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May 17, 2018
Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

10 S. Riverside Plaza, Chicago, IL 60606

Viveve Medical (VIVE-NASDAQ)

VIVE: Disappointing Start to 2018 But Not All Was Bad. Guidance Intact, May Now Be More Challenging

We use a 10-year DCF model to value VIVE. We have revenue growing from $15.3M in 2016 to $44M in 2020 and to approximately $100M 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 $8/share.

Current Price (05/17/18)	$1.94
Valuation	**$8.00**

OUTLOOK

Despite what we'd characterize as a pretty disappointing start to the year, management reiterated their previously issued 2018 revenue guidance in the range of $22M (+44%) to $24M (+57%). VIVE indicated that realignment of the sales force/territories and a national sales meeting (which sidelined the entire sales force for a week) significantly impacted Q1 domestic sales results. And relative weakness OUS, particularly in Latin America, was also a major contributor. Given that Q1 revenue was up just 22%, the final three quarters need to average 49% (yoy) growth to hit the low end of that guidance. Q1 may have made that much more challenging. Certainly far from an impossibility, however, given the recent expansion of the sales force and, based on management's comments, what appears to be growing interest in SUI use and anticipated strength in OUS markets which they said "continue to show tremendously strong growth potential through 2018". Other potential tailwinds and benefits include the fact that two of the three remaining quarters are typically seasonally stronger than Q1 (at least from a utilization standpoint), adoption growth from VIVE's SUI 'buy-one-get-one' treatment tip program and awareness benefits from U.S. RCTs (in both SUI and vaginal laxity). And, with the national sales meeting and territorial rejiggering behind them, those disruptions should not repeat.

SUMMARY DATA

52-Week High	**$8.75**
52-Week Low	**$1.60**
One-Year Return (%)	**-73.13**
Beta	**-0.44**
Average Daily Volume (sh)	**381,351**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**41**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**115.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2017	3041 A	3073 A	4070 A	5101 A	15288 A
2018	3699 A	5224 E	5624 E	7052 E	21599 E
2019					34969 E
2020					43536 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.57 A	-$0.54 A	-$0.50 A	-$0.53 A	-$2.12 A
2018	-$0.49 A	-$0.38 E	-$0.37 E	-$0.37 E	-$1.60 E
2019					-1.17 E
2020					-0.96 E

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

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WHAT'S NEW…

Q1 Results: *Disappointing But Not All Was Bad. Guidance Intact But That May Now Be More Challenging…*

Viveve reported Q1 2018 financial results and provided a business update. Despite what we'd characterize as a pretty disappointing start to the year, management reiterated their previously issued 2018 revenue guidance in the range of $22M (+44%) to $24M (+57%). VIVE indicated that realignment of the sales force/territories and a national sales meeting (which sidelined the entire sales force for a week) significantly impacted Q1 domestic sales results. And relative weakness OUS, particularly in Latin America, was also a major contributor.

Given that Q1 revenue was up just 22%, the final three quarters need to average 49% (yoy) growth to hit the low end of that guidance. Q1 may have made that much more challenging. Certainly far from an impossibility, however, given the recent expansion of the sales force and, based on management's comments, what appears to be growing interest in SUI use and anticipated strength in OUS markets which they said "continue to show tremendously strong growth potential through 2018".

Other potential tailwinds and benefits include the fact that two of the three remaining quarters are typically seasonally stronger than Q1 (at least from a utilization standpoint), adoption growth from VIVE's SUI 'buy-one-get-one' treatment tip program and awareness benefits from U.S. RCTs (in both SUI and vaginal laxity). And, assuming no more (or at least to a much lesser extent) BOGO's and what also appeared to be some discounting on the consoles (or at least meaningful reduction in ASP) in Q1, revenue (as well as gross margin) in the remainder of 2018 should benefit from relatively higher pricing. And, with the national sales meeting and territorial rejiggering behind them, those disruptions should not repeat. Our back-of-the-envelope indicates the lost week alone (i.e. does not consider disruption from territory realignment) may have cost VIVE about $220k, or ~6%, of revenue in Q1. And, finally, OUS can be somewhat variable – assuming growth does materialize as VIVE expects, that could represent a significant portion of incremental topline.

And, to be fair, Q1 was far from a complete disappointment. There were some highlights – particularly on the operational front (discussed below), but also on the financial results side as well. Relative to the financial high(er)-points; of the treatment tips not BOGO'd, it appears (VIVE does not disclose enough info for exact calculation) pricing may have been relatively very strong. And while Q1 revenue missed big (-23% vs. our $4.8M E and -32% vs. $4.9M consensus) it was well ahead of both 1H '17 quarters (Q1:+22%, Q2:+20%) – and Q2 is typically seasonally stronger. In addition, Q1 '18 U.S. (i.e. via direct) revenue was up a much healthier 38% (which, again, presumably would have been even better if not for the sales team/territory issue).

So, while we now model a slight miss ($21.6M) to guidance, we think there's reasonable reasons why (such as better pricing, bigger and non-idled sales force, BOGO-hooks set, RCT-awareness-halo, seasonal tides and OUS strength?) the remainder of 2018 could show a steep enough guidance-hitting revenue ramp. Q2's numbers may provide a lot more insight in that regard. And while we have slightly less confidence in meeting guidance, management appears to be unwavered – noting on five different instances on the Q1 call that they are "confident" (or "very confident") in meeting their 2018 revenue guidance.

Q1 total revenue was $3.7M, up 22% yoy, down 28% sequentially and 23% below our $4.8M estimate. Console placements totaled 53 units (vs. 61 E) including 38 U.S. (43 E) and 15 OUS (18 E). Treatment tips shipped totaled 5,400 (5,303 E), approximately 1,900 (35%) of which were included as part of the SUI BOGO program (i.e. free).

Revenue (proportional contribution) per geographic territory was:

	Q1 2018		+/- yoy	Q1 2017		FY 2017	
North America	$2,606	(70%)	38%	$1,895	(62%)	$11,083	(72%)
Asia Pacific	$891	(24%)	20%	$743	(24%)	$3,178	(21%)
Europe & Middle East	$202	(5%)	79%	$113	(4%)	$667	(4%)
Latin America	-	(0%)	-100%	$290	(10%)	$360	(2%)
Total	$3,699	(100%)	22%	$3,041	(100%)	$15,288	(100%)

Note that North America, while softer than what we had expected, still managed almost 40% growth. Pro forma for the lost (sales meeting) week, BOTE calculation ([$2.6M/12 weeks] x 13 weeks), puts direct sales at more than $2.8M (+49%). The BOGO SUI tip program may have cost additional revenue – although it is impossible to know, given that it may have been offset by higher console or incremental (sold) tips.

The 38 U.S. console placements is up 31% from 29 in Q1 '17. VIVE launched in the U.S. in January 2017 and had 10 direct reps as of May 2017 (i.e. as of the reporting of Q1'17 results), 16 as of the end of 2017 and 24 as of today. Console placements per rep per month (PPM) averaged 1.0 in Q1 '17. At-best (i.e. using 16 reps as the basis), PPM averaged ~0.8 in Q1 '18. We don't know the avg sales team size throughout 2017 but with 160 domestic placements, PPM for the full year 2017 averaged between 0.8 and 1.3 (management noted that it was above 1.0). Management also noted that, given that the sales force training and rejiggering is done, that they expect productivity will improve (from that of Q1 '18) through the remainder of 2018. So, with 16 reps starting the year, 24 on board now and assuming PPM of 1.0, we should see at least 48 domestic placements in Q2 and at least 72 per quarter by Q4.

On the OUS side, Latin America was blank in Q1 '18, down $290k. We have no insight. But, VIVE mentioned on the call that awareness is building and that they expect momentum to continue through 2018. While we had hoped to see relatively strong uptake in certain parts of Latin America, particularly Brazil which for several years had lead the world in vaginal rejuvenation procedures (and in which Viveve System has been approved for treatment of sexual function since October 2016) that clearly has not materialized – at least not yet anyway.

As it relates to consumables, 5,400 went out the door, ~1,900 of which were BOGOs – and done in order to stimulate SUI use and system adoption. While the freebees likely cost some topline and margin, of the ~3,500 that were sold, it looks like (our rough calculations) pricing may have been at an almost 20% premium to historical. Clearly the hope is that BOGO=adoption=utilization. VIVE indicated SUI-related interest has blossomed and use in this indication is growing. That could accelerate with the start of the two related clinical studies as well as (possible) future introduction of an SUI-customized treatment tip.

With and without the BOGOs, tips/per-unit/month (using 2017YE installed base 444) was 4.1 and 2.6 in Q1 '18. These compare to 3.4 in Q1 '17 and a 3.3 average throughout 2017. Q2 and Q4 are typically seasonally stronger so we could see utilization benefit as well.

Gross margin was one of the low-lights in Q1. The 36.4% GM is the weakest since Q2 '16 (34.3% on $1.6M revenue) and compares to 46.8% in Q1 '17 and 48.7% average in 2017. The BOGO certainly impacted margin but it looks like U.S. consoles (and perhaps OUS as well) ASP was also on the soft side – we have no insight and would hope to see ASP's firm up. Narrowing GMs, BOGOs, soft ASPs and relatively low sales rep productivity do not lend themselves to the idea of brisk and growing demand. While we think the explanations are valid, given that GMs oftentimes provide lots of insight, the fact that it plummeted (yoy) 1,040 basis points is certainly interest-piquing, if not (yet) concerning.

Operational Update: VIVEVE II Starts, SUI Clinical Studies…

VIVEVE II IDE Approval, Begins…

VIVE received IDE approval of VIVEVE II in March and on May 16th announced that the study had started. VIVEVE II, if successful, is expected to provide the backbone for an eventual U.S. regulatory filing seeking an indication for 'treatment of sexual function'.

VIVEVE II will use a 'staged roll-in' enrollment approach which is further aimed at ensuring safety. While total enrollment is expected to be 250, this staged roll-in requirement limits initial enrollment to just 50 patients, at least of 25 of which will need to be treated and assessed for safety purposes (one-month following treatment) before enrollment can be increased. At that point VIVE will need to submit an IDE supplement (during which time the remaining 25 of the initial 50 can run through treatment) with the initial patient safety information, approval of which will be required in order to expand to the intended n=250. Per VIVE's May 16th PR, they anticipate being able to submit this by the end of Q2.

Importantly, the proposed study design (aside from this staged enrollment) appears to remain unchanged from earlier expectations. This includes the expected FSFI primary endpoint, targeted enrollment (n=250) and number of study sites (n=25).

SUI Indication Could Be Next, Clinical Studies Planned…
In late January Viveve announced that, based on positive results from a small pilot study, that they expect to forge ahead with stress urinary incontinence (SUI) clinical programs – with U.S. and OUS registration studies planned.

According to the National Association for Incontinence, SUI affects approximately 15M American women and approximately 200M people across the globe suffer from some form of urinary incontinence. SUI, or urinary leakage associated with physical movements (such as coughing, sneezing or running), is a relatively common condition among women that have had children. Similar to vaginal laxity, SUI is also a result of a weakening of pelvic muscles, including those that support the bladder.

Viveve's initial push into a SUI indication came in August 2017 when they penned an agreement with InControl Medical whereby VIVE serves 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.

InControl is a leader in home-use incontinence therapy devices and if and when the Viveve System gains regulatory approval for an SUI indication, it could position VIVE as the top U.S. provider of women's incontinence therapy – in both the home and clinical settings. But, perhaps more importantly, an SUI indication would allow for an even broader formal marketing message. That message could resonate with both doctors and patients given that SUI is a condition that not only effects a sizable population but is also one in which currently available treatment options can be lacking. Unlike other devices and non-invasive options (such as pelvic muscle strengthening exercises), Viveve therapy may offer much longer duration of efficacy (~12 months) with only a single treatment. Other options include surgery (i.e. vaginal slings) – which suffers from the usual related drawbacks including higher cost, more invasive, longer recovery and more risks.

While we think it is likely that many of the current providers of Viveve therapy are already promoting its benefits for SUI (i.e. off-label), supporting clinical evidence from randomized, sham-controlled studies and FDA marketing approval would significantly increase robustness of the marketing message and overall awareness-building potential. It could also substantially aid initial adoption of the Viveve System given that it would provide clinicians with an incremental revenue opportunity either as a stand-alone procedure or as an upsell to treatment for vaginal laxity/sexual function.

SUI Pilot Study
N=10, single-arm. Conducted in Calgary, Alberta by Dr. Bruce Allan (Dr. Allan was also one of the principal investigators of the VIVEVE I study). Safety and clinical measures were reported at months 4, 6, 9 and 12 months post-treatment. Press release mentions the study used a "proprietary treatment protocol" (specifics were not disclosed). Clinical measures included composite scores of the ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form) and UDI-6 (Urogenital Distress Inventory-Short Form) outcome questionnaires. Both questionnaires are industry-accepted as measures of urinary incontinence-related quality of life and symptom distress[1].

While the PR discloses only limited details of the results it does note that at 12 months (9 patients were evaluable), 89% - 100% of patients were "responders" and mean improvement was 40% - 51% at 12 months based on the ICIQ-UI-SF and UDI-6 measures, respectively. Additional details, such as response and mean improvement at the earlier timepoints was not disclosed. It is also unclear whether other efficacy measures were included as part of the study. In terms of safety, the PR notes that no device-related safety issues were reported in any of the patients.

Relative to the results of the study, Dr. Allan said, "In the pilot study, we found that SUI symptoms were significantly improved, providing strong support for the planned clinical registration studies and the potential to represent a major advance in the non-invasive treatment of SUI".

On the Q1 '18 call VIVE mentioned that they began (earlier in 2018) a second pilot study and that they expect to report 6-month data "very soon". We assume it is this http://bit.ly/2k3OX9p on clinicaltrials.gov, which appears to be a dose-response study; n=36, randomized to a) Viveve single treatment or b) Viveve two treatments.

[1] Uebersax JS. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn. 1995;14(2):131-9.

Pad weight test at 12 months is primary endpoint. QOL questionnaires and bladder-voiding diary are also listed as evaluation criteria.

Pivotal Registration Trials Planned, To Kick-Off Following Go-Ahead From Regulators
VIVE hopes to go to conduct pivotal registration trials in both the U.S. and Canada – success of which would be used to support FDA and Health Canada filings seeking an indication for the temporary improvement of mild-to-moderate SUI symptoms. The Canadian study is also expected to accompany a CE Mark application (for European markets).

Design of the U.S. and Canadian studies are similar, although not identical. Importantly, both are multi-site RCTs. Both also use change from baseline in the one-hour pad weight test as the primary endpoint. With the pad weight test, the subject wears a pre-weighed pad, drinks a specified amount of liquid and then performs certain activities (such as walking, climbing stairs, coughing etc). After one-hour, the pad is again weighed to determine the amount of urinary leakage.

An Investigational Trial Application (ITA, analogous to IDE in U.S.) was submitted to Health Canada – VIVE noted on the Q1 call (March 10th) that they expect to hear back in Q2. Presumably (our presumption), results of their ongoing pilot study will be used to support an IDE for approval to commence the U.S. Liberate study. VIVE expects (per Q1 call) to make that submission in Q2.

The pad weight test (which can also be performed over a 24-hour period) is widely accepted as a standard measure of SUI and is one of two measures that is recommended by FDA as a primary efficacy endpoint in clinical trials assessing the efficacy of urinary incontinence devices[2]. Relative to the what is considered clinically meaningful (with the objective on dryness) with the one-hour pad weight test, FDA recommends a goal of an increase in pad weight of less than 1 gram or a 50% or more decrease in weight from baseline. Secondary endpoints will also be included. FDA's general guidance relative to urinary incontinence clinical trial secondary endpoints includes measures related to quality of life (via questionnaires), sexual function, leak point pressure and patient satisfaction, among others. (Note, that we provide this FDA-recommendation information only as background for outcome measures that may be incorporated into VIVE's pivotal studies, the ultimate design and protocol of which will be part of the anticipated upcoming IDE filing).

The U.S. and Canadian studies are expected to enroll 200 and 100 patients across 25 and 10 sites, respectively (~10 patients/site). Given the already sizeable installed base, we would expect enrollment may be accomplished fairly swiftly, assuming both the U.S. and Canadian studies can utilize certain of the current Viveve System practitioners' locations as trial sites.

The following is information disclosed by VIVE relative to the two pivotal (LIBERATE) studies.

U.S. LIBERATE Study

- Design
  - N=200 w/ mild-to-moderate SUI
  - Randomized, double-blind, sham-controlled
  - Sites = 25, in U.S.
  - Outcomes
    - Primary: 1-hour pad weight test, change from baseline to 12 months
    - Secondary: (undisclosed) "other secondary endpoints"
    - Safety: through 12 months
- Status: VIVE expects to submit IDE to FDA for "temporary improvement of mild-to-moderate SUI"

International LIBERATE Study

- Design
  - N=100 w/ mild-to-moderate SUI
  - Randomized, double-blind, sham-controlled
  - Sites = 10, in Canada
  - Outcomes
    - Primary: 1-hour pad weight test, change from baseline to 6 months

[2] Guidance for Industry and Food and Drug Administration Staff Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence. Document issued on: March 8, 2011

- Secondary: (undisclosed) “other secondary endpoints”
- Safety: through 12 months

- Status: currently in the process of reviewing the protocol with Health Canada

o Purpose: if positive, will use study to support Health Canada registration filing and CE Mark application for “temporary improvement of mild-to-moderate SUI symptoms

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 averaged 2.7 tips per console per month during 2017. We think revenue accelerates further on the backs of several catalysts including;

- U.S. sales: sales force tripled in size (including associates, practice development and regional mgrs.) since early 2017 and expected to expand again before end of 2018. Recent addition of practice development managers should help drive further growth in utilization
- Clinical Data / Regulatory: 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 and appears to have catalyzed adoption and utilization. IDE approval and start of VIVEVE II are major milestones and could further promote awareness and adoption. Initial SUI pilot study benefitted uptake – results of 2nd pilot expected in very near-term and could spark additional adoption. Registrations studies, if successful, would likely further drive demand.
- Recent key OUS launches: S. Korea, Taiwan, Mexico and Brazil all hold out-sized growth prospects, in our opinion, and almost certainly remain largely untapped. With regulatory clearance in 64 countries and others that could come online soon, the geographic footprint continues to rapidly grow.

With 16 capital reps as of YE2017, 24 today (and incremental adds later in 2018) and expected productivity gains as newer reps gain footing, we model 49 U.S. placements in Q2 and growing to 70 in Q4. We have OUS placements tracking at about 30% of the total. We model 305 total console sales in 2018 (vs 227 in 2017), including 215 in the U.S. (vs 160) – this implies slow but consistent productivity gains – which could prove conservative. We estimate consumable sales average ~2.9 per installed console per month in the remaining three quarters of 2018.

We think that if all goes well, in 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. An SUI indication could also drive demand and potentially significantly expand the overall size of the targeted markets.

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.

DCF Values VIVE at $8/share

We use a 10-year DCF model to value VIVE. Using the inputs discussed above, we have revenue growing from $15.3M in 2016 to $43.5M in 2020 and to approximately $100M in 2026 (for reference, Thermage's sales were

$50M+ at second year after ThermaCool launch). OpEx has trended higher than we had expected – which has prompted upward adjustments to our estimate operating expenses.

Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. While our out-year revenue has tweaked up, near-term revenue downward revisions and across-the-model OpEx adjustments offset the benefit. Based on our DCF model, VIVE is valued at approximately $8/share (revised down from $9/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. In addition, we have yet to include assumed market expansion related to any non-sexual function/vaginal laxity indications. As such, outsized adoption and utilization for indications such as SUI (or potentially others) could result in upside to our estimates, which should be assumed to be constantly under review and subject to updating.

FINANCIAL MODEL

Viveve Medical, Inc

	2016 A	2017 A	Q1A	Q2E	Q3E	Q4E	2018	2019	2020
Total Revenues	$7,141.0	$15,288.0	$3,699.0	$5,223.9	$5,623.7	$7,052.1	$21,598.7	$34,968.5	$43,535.8
YOY Growth	393.5%	114.1%	21.6%	69.8%	38.2%	38.2%	41.3%	61.9%	24.5%
Cost of Goods Sold	$4,612.0	$7,844.0	$2,352.0	$2,895.0	$2,858.1	$3,480.3	$11,585.3	$15,858.6	$17,757.5
Gross Income	$2,529.0	$7,444.0	$1,347.0	$2,328.9	$2,765.6	$3,571.8	$10,013.4	$19,110.0	$25,778.3
Gross Margin	35.4%	48.7%	36.4%	44.6%	49.2%	50.6%	46.4%	54.6%	59.2%
SG&A	$12,868.0	$28,831.0	$8,931.0	$8,985.2	$9,318.5	$9,957.5	$37,192.1	$45,249.3	$48,934.2
% SG&A	180.2%	188.6%	241.4%	172.0%	165.7%	141.2%	172.2%	129.4%	112.4%
R&D	$8,365.0	$12,343.0	$3,756.0	$3,996.3	$4,020.9	$4,160.7	$15,934.0	$11,434.7	$9,664.9
% R&D	117.1%	80.7%	101.5%	76.5%	71.5%	59.0%	73.8%	32.7%	22.2%
Operating Income	($18,704.0)	($33,730.0)	($11,340.0)	($10,652.5)	($10,573.8)	($10,546.4)	($43,112.7)	($37,574.0)	($32,820.9)
Operating Margin	-261.9%	-220.6%	-306.6%	-203.9%	-188.0%	-149.6%	-199.6%	-107.5%	-75.4%
Total Other Income (Expense)	($1,407.0)	($3,229.0)	($1,080.0)	($1,118.2)	($1,132.8)	($1,147.5)	($4,478.5)	($4,368.8)	($4,531.8)
Pre-Tax Income	($20,111.0)	($36,959.0)	($12,420.0)	($11,770.7)	($11,706.6)	($11,693.9)	($47,591.2)	($41,942.8)	($37,352.7)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Gain/(Loss) from Minority Interest	0.0	0.0	(249.0)	0.0	0.0	0.0	(249.0)	0.0	0.0
Net Income (continuing ops)	($20,111.0)	($36,959.0)	($12,669.0)	($11,770.7)	($11,706.6)	($11,693.9)	($47,840.2)	($41,942.8)	($37,352.7)
YOY Growth	61.8%	83.8%	117.7%	-41.5%	74.9%	12.2%	29.4%	-12.3%	-10.9%
Net Margin	-281.6%	-241.8%	-342.5%	-225.3%	-208.2%	-165.8%	-221.5%	-119.9%	-85.8%
EPS (continuing ops)	($2.18)	($2.12)	($0.49)	($0.38)	($0.37)	($0.37)	($1.60)	($1.17)	($0.96)
YOY Growth	-12.2%	-3.1%	-10.3%	-82.7%	-34.9%	-30.7%	-24.5%	-27.1%	-17.8%
Diluted Shares O/S	9,215	17,470	25,847	31,250	31,320	31,370	29,947	36,000	39,000

Brian Marckx, CFA

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APPENDIX

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;[3]
- Inclusion:
  - pre-menopausal and ≥ 18 years of age
  - had least one full term vaginal delivery (>37 completed weeks) at least 12 months prior to enrollment date
  - experienced vaginal looseness (i.e. VSQ < 4) during vaginal intercourse
- **Exclusion:**
  - Pregnant or planning to become pregnant within the next 12 months or has had a delivery within the last 12 month
  - currently meets the criteria for a female sexual disorder including DSM V, FSAD, FOD, Genitopelvic Pain, Sexual Aversion, Dyspareunia or Vaginismus and has not been treated for this condition within the past 12 months
  - taking SSNRI or SSRI drugs

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

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

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

VSQ
Of the 174 subjects enrolled and randomized, 19 were not evaluable for efficacy purposes due to not completing the 6-month follow-up or for other protocol violations. The per-protocol population included 103 active and 52 sham subjects. At the 6-month follow-up, 41.7% (43/103) of active subjects reported having no vaginal laxity (i.e. VSQ > 4) compared to just 19.2% (10/52) of subjects that received sham treatment. The difference was highly statistically

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

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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

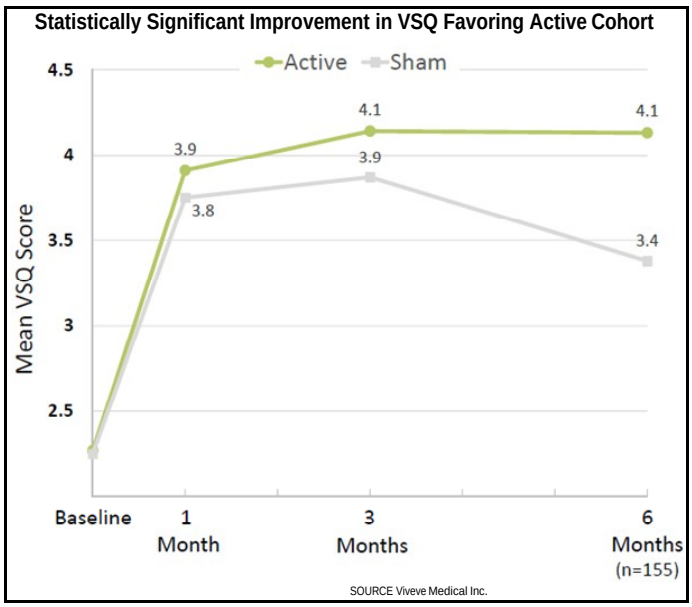
				Logistic Regression			
Timepoint	Treatment Group	N	No Laxity n (%)	Chi-Squared p-value	Odds Ratio	95% CI	p-value
Month 6	Active	103	43 (41.7%)	0.005	3.05	(1.37, 6.79)	0.006
	Sham	52	10 (19.2%)				

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.[4]

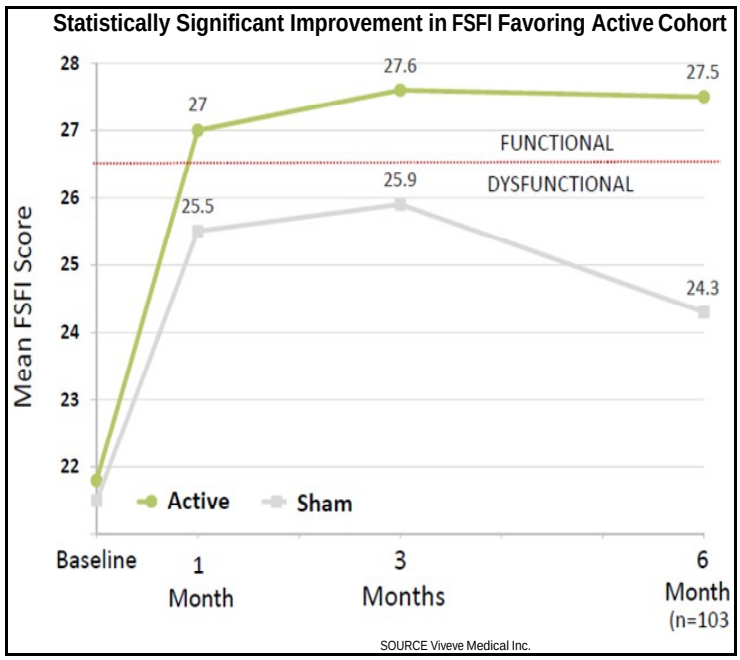
103 (71 active, 32 sham) patients were included in the FSFI per-protocol population. Of the six domains, two (sexual arousal and orgasm) were statistically different favoring the active arm (arousal and orgasm are expected to be included as secondary endpoints in VIVEVE II). And while the other four were not statistically different, there

[4] 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.

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 0.007
- 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.

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

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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.[5]

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)[6]
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).

[5] 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.
[6] Description taken verbatim from Viveve's Protocol Report for the VIVEVE 1 study

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