although management's guidance for the final analysis has slipped by roughly a quarter. The first patient was enrolled in mid-December and full enrollment completed in early April. The interim analysis was done in Q3, as the company had previously guided towards. They now expect the full six-month data to be announced "early next year" – which is a slight delay from earlier expectations of Q4 of this year. As a reminder, this study, named *VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness* ("VIVEVE 1"), is the largest study to date and the first sham-controlled study evaluating the Viveve System for the treatment of vaginal laxity. Subjects are randomized 2:1 (active:control) – patients are blinded, treating personnel are not. Enrollment is 113 patients at up to ten sites in Canada and Europe and should provide even more insight than previous smaller studies (which showed very promising results) into the safety and effectiveness of the Viveve System. Assuming positive results, the trial data is expected to help further support the roll out of the device outside of the U.S.

Relative to distribution, since late February VIVMF has consummated agreements with eleven companies (ten of which were added since the end of Q1) for ex-U.S. distribution of the Viveve System covering an additional 30 countries. VIVMF now has twelve distribution partnerships covering 32 countries. We expect, following gaining requisite regulatory approvals in those areas where the Viveve System is not yet approved (Asia, Middle East, Russia), that the company will begin commercializing shortly afterwards. But with CE Mark already in-hand, VIVMF should have an opportunity to exploit areas of Europe where they have just gained distribution footprint including the U.K., Ireland, Spain, The Netherlands, Belgium, Switzerland, Germany and Luxembourg.

U.S. Pathway (refresher): As a reminder, per a meeting that Viveve had with FDA in Summer of 2012, the agency verbally communicated that they believed the de novo 510(k) regulatory pathway would be sufficient. To support the filing Viveve expects to run a U.S.-based study, which will require IDE approval. Viveve hopes to submit an IDE in Q1 2016.

In the meantime, Viveve's current plan is to seek labeling for general surgical procedures for coagulation and hemostasis for their current device, which includes enhancements of their legacy device which already has FDA clearance for general surgical procedures. VIVMF noted in a May 2015 presentation that they submitted a Special 510(k) in Q1 for this additional labeling. If granted, Viveve could introduce the system to the U.S. market with the general surgical procedure label which would still allow it to be used off-label for vaginal laxity. While we think this may not provide much in the way of financial contribution, it would allow for awareness-building which could be a meaningful in terms of early-marketing, particularly at the key opinion leader level. And if and when the system gains FDA clearance for a vaginal laxity indication, this early introduction may provide a head start as they begin to market it for that indication.

BACKGROUND

Vaginal Laxity: *under-reported and associated with significant quality-of-life issues…*

Vaginal laxity, or a feeling of looseness, is a result of the introitus (i.e. - vaginal opening) collagen tissue losing some of their resilience and contractibility. Often this is a result of severe stretching caused by vaginal childbirth. And while other occurrences can result in vaginal laxity, including advanced age, certain genetic disorders and sexual activity, vaginal childbirth is the most common cause with subsequent deliveries increasing the risk and extent of looseness.

Vaginal laxity is often associated with reduced sensation and sensitivity during sexual intercourse, resulting in a decrease in sexual satisfaction. A study published in October 2006 in the Journal of Obstetrics and Gynecology which assessed the sexual satisfaction of a population of women post-delivery found a significant decrease in sexual satisfaction scores (as measured by a questionnaire) among women who underwent normal vaginal delivery as compared to those who delivered via caesarean section.[1]

The prevalence, consequences and potential demand to address vaginal laxity has garnered little attention or study, likely at least in part due to women being embarrassed to discuss it. In that regard Viveve has been somewhat of a pioneer, sponsoring several studies in order to better understand the thoughts of women and physicians on the subject. The evidence, garnered through Viveve's own research as well as studies unrelated to the company, suggest that vaginal laxity is under-reported, is of significant concern to women and is associated with lower sexual satisfaction. And in our opinion, this supports the potential demand for a therapy that can effectively address vaginal laxity and the adverse quality-of-life issues with which it is associated.

A study that Viveve sponsored titled *A Cross-Sectional Survey to Assess the Prevalence and Symptoms Associated with Laxity of the Vaginal Introitus*[2] queried 421 women ages in order to assess the prevalence of vaginal laxity and its effect on sexual satisfaction. Women aged 25 - 55 who had at least one vaginal delivery completed a questionnaire which included questions about interaction with their OB/GYN regarding sexual function, sexuality following childbirth and potential benefits to improving vaginal laxity. Results of the survey were that 48% (201 of 421) expressed laxity of the vaginal introitus as a concern ("some" or "a little" or "a lot), 80% (n=335) had not discussed vaginal laxity with their OB/GYN and only 48% (n=204) though Kegel exercises were effective.

A second study that was sponsored by Viveve, which was in collaboration with the OBGYN Alliance, surveyed 525 practicing OB/GYNs had a more distinct focus on what the potential demand might be for a procedure that would effectively address vaginal laxity. The survey found that 84% (n=441) of the OB/GYNs queried believed that vaginal laxity is the most common physical change in women after childbirth - ahead of weight gain, urinary incontinence and stretch marks. Additionally, the survey found that OB/GYN's believe vaginal laxity is under-reported.

The notion that the condition is under-reported as well as negatively effecting sexual satisfaction is further supported by a study published in the International Urogynecology Journal in October 2012 titled *Vaginal laxity: a poorly understood quality of life problem; a survey of physician members of the International Urogynecological Association (IUGA)*. A survey of 563 members of the IUGA included 27 questions related to attitudes and practices related to vaginal laxity. Among the findings were that 83% (n=467) believed that vaginal laxity was under-reported, and that the majority viewed vaginal laxity as something that adversely impacts sexual function.

Inadequate Means to Address Vaginal Laxity…

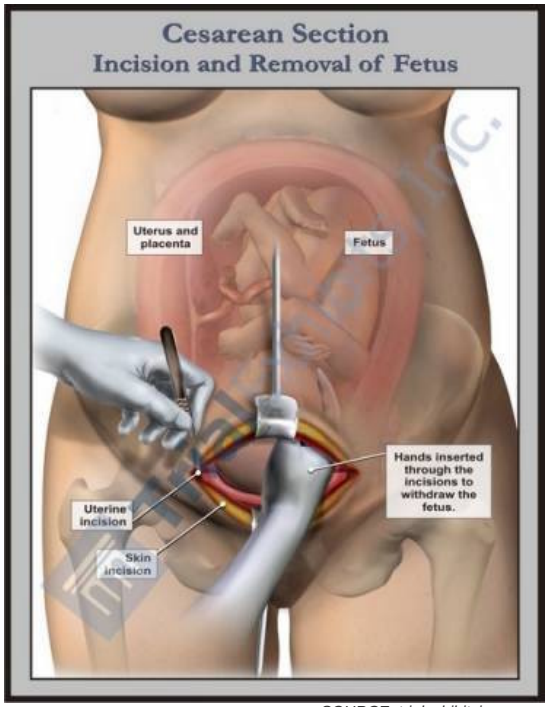
Options to address vaginal laxity include avoidance through elective cesarean section in lieu of normal vaginal delivery or through post-delivery treatment. However, given the certain risks, scarring and recovery time associated with a cesarean section (c-section) and various drawbacks of the most common treatment regiments, these may not be considered the most ideal options.

In a **c-section**, the baby is delivered through the mother's abdomen. It is a major surgical procedure which involves cutting through the abdomen, muscle and then into the uterus and adjusting organs for access. Risks of the surgery include major bleeding, infection, blood clots and damage to nearby organs. These risks increase with

[1] Griffiths A, et al. *Female genital tract morbidity and sexual function following vaginal delivery or lower segment caesarean section.* J Obstet Gynaecol. 2006 Oct;26(7):645-9

[2] http://www.ics.org/Abstracts/Publish/105/000206.pdf

subsequent cesarean sections. In fact, research has shown that approximately 40% of women that have three or more c-sections will experience complications. And since many doctors will recommend against vaginal delivery after a woman has already had a c-section, the risks of complications can become even greater. Recovery time is also longer with c-section versus vaginal delivery with the former requiring hospital stays averaging about twice that (4 days vs. 2 days) of normal vaginal delivery and relegating the mother to mostly inert activities for several weeks after discharge. And finally, c-sections can be cosmetically unpleasing, leaving a several inch scar on the lower abdomen.



SOURCE: trialexhibitsinc.com

There is also recent evidence that suggests babies born by c-section are more likely to be overweight or obese as adults. The study, titled *Mode of Delivery and Offspring Body Mass Index, Overweight and Obesity in Adult Life: A Systematic Review and Meta-Analysis*[3], was published in PLoS ONE in February 2014. The study, which analyzed data from 15 studies on more than 38k women from ten countries, suggests that babies born by c-section have a 26% greater chance of being overweight as adults compared to those born vaginally. But while study did show an association between c-section births and risk of being overweight, for which the authors hypothesized certain reasons including differences in stomach bacteria of babies born by c-section versus vaginally, the study did not prove a cause-and-effect. So while adult obesity may be another risk of c-section, more research would need to be done to determine if this should be considered a functional concern.

But despite the known risks and drawbacks of c-sections, these have not reduced the procedures' popularity. The rate of c-section procedures have doubled over approximately the last ten years and now accounts for 32% of all births in the U.S. and about 25% in the U.K. And while some of this increase can be attributed to clinical reasons and changes in clinical practice patterns, increasing concern over vaginal laxity is also likely to be a contributing factor and prompting women to choose elective (as opposed to emergency or physician-recommended) c-sections. In fact a U.K. survey of 282 obstetricians found that 31% would choose elective c-section in lieu of vaginal delivery in order to avoid certain pelvic floor dysfunction and quality-of-life issues associated with vaginal delivery, including vaginal laxity.[4]

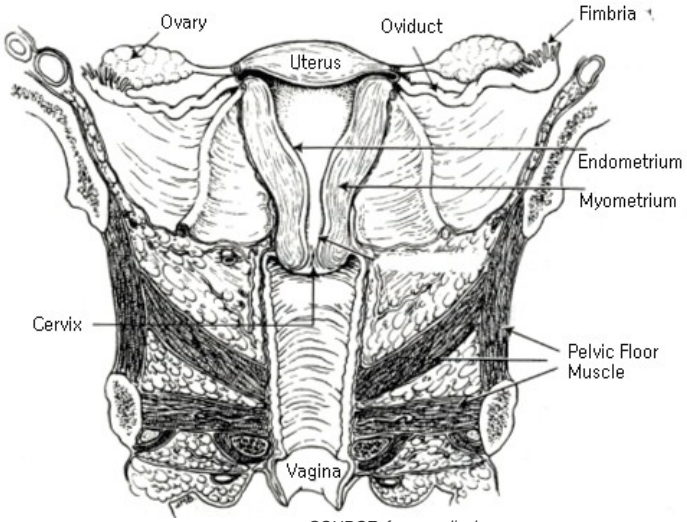
Barring avoidance through c-section, the most common methods to address vaginal laxity are pelvic floor exercises such as Kegels or reconstructive vaginal surgery.

[3] Darmasseelane, K., Hyde MJ, Santhakumaran S., Gale C., Modi N. *Mode of Delivery and Offspring Body Mass Index, Overweight and Obesity in Adult Life: A Systematic Review and Meta-Analysis.* PLoS ONE. 2014 Feb

[4] Al-Mufti R., McCarthy A., Fisk NM. *Survey of obstetricians' personal preference and discretionary practice.* Eur J Obstet Gynecol Reprod Biol. 1997 May;73(1):1-4

Kegel exercises involve rapid and repeated active contraction of the muscles that surround the pelvic floor, specifically the pubococcygeus. Kegels are designed to strengthen the pelvic muscles in order to address urinary incontinence and improve sexual function. And while Kegels are often recommended to address vaginal laxity, particularly following childbirth, and have shown to be effective in tightening the muscles around the vagina, scant evidence suggests that they are effective in improving the resilience or contractibility of the vaginal collagen tissue (i.e. - vaginal introitus). In fact, since Kegels only work the pelvic floor muscles, which surround the vaginal entrance but are not part of the vaginal canal, anatomy would support the evidence that suggest these exercises have little or no effect on tightening the vaginal opening.

Position of pelvic floor muscles in relation to vaginal introitus



SOURCE: furunmedical.com

An option to address introital laxity that has largely proven effective is **vaginal rejuvenation surgery**. Laser vaginal rejuvenation (LVR) is the most common female genital plastic surgery performed. According to the International Society of Aesthetic Plastic Surgeons (ISAPS), in 2011 there were 56k vaginal rejuvenation procedures performed worldwide (Brazil, with over 9k, is the country with the most procedures performed), including over 2k in the U.S.[5] LVR is a relatively new procedure, the rate of which has been increasing rapidly. According to the American Society for Aesthetic Plastic Surgery, there were over 5k vaginal rejuvenation procedures performed in the U.S. in 2013, an increase of 44% from the 3.5k performed in 2012.[6]

Vaginal rejuvenation is a surgical procedure performed under local anesthesia which tightens and restores the aesthetics of the vagina. It improves vaginal muscle tone and reduces internal and external vaginal diameters. Most commonly, women elect to have LVR following childbirth in order to improve the appearance of the vagina, restore tightness and to improve sexual satisfaction.

While several studies[7,8,9] have indicated that vaginal rejuvenation surgery is effective in restoring vaginal tightness and in improving sexual function/satisfaction, there are significant drawbacks to this procedure. Cost, which can vary between $4k and $10k, can be a serious impediment, particularly for those in lower income brackets. And with almost any surgery, complications can be a concern. Specific to vaginal rejuvenation, bladder injury, excessive bleeding and infection are potential procedural complications. There is also risk of loss of clitoral sensation and potential for scarring. Recovery is also longer (i.e. 5 - 6 days) and more uncomfortable (bruising, swelling, pain) compared to less invasive methods.

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[5] ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2011

[6] The American Society for Aesthetic Plastic Surgery. 2013 Cosmetic Surgery National Data Bank

[7] Goodman MP, et al. *A Large Multicenter Outcome Study of Female Genital Plastic Surgery.* Journal of Sexual Medicine (Impact Factor: 3.51). 11/2009; 7(4pt1):1565 - 1577.

[8] Pardo, J. S., Solà, V. D., Ricci, P. A., Guiloff, E. F. and Freundlich, O. K. (2006), *Colpoperineoplasty in women with a sensation of a wide vagina.* Acta Obstetricia et Gynecologica Scandinavica, 85: 1125–1127

[9] Goodman, M. P. (2011), *Female Genital Cosmetic and Plastic Surgery: A Review*. Journal of Sexual Medicine, 8: 1813–1825. doi: 10.1111/j.1743-6109.2011.02254

Viveve System

The minimally invasive, non-ablative Viveve System uses patented, reverse-thermal radio frequency (RF) technology to tighten vaginal tissue. Viveve has a perpetual, fully paid, royalty free license to the patents behind the technology from Solta Medical, Inc. Solta was formerly known as Thermage, Inc. (founded by Edward Knowlton) and was acquired by Valeant Pharmaceuticals in 2014. Thermage had designed the technology for use in tightening skin on the face and certain areas of the body such as the legs and stomach.

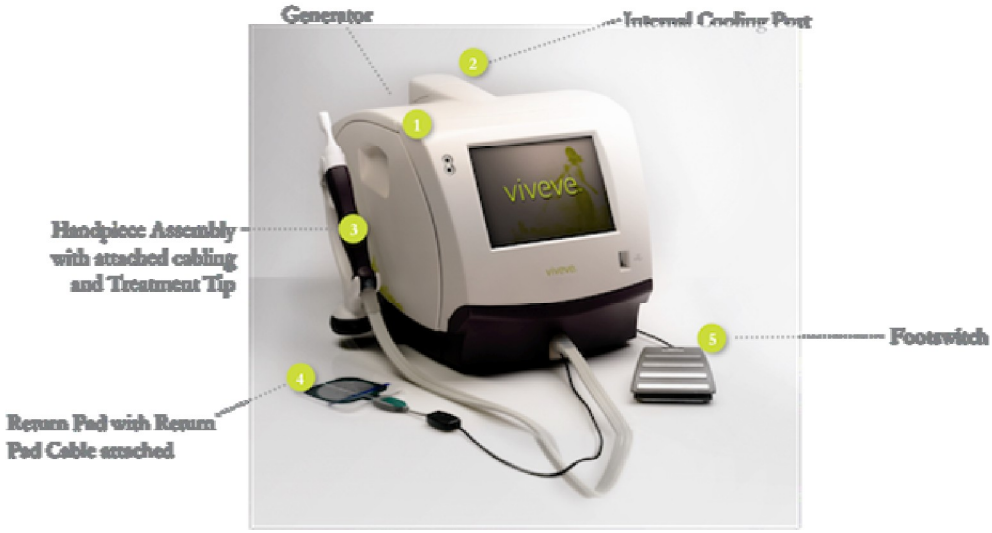
The Viveve System was designed using the same technology as that of Thermage's ThermaCool System, which has been used in over 280k procedures for skin tightening - mostly for facial skin. Slight modifications were made to the software of the RF generator as well as to the design of the handpiece and treatment tips in order to optimize the system for vaginal treatment. The Viveve System is currently manufactured by Stellartech Research Corporation, the original manufacturer of the Thermage device.

The Viveve System consists of three components; a small table-top console, a handpeice and a single-use (consumable) treatment tip. The monopolar RF energy generated by the console sends an electrical current through an electrode contained in a handpiece that was specially designed for use on vaginal tissue. The RF energy produces heat which is delivered to the body via the treatment tip at the end of the handpiece. The capacitive coupling mechanism inherent in the technology creates an electrical field where the treatment tip contacts the body, producing a current throughout the surrounding tissue and resulting in uniform heating of the area. Heating shrinks and shortens the fibrous saptae, collagen fibers which connect the dermis to the muscle, which results in tightening of the tissue. In addition, over several (1 - 3) months following the procedure, new collagen strands may form as a result of the application of the RF energy, providing further tightening of the tissue.

Viveve Treatment Tip



Viveve Console

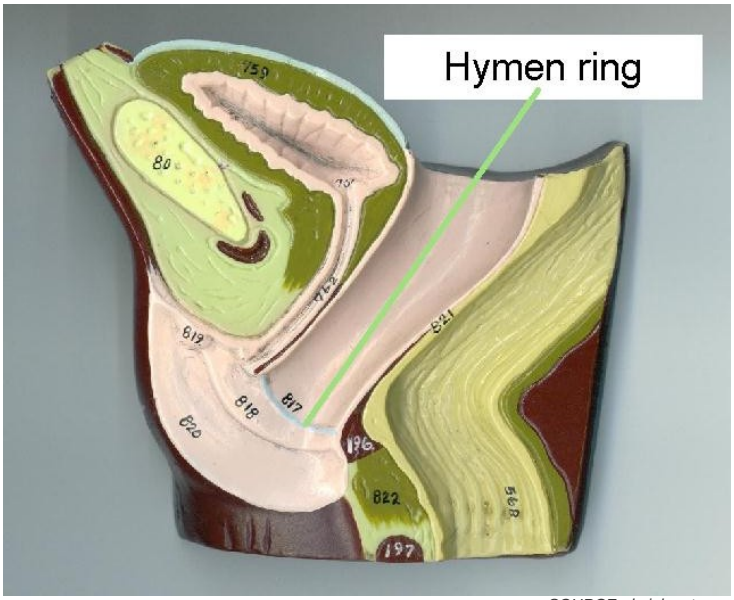


The RF generator produces a six megahertz signal. Also housed in the console is a special coolant and coolant system, which is also licensed from Solta. The coolant is delivered through the handpiece to the tissue immediately before and after the application of heat in order to cool and protect the tissue.

List price for the Viveve System console is approximately $60k while total selling price for the aggregate consumables, including the treatment tip, used in each treatment is approximately $600. The treatment tips have been designed as single-use with a memory chip that disables the tip after a pre-programmed number of pulses. In addition to the single-use tips, Viveve sells other consumables including cooling fluid (~5 - 6 procedures per canister), single-use return pads which are adhered to the body during the procedure and viscous fluid, which is used to ensure proper current flow from the treatment tip to the body.

The Viveve treatment is done on an outpatient basis in a physician's office without the need for anesthesia. During the ~30 minute procedure the physician delivers pulses in a horseshoe-type pattern from the 1:00 o'clock to the 11:00 o'clock positions inside the hymenal ring in three phases; cooling, heating (of 90 Joules/cm^2) and then cooling with each sequence lasting approximately eight seconds. Each sequence is repeated for a total of five times with overlapping pulses. In total, a typical procedure will consist of approximately 105 pulses over the five passes. The

patient typical experiences only warming and cooling but no pain. Efficacy has been demonstrated to last for 12 months.



SOURCE: drcink.net

As the Viveve procedure is minimally invasive, non-ablative and does not require anesthesia, recovery is essentially instantaneous and few complications have been reported. Of the complications that patients have experienced, almost all have been mild and consisted of slight vaginal discharge, redness/swelling and mild abdominal discomfort. No permanent complications have been reported.

Intellectual Property Protection…

Viveve has an exclusive license to 9 issued U.S. patents, the earliest of which expires in 2015, 3 pending U.S. patents, 12 foreign patents and 17 foreign patent applications. Below[10] is the list of patents owned and licensed by Viveve. Note that Edward Knowlton is the founder of Thermage, Inc and the related patents below are those licensed by Viveve from Thermage/Solta/Valeant.

[10] Viveve Inc.

Licensed Patents

Intellectual Property Description for Edward W. Knowlton	Status at US Patent and Trademark Office
US Patent Number 5,660,836, Application Number 08/435,544, filed May 5, 1995, entitled "Method and Apparatus for Controlled Contraction of Collagen Tissue"	Issued
US Patent Number 5,755,753, Application Number 08/435,822, filed May 5, 1995, entitled "Method and Apparatus for Controlled Contraction of Collagen Tissue"	Issued
US Patent Number 5,871,524, Application Number 08/794,003, filed February 3, 1997, entitled "Apparatus for Controlled Contraction of Collagen Tissue"	Issued
US Patent Number 6,241,753, Application Number 08/583,815, filed January 5, 1996, entitled "Method for Scar Collagen Controlled Formation and Contraction"	Issued
US Patent Number 6,387,380, Application Number 08/635,202, filed April 17, 1996, entitled "Apparatus for Controlled Contraction of Collagen Tissue"	Issued
US Patent Number 6,430,446, Application Number 08/827,237, filed March 28, 1997, entitled "Apparatus for Tissue Remodeling"	Issued
US Patent Number 6,461,378, Application Number 08/825,445, filed March 28, 1997, entitled "Apparatus for smoothing contour irregularities of skin surface"	Issued
US Patent Number 6,470,216, Application Number 08/825,443, filed March 28, 1997, entitled "Method for smoothing contour irregularities of skin surface"	Issued
US Provisional Patent Application Number 60/023,377, filed August 6, 1996, entitled "Method of Tightening Skin"	Expired
Foreign Patent serial number PCT/US97/00162, filed January 2, 1997, entitled "Method for Scar Collagen Formation and Contraction"	RO processing completed – placed in storage as of 11/19/2002
Foreign Patent serial number PCT/US96/06274, filed May 3, 1996, entitled "Method and Apparatus for Skin Resurfacing;"	RO processing completed – placed in storage as of 11/19/2002

Internally-Developed IP

Title	Application No.	Filing Date	US or OUS Application	Publication No.	Publication Date	Issue Date	Status
VAGINAL REMODELING DEVICE AND METHODS	11/704,067	February 7, 2007	US	US-2007-0233191-A1	October 4, 2007		Published
VAGINAL REMODELING DEVICE AND METHODS	12/884,108	September 16, 2010	US	US-2011-0178584-A1	July 21, 2011		Published
VAGINAL REMODELING DEVICE	201220099603.8	March 16, 2012	OUS			April 10, 2013	Patented
VAGINAL REMODELING DEVICE WITH ELECTRODE FINGER HOLDER	201220099605.7	March 16, 2012	OUS			April 10, 2013	Patented
VAGINAL REMODELING DEVICE WITH TEMPERATURE SENSOR	201220099618.4	March 16, 2012	OUS			February 13, 2012	Patented
VAGINAL REMODELING DEVICE WITH DIRECTIONAL SENSORS	201220099620.1	March 16, 2012	OUS			February 27, 2013	Patented
VAGINAL REMODELING DEVICE AND SYSTEM WITH DEPTH MARKERS	201220099634.3	March 16, 2012	OUS			March 20, 2013	Patented
VAGINAL REMODELING DEVICE	201210069908.9	March 16, 2012	OUS		September 25, 2013		Pending
VAGINAL REMODELING DEVICE WITH TEMPERATURE SENSORS OR DEPTH MARKERS	201210069910.6	March 16, 2012	OUS		September 25, 2013		Pending
VAGINAL REMODELING DEVICE WITH DIRECTIONAL SENSORS OR DEPTH MARKERS	201210069909.3	March 16, 2012	OUS		September 25, 2013		
VAGINAL REMODELING DEVICE	201220099648.5	March 16, 2012	OUS			April 10, 2013	Patented

CLINICAL DATA

Effective in Treating Introitus Laxity and Improving Sex Without the Drawbacks of Surgery

The Viveve System has been evaluated in a preclinical study and two clinical trials, all of which have indicated that the Viveve treatment significantly improves vaginal laxity. One of the clinical trials was conducted in the U.S. and the other in Japan. In addition to significant efficacy, there have been no treatment-related adverse events.

Important to note, however, is that while all of these studies indicate the Viveve System is effective in significantly improving vaginal laxity, sexual function and sexually-related distress, the studies do have certain shortcomings. These include the small size of the studies, lack of a control group (i.e. - comparator) and the inherent subjectivity of questionnaires used as outcome measures. Despite these potential limitations, we believe the totality of the data to date offers certain meaningful evidence of the potential of the Viveve System to improve vaginal laxity and sexual function/satisfaction.

And in addition to these already completed small, single-arm studies, Viveve recently commenced a much larger (n= ~113) single-blind, sham-controlled clinical trial. This study, being conducted in Canada and Europe, began enrolling patients in late 2014 and should provide even greater insight into the safety and effectiveness of the Viveve System and is expected to help accelerate OUS commercialization.

> Preclinical Study

Viveve, in collaboration with West Virginia University, conducted a preclinical study on sheep to assess safety and to help determine the optimal level of RF energy delivery. The study, conducted in 2010, treated five sheep with the Viveve System at RF energy levels ranging from 75 to 90 Joules/cm^2. Following treatment, at one week, one month, three months and six months, vaginal biopsies were performed with 4 to 5 samples taken from each. These were compared to a control cohort of three sheep. Biopsies examined vaginal mucosa and connective tissue for changes associated with the RF treatment over the six month evaluation period.

Results determined the optimal RF energy delivery level to be 90 Joules/cm^2 (which is the level used in clinical practice) and tissue heating via RF energy appears to promote tightening of fibrous saptae and collagen production. Investigators also concluded a strong safety profile due to the absence of damaged tissue.

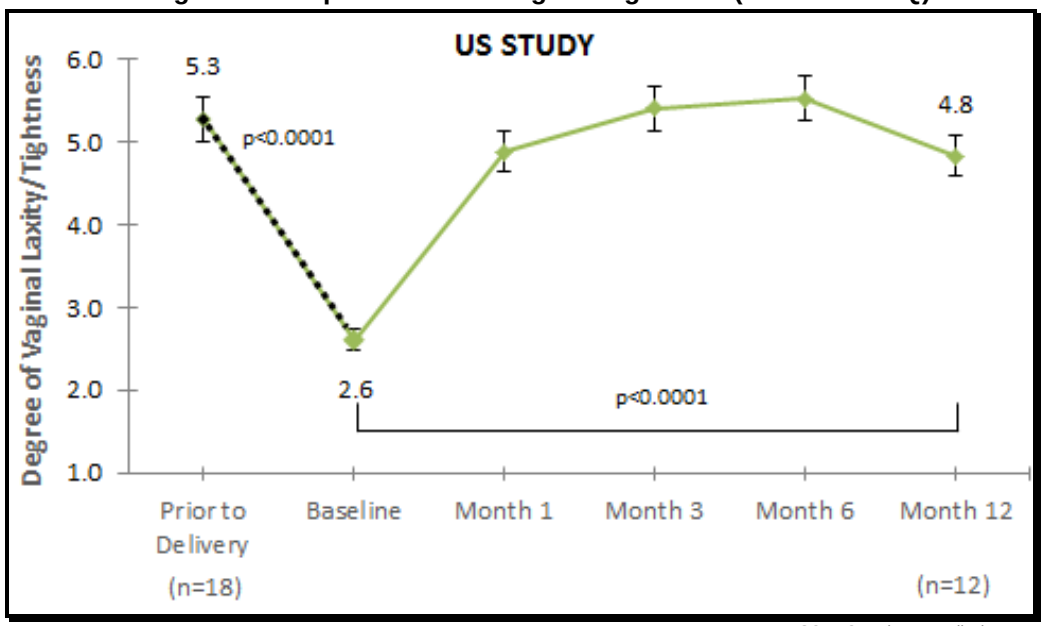
> U.S. Study

The single-center, single-arm U.S. study, which commenced in 2008, enrolled 24 women ages 25 - 44 years old which had had at least one vaginal delivery. All subjects were treated once with RF energy at various levels delivered via the Viveve System through the vaginal mucosa. The first three women received 60 Joules/cm^2, the next three received 75 Joules/cm^2 and the remaining 18 received 90 Joules/cm^2. Outcomes were measured at five time points; day zero (i.e. - prior to treatment), one month, three months, six months and 12 months. Outcomes were measured using self-reporting questionnaires (with questions focused on level of vaginal tightness and sexual satisfaction), modified Female Sexual Function Index (mFSFI), Female Sexual Distress Scale-Revised (FSDS-R) and the Global Response Assessment (see Appendix for a detailed description of the outcomes). Pelvic exams were performed to assess safety.

At baseline, all of the women in the study expressed significant vaginal laxity (based on a Vaginal Laxity Questionnaire or VLQ) with an average score of 2.6 on a 1.0 - 6.0 scale (higher = tighter). In addition, approximately 50% of the study population conveyed reduced sexual satisfaction (based on a Sexual Satisfaction Questionnaire or SSQ) as compared to prior to giving birth.

23 (of 24) of the subjects completed the three and six month evaluations, 18 the nine month evaluation and 17 the twelve month evaluation. A 95% confidence interval was used to designate statistical significance on all measures. Results showed rapid and prolonged improvement in vaginal laxity with a statistically significant ($p<0.0001$) increase in tightness to pre-childbirth levels occurring by the one-month assessment point in all 24 women. This tightness level was sustained through to the final 12-month assessment time point. In addition, at every assessment point there was a statistically significant ($p>0.0001$) improvement in vaginal laxity.

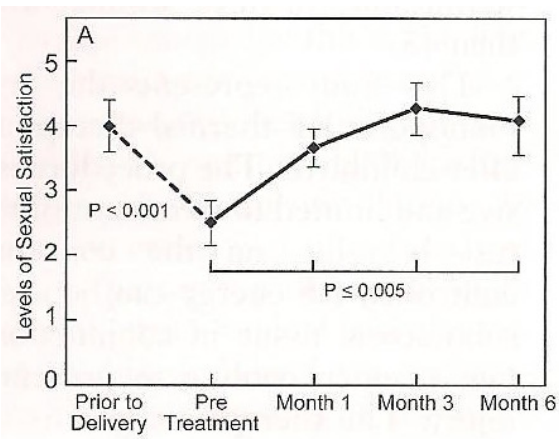
Significant Improvement in Vaginal Tightness (based on VLQ)

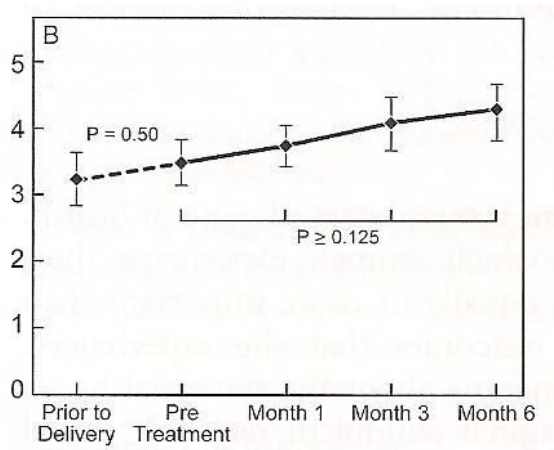


SOURCE: Viveve Medical Inc.

Top-line results, through the six-month evaluation period, were published in the Journal of Sexual Medicine in September 2010 and presented at the American College of Obstetricians and Gynecologists annual meeting earlier that year.

Sexual satisfaction also improved with treatment. Prior to treatment, 12 (of the 24) women expressed a diminished level of sexual satisfaction after their vaginal deliveries. The other 12 women reported either no change in sexual satisfaction or an increase in sexual satisfaction after their vaginal deliveries. SSQ scores significantly improved for all of the women who had reported a diminished level of sexual satisfaction (chart A below)[11] at six months following treatment (from an average of 2.5 to 4.1). There was no significant change in SSQ scores of the women who had reported no change in sexual satisfaction (chart B below)[11].





The FSFI and FSDS measures are used to assess changes in sexual function and sexually related distress, respectively. These showed the study participants did not experience any negative effects related to sexual function related to the RF treatment. In addition, throughout the six-month evaluation period, all FSFI scores (other than pain) significantly improved and personal distress (measured by FSDS) decreased significantly for all 24 patients at one month and all 23 patients at three and six months.

FSFI and FSDS Scores Indicate Treatment Improved Sexual Function and Reduced Distress[11]

Table 2 Changes in sexual function (mv-FSFI) and sexually related personal distress (FSDS-R) scores before and after RF treatment

Questionnaire	Possible score (range)	Pre-treatment N = 24	Month 1 N = 24	*P* value	Month 3 N = 23	*P* value	Month 6 N = 23	*P* value
mv-FSFI								
Desire	(1.2–6)	4.1 ± 0.9	4.7 ± 0.9	0.008	4.8 ± 0.8	0.002	4.8 ± 0.8	0.002
Arousal	(0–6)	4.5 ± 0.9	5.2 ± 0.8	<0.001	5.5 ± 0.5	<0.001	5.5 ± 0.5	<0.001
Lubrication	(0–6)	4.6 ± 1.1	5.3 ± 0.8	<0.001	5.3 ± 0.9	0.010	5.5 ± 0.8	0.001
Orgasm	(0–6)	4.1 ± 1.2	5.0 ± 1.2	0.001	5.4 ± 0.9	<0.001	5.3 ± 1.1	<0.001
Satisfaction	(0.8–6)	4.4 ± 1.0	5.1 ± 1.0	0.002	5.3 ± 0.7	<0.001	5.3 ± 0.7	<0.001
Pain	(0–6)	5.9 ± 0.5	5.8 ± 0.5	0.354	5.8 ± 0.4	0.732	5.6 ± 0.9	0.255
Total score	(2–36)	27.4 ± 3.6	31.1 ± 3.0	<0.001	32.2 ± 2.7	<0.001	32.0 ± 3.1	<0.001
FSDS-R								
Total score	(0–52)	13.6 ± 8.7	7.0 ± 6.5	0.001	4.4 ± 5.9	<0.001	4.3 ± 5.0	<0.001

Data are mean ± SD.
P value determined by paired *t*-test at months 1, 3, and 6 compared with pretreatment.
N = number of subjects; mv-FSFI = modified Female Sexual Function Index; FSDS-R = Female Sexual Distress Scale-Revised; RF = radiofrequency.

There were no treatment-related adverse events during either the treatment phase or throughout the 12-month follow-up period. Most of the women experienced a sensation of warmth during treatment but no significant pain.

> Japan Study

In March 2010 the Viveve System commenced evaluation in a second clinical trial, this time in Japan. The study design was very similar to that of the U.S. trial, with the most significant exception being no variability in the treatment dose with the Japan study.

The single-arm, single-site study enrolled 30 women ages 21 - 55 years old which had had at least one vaginal delivery. All women were treated once with RF energy of 90 Joules/cm^2. Outcomes were measured at baseline (i.e. - prior to treatment), one month, three months, six months and 12 months. Outcome measures were also similar to the U.S. study and included questionnaires related to vaginal tightness (VLQ) and sexual satisfaction (SSQ), mFSFI, FSDS-R and Global Response Assessment.

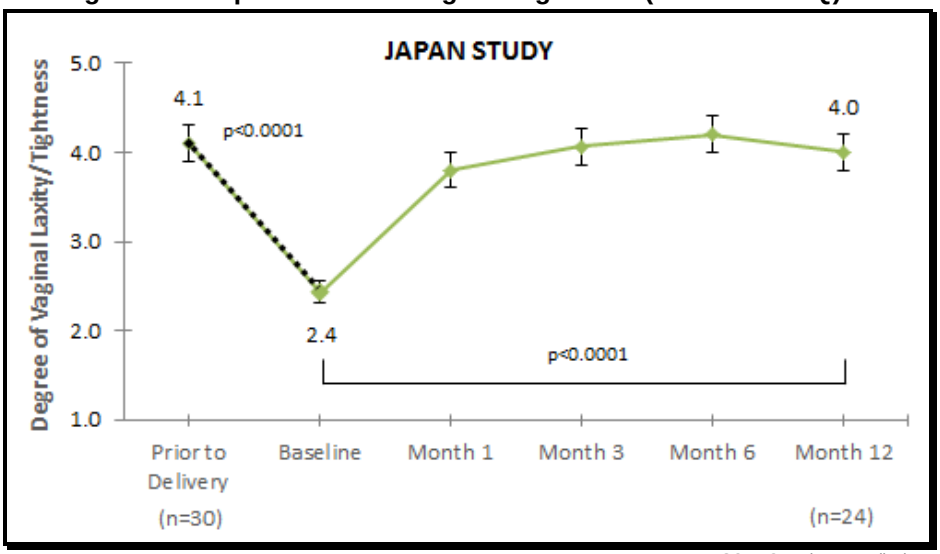
All 30 women completed the one month, three month and six month evaluations. At 12 months, 23 women completed the VLQ and SSQ questionnaires and 22 women completed were evaluable in FSFI and FSDS.

Results were published in the Journal of Women's Health in September 2013. At baseline 17 of the 30 subjects reported a decrease in sexual satisfaction with 13 reporting no change or decrease in sexual satisfaction since their last vaginal delivery. Average vaginal laxity of all the women prior to treatment was 2.4 on a 1.0 - 6.0 scale (higher = tighter).

A 95% confidence interval was used to designate statistical significance on all measures. Results showed statistically significant improvement in vaginal laxity within one month of treatment and throughout the 12-month evaluation period. The pre-treatment mean score of 2.4 increased to 4.2 at six months and was 4.0 at twelve months (23 patients were evaluable at 12 months).

[11] Millheiser LS. et al. *Radiofrequency Treatment of Vaginal Laxity after Vaginal Delivery: Nonsurgical Vaginal Tightening.* Journal of Sexual Medicine. Sept 2010

Significant Improvement in Vaginal Tightness (based on VLQ)

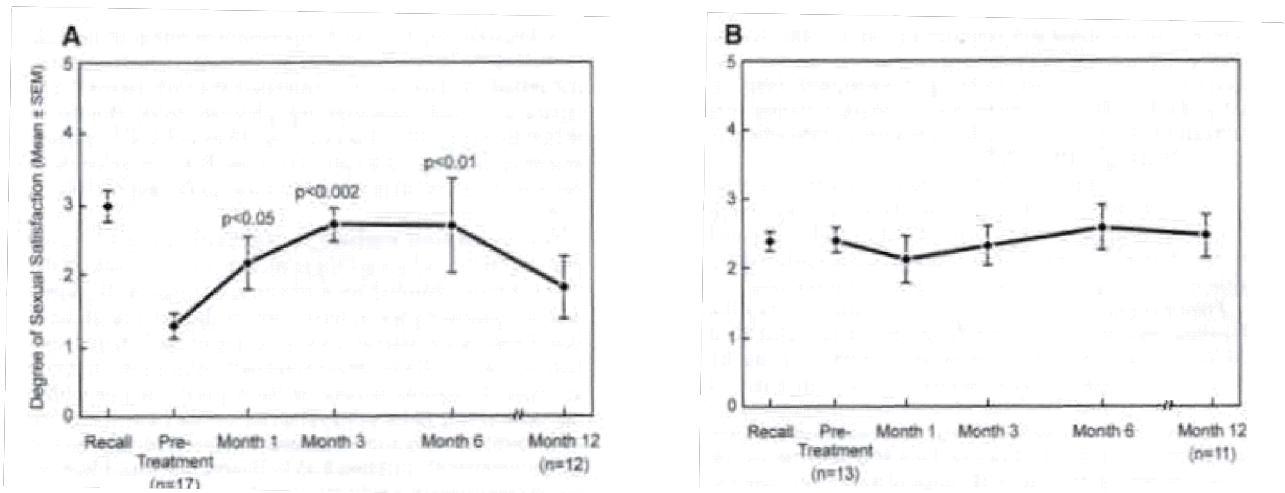


SOURCE: Viveve Medical Inc

Also, similar to results of the U.S. study, sexual satisfaction improved significantly. As reported by the Sexual Satisfaction Questionnaire (SSQ), sexual satisfaction improved at each follow-up period in 13 of the 17 women who expressed decreased sexual satisfaction at baseline. SSQ assesses sexual satisfaction using six levels of response (none, poor, fair, good, very good or excellent), with a higher score reflecting more satisfaction. SSQ scores of the 13 women who expressed decreased sexual satisfaction prior to treatment increased from an average of 1.29 at baseline to 2.71 at six months. At 12 months only 13 of these 17 women remained evaluable.

The SSQ scores of the 13 women who expressed no change (or no decrease) in sexual satisfaction prior to treatment remained significantly unchanged throughout the treatment period.

SSQ Improved in Those Expressing Sexual Dissatisfaction (A), No Change in Those Expressing No Dissatisfaction (B)[12]



Sexual function, as measured by FSFI showed significant improvement through the six month evaluation period, although not through 12 months (note that all 30 women were evaluable at six months while 22 were evaluable at 12 months). FSFI improved from a mean of 22.4 prior to treatment to 26.0 (p=0.002) at six months. Five of the six

[12] Sekiguchi Y. et al. *Laxity of the Vaginal Introitus After Childbirth: Nonsurgical Outpatient Procedure for Vaginal Tissue Restoration and Improved Sexual Satisfaction Using Low-Energy Radiofrequency Thermal Therapy.* Journal of Women's Health. Vol 22. Number 9 2013

FSFI measures showed statistically significant improvement (all but "desire") at six months. At 12 months mean FSFI was 26.0 (p=0.080).

Distress related to sexual activity, as measured by FSDS-R, also significantly improved. Mean FSDS-R prior to treatment of 15.8 decreased to 9.8 at one month (p<0.001) and remained statistically lower throughout the evaluation period. At 12 months mean FSDR-R (for the remaining 22 evaluable subjects) was 10.3 (p<0.005).

Significant Improvement in Sexual Function (FSFI) and Sexually-Related Distress (FSDS-R)[12]

TABLE 2. CHANGES IN SEXUAL FUNCTION (FSFI) AND SEXUALLY-RELATED PERSONAL DISTRESS (FSDS-R) SCORES AFTER RF THERAPY FOR VAGINAL INTROITAL LAXITY

	Possible Score (Range)	*Baseline N=30*	*1M N=30*	*P*	*3M N=30*	*P*	*6M N=30*	*P*	*12M N=22*	*P*
FSFI										
Desire	(1.2–6)	3.3±0.8	3.0±0.8	0.043	3.1±0.9	0.190	3.2±1.0	0.310	3.25±1.0	0.741
Arousal	(0–6)	3.2±1.3	3.2±1.2	0.873	3.7±1.0	0.023	3.7±0.5	<0.01	3.6±1.6	0.363
Lubrication	(0–6)	4.5±1.5	4.7±1.5	0.219	5.0±1.1	0.089	5.1±1.3	<0.01	4.6±1.5	0.271
Orgasm	(0–6)	3.4±1.5	3.8±1.5	0.082	4.4±1.1	<0.002	4.2±1.4	<0.002	4.2±1.2	0.080
Satisfaction	(0.8–6)	3.6±1.5	4.1±1.2	0.052	4.5±1.1	<0.001	4.4±1.1	0.001	4.2±1.3	0.119
Pain	(0–6)	4.5±1.7	5.1±1.8	<0.01	5.3±1.3	<0.02	5.3±0.9	0.005	4.8±1.8	0.503
Total Score	(2–36)	22.4±6.7	23.9±6.7	0.038	26.0±5.1	0.002	26.0±5.8	0.002	26.0±5.2	0.080
FSDS-R										
Total Score	(0–52)	15.8±11.7	9.8±8.0	<0.001	8.9±7.4	<0.001	9.9±8.2	0.002	10.3±8.7	<0.005

Data are mean±SD.
P value determined by Wilcoxon signed rank test for paired samples, months 1, 3, 6, and 12 compared to pretreatment.
N, number of subjects.

Relative to safety, there were no serious treatment related adverse events. On a visual analog (VAS) pain scale of 1 - 10 (10 most pain) the average score was 1.5 with seven subjects reporting sproadic pain in the range of 5 - 7. All women reported returning to their normal activities when questioned at 72-hour follow-up. Subjects reported that they returned to vaginal intercourse within 10 days post-treatment.

> Sham-Controlled, Larger Study Ongoing

While the studies that have been completed so far have been relatively small and single-arm, a much larger and sham-controlled clinical trial commenced enrollment in December 2014. Full enrollment of all 113 patients completed in early April 2015. This study, named *VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness* ("VIVEVE 1"), is being conducted at up to ten sites in Canada and Europe and should provide even greater insight into the safety and effectiveness of the Viveve System. Assuming positive results, the trial data is expected to help further support the roll out of the device outside of the U.S.

Total evaluable enrollment 113 women (75 active, 38 sham) who report vaginal introital laxity and have had at least one vaginal delivery at least 12 months prior to the enrollment date. Primary efficacy endpoint is the proportion of women in the treatment arm as compared to the proportion of women in the sham (i.e. - control) arm that report no vaginal laxity six months following treatment. "No vaginal laxity" is determined by a score of >4 on Viveve's specially designed questionnaire ("Viveve System Questionnaire" or VSQ). The VSQ is similar to questionnaires used in the Japan and prior U.S. study and is used to assess level of sexual satisfaction and level of vaginal laxity/tightness before and after treatment.

Secondary efficacy endpoints are the percentage change in mean score from baseline to six months following treatment of the active arm as compared to the control arm in 1) the Vaginal Laxity Inventory[13] (VALI), 2) Total FSFI and 3) FSDS-R.

Safety will be measured by the proportion of women in the treatment arm versus that of the control arm experiencing adverse events six months following treatment.

Subjects are randomized in a 2:1 ratio (active:control) to either the treatment or sham group. Patients are blinded to which group they have been randomized to while the treating personnel will not be. The treatment group will receive 90 Joules/cm^2 of RF energy delivered via the Viveve System while the sham group will receive <1 Joule/cm^2 RF energy from the Viveve System. All subjects will be followed through the six month follow-up period with assessments at day 10 and months one, three and six.

[13] See Appendix for description of Vaginal Laxity Inventory

Total study duration is expected to be approximately 12 - 15 months. In mid-July 2015 Viveve announced that an evaluation had been done on 62 patients which reported no serious adverse events and that no changes to the study protocol were planned. Also that, "The company believes, based on this prospective unblinded analysis, that the study is on track to meet its primary efficacy and safety outcomes". While the company did not provide any efficacy data, the interim analysis was enough to satisfy the milestone in the loan indenture required to draw the $1 million third tranche. That requirement is to have provided "positive 3-month interim results" with respect to this VIVEVE 1 trial. The company currently expects the full six-month data to be announced "early next year" (i.e 2016) – which is a slight delay from earlier expectations of Q4 of this year.

COMPETITION

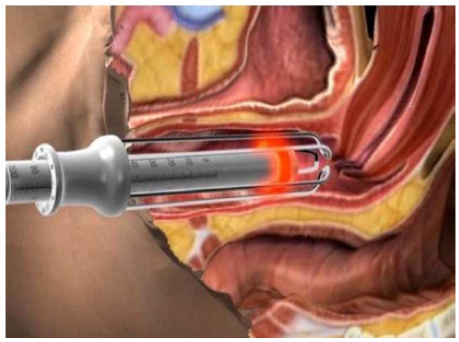
Aside from Kegel's and vaginal surgery, which we believe suffer from significant drawbacks, the Viveve System will face other competition. Our due diligence uncovered two therapies that are aimed specifically at treating vaginal laxity by non-invasive means. These are IntimaLase, a 2940nm Er:YAG "non-contact, non-invasive" laser made by Fotona, a significant laser manufacturer based in California and FemiLift, a CO_2 laser manufactured by Alma Surgical, a medical laser company based in Illinois.

IntimaLase

Treatment with IntimaLase consists of two treatment sessions, spaced approximately 15 - 30 days apart. No anesthesia is required. Per Fotona, the laser tightens the walls of the vagina through precisely placed non-ablative laser pulses which heat the collagen in the vaginal tissue.

IntimaLase was used in a 21-patient pilot study[13] from June 2011 to January 2012. The subjects, aged 21 -61 years old, all reported suffering from vaginal looseness. Only 10 of the patients had had one or more vaginal deliveries, with three having deliveries via c-section and eight never having had children.

IntimaLase Procedure[14]



A specially designed laser vaginal tightening questionnaire was used to assess vaginal tightening - which was given to both the patient and their partners. This questionnaire also included one question to assess the subject's perception of changes in their sexual gratification following treatment. Follow-up occurred at 48 hours following each treatment, prior to the second session and three months after completion of treatment.

Results on the laser vaginal tightening questionnaire showed that all 21 patients reported improved vaginal tightness with one reporting mild improvement, 16 as moderate and 4 as strong. 20 of the 21 patients responded to the questionnaire with 3 reporting mild improvement, 10 moderate and 7 strong improvement. In terms of changes in sexual gratification, 20 of the 21 patients reported improvement in sexual gratification following treatment. Pain was assessed using a VAS scale. 10 of the 21 patients reported the procedure was totally painless (score of 0) with 11 reporting mild pain (scores of 1 and 2). No treatment related serious adverse events were reported and patients returned to normal daily activities within three days of treatment.

We note that given the very small study populations of both the Viveve System and IntimaLase, coupled with the subjectivity of questionnaires and inherent non-comparability of the studies based on differences in study designs (including outcome measures), that it is not possible to make a scientific comparison between the efficacy of the two devices. We think it is relevant to note, however, that follow-up with the Viveve studies was up to 12 months, while this IntimaLase study follow up was only up to three months.

Aside from potential differences in efficacy (or safety) - which, again we do not think is currently possible to confidently ascertain, competitiveness may favor the Viveve System due to a lower treatment burden. Treatment

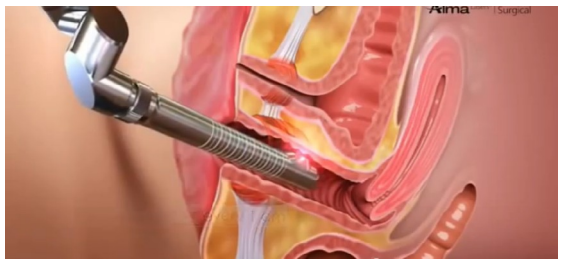
[14] Gaviria P, JE, Lanz L, JA. *Laser Vaginal Tightening (LVT) - evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome.* Journal of the Laser and Health Academy. Vol. 2012, No.1 www.laserandhealth.com

with the Viveve system consists of one ~30-minute session while treatment with IntimaLase requires two sessions spaced 15 - 30 days apart.

FemiLift
Alma Lasers' FemiLift uses a 30W CO_2 laser. Similar to IntimaLase, the laser is non-invasive and is used to heat the vaginal tissue to tighten it. Per Alma, the procedure can be done in one 30 minute session, does not require anesthesia and is virtually painless.

CO_2 lasers have been used for a decade or more for the treatment of skin conditions including wrinkles, sun exposure and acne. More recently they have been used for rejuvenation of vaginal tissue, although most of which appears to be focused on symptoms such as dryness, urinary burning and itching, as opposed to vaginal laxity. We have found no clinical studies which evaluate CO_2 lasers in the treatment of vaginal laxity - although we are not implying that they may potentially be efficacious or safe in that application.

FemiLift Procedure



SOURCE: Alma Surgical

REGULATORY / COMMERCIALIZATION

Distribution
Until very recently The Viveve System was available in just three geographic areas; Canada, Europe and Japan. But since February 2015 Viveve has consummated agreements with eleven companies (ten of which were added since the end of Q1) for ex-U.S. distribution of the Viveve System covering an additional 30 countries. VIVMF now has twelve distribution partnerships covering 32 countries. We expect, following gaining requisite regulatory approvals in those areas where the Viveve System is not yet approved (Asia, Middle East, Russia), that the company will begin commercializing shortly afterwards. But with CE Mark already in-hand, VIVMF should have an opportunity to exploit areas of Europe where they have just gained distribution footprint including the U.K., Ireland, Spain, The Netherlands, Belgium, Switzerland, Germany and Luxembourg.

U.S. Clearance Expected to Follow De Novo 510(k)…
Relative to the U.S. market, for class I and II devices (which are considered low-to-moderate risk in terms safety) for which there is a predicate device, the typical 510(k) pathway (i.e.- relatively simple, inexpensive and swift) can usually be used to gain FDA clearance. However, in instances where there is no predicate device, by default, FDA had required that the PMA pathway (i.e. - relatively expensive and 1+ year for FDA decision) be followed. This has recently changed, to an extent. Now, through a Direct De Novo petition, a company seeking regulator clearance of a class I/II device where no predicate exists can request FDA to consider, based on sufficient safety of that device, that the 510(k) pathway be allowed.

Per a meeting that Viveve had with FDA in Summer of 2012, the agency verbally communicated that they believed the de novo 510(k) regulatory pathway would be sufficient. While this still needs to be confirmed in writing, we think it makes sense FDA will confirm this. We point to Thermage's ThermaCool System which uses the same technology for skin tightening of the face and body and which is classified as a class II device (i.e. - moderate risk) and was cleared via 510(k) through citing a predicate device.

But while the typical 510(k) pathway (for low-to-moderate risk devices for which a predicate exists) usually will not require clinical trial data to support the regulatory filing, de novo 510(k)s generally will. In that regard, Viveve expects to design and complete a U.S.-based clinical trial. Specifics in terms of design and timing are still uncertain although we think the company will likely wait until data is available from the OUS sham-controlled study in order to help guide them in building the U.S. study protocol. As it is currently, Viveve expects to submit an Investigational Device Exemption (IDE) to FDA in Q1 2016 for approval to initiate a U.S. clinical trial.

In the meantime, Viveve's current plan is to seek labeling for general surgical procedures for coagulation and hemostasis for their current device, which includes enhancements of their legacy device which already has FDA clearance for general surgical procedures. VIVMF noted in a May 2015 presentation that they submitted a Special 510(k) in Q1 for this additional labeling. If granted, Viveve could introduce the system to the U.S. market with the general surgical procedure label which would still allow it to be used off-label for vaginal laxity. While we think this may not provide much in the way of financial contribution, it would allow for awareness-building which could be a meaningful in terms of early-marketing, particularly at the key opinion leader level. And if and when the system gains FDA clearance for a vaginal laxity indication, this early introduction may provide a head start as they begin to market it for that indication.

Commercialization
Commercialization to-date has been very limited with just sixteen systems placed to-date. In addition, approximately 890 treatment tips have been sold. While sales have disappointed in 2015 relative to our expectations, we still expect a steepening in the placement and utilization curve as a result of sales through the new distributors and further facilitated by the sales/marketing infrastructure build-out made possible by the significantly beef-up cash balance. But, as noted, we have recently made meaningful downward revisions to our current year revenue estimates.

The U.S. market is a longer-term goal, timing of entry which will ultimately be dependent on successfully gaining FDA clearance - which, in turn, is likely to be dependent on positive outcomes of a U.S.-based sham-controlled study. As such, we do not anticipate that Viveve will commercialize in the U.S. market for at least the next two years. If and when the Viveve System enters the U.S. market, we think the company may look to sell direct through an in-house sales force initially targeting OB/GYNs, which we view as the low-hanging fruit.

VALUATION / RECOMMENDATION

We think it is relevant to look at Thermage, Inc.'s (Thermage was acquired by Valeant Pharmaceuticals in early 2014) ThermaCool system as a rough guide on which to base a forecast for the roll-out and economics of the Viveve System. The Viveve System is based on the same technology as the ThermaCool system, which launched in late 2002 for the treatment of wrinkles and skin tightening on the face and other parts of the body. The ThermaCool revenue model is also similar to that of the Viveve System - essentially to build a sufficient installed base of consoles which will then feed an ever-growing revenue stream of consumables. The consumables are also very similar and include a treatment tip, return pad, coolant and other small accessories.

The potential market size for skin tightening is many multiples larger than that for vaginal tightening. According to ISAPS there were 309k facelift procedures and 56k surgical vaginal rejuvenation procedures performed in 2011. Using these as rough proxies for the respective U.S. markets for non-invasive skin tightening and vaginal tightening, implies the former is 5x - 6x the size of the latter.

Another difference related to the end-user markets, which we account for in our financial projections, is that the availability of facial and body non-invasive skin tightening is almost certainly much more common knowledge than it is for non-invasive vaginal tightening. Also, while there is little embarrassment associated with inquiring about addressing facial wrinkles, uptake of cosmetic vaginal procedures has been hampered as a result. We think these differences will be reflected in a more moderate adoption curve of the Viveve System as compared to that of ThermaCool.

In addition to selling to a significantly larger target market, Thermage has had the benefit of a highly scaled distribution platform. Their distribution as of the end of 2006 (ThermaCool's fourth year on the market), the earliest period in which we were able to find this information, included sales through 29 distributors in 70 countries and a direct sales force in the U.S.

In the first full year on the market (i.e. - 2003) 587 ThermaCool consoles and 40k treatment tips (including the other consumables) were sold. Thermage notes in their filings that each treatment tip represents approximately one treated patient. Thermage averaged annual sales of over 500 consoles and almost 100k per-patient consumables during the first six years following ThermaCool launch and had an installed base of approximately 525k consoles at the end of that period (i.e. - 2008). Their total installed base at the end of 2012, which includes complementary products acquired since 2009, was approximately 9,300 units.

	ThermaCool Years on the market						
	1	2	3	4	5	6	**Avg**
Tips/Cons Sold	40,233	94,099	83,662	130,690	136,000	112,000	**99,447**
Consoles Sold	587	612	408	437	633	478	**526**
Tips sold to-date	40,233	80,466	174,565	258,227	388,917	524,917	
Consoles sold to-date	587	1,199	1,607	2,044	2,677	3,155	

In terms of pricing and utilization, Thermage averaged approximately $30k per console and $300 of consumables per-patient during the first six years. Utilization per console averaged approximately 5x per month over the same period.

	ThermaCool Years on the market						
	1	2	3	4	5	6	**Avg**
Sale price / tip	$180	$321	$323	$301	$332	$370	**$304**
Sale price / console	$29,705	$32,104	$30,886	$30,435	$25,750	$28,452	**$29,555**
Average Monthly Utilization per console	5.7	6.5	4.3	5.3	4.2	3.0	**4.9**

Our Financial Model Assumptions…

So while certain differences in Thermage's product, target market, competitive landscape and early distribution capabilities may not provide a specific template for what to expect with the roll-out of the Viveve System, we think it is a useful gauge, at least in terms of illustrating the potential demand for the technology (which is essentially the same), pricing and utilization in the respective end-user markets.

We currently model a unit placement rate of about one per month for the remainder of 2015, which is revised down from 5 per month prior to the disappointing Q2 results. Our modeled utilization remains at 1x – 2x per month.

Assuming positive clinical data from the OUS sham-controlled study in early 2016 and additional distribution reach, we think the placement rate will accelerate and model (perhaps conservatively) 90 units sold in 2016 with utilization ticking up to 3x per month.

Entry into the U.S. market could come in 2018 and, coupled with a greater marketing push, expanded OUS distribution and additional clinical data to support sales, we think it is reasonable that Viveve could increase the unit placement rate by approximately 15 - 20 consoles per year from 2016 to 2024. This results in a total installed base of almost 1,700 units after ten years on the market, which compares to ~9,300 units with Thermage's products over roughly the same period of time. Again we account for the much more moderate roll-out with the Viveve System and much smaller market as compared to Thermage. We also think that a reasonable case would be made that our forecasted unit placement rate is conservative, particularly given that competition in Thermage's target market is much more intense and widespread than that of Viveve's.

We model utilization to improve with greater awareness of the benefits of non-invasive vaginal tightening and, potentially with a generation of women that may feel less embarrassed about broaching the subject of vaginal laxity with their physician. Our modeled utilization improves from 1x - 2x per month to just over 5x per month at year 2024.

Relative to pricing, we again may be erring on the side of conservatism. While list price of the Viveve console is $60k and per-patient consumables are estimated to sell for approximately $600, we use initial pricing of $30k and $350, respectively. This more closely mirrors Thermage's legacy pricing over the first six years - although inflation and less competition in the vaginal tightening space may imply that these estimates are on the low end.

DCF Values VIVMF at $1.10/share

We use a 10-year DCF model to value VIVMF. Using the inputs discussed above, we have revenue growing from $550k in 2015 to $12.1M in 2018 and to approximately $71M in 2025 (for reference, Thermage's sales were $50M+ at second year after ThermaCool launch). We use estimated gross margins for both the consoles and consumables that are similar to those of ThermaCool.

Other key inputs to our DCF include a 10.5% discount rate and 2% terminal growth rate. Based on our DCF model, VIVMF is valued at approximately $1.10/share. This is adjusted from $1.25/share from our previous update as a result of downward revisions to revenue and upward revisions to OpEx for the remainder of 2015. Our outlook and financial estimates are subject to change based on progress with expansion of distribution, results of clinical trial data and regulatory approvals, among other events. We are maintaining our Buy recommendation.

APPENDIX

Outcome Measures of Completed U.S. Study[15]

> Female Sexual Function Index

The FSFI is a brief questionnaire to assess sexual functioning in women (Rosen et al 2000). It was developed for the specific purpose of assessing six domains of sexual functioning (desire, sexual arousal, lubrication, orgasm, satisfaction and pain) in clinical trials. It is not a measure of sexual experience, knowledge, attitudes, or interpersonal functioning in women. The FSFI has been validated in two groups of women, including subjects with sexual arousal disorder (FSAD, as determined by history) and age-matched controls with no history of sexual dysfunction. The instrument sensitively reliably differentiated these two groups on all domains of sexual functioning. In this pilot study, we utilized a sponsor-modified version of the FSFI (mv-FSFI) which was collected at screening, at months 1 and 3 in the required study period and in the optional extended follow-up period of months 6 through 12. Full scale scores can range from 2 to 36. The mv-FSFI comprised the same questions as the original but with slight alterations in wording of certain question responses. The modification was due to an inadvertent typographical error. However, the ordinal/interval scale of responses from highest to lowest frequency or highest to lowest degree was similar and there was no change in the scoring algorithm as originally reported by Rosen et al (2000).

The FSFI developed by Rosen et al 2000 has been useful in identifying women with sexual dysfunction. For example, the original Rosen et al study evaluated the discriminate validity of the FSFI to discern differences between age-matched, normal control women and those with sexual dysfunction (i.e., female sex arousal dysfunction, FSAD). In the Rosen report the mean FSFI full scale score was 30.5 ± 5.29 for control women and 19.2 ± 6.63 for women with FSAD, respectively ($p \leq 0.001$). In the pilot study reported herein, the mv-FSFI served the dual purpose of evaluating the safety and effectiveness of the RF treatment but was not used for diagnosis or to identify the presence of sexual dysfunction in the study population.

> Female Sexual Distress Scale-Revised

The FSDS-R is a validated scale used to measure sexually related personal distress in women (Derogatis et al 2002). The questionnaire has recently been revised to enhance the sensitivity of the instrument and to extend the validation of the scale by demonstrating that both instruments possess reliability and discriminative validity in pre-menopausal women with hypoactive sexual desire disorder (Derogatis et al 2008). The FSDS-R has a high degree of discriminative sensitivity to distinguish between sexually dysfunctional and normal functional women and is sensitive to therapeutically inducted changes in function. Total score of the FSDS-R can range from 0 to 52. The provisional cut-off score of ≥15 reliably identifies over 90% of women who are currently experiencing sexually related personal distress. The FSDS-R was scheduled to be collected at screening and at Months 1 and 3, and at the optional extended follow-up visits at months 6, 9 and 12.

> TCRS Treatment (Pre- and Post-) Specific Questionnaires

The TCRS Treatment Specific Questionnaire is intended to acquire patient subjective assessments related to sexual satisfaction and vaginal laxity/tightness. It was designed especially for this study to serve as a measure of both safety and effectiveness outcomes; the questionnaire documents participants' responses to Likert items. The Likert scale is one of the most widely used bipolar scaling method instruments in survey research. The TCRS Treatment Specific Questionnaire scale item on level of vaginal laxity/tightness uses a balanced keying (an equal number of positive and negative statements) to obviate the problem of acquisition bias. The item on sexual satisfaction uses an incremental ordered response about level of sexual satisfaction. The TCRS Pre-Treatment Questionnaire was administered prior to treatment (assessing subjects' status prior to vaginal deliveries and currently) and the TCRS Post-Treatment Questionnaire was to be administered at office visits at Months 1 and 3 and at the optional extended follow-up visits at months 6, 9 and 12.
The TCRS Questionnaire uses two Likert items.
• The first question related to "level of sexual satisfaction from vaginal intercourse" and was assessed with 6-level ordered responses (none, poor, fair, good, very good or excellent).
• The second question related to "level of vaginal laxity/tightness" and was assessed with 7-level ordered responses (very loose, moderately loose, slightly loose, neither loose nor tight, slightly tight, moderately tight or very tight).

> Global Response Assessment Questionnaire

[15] These descriptions were taken verbatim from; *CLINICAL STUDY REPORT, A Single-Arm Study of the TivaMed Cooled Radiofrequency (RF) System (TCRS) in the Treatment of Vaginal Laxity*. May 26, 2010

The GRA is a self-report instrument to assess the participant's perception of responses to the treatment procedure with the TCRS and utilizes balanced keying responses to two Likert items:
• The first query "As compared to when you started the current study, how would you rate your overall level of sexual satisfaction now?"
• The second query "As compared to when you started the current study, how would you rate your vaginal laxity/tightness now?"

Response categories comprised a balanced keying of 7-level ordered responses (markedly improved, moderately improved, slightly improved, no change, slightly worse, moderately worse or markedly worse). The GRA was to be administered during office visits at Months 1 and 3 and during the optional extended follow-up visits at months 6, 9 and 12. The Likert scaling in the GRA questionnaire is a frequently used bipolar scaling method to assess outcomes in clinical research.

Description of Vaginal Introitus Laxity Inventory (secondary outcome in VIVEVE 1 study)[16]

Vaginal Introitus Laxity Inventory (VALI) is a 12-item patient reported outcome measure (i.e., PRO) designed to describe and quantify the nature of a female respondent's concern with the perception of laxity ("looseness") and its impact on the qualities of satisfaction and enjoyment of her sexual functioning. Items of the VALI address the impact of laxity on the major aspects of the female sexual response cycle (i.e., sexual desire, arousal and orgasm), and quantify the patient's experience of sexual pleasure, sensitivity and satisfaction. The VALI items also address the potential impact of vaginal introitus laxity on sexual confidence and the patient's partner. All 12 items are measured on 5-point Likert scales and scores are summed to achieve a VALI Total score, range 0-48).

[16] This description was taken verbatim from Viveve's Protocol Report for the VIVEVE 1 study

FINANCIAL MODEL

Viveve Medical, Inc

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018
Total Revenues	$90.0	$38.0	$73.0	$145.2	$290.4	$546.6	$4,035.6	$8,368.9	$12,084.2
YOY Growth	*-40.8%*	*-75.0%*	*54.4%*	*207.0%*	*-*	*507.3%*	*638.3%*	*107.4%*	*44.4%*
Cost of Goods Sold	$50.0	$50.0	$53.0	$96.6	$181.2	$380.8	$2,167.0	$3,914.6	$4,807.0
Gross Income	$40.0	($12.0)	$20.0	$48.6	$109.2	$165.8	$1,868.6	$4,454.4	$7,277.3
Gross Margin	*44.4%*	*-31.6%*	*27.4%*	*33.5%*	*37.6%*	*30.3%*	*46.3%*	*53.2%*	*60.2%*
SG&A	$4,276.0	$1,577.0	$1,821.0	$1,981.0	$2,060.0	$7,439.0	$7,894.0	$8,201.5	$8,700.7
% SG&A	*4751.1%*	*4150.0%*	*2494.5%*	*1364.3%*	*709.4%*	*1361.0%*	*195.6%*	*98.0%*	*72.0%*
R&D	$1,426.0	$845.0	$1,086.0	$988.0	$808.0	$3,727.0	$3,244.0	$2,911.0	$2,121.0
% R&D	*1584.4%*	*2223.7%*	*1487.7%*	*680.4%*	*278.2%*	*681.9%*	*80.4%*	*34.8%*	*17.6%*
Operating Income	($5,662.0)	($2,434.0)	($2,887.0)	($2,920.4)	($2,758.8)	($11,000.2)	($9,269.4)	($6,658.2)	($3,544.4)
Operating Margin	*-6291.1%*	*-6405.3%*	*-3954.8%*	*-2011.3%*	*-950.0%*	*-2012.5%*	*-229.7%*	*-79.6%*	*-29.3%*
Total Other Income (Expense)	($518.0)	($90.0)	($119.0)	($94.0)	($95.0)	($398.0)	($308.1)	($157.5)	($49.2)
Pre-Tax Income	($6,180.0)	($2,524.0)	($3,006.0)	($3,014.4)	($2,853.8)	($11,398.2)	($9,577.5)	($6,815.7)	($3,593.6)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0		
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income (continuing ops)	($6,180.0)	($2,524.0)	($3,006.0)	($3,014.4)	($2,853.8)	($11,398.2)	($9,577.5)	($6,815.7)	($3,593.6)
YOY Growth	*48.9%*	*-39.2%*	*275.0%*	*276.1%*	*152.2%*	*84.4%*	*-16.0%*	*-28.8%*	*-47.3%*
Net Margin	*-6866.7%*	*-6642.1%*	*-4117.8%*	*-2076.0%*	*-982.7%*	*-2085.3%*	*-237.3%*	*-81.4%*	*-29.7%*
EPS (continuing ops)	($1.27)	($0.14)	($0.08)	($0.06)	($0.05)	($0.29)	($0.15)	($0.10)	($0.05)
YOY Growth	*128.9%*	*-75.2%*	*-*	*-71.1%*	*-81.0%*	*-77.4%*	*-47.1%*	*-36.9%*	*-52.0%*
Diluted Shares O/S	4,866	18,341	35,441	52,000	53,000	39,696	63,000	71,000	78,000

Brian Marckx, CFA

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LEADERSHIP

Management

Patricia Scheller
Chief Executive Officer and Director
Patricia's commitment to the healthcare industry spans more than 25 years. Prior to joining Viveve, she served as the CEO of Prescient Medical, Inc., a privately held company that developed diagnostic imaging catheters and coronary stents designed to reduce deaths from heart attacks. Before PMI she was the CEO of SomaLogic, a molecular diagnostic company dedicated to developing protein signature arrays. Patricia also managed several business units at Ortho-Clinical Diagnostics, a Johnson & Johnson company, and served in key executive positions at Dade Behring, a clinical diagnostics firm. In addition, she was director of cardiology systems at Cordis, a Johnson & Johnson company renowned for pioneering vascular disease treatments. There, she was responsible for launching the PALMAZ-SCHATZ® balloon-expandable Stent, the first stent to achieve over a billion dollars in sales. Patricia received a B.S.E. degree in Biomedical Engineering from Duke University and completed executive business education programs at Harvard University, Massachusetts Institute of Technology, Columbia University and Northwestern University.

Scott Durbin
Chief Financial Officer
Scott joined Viveve as Chief Financial Officer in January 2013. His 20 year career in corporate finance and strategy for the life science industry brings a wealth of finance experience to our organization. Prior to joining Viveve, he was Chief Financial Officer of Aastrom Biosciences, a publicly traded, cardiovascular cell therapy company. Before Aastrom, he spent six years as Chief Operating and Financial Officer for Prescient Medical, a privately held company that developed diagnostic imaging catheters and coronary stents designed to reduce deaths from heart attacks. Prior to Prescient, he spent several years as a financial consultant for two publicly traded biotech companies, Scios, Inc. – a Johnson & Johnson company and Alteon, Inc. He began his career in corporate finance as an investment banker in the Healthcare and M&A groups at Lehman Brothers Inc., where he focused on mergers and acquisitions and financings for the life science industry. At Lehman, he successfully executed over $5 billion in transactions for medical device and biotech companies. He began his career as a Director of Neurophysiology for Biotronic, Inc. Scott received a B.S. from the University of Michigan and an M.P.H. in Health Management with Honors from the Yale University School of Medicine and School of Management.

Alan Curtis
Vice President of Regulatory, Clinical and Quality
Alan joined Viveve in January 2010. In his role as Vice President of Regulatory, Clinical and Quality, Alan brings over 30 years of experience to the organization. Alan has been involved in many medical device start-ups including Aragon Surgical, Reliant Technologies, SURx, and Endosonics. Alan also gained PMA approval for an interventional cardiology device while with W.L. Gore and Associates. He has created and implemented robust Quality Systems to meet domestic and international regulatory requirements. In addition, Alan has established successful clinical and regulatory strategies that led to device commercialization in the U.S. as well as CE Mark for international distribution. Alan is a member of the Regulatory Affairs Professionals Society (RAPS) and is certified as an RAC. Alan attended California State University and received a B.Sc. in Microbiology.

Steve Lopez
Director of Operations
Steve joined Viveve in April 2009. He brings over 20 years of engineering, manufacturing, quality and operational experience supporting asthma, cardiovascular, esophageal, oncology, and surgical products, both in early stage and Fortune 500 companies. More recently, Steve worked at Asthmatx (now Boston Scientific) as the Director of Operations where he led the transition from R&D assembly into clinical manufacturing along with managing scale-up activities for commercial release. Steve has held various leadership and technical roles at BÂRRX Medical (now Covidien), Boston Scientific, RadioTherapeutics (now Boston Scientific), Johnson & Johnson, and Guidant (now Abbott Vascular). Steve earned his M.S. degree in Engineering Management from California State University, Northridge, received his B.S. degree in Engineering from California State Polytechnic University, Pomona, and is a Certified Manufacturing Engineer.

James Atkinson
Chief Business Officer and President
Prior to joining Viveve as Chief Business Officer and President, Jim was the Senior Vice President of Global Sales at Ulthera, Inc. through April, 2014. He was the third employee to join the company in October, 2006 as Senior Vice President of Sales and Marketing. While at Ulthera, he helped grow the company from 3 to 165 employees and established a global distribution network that included 42 distributors, covering 52 countries. Ulthera was purchased by Merz Aesthetics for $600 million in 2014. Before joining Ulthera, Mr. Atkinson served as Vice President of Sales and Marketing for the Cardiac Surgery Division at St. Jude Medical, where his responsibilities included launching the Biocor stented tissue valve, recognized as the fastest growing heart valve brand in the industry. Prior to St. Jude Medical, he served as Vice President of Sales for Medtronic Vascular, a $200 million division of Medtronic, Inc. Mr. Atkinson's entrepreneurial spirit led him to co-found and serve as Vice President of Sales and Business Development for Medical Simulation Corporation, the leading developer of state-of-the-art simulation technologies and services for the cardiology, cardiac surgery and nursing industries. His career began as a sales representative at Ethicon Endosurgery where he progressed through positions of increasing responsibility to Regional Manager.

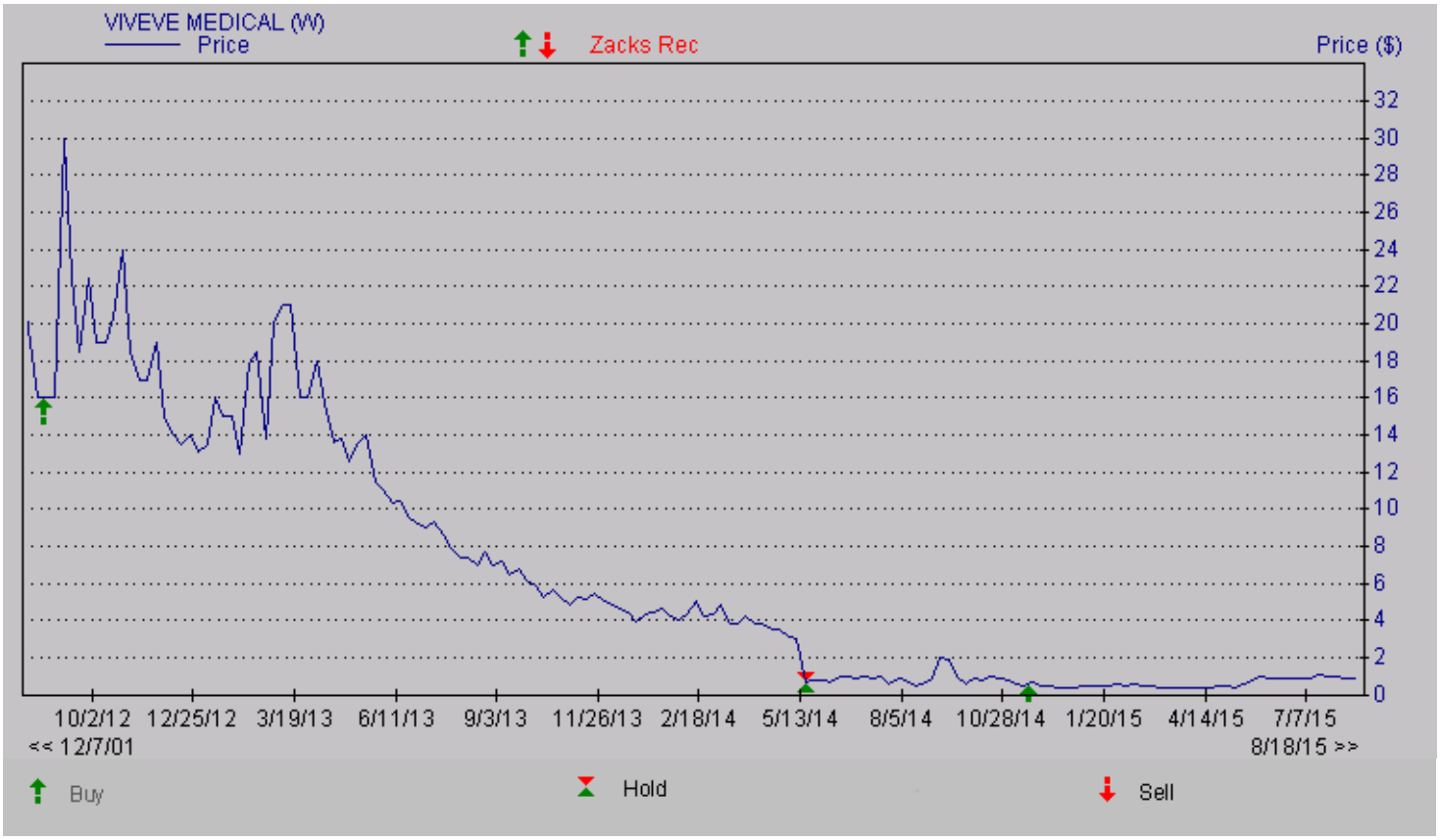
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Scientific Advisory Board

Sheryl A. Kingsberg, Ph.D
Dr. Sheryl Kingsberg is the chief of behavioral medicine at MacDonald Women's Hospital/University Hospitals Case Medical Center and Professor in Reproductive Biology and Psychiatry at Case Western Reserve University. Her areas of clinical specialization include sexual medicine, female sexual disorders, menopause, pregnancy and postpartum mood disorders, and psychological aspects of infertility.
Dr. Kingsberg's primary research interests are in treatments for female sexual disorders and the psychological aspects of infertility and menopause. She has been the principal investigator for several clinical trials for treatments for female sexual disorders and consults for many pharmaceutical companies that are developing investigational drug treatments for sexual problems. She has numerous publications in many national and international journals and is an Associate Editor for the Journal of Sexual Medicine and sits on the editorial board of the journal Menopause.
Dr. Kingsberg is a leader in a number of national and international organizations. She currently sits on the Board of Trustees of The North American Menopause Society, and is a past president of The International Society for the Study of Women's Sexual Health.

Michael Krychman, M.D.
Michael is Executive Director, President and CEO of the Southern California Center for Sexual Health and Survivorship Medicine, and Associate Clinical Professor at USC, Department of Obstetrics and Gynecology. He is a Member-at-Large on the Executive Board of the International Society for the Study of Women's Sexual Health and is a member of the Standards Committee for the International Society for Sexual Medicine. He has been the visiting professor at Oxford University, UK and has served in a consulting or Advisory Board role for many women's health companies including Boehringer Ingelheim and Pfizer Women's Healthcare.

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The current distribution is as follows: Buy/Outperform- 27.4%, Hold/Neutral- 56.0%, Sell/Underperform – 13.6%. Data is as of midnight on the business day immediately prior to this publication.