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, Chicago, IL 60606

Viveve Medical (VIVE-NASDAQ)

VIVE: New $20M (up to $30M) Loan Provides Further Fuel For Growth Initiatives

We use a 10-year DCF model to value VIVE. We have revenue growing from $7.1M in 2016 to $33.9M in 2020 and to approximately $95M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVE is valued at approximately $11/share.

Current Price (07/11/17)	$7.20
Valuation	**$11.00**

OUTLOOK

Relative to the U.S., while VIVE is off to a strong start, we expect domestic sales to accelerate throughout 2017. Viveve has their initial U.S. sales team in place which they expect to incrementally add to later in the year. VIVE expects to add an additional four reps by the end of July and have a total of 16 to 18 by the end of this year. VIVE hopes to eventually gain FDA clearance of the Viveve System for an indication related to the improvement of sexual function. While we had hoped the pivotal study would begin this year, that timeline may now be pushed to 2018 given that FDA recently asked for additional safety related data. Meanwhile the 13 OUS console placements in Q1 was relatively soft. While this is the lowest number in international console unit sales since Q3 2015, we think that's more a timing factor than anything fundamental. In fact there's several reasons why we expect international sales to pick up throughout 2017 – including the agreement with their distributor in China, requiring that company to purchase at least 75 units this year – Q1 included none. Additionally, recent regulatory approval in Brazil and label expansion in S. Korea to include a vaginal laxity indication, could be significant catalysts for international sales. And, finally, regulatory clearance could come in another 14 countries before year end.

SUMMARY DATA

52-Week High	**$11.16**
52-Week Low	**$3.75**
One-Year Return (%)	**66.67**
Beta	**0.38**
Average Daily Volume (sh)	**270,535**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$144**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**61**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**41.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	1284 A	1556 A	1849 A	2452 A	7141 A
2017	3041 A	3259 E	3979 E	4538 E	14817 E
2018					21365 E
2019					27446 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.55 A	-$0.66 A	-$0.46 A	-$0.55 A	-$2.18 A
2017	-$0.57 A	-$0.36 E	-$0.35 E	-$0.35 E	-$1.55 E
2018					-$1.06 E
2019					-$0.79 E

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

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WHAT'S NEW…

New $20M (up to $30M) Loan Provides Further Fuel For Growth Initiatives…
In late May Viveve entered into a new term loan. Approximately $10.8M of the $20M (initially) borrowed was used to repay a legacy loan - we expect at least a portion of the balance will be slated towards growth-related initiatives such as further build-out of the U.S. sales force.

As a reminder, VIVE used approximately $8.1M ($6.2M ex-changes in working capital) in cash for operations in Q1 (i.e. the most recent reporting period). Bolstered by the March equity raise (8.625M shares @ $4/share) that netted approximately $31.5M, cash balance at Q1 quarter end was ~$31.4M. Pro forma for net proceeds of this new term loan that the company entered into in late May (i.e. subsequent to Q1 quarter end), cash balance would be almost $41M - or equal to about 20 months worth of operating capital at the current EBITDA burn rate. This should provide more than enough runway to initiate (and potentially complete) the U.S.-based VIVEVE II clinical study (for support of a sexual function indication).

An additional $10M (in $5M increments) is available under this loan agreement subject to; VIVE meeting a minimum revenue threshold of $16M over any consecutive twelve month period prior to July 1, 2018 and maintaining an average market cap of at least $60M over the 30 days prior to the notice of borrowing. We think both of these milestones should be easily attainable - for context, we model VIVE to generate in excess of $21M of revenue in 2018 and current market capitalization is over $140M (and our target price implies market cap of over $240M).

Q1 Financial Results: *U.S. Demand Already Robust, Driving Both Revenue and Gross Margin…*

In mid-May Viveve reported Q1 financial results and provided a business update. Management also reiterated 2017 financial guidance of revenue between $14M and $16M (implying growth of 96% - 124%) and strong improvement in gross margin.

Total revenue increased 137% yoy and 24% sequentially to $3.04M, a new record and ahead of our $2.76M estimate by about 9%. Q1 marked the seventh straight quarter of sequential double-digit percentage increase in revenue growth. While the 42 consoles sold in the quarter was well below our 62 estimate, this was more than offset by what appears (the company does not disclose pricing) to be very strong average pricing as well as more sales of treatment tips, which at 2,200 were more than 50% above our expectations and also at a record high.

Particularly noteworthy is that U.S. demand appears to already be quite robust with 29 of the consoles placed in the domestic market – and that was accomplished in just nine weeks as the official launch in this country happened at the end of January. The significant U.S.-related contribution which comes at a higher net average selling price, coupled with a record number of tips sold, resulted in a big jump in gross margin.

As a reminder, Viveve is using a direct sales force in the U.S. and third-party distribution overseas. Management indicated on the call that demand here remains strong, that they anticipate adding another four direct reps by the end of July and that they expect U.S. sales will grow sequentially throughout 2017. Selling direct not only affords more control over the sales strategy, it also provides much more at the margin.

Meanwhile the 13 OUS console placements was relatively soft, down from 33 in Q1 2016 and 48 in Q4 2016. While this is also the lowest number in international console unit sales since Q3 2015, we think that's more a timing factor than anything fundamental. In fact there's several reasons why we expect international sales to pick up throughout 2017 – including the agreement with Dynamic Medical Technologies, their distributor in China, requiring that company to purchase at least 75 units this year – Q1 included none. Additionally, recent regulatory approval in Brazil and label expansion in S. Korea to include a vaginal laxity indication, could be significant catalysts for international sales. Both of those countries consistently rank among the top in the world in number aesthetic-related procedures performed each year. And, finally, VIVE believes they could receive regulatory clearance for their device in another 14 countries before year end.

The significant U.S.-related sales (approximately 62% of total revenue in Q1 came from North America) had a dramatically positive effect on gross margin – which jumped to 46.8%, dwarfing historical levels. This compares to 27.1% in Q1 2016 and an average of 35.4% for the full year 2016 – it was also well ahead of our 40.3% estimate. Gross margin should continue to benefit as U.S. sales and treatment tip revenue, both which carry higher margins

than that of international consoles, continue to increase as a percentage of total revenue. Based on our calculations, we estimate that in Q1 VIVE realized an approximate 67% premium in average (net) price per console sold in the U.S. as compared to those shipped internationally. As such, U.S. sales growth will provide an outsized benefit to the top-line and at the margin. Gross margin may also benefit from VIVE's direct efforts to reduce COGS – something that they alluded to on the earnings call and that they expect to talk about more in the future.

System placements continue to drive the vast majority of the top line, although we continue to expect consumables (i.e. treatment tips) sales to accelerate from a growing installed base (currently at 259) and increased utilization as a result of greater awareness, including clinical evidence, supporting the benefits of Viveve System therapy. While VIVE does not disclose console vs. consumable revenue, we estimate ~85% of 2016 revenue related to consoles and the remainder to consumables.

Cash
VIVE used approximately $8.1M ($6.2M ex-changes in working capital) in cash for operations in Q1. Bolstered by the March equity raise (8.625M shares @ $4/share) that netted approximately $31.5M, cash balance at Q1 quarter end was ~$31.4M. Pro forma for net proceeds of a new term loan agreement that the company entered into in late May (i.e. subsequent to Q1 quarter end), cash balance would be almost $41M - or equal to about 20 months worth of operating capital at the current EBITDA burn rate. This should provide more than enough runway to initiate (and potentially complete) the U.S.-based VIVEVE II clinical study (for support of a sexual function indication). Approximately $10.8M of the $20M (initially) borrowed was used to repay a legacy loan - we expect at least a portion of the balance will be slated towards growth-related initiatives such as further build-out of the U.S. sales force.

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Operational Update: U.S. Expected to Accelerate Revenue, Widen Margins. FDA Asks For More Data…

Management is guiding for 2017 revenue of $14M - $17M. While not offering geographically-itemized revenue guidance, we expect much of this anticipated ~100%+ revenue growth is attributable to expectations of continued strong demand in the U.S. As noted, management indicated that the U.S. launch drew strong interest and will look to capitalize on this as they layer on additional sales personnel – including another four reps by the end of July and possibly another two to four by year-end 2017.

We also think other high-potential territories which recently came online, including Brazil and S. Korea, along with regulatory clearance and launch in more countries to be meaningful contributors to revenue growth in 2017. S. Korea, where the Viveve System just received a vaginal laxity indication, is an area to keep a particularly keen eye on. With regulatory clearance in 54 countries and another ~14 that could come online before year end, the geographic footprint continues to rapidly grow. Additionally, we expect to see substantial increase in consumable sales from incremental increase in utilization but more significantly from increase in the installed base (which has increased by more than 6x since the end of 2015 - from 42 to 259 as of the close of Q1 2017).

Relative to the U.S., while VIVE is off to a strong start, we expect domestic sales to accelerate throughout 2017. Viveve has their initial U.S. sales team in place which they expect to incrementally add to later in the year. The U.S. sales team currently consists of ten direct reps which cover the entire U.S.(and part of Canada), two regional directors and an executive VP. VIVE expects to add an additional four reps by the end of July and have a total of 16 to 18 by the end of this year.

VIVE hopes to eventually gain FDA clearance of the Viveve System for an indication related to the improvement of sexual function - a randomized study for which an IDE application has been submitted. While we had hoped the pivotal study would begin this year, that timeline may now be pushed to 2018 given that FDA recently asked for additional safety related data – which will require VIVE to conduct additional preclinical work – more on that below.

In the meantime, the initial formal marketing message in the U.S. is limited for "use in general surgical procedures for electrocoagulation and hemostasis", the indication for which the Viveve System (recently rebranded as "Geneveve") received FDA clearance in October of last year. However, clearly initial demand is driven by 'off-label'

use – likely for the reduction of vaginal laxity and for the improvement of sexual function – both of which were endpoints in the U.S. VIVEVE I study. The informal sexual function-related marketing message was significantly enhanced with the recently published results of the VIVEVE study in the February 2017 issue of the Journal of Sexual Medicine. That is likely having a positive impact on U.S. sales. VIVE noted that ~2/3 of U.S.-related sales in Q1 were to the aesthetic medicine channel and the other 1/3 to gynecological clinics.

As a reminder, VIVEVE I was a multi-site, randomized, sham-controlled study which showed that just one ~30-minute treatment with the Viveve System resulted in a highly statistically significant difference in vaginal laxity and improvement in sexual function among those patients receiving treatment versus those given sham (i.e. control).

While other energy-based devices targeted to the U.S. vaginal laxity market have preceded Viveve's entry, none are FDA-cleared for an indication related to that use. And, more importantly, the Viveve System is the only device that has demonstrated significant efficacy for the improvement in vaginal laxity and/or sexual function. As clinicians look to and often demand robust clinical evidence (i.e. U.S., multi-site, randomized, sham-controlled studies) as a prerequisite to adoption of a particular device, we believe Viveve will have a meaningful competitive advantage.

On the international front, VIVE has been aggressively expanding their commercial footprint. In October 2016 they met another significant milestone – gaining regulatory clearance of the Viveve System in Brazil for "the treatment of the vaginal introitus, after childbirth, to improve sexual function". As Brazil ranks #2 to only the U.S. in not only vaginal rejuvenation but in total number of all types of cosmetic/aesthetic procedures, we think that country also offers substantial near-term revenue potential.

And another potential potent catalyst that came online even more recently was expanding the label in S. Korea to include a vaginal laxity indication – as a reminder Geneveve received initial regulatory clearance (for general surgical procedures) in the country in August 2016. The vaginal laxity indication (May 2017) provides the ability to market specifically for that claim. S. Korea ranks third behind Brazil in total number of cosmetic/aesthetic procedures performed and ranks #1 in the number of procedures performed on a per-capita basis. And it appears Viveve's system has already been well received in that country as management noted on recent earnings calls that sales in S. Korea have been brisk.

The Viveve System is now cleared for sale in 54 countries. In addition, regulatory submissions in approximately 14 other countries are currently pending.

U.S. VIVEVE II (Sexual Function) Study Update: FDA Asks For Add'l Safety Data, Could Be ~6-Month Delay…

In late September 2016 the company submitted an IDE to FDA seeking approval to commence VIVEVE II, a pivotal U.S.-based study expected to support an eventual regulatory filing seeking clearance (via de novo 510(k)) for an indication related to improvement in sexual function. Management noted on the Q4 2016 (February 2017) call that FDA had recently came back with a second round of questions related to the study protocol. Then on the Q1 2017 call (May 2017) management noted that late in Q1 2017 they received additional notice from FDA – including that the agency "signed off on all major components of the protocol" but also that they requested additional safety data.

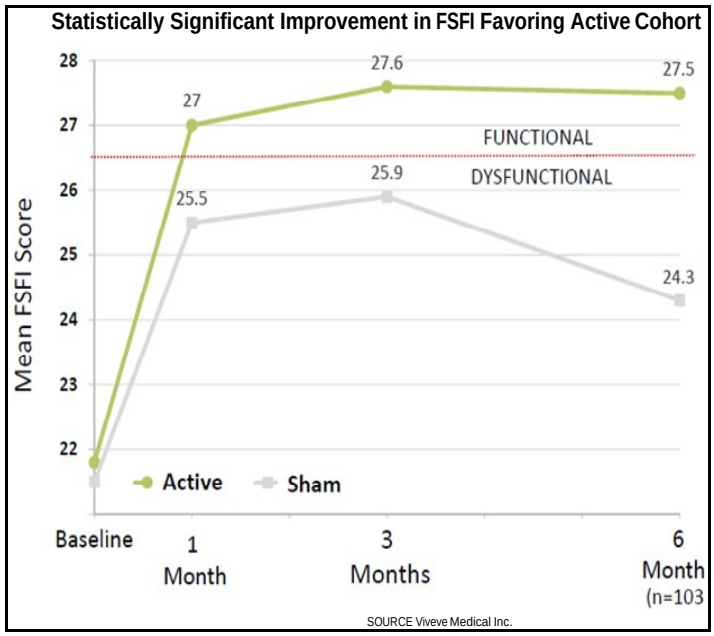
Specifically, FDA has asked VIVE to conduct ex vivo tissue studies to "understand the impact of RF energy on vaginal tissue that has undergone prior episiotomies." (Episiotomies are surgical cuts made at the opening of the vagina to aid difficult deliveries). Management noted that they hope to have the studies completed over the next four to six months (i.e. ~Sept – Nov 2017) and resubmit the IDE at that point. If all goes well, VIVE believes they may still be able to start VIVEVE II before year-end – that timeline, however may prove somewhat aggressive depending on when VIVE completes these studies. As such, we think VIVEVE may not start until sometime in 2018.

While the delay is a disappointment, particularly as VIVE had previously hoped to begin VIVEVE II in Q1 2017, it may prove to be relatively meaningless if these tissue studies satisfy FDA's concerns, particularly given that there are no direct competitors on the horizon seeking a claim as robust as that of Geneve in the U.S. And while the delay did impact our modeled U.S. revenue (mostly in 2018 and 2019), much of the effect was actually offset by upward revisions to our modeled revenue related to off-label use – the latter which was prompted by the strong showing in Q1 and management's comments related to growing robust domestic demand.

And on the positive side, the fact that FDA signed off on the study protocol is a meaningful 'win'. As it relates to that – earlier indications were that FDA would require a 12-month follow-up for the primary efficacy endpoint, mean

change in FSFI score. However, management noted on the Q1 2017 call that FSFI follow-up will be at 6 months, not 12 months. Change in FSFI at 6 months was a secondary endpoint in VIVEVE I.

As a reminder, results of the randomized, sham-controlled VIVEVE I study (chart below and more detail later in this report), announced in April 2016, showed a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, patients receiving Viveve treatment were 3x more likely to report no vaginal laxity at 6-month follow-up compared to control. Safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts.



Proposed VIVEVE II study will include ~250 patients at up to 25 study sites in the U.S. and Canada which will be randomized 1:1 active/sham. Primary endpoint is expected to be mean change in total FSFI score at 6 months. FSFI is a clinical industry metric which has already been well-validated and documented. Secondary endpoints are expected to include two of the six domains of the FSFI questionnaire that contributed the most to the overall (statistically significant) outcome of the total FSFI score in VIVEVE I – those being the arousal and orgasm domains (both of which were highly statistically significant – see below for VIVEVE I results). Follow-up on the secondary efficacy measures as well as on safety will be through 12 months.

Refresher of VIVEVE I: U.S Multi-Site, Randomized Sham-Controlled Study
Results of VIVEVE I showed that just one ~30-minute treatment with the Viveve System resulted in a highly statistically significant difference in vaginal laxity and sexual function among those patients receiving treatment versus those given sham (i.e. control). This also marked the first time that any company was able to demonstrate significant efficacy of their energy-based device in a controlled clinical study.

Viveve announced positive top-line results of VIVEVE I (VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness), its sham-controlled clinical trial assessing safety and efficacy of the Viveve System in more than 150 patients at 9 sites in Europe, Canada and Japan. While results of two previous smaller studies (one in U.S.: n = 23, one in Japan: n = 30) had already demonstrated that treatment with the Viveve System can significantly reduce vaginal laxity and improve sexual function, this VIVEVE I study is the largest to-date and the first sham-controlled study evaluating the Viveve System for the treatment of vaginal laxity as well as for sexual function.

VIVEVE I Design / Protocol…
Enrollment was initially expected to be 113 patients - the study protocol was subsequently updated (per clinicaltrials.gov) to enroll an expected 145 – final enrollment ended up being 174 patients (117 active, 57 sham) with vaginal laxity efficacy data on a 'per-protocol' population of 155. Subjects were randomized 2:1 (active:control)

- patients were blinded, treating personnel were not. The treatment group received 90 Joules/cm2 of RF energy delivered via the Viveve System while the sham group received <1 Joule/cm2. Subjects were followed through the six month follow-up period with assessments at day 10 and months 1, 3 and 6.

Key inclusion / exclusion criteria included;[1]

- Inclusion:
  - pre-menopausal and ≥ 18 years of age
  - had least one full term vaginal delivery (>37 completed weeks) at least 12 months prior to enrollment date
  - experienced vaginal looseness (i.e. VSQ < 4) during vaginal intercourse
- Exclusion:
  - Pregnant or planning to become pregnant within the next 12 months or has had a delivery within the last 12 month
  - currently meets the criteria for a female sexual disorder including DSM V, FSAD, FOD, Genitopelvic Pain, Sexual Aversion, Dyspareunia or Vaginismus and has not been treated for this condition within the past 12 months
  - taking SSNRI or SSRI drugs

Primary efficacy endpoint was 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 as measured by Viveve's specially designed questionnaire, VSQ ("Viveve System Questionnaire"). VSQ, which is similar to the VLQ questionnaire used in the two prior studies, is based on a seven point scale (1:very loose, 2:moderately loose, 3:slightly loose, 4:neither loose nor tight, 5:slightly tight, 6:moderately tight, 7:very tight). "No vaginal laxity", as defined in the VIVEVE study protocol, is a VSQ score of >4.

Secondary efficacy endpoints were 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 (VALI), 2) Total FSFI and 3) FSDS-R. See our Appendix for detailed description of these secondary measures.

Study Results: Primary and FSFI Endpoints Highly Statistically Significant….

Results were positive, showing a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts.

VSQ

Of the 174 subjects enrolled and randomized, 19 were not evaluable for efficacy purposes due to not completing the 6-month follow-up or for other protocol violations. The per-protocol population included 103 active and 52 sham subjects. At the 6-month follow-up, 41.7% (43/103) of active subjects reported having no vaginal laxity (i.e. VSQ > 4) compared to just 19.2% (10/52) of subjects that received sham treatment. The difference was highly statistically significant with a Chi-squared p-value of 0.005. Active subjects were 3.05x more likely to achieve 'no vaginal laxity' at 6 months than were sham subjects (95% confidence interval, p-value = 0.006).

Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity

					Logistic Regression		
Timepoint	Treatment Group	N	No Laxity n (%)	Chi-Squared p-value	Odds Ratio	95% CI	p-value
Month 6	Active	103	43 (41.7%)	0.005	3.05	(1.37, 6.79)	0.006
	Sham	52	10 (19.2%)				

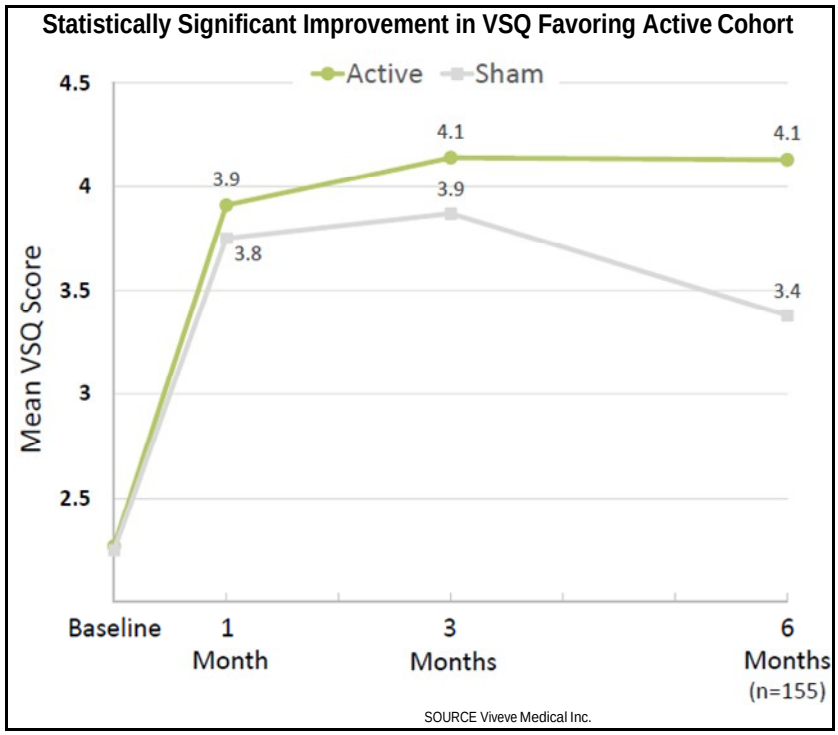
SOURCE Viveve Medical Inc.

Mean VSQ scores at the 1, 3 and 6 month follow up periods were;

- 1-month: 3.9 active vs. 3.8 sham (difference of 0.1)
- 3-month: 4.1 active vs. 3.9 sham (difference of 0.2)
- 6-month: 4.1 active vs. 3.4 sham (difference of 0.7)
  - 6-month mean VSQ score from baseline was 1.9 for active vs. 1.1 for sham

[1] Clinicaltrials.org. ClinicalTrials.gov Identifier: NCT02261974. VIveve Treatment of the Vaginal Introitus to EValuate Effectiveness (VIVEVE I)

The mean change from baseline of the active (1.9) versus shame (1.1) is statistically significant at a 95% confidence interval (p=0.007). The widening difference in mean VSQ over the course of the assessment periods is believed to be representative of weakening of a placebo effect in the sham arm.



FSFI

Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total score. It was developed for the specific purpose of assessing sexual functioning in clinical trials. These 19 items include: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items) and are scored from 0 to 5. The FSFI total score is a weighted average of the six domains with each contributing a maximum of six points to the total (maximum score of 36). Wiegel, Meston and Rosen demonstrated that a cutoff of 26.55 discriminates between women with and without sexual dysfunction.[2]

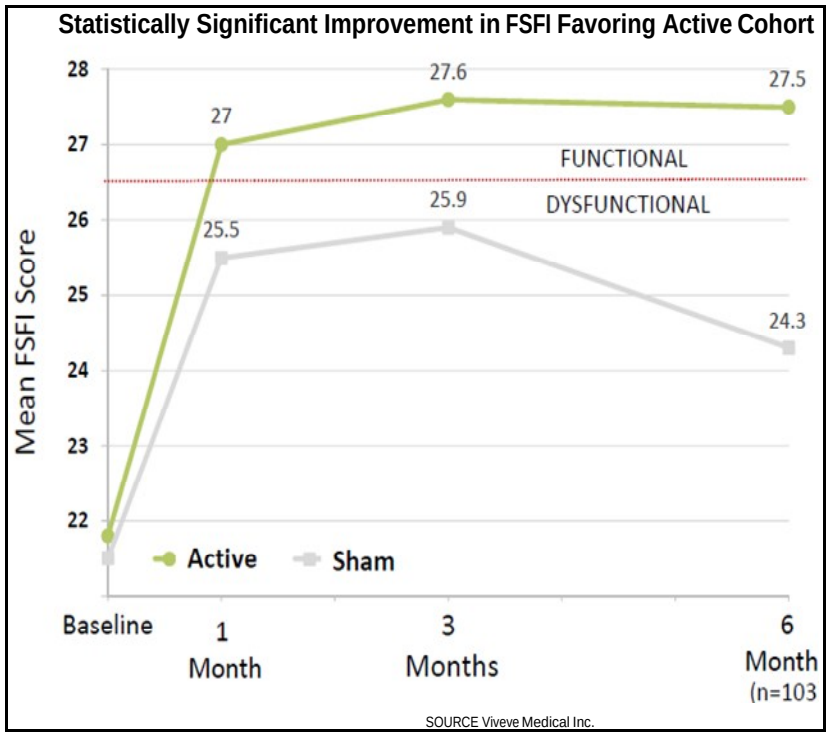
103 (71 active, 32 sham) patients were included in the FSFI per-protocol population. Of the six domains, two (sexual arousal and orgasm) were statistically different favoring the active arm (arousal and orgasm are expected to be included as secondary endpoints in VIVEVE II). And while the other four were not statistically different, there was a positive response favoring the active group. The individual p-values were (p-value < 0.05 is considered statistically significant);

- desire 0.081
- arousal 0.007
- lubrication 0.095
- orgasm 0.004
- satisfaction 0.097
- pain 0.122

But while just two of the six individual domains hit statistical significance, the weighted average of the six domains of the active arm (27.5) was statistically different from that of the sham arm (24.3) at the 6-month follow-up (p=0.009). In addition, the weighted average scores of the six domains on the active arm at 1-month (27.0), 3-month (27.6) and 6-month (27.5) follow up were all above 26.55 (i.e. considered sexually functional) while the scores of the sham arm at each of these timepoints (1-month: 25.5, 3-month: 25.9, 6-month: 24.3) were all below

[2] Wiegel M1, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.

26.55 (i.e. considered sexually dysfunctional). Similar to the VSQ measure, there was some placebo effect in the sham arm that began to wane at about 3 months following initiation of treatment.



Importantly, the expectation is that the mean change in total FSFI score, as opposed to individual domain scores, is what FDA will be looking for as a primary endpoint in VIVE's proposed pivotal U.S. study. Additionally, secondary endpoints are expected to include the FSFI arousal and orgasm domains, which were statistically significant in VIVEVE I.

VALI and FSDS-R

Vaginal Introitus Laxity Inventory and Female Sexual Distress Scale-Revised were the other two secondary endpoints. VALI relates to the respondents' concern of laxity and how that may affect sexual functioning while FSDS-R relates to a respondents' feelings of sexual activity-related distress based on a 13-item questionnaire.

While neither VALI or FSDS-R scores were statistically different between active and sham arms in VIVEVE I, we do not view this as problematic as it relates to the proposed U.S.-based controlled study as they have no cross-over relevance to the expected primary (FSFI) endpoint for VIVEVE II (i.e. – upcoming study). We think VIVE likely included VALI and FSDS-R in VIVEVE I in order to stack in additional metrics so as to offer other options in the event FSFI and/or VSQ failed to show statistical significance.

SAFETY

Similar to the two prior studies, safety was considered excellent in VIVEVE I. All 174 (117 active, 57 sham) enrolled and randomized patients underwent a safety evaluation. There was no statistical difference in safety measures between the two arms;

- treatment-emergent adverse events; 38 (32.5%) active vs. 20 (35.1%) sham
- related treatment-emergent adverse events; 13 (11.1%) active vs. 7 (12.3%) sham
- serious treatment-emergent adverse events; 0 (0.0%) active vs. 1 (1.8%) sham

Valuation

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 412k facelift procedures and 50k surgical vaginal rejuvenation procedures performed in 2015. Using these as rough proxies for the respective U.S. markets for non-invasive skin tightening and vaginal tightening, implies the former is ~8x 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 non-invasive facial and body 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 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.

In 2016 VIVE averaged a console unit placement rate of approximately 15 per month. Utilization, per management's comments on the Q4 2016 call, has averaged approximately 1.5x per console per month. We think revenue accelerates further in 2017 on the backs of several catalysts including;

- U.S. sales: commenced in late 2016. U.S. sales are already off to a strong start in 2017 and expected to accelerate throughout the year. VIVE put their initial sales force in place in late 2016 and expects to incrementally add reps during this year
- VIVEVE I data: showing statistically significant efficacy of Viveve treatment on sexual function and vaginal laxity. Data was published in the February 2017 issue of the Journal of Sexual Medicine. Expect marketing programs in both the OUS and U.S. markets to leverage this
- Recent key OUS launches: recently launched in Brazil and S. Korea the #1 and #2, respectively, markets for total number of cosmetic/aesthetic procedures performed. In addition, Brazil ranks #2 (to only the U.S.) in vaginal rejuvenation. Label just expanded in S. Korea to include vaginal laxity could further catalyze demand in that country
- Additional regulatory approvals/launches: at the beginning of 2016 VIVE had regulatory approval in 22 countries. Today that number is 54 countries and regulatory approval is pending in another 14 countries
- Expect to see substantial increase in consumable sales from incremental increase in utilization but more significantly from increase in installed base (which grew from 42 at the end of 2015 to 257 at the end of Q1 2017)

For the remainder of 2017 we currently model a unit placement rate of about 22 per month and estimate consumable sales will average ~1.6 per installed consoles per month.

We think that if all goes well, in 2018 – 2019 the U.S. label could possibly be expanded to a more substantive 'treatment of vaginal tissue to improve sexual function' indication. 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 our estimated 2017 unit placement rate. As it is now, we maintain a ~18 - 20 average per month console unit placement rate from 2018 to 2024. This results in a total installed base of more than 2,500 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 improvement in sexual function and 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 ~1.5x per month to approximately 5x per month at year 2025.

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 current pricing of ~$36k (net) for OUS sales and ~$60k for U.S. console sales. Treatment tips we peg at ~$360 - ~$400 sales price on average. As U.S. sales and utilization increase, so should the blended average selling prices and gross margins.

DCF Values VIVE at $11/share

We use a 10-year DCF model to value VIVE. Using the inputs discussed above, we have revenue growing from $7.1M in 2016 to $33.9M in 2020 and to approximately $95M in 2026 (for reference, Thermage's sales were $50M+ at second year after ThermaCool launch).

Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVE is valued at approximately $11/share. 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.

FINANCIAL MODEL

Viveve Medical, Inc

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018	2019	2020
Total Revenues	$7,141.0	$3,041.0	$3,259.1	$3,979.4	$4,538.1	$14,817.6	$21,364.5	$27,445.8	$33,902.9
YOY Growth	*393.5%*	*136.8%*	*109.5%*	*115.2%*	*85.1%*	*107.5%*	*44.2%*	*28.5%*	*23.5%*
Cost of Goods Sold	$4,612.0	$1,619.0	$1,740.2	$2,109.5	$2,402.0	$7,870.7	$10,250.1	$11,296.4	$11,940.5
Gross Income	$2,529.0	$1,422.0	$1,518.9	$1,869.9	$2,136.1	$6,946.9	$11,114.4	$16,149.4	$21,962.4
Gross Margin	*35.4%*	*46.8%*	*46.6%*	*47.0%*	*47.1%*	*46.9%*	*52.0%*	*58.8%*	*64.8%*
SG&A	$12,868.0	$5,450.0	$5,690.3	$5,897.5	$5,999.4	$23,037.2	$26,321.1	$29,751.3	$32,207.8
% SG&A	*180.2%*	*179.2%*	*174.6%*	*148.2%*	*132.2%*	*155.5%*	*123.2%*	*108.4%*	*95.0%*
R&D	$8,365.0	$2,388.0	$2,418.2	$2,483.1	$2,650.3	$9,939.6	$8,759.4	$6,230.2	$5,424.5
% R&D	*117.1%*	*78.5%*	*74.2%*	*62.4%*	*58.4%*	*67.1%*	*41.0%*	*22.7%*	*16.0%*
Operating Income	($18,704.0)	($6,416.0)	($6,589.6)	($6,510.7)	($6,513.5)	($26,029.9)	($23,966.1)	($19,832.0)	($15,669.9)
Operating Margin	*-261.9%*	*-211.0%*	*-202.2%*	*-163.6%*	*-143.5%*	*-175.7%*	*-112.2%*	*-72.3%*	*-46.2%*
Total Other Income (Expense)	($1,407.0)	($279.0)	($356.5)	($640.0)	($646.3)	($1,921.8)	($3,276.9)	($4,048.3)	($4,210.2)
Pre-Tax Income	($20,111.0)	($6,695.0)	($6,946.1)	($7,150.7)	($7,159.8)	($27,951.7)	($27,243.0)	($23,880.3)	($19,880.1)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income (continuing ops)	($20,111.0)	($6,695.0)	($6,946.1)	($7,150.7)	($7,159.8)	($27,951.7)	($27,243.0)	($23,880.3)	($19,880.1)
YOY Growth	*61.8%*	*82.1%*	*-44.1%*	*74.2%*	*34.7%*	*39.0%*	*-2.5%*	*-12.3%*	*-16.8%*
Net Margin	*-281.6%*	*-220.2%*	*-213.1%*	*-179.7%*	*-157.8%*	*-188.6%*	*-127.5%*	*-87.0%*	*-58.6%*
EPS (continuing ops)	($2.18)	($0.57)	($0.34)	($0.32)	($0.32)	($1.45)	($1.16)	($0.94)	($0.74)
YOY Growth	*-12.2%*	*7.1%*	*-86.5%*	*-41.7%*	*-51.5%*	*-33.7%*	*-19.6%*	*-19.6%*	*-21.4%*
Diluted Shares O/S	9,215	11,664	20,700	22,400	22,450	19,303	23,400	25,500	27,000

Brian Marckx, CFA

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APPENDIX

VIVEVE I Secondary Outcome Measures

Female Sexual Function Index (FSFI)
FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total score. It was developed for the specific purpose of assessing sexual functioning in clinical trials. These 19 items include: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items) and are scored from 0 to 5. The FSFI total score is a weighted average of the six domains with each contributing a maximum of six points to the total (maximum score of 36). Wiegel, Meston and Rosen demonstrated that a cutoff of 26.55 discriminates between women with and without sexual dysfunction.[3]

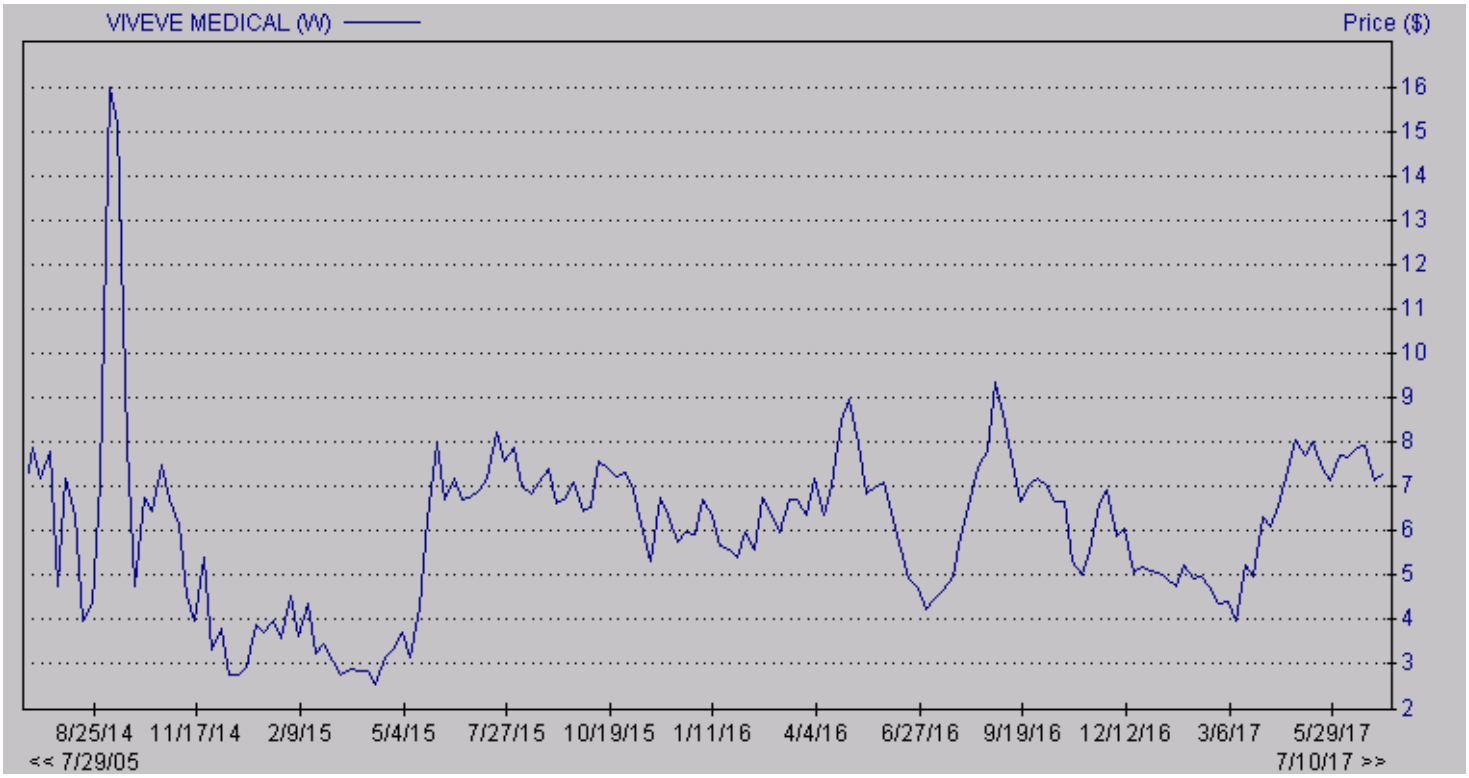
Female Sexual Distress Scale-Revised (FSDS-R)[Error! Bookmark not defined.]
FSDS-R is a patient-reported outcomes measure consisting of 13 items assessing different aspects of sexual activity-related distress in women. It has a high degree of discriminative sensitivity to distinguish between sexually dysfunctional and normal functional women and is sensitive to therapeutically inducted changes in function. Items are scored on a five-point Likert-type scale as never (0), rarely (1), occasionally (2), frequently (3), or always (4). A total score, ranging from 0 to 52, can be computed by adding all 13 item scores. Higher scores indicate higher levels of sexual distress. The provisional cut-off score of $\geq$15 reliably identifies over 90% of women who are currently experiencing sexually related personal distress (Derogatis et al 2008).

Vaginal Introitus Laxity Inventory (VALI)[4]
Vaginal Introitus Laxity Inventory 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).

[3] Wiegel M1, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. J Sex Marital Ther. 2005 Jan-Feb;31(1):1-20.
[4] Description taken verbatim from Viveve's Protocol Report for the VIVEVE 1 study

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