Zacks Small-Cap Research

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Viveve Medical (VIVE-NASDAQ)

VIVE: Huge Jump in Consumables, Guiding for ~100%+ Revenue Growth in 2017

We use a 10-year DCF model to value VIVMD. We have revenue growing from $7.1M in 2016 to $35.2M in 2020 and to approximately $97M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVMD is valued at approximately $11/share.

Current Price (02/21/17)	$4.73
Valuation	**$11.00**

OUTLOOK

VIVEVE I large, randomized clinical study results confirmed earlier findings that Viveve System significantly improves sexual function and reduces vaginal laxity. This marketing study, along with data from previous studies and the recent significantly beefed-up distribution is expected to help accelerate the roll-out of the Viveve System. Approval in Brazil and the U.S., which lead the world in vaginal rejuvenation procedures, came in October. S. Korea represents another high potential territory where Geneveve was recently approved for sale.
Viveve recently crossed what we characterize as a major milestone with the entry of the Viveve System into the U.S. market and the recent announcement last week that they have begun deployment of their initial domestic sales force. 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. Next steps are to conduct U.S. study in support of FDA filing for treatment of vaginal tissue to improve sexual function – study could initiate in 1H 2017.

SUMMARY DATA

52-Week High	**$9.38**
52-Week Low	**$4.10**
One-Year Return (%)	**-30.44**
Beta	**0.96**
Average Daily Volume (sh)	**36,131**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$51**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**54**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**28.0**
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	**N/A**
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	2759 E	3211 E	4049 E	4729 E	14748 E
2018					21976 E
2019					28596 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	-$0.56 E	-$0.62 E	-$0.62 E	-$0.56 E	-$2.35 E
2018					-$1.53 E
2019					-$1.14 E

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

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WHAT'S NEW…

Q4 Financial Results: *Huge Jump in Consumables, Guiding for ~100%+ Revenue Growth in 2017*

Viveve reported financial results for the fourth quarter ending December 31st and provided a business update. Management also provided initial 2017 revenue guidance of $14M - $16M, which implies growth of 96% - 124%, and also noted that they expect strong improvement in gross margin.

Relative to Q4, it marked the sixth straight quarter of sequential double-digit percentage increase in revenue growth. It also set new records in both the number of consoles and treatment tips sold. And while the 55 consoles sold was inline with our 55 estimate, the 1,300 treatment tips was not only more than twice the prior best (522 in Q3 2016), it was also well ahead of our 911 estimate. While the big jump in treatment tips likely represents some stocking (or otherwise lumpy ordering patterns), we remain very encouraged that this continues to show a significant ramp given that consumables sales are relatively high-margin and a rough proxy for utilization.

Total revenue increased 226% yoy and 33% sequentially to $2.45M, a new record and ahead of our $2.19M estimate by about 12%. Viveve system placements, which included 55 in Q4 (vs. our 55 estimate), up from 47 in Q3 (the prior record) and almost 62% more than the 34 sold in all of 2015, continue to drive the vast majority of the top-line. However, we continue to expect consumables (i.e. treatment tips) sales to accelerate from a growing installed base (currently at 217) and increased utilization as a result of greater awareness, including clinical evidence, supporting the benefits of Viveve System therapy. There were 1,300 treatment tips sold in Q4, compared to 216 in the comparable prior year period and 522 in Q3 of this year.

For the full year 2016, total revenue grew 394% to $7.14M with consoles increasing from 34 to 175 and the number of treatment tips sold growing from 615 to 2,698.

Q4 gross margin, at 39.0%, was ahead of our 36.2% estimate. Gross margin has shown fairly significant and regular widening - growing from 27.1% in Q1 2016 and from 31.9% in 2015 to 35.4% for the full year 2016. Management noted on the Q4 call that they expect GM to continue to expand due to a combination of increased average selling price (direct sales in U.S.) of both the treatment tips and consoles and through a reduction in COGS. We also expect gross margin to benefit as the company moves from initial launch and marketing strategies which include preferred pricing to KOL's to help build awareness to more account maintenance and growth related strategies, at which point there should be much less of a dilutive-pricing effect.

Cash
VIVE used approximately $5.9M ($5.4M ex-changes in working capital) and $18.1M ($18.4M ex-changes in working capital) of cash in the three and twelve months ending December 31, 2016. Cash balance stood at $8.1M at year-end which represents approximately four months of operating capital based on management's ~$2M/month anticipated burn rate throughout 2017.

Operational Update: U.S. Expected to Accelerate Revenue, Widen Margins. IDE Response Could Be Soon…

Management is guiding for 2017 revenue of $14M - $17M. While not offering geographically-itemized revenue guidance, we expect much of this anticipated ~100%+ revenue growth is attributable to an expected warm reception of the Viveve System in the U.S. We also think other high-potential territories which recently came online, including Brazil and S. Korea, along with regulatory clearance and launch in more countries to be meaningful contributors to revenue growth in 2017. 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 grew from 42 at the end of 2015 to 217 at the end of 2016).

Relative to the U.S., while Q4 included initial sales (seven consoles) of the Viveve System in this country, we expect 2017 to benefit from a much more significant contribution. Viveve has their initial U.S. sales team in place which they expect to incrementally add to later in the year. The U.S. sales team currently consists of eight direct reps which cover the entire U.S.(and part of Canada), two regional directors and an executive VP. VIVE expects to add an additional four to six reps in 2H 2017.

VIVE hopes to eventually gain FDA clearance of the Viveve System for an indication related to the improvement of sexual function - a randomized study for which an IDE application has been submitted and which could commence in the very near term (details below). In the meantime, the initial formal marketing message in the U.S. will be

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, we expect ‘off-label’ use related to reduction of vaginal laxity and for the improvement of sexual function – both of which were endpoints in the U.S. VIVEVE I study, to drive demand. The informal sexual function-related marketing message was significantly enhanced with the recently published results of the VIVEVE study in the February 2017 issue of the Journal of Sexual Medicine.

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

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

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

And another potential potent catalyst that recently came online was gaining regulatory approval (for general surgical procedures) of Geneveve in S. Korea in August 2016. S. Korea ranks third behind Brazil in total number of cosmetic/aesthetic procedures performed and ranks #1 in the number of procedures performed on a per-capita basis. And it appears Viveve’s system has already been well received in that country as management noted on recent earnings calls that sales in S. Korea have been brisk. Viveve is looking to further exploit the potential in S. Korea and submitted an application to expand the label to include the treatment of the vaginal introitus. Management noted on the Q4 call (February 2017) that they expect to hear back from S. Korean regulators related to this application in 1H 2017.

The Viveve System is now cleared for sale in 51 countries with the most recent regulatory approvals coming since the beginning of 2017 which included Colombia, Costa Rica and Malaysia. In addition, regulatory submissions in approximately 14 other countries are currently pending. Viveve has distribution agreements in place that cover approximately 67 countries.

U.S. VIVEVE II (Sexual Function) Study Update: Responding to add’l questions, IDE approval could be forthcoming…

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 call that FDA recently came back with a second round of questions related to the study protocol which they expect to respond to by the end of this month (i.e. February). Assuming timely approval of the IDE, this study could potentially commence in Q1 2017.

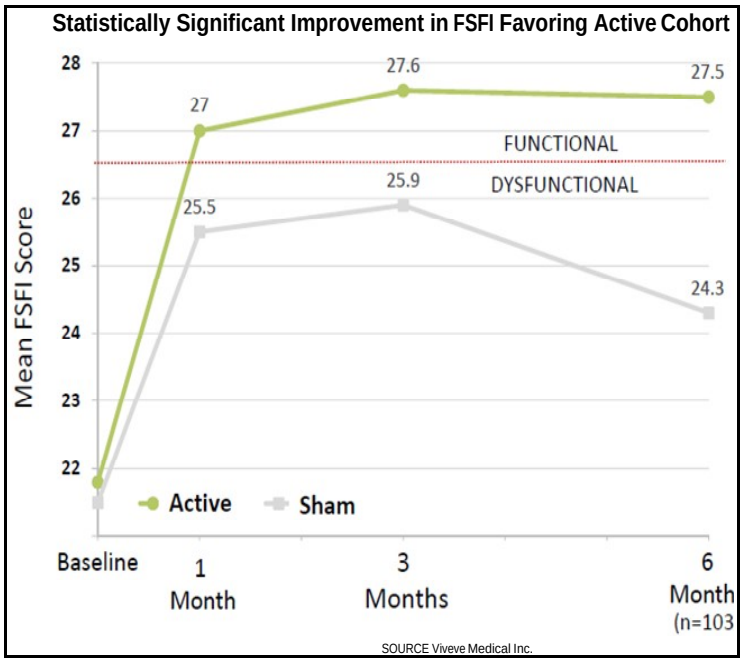
The recent discussions with FDA and the agency’s questions largely related to the proposed study design of VIVEVE II. FSFI, expected to serve as the primary endpoint, is a clinical industry metric which has already been well-validated and documented.

Proposed study will include ~250 patients at up to 25 study sites in the U.S. and Canada which will be randomized 1:1 active/sham. Primary endpoint is expected to be mean change in total FSFI score. Secondary endpoints are expected to include two of the six domains of the FSFI questionnaire that contributed the most to the overall (statistically significant) outcome of the total FSFI score in VIVEVE I – those being the arousal and orgasm domains (both of which were highly statistically significant – see below for VIVEVE I results). Patient follow-up is expected to be at 12 months post-procedure (we note that VIVEVE I follow-up was through six months).

As a reminder, results of the randomized, sham-controlled VIVEVE I study, announced in April 2016, showed a highly statistically significant difference between the active and sham arms on the VSQ (i.e. laxity) primary endpoint as well as the FSFI (i.e. sexual function) secondary endpoint. In addition, patients receiving Viveve treatment were

3x more likely to report no vaginal laxity at 6-month follow-up compared to control. Safety was considered excellent with no difference in adverse event rates between the treatment and sham cohorts.

Our comments: a significant update to the proposed study design of VIVEVE II is the 12-month follow-up. While this differs from the 6-month follow-up used in VIVEVE II, the longer follow-up may actually improve on the already compelling efficacy seen in VIVEVE I given the drop-off observed in FSFI scores of the sham arm beginning after month 3 (chart below) – this is believed to be due to a placebo effect in the sham patients that started to wane after about three months.



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

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

VIVEVE I Design / Protocol…
Enrollment was initially expected to be 113 patients - the study protocol was subsequently updated (per clinicaltrials.gov) to enroll an expected 145 – final enrollment ended up being 174 patients (117 active, 57 sham) with vaginal laxity efficacy data on a 'per-protocol' population of 155. Subjects were randomized 2:1 (active:control) - patients were blinded, treating personnel were not. The treatment group received 90 Joules/cm2 of RF energy delivered via the Viveve System while the sham group received <1 Joule/cm2. Subjects were followed through the six month follow-up period with assessments at day 10 and months 1, 3 and 6.

Key inclusion / exclusion criteria included;[1]
- Inclusion:
    - o pre-menopausal and ≥ 18 years of age

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

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

Primary efficacy endpoint was the proportion of women in the treatment arm as compared to the proportion of women in the sham (i.e. - control) arm that report no vaginal laxity six months following treatment as measured by Viveve's specially designed questionnaire, VSQ ("Viveve System Questionnaire"). VSQ, which is similar to the VLQ questionnaire used in the two prior studies, is based on a seven point scale (1:very loose, 2:moderately loose, 3:slightly loose, 4:neither loose nor tight, 5:slightly tight, 6:moderately tight, 7:very tight). "No vaginal laxity", as defined in the VIVEVE study protocol, is a VSQ score of >4.

Secondary efficacy endpoints were the percentage change in mean score from baseline to six months following treatment of the active arm as compared to the control arm in 1) the Vaginal Laxity Inventory (VALI), 2) Total FSFI and 3) FSDS-R. See our Appendix for detailed description of these secondary measures.

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

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

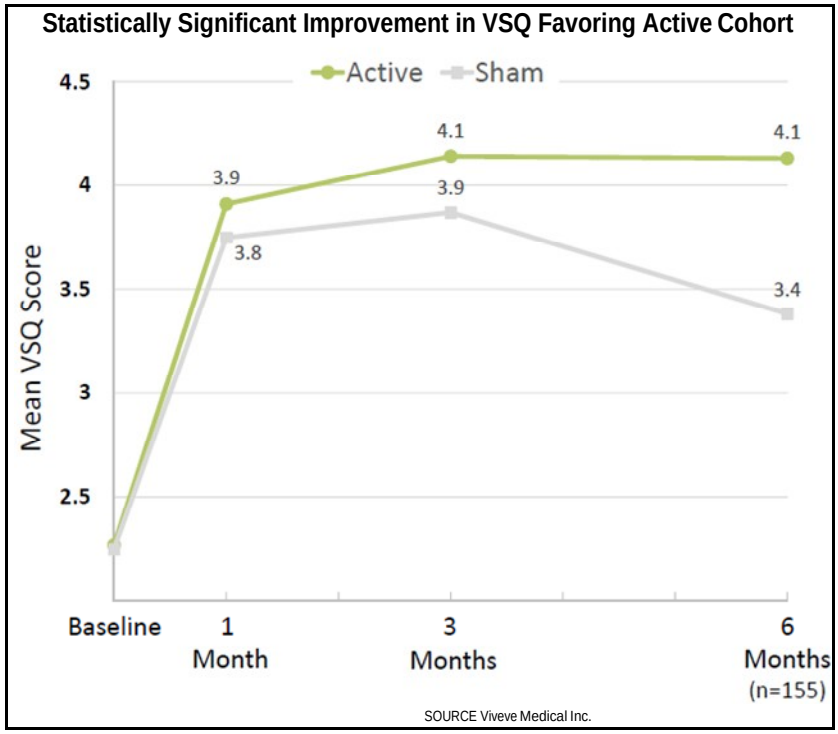
Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity

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

SOURCE Viveve Medical Inc.

Mean VSQ scores at the 1, 3 and 6 month follow up periods were;
- 1-month: 3.9 active vs. 3.8 sham (difference of 0.1)
- 3-month: 4.1 active vs. 3.9 sham (difference of 0.2)
- 6-month: 4.1 active vs. 3.4 sham (difference of 0.7)
    - 6-month mean VSQ score from baseline was 1.9 for active vs. 1.1 for sham

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

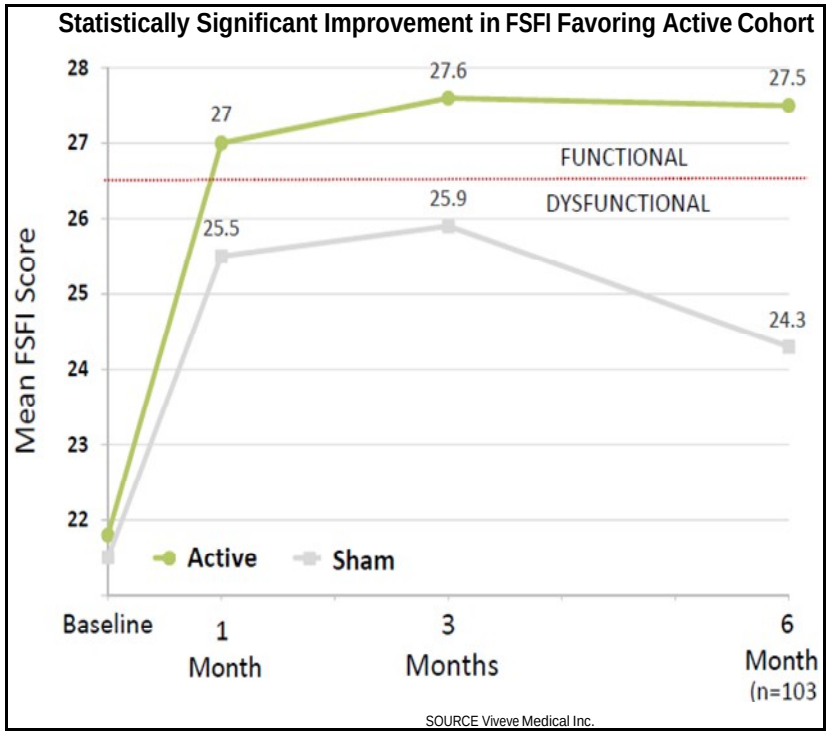
Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total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

NEXT STEPS

U.S. IDE: 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 call (February 2017) that FDA recently came back with a second round of questions related to the study protocol which they expect to respond to by the end of this month (i.e. February). Assuming timely approval of the IDE, this study could potentially commence in Q1 2017.

The recent discussions with FDA and the agency's questions largely related to the proposed study design of VIVEVE II. FSFI, expected to serve as the primary endpoint, is a clinical industry metric which has already been well-validated and documented.

So assuming eventual FDA clearance for an indication related to the treatment of vaginal tissue to improve sexual function, the Viveve System would be the only therapy approved for that claim providing significant and substantive difference from all other vaginal laxity-related devices. This, in our opinion, could be a game-changer for Viveve.

U.S. Study: assuming IDE approval, VIVE will move towards clinical trial site selection and IRB approvals. Proposed study will include ~250 patients at up to 25 study sites in the U.S. and Canada which will be randomized 1:1 active/sham. Primary endpoint is expected to be mean change in total FSFI score. Secondary endpoints are expected to be two of the six domains of the FSFI questionnaire that contributed the most to the overall (statistically significant) outcome of the total FSFI score in VIVEVE I – those being the arousal and orgasm domains (both of which were highly statistically significant). Patient follow-up is expected to be at 12 months post-procedure (we note that VIVEVE I follow-up was through six months).

Valuation

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

The potential market size for skin tightening is many multiples larger than that for vaginal tightening. According to ISAPS there were 412k facelift procedures and 50k surgical vaginal rejuvenation procedures performed in 2015. Using these as rough proxies for the respective U.S. markets for non-invasive skin tightening and vaginal tightening, implies the former is ~8x the size of the latter.

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

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

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

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

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

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

Our Financial Model Assumptions…

So while certain differences in Thermage's product, target market, competitive landscape and early distribution capabilities may not provide a specific template for what to expect with the roll-out of the Viveve System, we think it

is a useful gauge, at least in terms of illustrating the potential demand for the technology (which is essentially the same), pricing and utilization in the respective end-user markets.

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

- U.S. sales: commenced in late 2016. 2017 will benefit from a full year of U.S. sales. VIVE put their initial sales force in place in late 2016 and expects to incrementally add reps later this year
- VIVEVE I data: showing statistically significant efficacy of Viveve treatment on sexual function and vaginal laxity. Data was published in the February 2017 issue of the Journal of Sexual Medicine. Expect marketing programs in both the OUS and U.S. markets to leverage this
- Recent key OUS launches: recently launched in Brazil and S. Korea the #1 and #2, respectively, markets for total number of cosmetic/aesthetic procedures performed. In addition, Brazil ranks #2 (to only the U.S.) in vaginal rejuvenation
- Additional regulatory approvals/launches: at the beginning of 2016 VIVE had regulatory approval in 22 countries. Today that number is 51 countries and regulatory approval is pending in another 14 countries
- Expect to see substantial increase in consumable sales from incremental increase in utilization but more significantly from increase in installed base (which grew from 42 at the end of 2015 to 217 at the end of 2016)

For 2017 we currently model a unit placement rate of about 25 per month and estimate consumable sales will average ~1.7- 1.8 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 ~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 ~2x per month to just over 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 $35k and $360, respectively, but expect this to increase throughout 2017 with additional direct sales in the U.S. This more closely mirrors Thermage's legacy pricing over the first six years - although inflation and less competition in the vaginal tightening space may imply that these estimates are on the low end, particularly given the potential for higher pricing in the U.S. market.

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 $35.2M in 2020 and to approximately $97M 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	Q1E	Q2E	Q3E	Q4E	2017 E	2018	2019	2020
Total Revenues	$7,141.0	$2,758.5	$3,210.7	$4,049.4	$4,729.2	$14,747.7	$21,976.2	$28,596.1	$35,182.8
YOY Growth	*393.5%*	*114.8%*	*106.3%*	*119.0%*	*92.9%*	*106.5%*	*49.0%*	*30.1%*	*23.0%*
Cost of Goods Sold	$4,612.0	$1,647.1	$1,875.4	$2,232.5	$2,499.0	$8,254.0	$10,523.0	$11,742.6	$12,293.0
Gross Income	$2,529.0	$1,111.4	$1,335.2	$1,817.0	$2,230.1	$6,493.7	$11,453.2	$16,853.5	$22,889.8
Gross Margin	*35.4%*	*40.3%*	*41.6%*	*44.9%*	*47.2%*	*44.0%*	*52.1%*	*58.9%*	*65.1%*
SG&A	$12,868.0	$4,722.5	$5,085.7	$5,527.5	$6,166.8	$21,502.5	$26,063.7	$29,082.2	$32,368.2
% SG&A	*180.2%*	*171.2%*	*158.4%*	*136.5%*	*130.4%*	*145.8%*	*118.6%*	*101.7%*	*92.0%*
R&D	$8,365.0	$2,074.4	$2,639.2	$3,195.0	$3,409.7	$11,318.3	$8,680.6	$6,491.3	$5,629.2
% R&D	*117.1%*	*75.2%*	*82.2%*	*78.9%*	*72.1%*	*76.7%*	*39.5%*	*22.7%*	*16.0%*
Operating Income	($18,704.0)	($5,685.5)	($6,389.7)	($6,905.5)	($7,346.4)	($26,327.1)	($23,291.1)	($18,720.0)	($15,107.6)
Operating Margin	*-261.9%*	*-206.1%*	*-199.0%*	*-170.5%*	*-155.3%*	*-178.5%*	*-106.0%*	*-65.5%*	*-42.9%*
Total Other Income (Expense)	($1,407.0)	($255.5)	($255.5)	($241.9)	($228.3)	($981.2)	($701.6)	($356.7)	($120.0)
Pre-Tax Income	($20,111.0)	($5,941.0)	($6,645.2)	($7,147.4)	($7,574.7)	($27,308.2)	($23,992.7)	($19,076.7)	($15,227.6)
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)	($5,941.0)	($6,645.2)	($7,147.4)	($7,574.7)	($27,308.2)	($23,992.7)	($19,076.7)	($15,227.6)
YOY Growth	*61.8%*	*61.6%*	*-46.5%*	*74.1%*	*42.5%*	*35.8%*	*-12.1%*	*-20.5%*	*-20.2%*
Net Margin	*-281.6%*	*-215.4%*	*-207.0%*	*-176.5%*	*-160.2%*	*-185.2%*	*-109.2%*	*-66.7%*	*-43.3%*
EPS (continuing ops)	($2.18)	($0.56)	($0.62)	($0.62)	($0.56)	($2.35)	($1.53)	($1.14)	($0.87)
YOY Growth	*-12.2%*	*3.6%*	*-75.1%*	*12.4%*	*-14.7%*	*7.5%*	*-34.9%*	*-25.7%*	*-23.4%*
Diluted Shares O/S	9,215	10,695	10,750	11,600	13,500	11,636	15,700	16,800	17,500

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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