Zacks Small-Cap Research

August 21, 2017
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: Expect IDE Approval, Utilization Jumps

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 (08/21/17)	$5.12
Valuation	**$11.00**

OUTLOOK

One of the major operational items of interest since our Q1 update (May 19th) is an agreement with InControl Medical LLC (ICM), located outside Milwaukee, WI, for VIVE to serve as exclusive distributor of that company's innovative incontinence therapy devices to U.S. healthcare providers Importantly, per management's comments on the call, the call points for ICM's products are the same as VIVE's existing target customers. As such, ICM's products should provide a relatively seamless add-to-the-bag opportunity for Viveve's direct reps.
The other noteworthy update relates to the VIVEVE II clinical study. Management noted on the Q2 call that, since their May update, they completed the ex vivo study (which was requested by FDA late in Q1) and met with FDA on July 18th for feedback on the preclinical work aimed at supporting their IDE application. Management further commented that results of the ex vivo study were "extremely good", that their meeting with FDA "was very successful" and that they believe their preclinical protocol will be acceptable by FDA. Assuming positive feedback from FDA on the preclinical tissue studies, VIVE expects to resubmit the IDE by the end of Q3. Their expected timeline for commencement of VIVEVE II continues to be by current year-end.

SUMMARY DATA

52-Week High	**$11.16**
52-Week Low	**$3.75**
One-Year Return (%)	**-31.84**
Beta	**-0.43**
Average Daily Volume (sh)	**202,244**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$99**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**62**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**54.6**
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	3073 A	3707 E	4958 E	14779 E
2018					25163 E
2019					32812 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	-$0.54 A	-$0.43 E	-$0.46 E	-$1.97 E
2018					-$1.38 E
2019					-1.11 E

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW…

Q2 Results: *Jump In Utilization, OUS Pipeline, U.S. Sales Force Growth Bodes Well for 2H. VIVEVE II On-Track For Q4…*

Viveve reported Q2 financial results and provided a business update. Management also reiterated 2017 revenue guidance of $14M to $16M (implying growth of 96% - 124%). Gross margin is also expected to show strong improvement versus 2016.

Total revenue, of $3.1M, increased 98% yoy but was up just 1% from Q1 2017. It was also about 6% lower than our $3.3M estimate. The 45 consoles sold in Q2 were lower than the 52 we were looking for, although still up from 40 in the comparable prior-year period and 42 in Q1 of this year. While VIVE does not disclose the break-out of revenue from consoles versus that from consumables (i.e. treatment tips), we think the miss to our number and meager sequential growth was a result of lower than anticipated U.S. console sales.

On the much more encouraging side was very strong treatment tip unit sales – the ~3,300 tips sold in the period were a record and 50% higher than the prior best (2,200 in Q1 2017). Most of the treatment tips were sold internationally – which represents ~80% of the 304-unit total installed base. But with tips' sales price only a fraction of that of the consoles', the beat in consumables unit sales versus our 1,300 estimate was not enough to offset the miss in console placements. Reassuring, however, is management commenting on the call that utilization rates are rising substantially which they relate to sales and marketing efforts towards educating physicians on the benefits of treatment with Geneveve. We have since made upward revisions to our forecasted utilization rates and related consumable revenue.

Of the 45 consoles sold in Q2, 27 were sold in the U.S. – which is down from 29 in Q1 2017 and lower than our 35 estimate. As a reminder, the official domestic launch happened at the end of January 2017. Given that Viveve sells direct in the U.S., they benefit from a much higher average sales price as compared to OUS (distributor-based pricing) sales. So the 8-unit difference versus our estimate and 2-unit sequential decline in U.S. placements explains all of the total revenue miss to our number as well as the flattish sequential growth – both of which were partially offset by the very strong consumables sales. But, the rapid growth of the sales force - from ten in May to 23 today, is expected to accelerate both domestic console placements and utilization. And as U.S. sales grow as a percentage of total revenue, gross margin should benefit as well.

Meanwhile the 18 OUS console placements were dead-on with our 18-unit estimate – while this is down from 40 in Q2 2016, it is up from 13 in Q1 of this year. We continue to look for this to ramp in the second half of 2017, however. Dynamic Medical Technologies, their distributor in China, is required to purchase at least 75 units this year – the indication on the Q2 call was that most (perhaps all) of this minimum remains outstanding. Additionally, the 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, regulatory clearance in several more countries could materialize between now and the end of the year.

The lower than anticipated U.S. sales looks to have also negatively impacted gross margin, which came in at 40.2%. While up from 34.3% in Q2 2016 (when 100% of revenue was OUS), it is down from 46.8% in Q1 2017 and meaningfully lower than our 46.6% estimate. But, management is guiding for strong GM improvement in 2H which we think is highly achievable given expectations of outsized proportional growth of U.S. sales as well as from (relatively high-margin) consumables, the latter driven by the aforementioned accelerating utilization.

System placements continue to drive the vast majority of the top line (we estimate consoles currently contribute ~75% of total revenue), although we continue to expect consumables (i.e. treatment tips) sales to accelerate from a growing installed base (currently at 304) and increased utilization as a result of greater awareness, including clinical evidence, supporting the benefits of Viveve System therapy.

Cash

VIVE used in operating activities was $9.3M and $17.3M ($9.2M and $15.4M, ex-changes in working capital) in Q2 and 1H 2017. Cash balance, recently bolstered by the equity raise in March that netted $31.4M and $9.2M in net proceeds from a new debt facility that closed in May, was $31.0M at Q2 quarter-end. Management expects this to be sufficient to fund operations for at least the next 12 months – which, based on their current timelines, means current cash balance should be sufficient to fund operations through at least the beginning, and possibly to the conclusion of the U.S.-based VIVEVE II 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 $25M of revenue in 2018 and current market capitalization is approximately $100M (and our target price implies market cap of over $200M).

Operational Update: ICM Distribution, Ex Vivo Study Results "Extremely Good", IDE Approval Expected …

One of the major operational items of interest since our Q1 update (May 19th) is an **agreement with InControl Medical LLC** (ICM), located outside Milwaukee, WI, for VIVE to serve as exclusive distributor of that company's innovative incontinence therapy devices to U.S. healthcare providers. ICM's product line, sold under the apexM, InTone, InToneMV and Intensity names, mainly focus on female incontinence and pelvic floor muscle stimulation. InTone and InToneMV are used to treat incontinence and require a doctor's prescription. apexM is also an incontinence device but is available without a prescription. ICM lists apexM for $399 (currently discounted to $299) on their website. Intensity is used to help strengthen pelvic floor muscles, does not require a prescription and is listed for $179. Per the FDA's medical device database, ICM's products received regulatory clearance via 510(k) between January 2014 and April 2015.

Relative to the market size, VIVE notes that, based on third-party research, there are four million women who are actively seeking therapy related to these conditions. Importantly, per management's comments on the call, the call points for ICM's products are the same as VIVE's existing target customers. As such, ICM's products should provide a relatively seamless add-to-the-bag opportunity for Viveve's direct reps. And while we have little insight into how substantial the revenue opportunity may be, given that the agreement is not expected to result in any meaningful incremental cost to VIVE (aside from a $2.5M equity investment into ICM), this could result in accelerated improvement in operating loss (i.e. little financial downside risk). VIVE's reps are now in-process of training on the ICM product line and expect to begin selling the devices in early September.

The other noteworthy update relates to the **VIVEVE II clinical study**. Management noted on the Q2 call that, since their May update, they completed the ex vivo study (which was requested by FDA late in Q1) and met with FDA on July 18th for feedback on the preclinical work aimed at supporting their IDE application.

As a reminder, VIVE has been seeking IDE approval to conduct a U.S. clinical trial ("VIVEVE II") to support an eventual regulatory filing seeking clearance (via de novo 510(k)) for an indication related to improvement in sexual function. VIVE initially submitted the IDE to FDA in September 2016. Since then the agency has come back with two rounds of additional questions – the most recent of which was in May when FDA requested the company 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). While the delays have been disappointing, VIVE has been judicious in responding to the additional requests. In fact, their timelines for resubmitting the IDE remain on-track with what their expectations were in May.

Management further commented on the Q2 call that results of the ex vivo study (which focused on the safety of radio frequency energy on tissue damaged by vaginal birth) were "extremely good", that their meeting with FDA "was very successful" and that they believe their preclinical protocol will be acceptable by FDA. Assuming positive feedback from FDA on the preclinical tissue studies, VIVE expects to resubmit the IDE by the end of Q3 (~late September). Their expected timeline for commencement of VIVEVE II (assuming FDA approves the IDE), which includes a cushion for the possibility of additional questions from FDA, continues to be by current year-end. However, perhaps conservatively, we do not model the study to begin until 1H 2018 which accounts for the potential for additional delays in IDE approval as well as a subsequent longer runway for IRB approvals and related trial-site preparations.

Our Near-Term Outlook:

We think certain 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 during the remainder of 2017. S. Korea, where the Viveve System recently received a vaginal laxity indication, is an area to keep a particularly keen eye on. With regulatory clearance in 54 countries and others 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 40% over just the last 6 months - from 217 at YE2016 to 304 as of the close of Q2 2017).

Indication for Use:	No. of Countries:
General Surgical procedures for coagulation and hemostasis	2 (including the U.S.)
For treatment of vaginal laxity	37
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	14
For vaginal rejuvenation	1

Relative to the U.S., while Q2 console placements were lower than our estimate, VIVE already has more than 50 units in the domestic market and we expect the placement rate to accelerate. With 23 reps now onboard, the size of the U.S. sales force has more than doubled over the last three months and tripled since January and should be a catalyst in driving domestic (higher-margin) revenue.

A sexual function indication could be a significant catalyst in driving U.S. sales but will not happen before 2017 year-end. 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 published results of the VIVEVE study in the February 2017 issue of the Journal of Sexual Medicine. That should help buoy U.S. sales growth.

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 their device in Brazil for "the treatment of the vaginal introitus, after childbirth, to improve sexual function". While management noted on the Q2 call that political turmoil and a strike by customs personnel have been headwinds, we think Brazil offers substantial near-term revenue potential given that it ranks #2 to only the U.S. in not only vaginal rejuvenation but in total number of all types of cosmetic/aesthetic procedures.

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 that country in August 2016. The vaginal laxity indication (May 2017) provided 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 there as management noted on recent earnings calls that sales in S. Korea have been brisk.

2017 Guidance: 100%+ Revenue Growth, Expanding Gross Margins…

On the Q2 call management reiterated 2017 revenue guidance of $14M to $16M (implying growth of 96% - 124%). And while not offering geographically-itemized revenue guidance, we think much of this anticipated ~100%+ revenue growth is expected to come from accelerating demand in the U.S. Management has indicated that the U.S. launch drew strong interest and they appear to be looking to capitalize on this as they quickly ramped the size of the sales force. Meanwhile, with much (most, or all?) of Dynamic Medical Technologies' 75-unit quota still outstanding, coupled with other international catalysts (such as uptake in S. Korea, Brazil and regulatory clearances in other countries) OUS console sales should have a minimum of ~150% pent-up growth already in the barrel for Q3/Q4.

U.S. VIVEVE II (Sexual Function) Study Update: Ex Vivo Study Results "Extremely Good", Expecting IDE Approval…

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 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 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 on the Q2 call (August) that, since their May update, they completed the ex vivo study and met with FDA on July 18th for feedback on the preclinical work aimed at supporting their IDE application. Management further commented on the Q2 call that results of the ex vivo study were "extremely good", that their meeting with FDA "was very successful" and that they believe their preclinical protocol will be acceptable by FDA. Assuming positive feedback from FDA on the preclinical tissue studies, VIVE expects to resubmit their IDE by the end of Q3 (~late September). Their expected timeline for commencement of VIVEVE II (assuming FDA approves the IDE), which includes a cushion for the possibility of additional questions from FDA, continues to be by current year-end. However, perhaps conservatively, we do not model the study to begin until 1H 2018 which accounts for the potential for additional delays in IDE approval as well as a subsequent runway for IRB approvals and related trial-site preparations.

While the delays have been a disappointment, particularly as VIVE had at one point hoped to begin VIVEVE II in Q1 2017, it may prove to be relatively meaningless, particularly given that there are no direct competitors on the horizon seeking a claim as robust as that of Geneveve in the U.S.

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,

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

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).

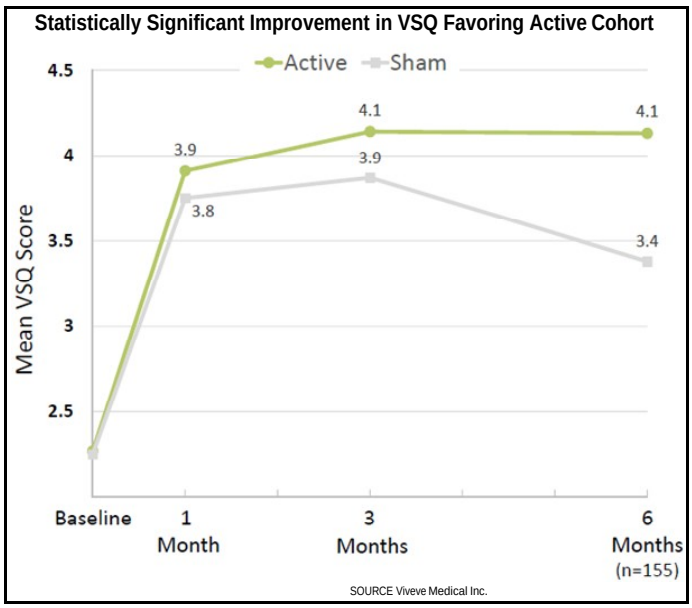
Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity

					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

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.



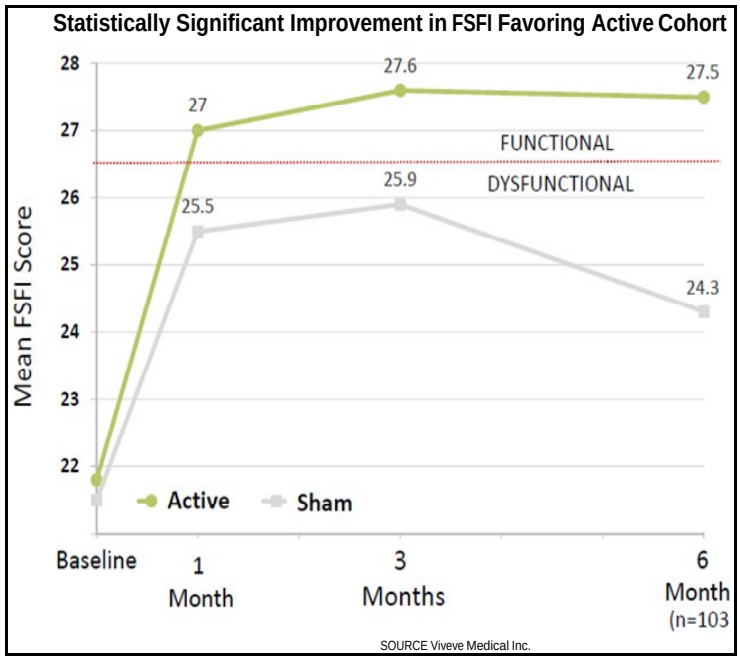
FSFI

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 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.

[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.

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 noted 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 and utilization (based on number of treatment tips sold per console) averaged 1.6 tips per console per month. Utilization has substantially increased, however, and through the first six months of 2017, averaged 3.2 tips per console per month. We think revenue accelerates further 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 has tripled the size of it since early 2017
- 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 several others
- Expect to see substantial increase in consumable sales from incremental increase in utilization but more significantly from increase in installed base (which grew from 217 at the end of 2016 to 304 at the end of Q2 2017)

For the remainder of 2017 we model a unit placement rate of about 25 per month and estimate consumable sales will average ~2.7 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 ~1.6x per month (average in 2016) 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	Q2A	Q3E	Q4E	2017 E	2018	2019	2020
Total Revenues	$7,141.0	$3,041.0	$3,073.2	$3,707.0	$4,957.7	$14,778.8	$25,162.9	$32,811.6	$39,861.1
YOY Growth	*393.5%*	*136.8%*	*97.5%*	*100.5%*	*102.2%*	*107.0%*	*70.3%*	*30.4%*	*21.5%*
Cost of Goods Sold	$4,612.0	$1,619.0	$1,837.0	$1,997.4	$2,692.0	$8,145.4	$11,978.8	$13,342.7	$13,906.0
Gross Income	$2,529.0	$1,422.0	$1,236.2	$1,709.6	$2,265.7	$6,633.5	$13,184.1	$19,468.9	$25,955.1
Gross Margin	*35.4%*	*46.8%*	*40.2%*	*46.1%*	*45.7%*	*44.9%*	*52.4%*	*59.3%*	*65.1%*
SG&A	$12,868.0	$5,450.0	$6,862.0	$6,861.6	$7,743.9	$26,917.5	$31,629.7	$36,158.4	$40,738.0
% SG&A	*180.2%*	*179.2%*	*223.3%*	*185.1%*	*156.2%*	*182.1%*	*125.7%*	*110.2%*	*102.2%*
R&D	$8,365.0	$2,388.0	$3,440.0	$2,580.0	$2,895.3	$11,303.3	$10,518.1	$7,448.2	$6,377.8
% R&D	*117.1%*	*78.5%*	*74.2%*	*69.6%*	*58.4%*	*76.5%*	*41.8%*	*22.7%*	*16.0%*
Operating Income	($18,704.0)	($6,416.0)	($9,065.8)	($7,732.0)	($8,373.5)	($31,587.3)	($28,963.7)	($24,137.7)	($21,160.7)
Operating Margin	*-261.9%*	*-211.0%*	*-295.0%*	*-208.6%*	*-168.9%*	*-213.7%*	*-115.1%*	*-73.6%*	*-53.1%*
Total Other Income (Expense)	($1,407.0)	($279.0)	($1,362.0)	($640.0)	($646.3)	($2,927.3)	($3,276.9)	($4,048.3)	($4,210.2)
Pre-Tax Income	($20,111.0)	($6,695.0)	($10,427.8)	($8,372.0)	($9,019.7)	($34,514.6)	($32,240.6)	($28,186.0)	($25,370.9)
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)	($10,427.8)	($8,372.0)	($9,019.7)	($34,514.6)	($32,240.6)	($28,186.0)	($25,370.9)
YOY Growth	*61.8%*	*82.1%*	*-16.1%*	*103.9%*	*69.7%*	*71.6%*	*-6.6%*	*-12.6%*	*-10.0%*
Net Margin	*-281.6%*	*-220.2%*	*-339.3%*	*-225.8%*	*-181.9%*	*-233.5%*	*-128.1%*	*-85.9%*	*-63.6%*
EPS (continuing ops)	($2.18)	($0.57)	($0.54)	($0.43)	($0.46)	($1.97)	($1.38)	($1.11)	($0.94)
YOY Growth	*-12.2%*	*7.1%*	*-78.3%*	*-21.4%*	*-29.7%*	*-9.6%*	*-30.2%*	*-19.8%*	*-15.0%*
Diluted Shares O/S	9,215	11,664	19,373	19,450	19,500	17,497	23,400	25,500	27,000

Brian Marckx, CFA

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

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]

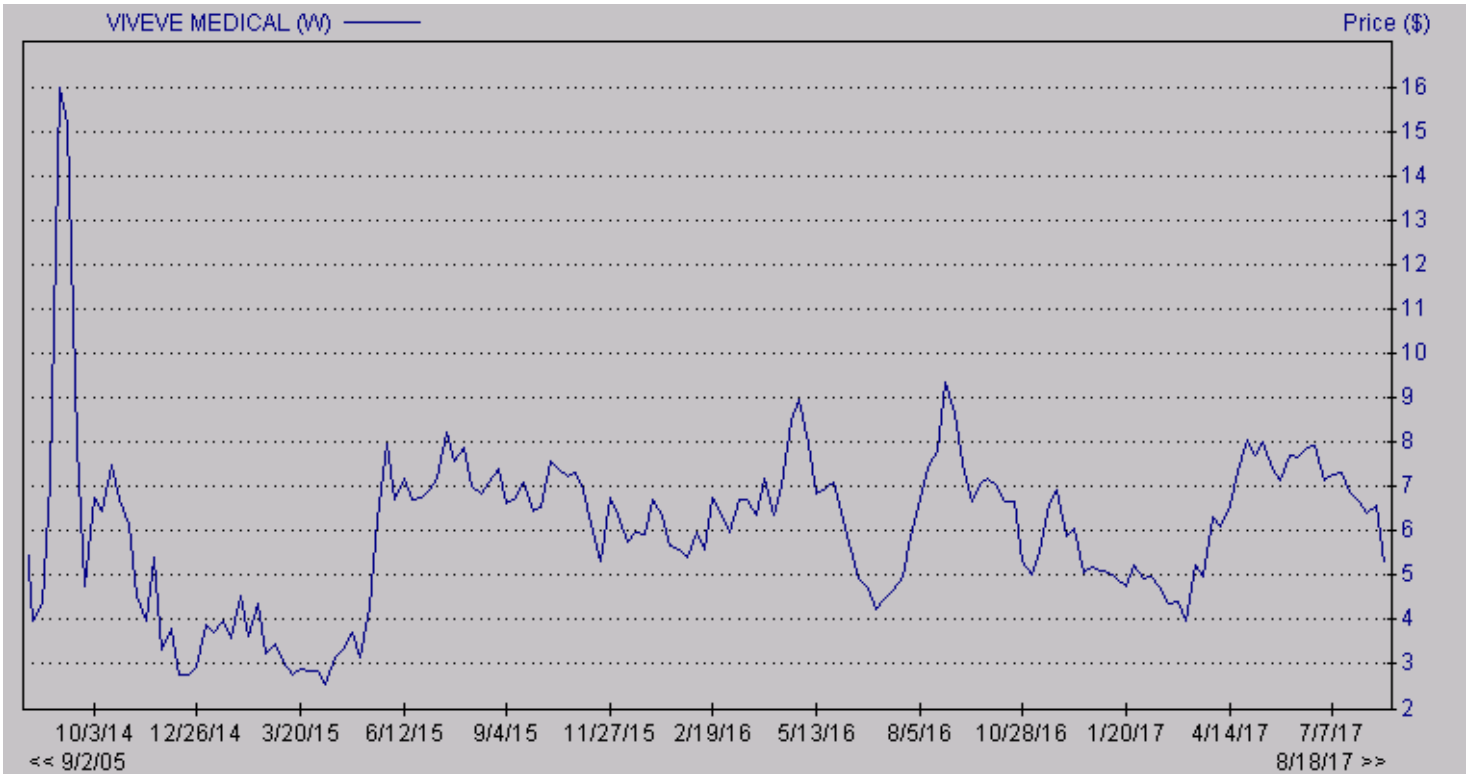
Female Sexual Distress Scale-Revised (FSDS-R)[Error! Bookmark not defined.]
FSDS-R is a patient-reported outcomes measure consisting of 13 items assessing different aspects of sexual activity-related distress in women. It has a high degree of discriminative sensitivity to distinguish between sexually 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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.