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Viveve Medical (VIVE-NASDAQ)

VIVE: Q3 U.S. Console Sales Jump 74% Q-o-Q as Domestic Adoption Gains Traction

We use a 10-year DCF model to value VIVE. We have revenue growing from $7.1M in 2016 to $36M 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 (11/15/17)	$4.76
Valuation	**$11.00**

OUTLOOK

Rapid growth of the domestic sales force, from ten in May to 23 today, has been a catalyst in driving U.S. sales. So apparently has the breadth of clinical data supporting the use of Geneveve, which management indicated has facilitated initial adoption as well as played an instrumental role in taking share from competing products. The 47 U.S. console placements in Q3 was, by-far, the strongest since the domestic launch in Q4 2016 and up from 27 in Q2 and 29 in Q1 of this year. VIVE will build on this early momentum in the U.S. and expects to incrementally increase the size of the sales force, including adding reps during the remainder of 2017.

Meanwhile OUS console placements were relatively weak and appear largely related to certain headwinds in China. But, while sales in China may not expand quite as rapidly as we had previously anticipated (DMT was to purchase a minimum of 109 systems in 2018, although that may not be met either), that disappointment may be more than offset by greater than expected U.S. sales – which also provide the additional benefit of bigger margins. And given VIVE's rapid geographic expansion, other international territories continue to hold significant promise. This includes Brazil, S. Korea and Taiwan.

SUMMARY DATA

52-Week High	**$11.16**
52-Week Low	**$3.75**
One-Year Return (%)	**-17.71**
Beta	**-0.59**
Average Daily Volume (sh)	**189,370**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**70.9**
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	4070 A	5210 E	15397 E
2018					23046 E
2019					29721 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	-$0.50 A	-$0.48 E	-$2.07 E
2018					-$1.53 E
2019					-1.25 E

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

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WHAT'S NEW…

Q3 Results: *U.S. Adoption Gaining Traction As Domestic Console Sales Jump 74% Sequentially…*

Viveve reported Q3 results and provided a business update. Management also narrowed the range of their previously issued full-year 2017 revenue guidance by raising the low end. **Guidance moved from $14M - $16M to $15M - $16M.** Importantly, while OUS system placements have been softer than anticipated, that has been more than offset by a greater than expected ramp in U.S. sales – which also provide the additional benefit of much higher margins.

Total revenue, of $4.1M, increased 120% yoy and 32% from Q2. It was also about 10% better than our pre-Q3 preannouncement estimate of $3.7M. Our revenue figure assumed 60 console placements, with 26 in the U.S. and 34 OUS. Actual Q3 consoles sold was 60, but with a much higher percentage placed in the U.S. than we had forecast. 47 of the 60 consoles sold in the quarter were placed in the U.S. – U.S. (direct) sales benefit from significantly higher pricing vs. international (third-party distributor sales) sales, which explains most of the beat to our total revenue and gross margin estimates. Meanwhile, as expected, InControl Medical LLC product sales contributed little in Q3 following their launch in September, but could be a more significant addition going forward.

Q3 set several new records including number of consoles sold, total revenue and gross margin. Treatment tip sales, at 2,724, were also relatively strong and the second-highest on record. We continue to model sequential growth in all of these categories and currently model Q4 revenue of $5.2M, implying yoy and sequential growth of 113% and 28%.

Rapid growth of the domestic sales force, from ten in May to 23 today, has been a catalyst in driving **U.S. sales**. So apparently has the breadth of clinical data supporting the use of Geneveve, which management indicated has facilitated initial adoption as well as played an instrumental role in taking share from competing products. The 47 U.S. console placements in Q3 was, by-far, the strongest since the domestic launch in Q4 2016 and up from 27 in Q2 and 29 in Q1 of this year. VIVE will build on this early momentum in the U.S. and expects to incrementally increase the size of the sales force, including adding reps during the remainder of 2017.

Meanwhile the 13 **OUS console placements** were relatively weak, down from 47 in the comparable prior year period and lower than the 18 sold in Q2 of this year. We had expected 18 OUS placements in Q3 and thought this would accelerate going into the final quarter of 2017 as a result of Dynamic Medical Technologies' (DMT) minimum purchase quota, most of which we believed was still outstanding. Per terms of the agreement with VIVE's Asian distributor, DMT was to purchase at least 75 units in 2017 (in order to maintain distribution exclusivity). However, based on management's comments on the Q3 earnings call (which we missed due to a timing conflict), certain headwinds in China likely means that quota will not be met. Specifically, the **possibility that China FDA (CFDA) will require regulatory approval** of RF medical devices has created some hesitancy among healthcare providers to purchase the Viveve system. Another hindrance to uptake in China that management cited was slowing sales from DMT's sub-distributors.

While it is unclear whether the CFDA-related issue may continue to be a headwind in the near-term, DMT indicated that they are addressing the sub-distributor issue by hiring direct (i.e. direct to DMT) sales people. In the meantime, in order to avoid any long-term regulatory-related hangover, VIVE will seek CFDA approval of their system, the cost of which will be split with DMT. But while sales in China may not expand quite as rapidly as we had previously anticipated (DMT was to purchase a minimum of 109 systems in 2018, although that may not be met either), that disappointment may be more than offset by greater than expected U.S. sales – which, again, provide the additional benefit of bigger margins.

And given VIVE's **rapid geographic expansion**, other international territories continue to hold significant promise. This includes Brazil, S. Korea and Taiwan. Brazil and S. Korea consistently rank among the top in the world in number aesthetic-related procedures performed each year. In October the Viveve system received approval in Taiwan, a country which DMT could represent up to 100 consoles worth of sales. We could see initial placements in Taiwan in Q4. The Viveve system has now been approved in 60 countries, nine of which granted approval since the beginning of 2017. Initial launch as well as additional regulatory approvals could happen in several new territories throughout 2018 and provide another potential tailwind to OUS sales.

As it relates to **consumables**, the 2,724 treatment tips sold in Q3 were down about 18% from the (record) 3,300 sold in Q2 but higher than every other period. Through the first nine months of the year, we calculate average utilization was approximately 3 treatment tips per installed unit per month – which was just about dead-on with what

we had been modeling. We are modeling slightly lower utilization (~2.5x) going forward, which almost exclusively relates to the assumption that the console placement rate steepens slightly faster than that of consumables sales throughout 2018 (due to a lag between hardware placement and a subsequent ramp in utilization).

Relative to **gross margin**, the outsized U.S. sales helped push GM to 49.4%, up 1,200 and 910 basis points from the year- and quarter-earlier periods, respectively, and better than our 47.5% estimate. For the full-year, we model GM of 46.6%, which compares to 35.4% in 2016. We think GM has some incremental room to widen as well and expect volume-related scaling as well as related efficiencies to benefit COGS throughout 2018.

Cash

Cash used in operating activities was $8.9M and $26.3M ($8.2M and $24.1M, ex-changes in working capital) in the three and nine months ending 9/30/2017. Cash balance was $19.2M at the end of Q3, which represents approximately six months' worth of operating capital at the current burn rate. Additional liquidity could come from $10M yet-to-be borrowed under the CRG loan which is available prior to 9/17/18 and contingent upon 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 $23M of revenue in 2018 and current market capitalization is approximately $92M. VIVE may also look to issue additional securities. On November 8th they filed an S-3 registration statement related to a shelf offering to sell up to $50M in securities, including up to $25M of common stock.

Operational Update: More Questions from FDA But We Like Chances of IDE Approval, ICM Contribution Expected Soon…

InControl Medical's product line launched via Viveve's domestic sales force in September (i.e. late in Q3) and, as expected, contributed little revenue in the most recent quarter. As a reminder, earlier this year Viveve announced 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 has noted 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, 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 were trained on the ICM product line and began selling the devices in early September.

While there was little contribution from ICM in Q3, based on management's comments on the call, early market feedback appears to be positive. Management noted that the ICM products were "met with a great reception both on the part of our sales team as well as our customers". As such, we could see a more significant revenue stream from these products going forward.

The other noteworthy update relates to the **VIVEVE II clinical study** and VIVE's quest for IDE approval to begin the study. As a reminder, late in Q1 FDA requested that the company conduct and submit results of an ex vivo tissue study to address certain safety/tolerability-related questions that the agency had. On the Q2 call (August) management noted that they had since submitted that data and met with FDA around mid-July for feedback on the preclinical work aimed at supporting their IDE application.

Then in late-September VIVE received a request from FDA that they do additional safety testing related to "safety testing to access the tissue temperature time history in relation of histopathology and the potential effects on vaginal and surrounding tissues of RF energy administration." Essentially, FDA just wants to make sure the heat from Viveve's system is safe and does not damage tissue. Why the agency is requesting so many hoop-jumps is unclear, particularly given that safety of the system has been demonstrated in previous clinical studies (including the U.S.-based VIVEVE I study) as well as in ever-how-many thousands of patients. We think, based on the

significant history of safe use of the device, coupled with the "extremely good" results of the ex vivo study (which focused on the safety of radio frequency energy on tissue damaged by vaginal birth), that IDE approval will eventually be granted.

VIVE submitted proposed protocol of an in vivo sheep study to FDA on October 18th. If deemed acceptable, the company believes they can complete the study in short-order and, if all the stars align correctly, resubmit the IDE and **be in a position to start VIVEVE II in Q1 2018. As we noted in our Q2 update, we had anticipated that there might be additional delays and, as such, were not modeling this pivotal study to begin until 1H 2018 anyway – so this new development has little effect on our forecasts.**

Our Near-Term Outlook:

While China may not be as significant a market, in at least the near-term, as we might have previously hoped, we think certain other high-potential territories will continue to push international sales higher. Brazil, S. Korea and Taiwan, along with regulatory clearance and launch in more countries, should be meaningful contributors to revenue growth. 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 60 countries and others that could come online soon, the geographic footprint continues to rapidly grow. Additionally, we expect to see substantial increase in consumable sales as a result of growth in the installed base (which has increased 68% over just the last 9 months - from 217 at YE2016 to 364 as of the close of Q3 2017).

Indication for Use:	No. of Countries:
General surgical procedures for electrocoagulation and hemostasis	3 (including the U.S.)
Treatment of vaginal laxity	41
Treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	15
Vaginal rejuvenation	1

Relative to the U.S., while Q2 console placements were lower than our estimate in that quarter, Q3 domestic sales were extraordinarily strong. VIVE now has over 100 units in the U.S. market and we expect the placement rate to accelerate on the backs of a growing sales force and leading clinical data. With 23 reps now onboard, the size of the U.S. sales force has tripled since January 2017 and is expected to expand to around 30 by January 2018. Management's most recent guidance is for **the sales force to continue to grow throughout next year and end the year at around 45 reps in the U.S. They also expect to have about 5 reps detailing in Canada.**

A sexual function indication could be a significant catalyst in driving U.S. sales but until then the current 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 (while reps are forbidden to market a sexual function indication, they are allowed to carry related literature, including the published data, and provide it as information if clinicians inquire). 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. Early indications are that this is helping to 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 Brazil is somewhat unique in that the aesthetic market is concentrated among only relatively few clinicians, we think the country offers substantial 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. While the concentrated nature of the Brazilian aesthetics market may mean a somewhat of a longer runway to entrenchment, once adopted we think the territory may offer a higher-utilization market than most other countries.

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.

Taiwan also offers significant opportunity. Regulatory clearance in Taiwan came on October of this year. VIVE's distribution partner believes Taiwan could represent a 100-unit market (possible $3M+ in consoles alone) over time.

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

On the Q3 call management raised the lower end of their previously issued 2017 revenue guidance, which now stands at $15M - $16M (changed from $14M - $16M previously). This implies yoy revenue growth of 96% - 137% for Q4 and 110% - 124% for the full-year. And while not offering geographically-itemized revenue guidance, we think much of the anticipated Q4 revenue growth is expected to come from accelerating demand in the U.S. The 74% qoq jump in U.S. console placements from Q3 to Q4 is clearly indicative of strong and growing interest and management indicated that they think this momentum continues through 2018.

Meanwhile, the international segment could prove a little more difficult to forecast. While VIVE's rapid geographic expansion could catalyze international sales, the China-related headwinds could be somewhat of an offset - although at least a portion of this may be addressed by DMT hiring their own sales force. Nonetheless, we will have to wait to see how likely it is that DMT can meet their 100+-unit quota in 2018. We are encouraged, however, that DMT agreed to split CFDA-related regulatory costs as it signals a commitment to VIVE.

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:**

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

- 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).

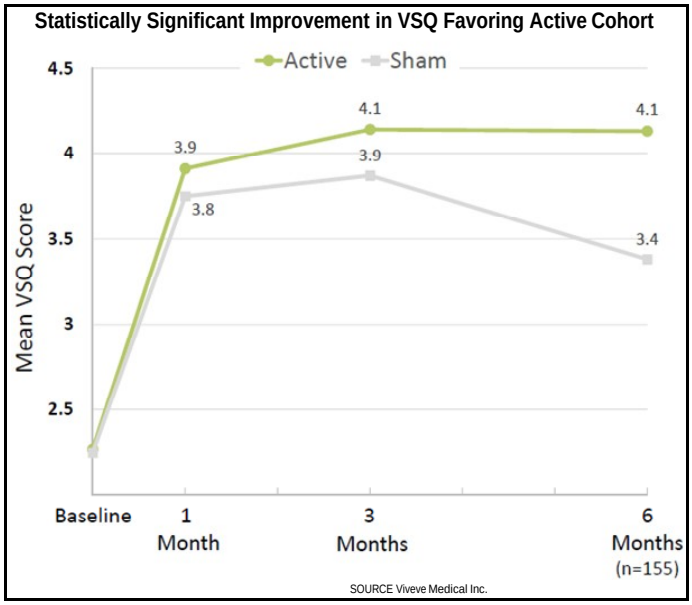
Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity

					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

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

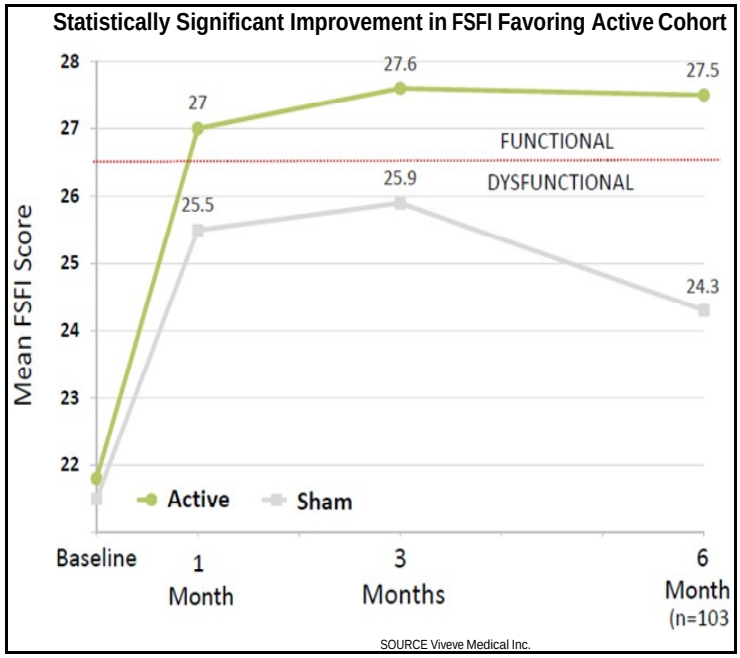
Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total 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.

[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.



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 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 nine of 2017, averaged 3.0 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. 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. Taiwan regulatory approval came in October 2017 and is expected to be another high-potential market
- Additional regulatory approvals/launches: at the beginning of 2016 VIVE had regulatory approval in 22 countries. Today that number is 60 countries and regulatory approval is pending in several others
- Expect to see substantial increase in consumable sales from increase in installed base (which grew from 217 at the end of 2016 to 364 at the end of Q3 2017)

Through the end of 2018 we model a unit placement rate of about 27 per month and estimate consumable sales will average ~2.5 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 near-term unit placement rate. As it is now, we assume a ~18 - 20 average per month console unit placement rate from 2019 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 ~$30k (net) for OUS sales and ~$66k for U.S. console sales. Treatment tips we peg at ~$250 - ~$300 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 $36.0M 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	Q3A	Q4E	2017 E	2018	2019	2020
Total Revenues	$7,141.0	$3,041.0	$3,076.0	$4,070.0	$5,210.0	$15,397.0	$23,046.2	$29,720.7	$36,000.2
YOY Growth	393.5%	136.8%	97.7%	120.1%	112.5%	115.6%	49.7%	29.0%	21.1%
Cost of Goods Sold	$4,612.0	$1,619.0	$1,837.0	$2,059.0	$2,714.0	$8,229.0	$11,019.4	$12,370.1	$12,873.2
Gross Income	$2,529.0	$1,422.0	$1,239.0	$2,011.0	$2,496.0	$7,168.0	$12,026.8	$17,350.6	$23,126.9
Gross Margin	35.4%	46.8%	40.3%	49.4%	47.9%	46.6%	52.2%	58.4%	64.2%
SG&A	$12,868.0	$5,450.0	$6,862.0	$7,369.0	$8,138.1	$27,819.1	$31,665.5	$35,991.8	$38,520.2
% SG&A	180.2%	179.2%	223.1%	181.1%	156.2%	180.7%	137.4%	121.1%	107.0%
R&D	$8,365.0	$2,388.0	$3,440.0	$3,464.0	$3,042.7	$12,334.7	$12,606.3	$8,797.3	$7,272.0
% R&D	117.1%	78.5%	111.8%	85.1%	58.4%	80.1%	54.7%	29.6%	20.2%
Operating Income	($18,704.0)	($6,416.0)	($9,063.0)	($8,822.0)	($8,684.7)	($32,985.7)	($32,244.9)	($27,438.5)	($22,665.3)
Operating Margin	-261.9%	-211.0%	-294.6%	-216.8%	-166.7%	-214.2%	-139.9%	-92.3%	-63.0%
Total Other Income (Expense)	($1,407.0)	($279.0)	($1,362.0)	($793.0)	($719.9)	($3,153.9)	($3,571.4)	($4,342.8)	($4,504.7)
Pre-Tax Income	($20,111.0)	($6,695.0)	($10,425.0)	($9,615.0)	($9,404.6)	($36,139.6)	($35,816.4)	($31,781.3)	($27,170.0)
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)	($10,425.0)	($9,615.0)	($9,404.6)	($36,139.6)	($35,816.4)	($31,781.3)	($27,170.0)
YOY Growth	61.8%	82.1%	-16.1%	134.2%	76.9%	79.7%	-0.9%	-11.3%	-14.5%
Net Margin	-281.6%	-220.2%	-338.9%	-236.2%	-180.5%	-234.7%	-155.4%	-106.9%	-75.5%
EPS (continuing ops)	($2.18)	($0.57)	($0.54)	($0.50)	($0.48)	($2.07)	($1.53)	($1.25)	($1.01)
YOY Growth	-12.2%	7.1%	-78.3%	-9.6%	-26.4%	-5.2%	-26.0%	-18.6%	-19.3%
Diluted Shares O/S	9,215	11,664	19,373	19,409	19,420	17,467	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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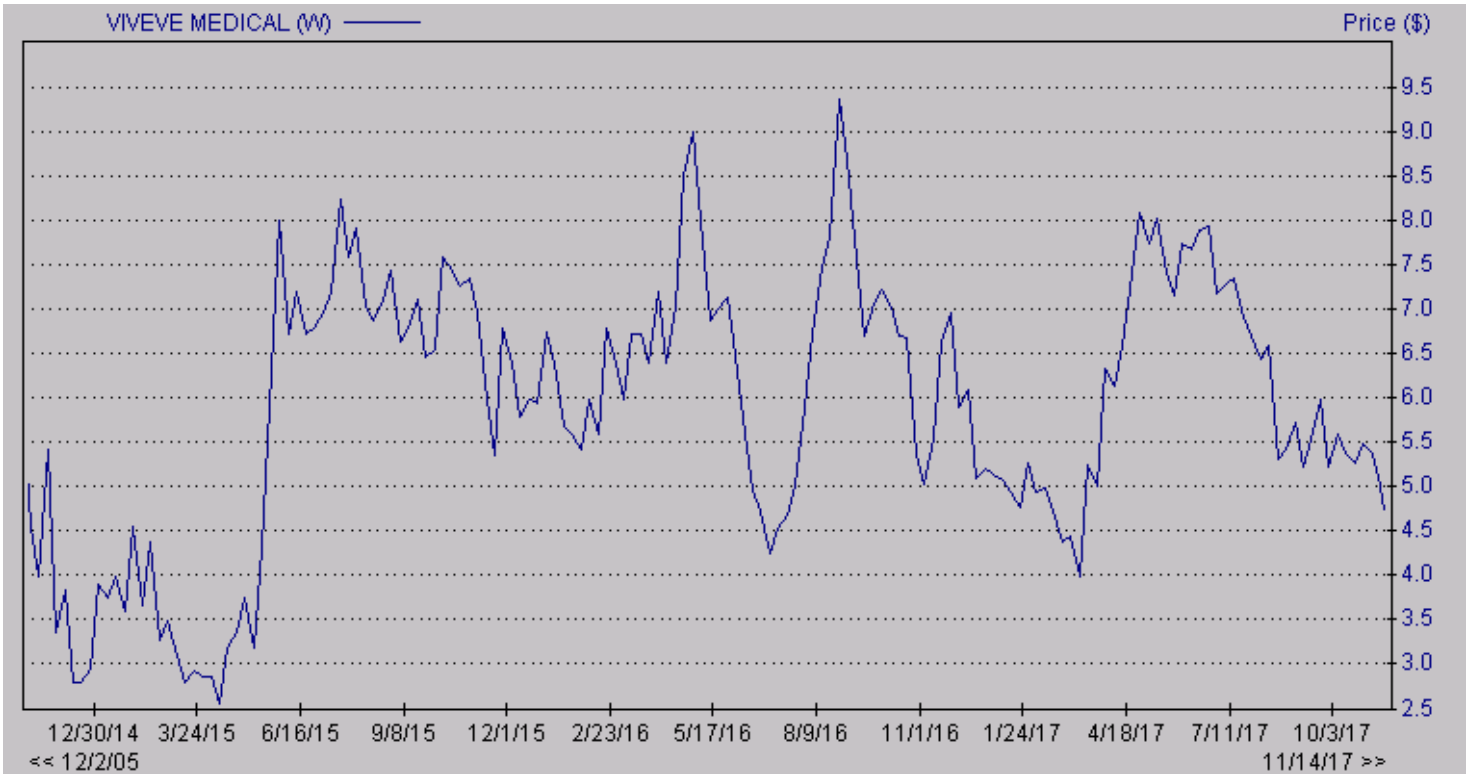

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