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Viveve Medical (VIVE-NASDAQ)

VIVE: Sales Force Realignment Appears To Be Paying Dividends As Q2 U.S. Systems Sales Crush Prior Record

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 $7.75/share.

Current Price (08/24/18)	$3.09
Valuation	**$7.75**

OUTLOOK

Strength of the U.S. business, which also saw big gains on treatment tip ASPs and resultant widening of related margins, was attributed to increased production following the sales force realignment. While that caused a disruption to domestic sales activity in the first quarter, it appears that the hoped-for benefits may have already begun to materialize. The 69 U.S. system sales in Q2 was more than 2.5x that in the prior year period and 21% more than VIVE had sold in any previous quarter. Unfortunately, sales of consumables were not nearly as robust and actually rather disappointing – although the weakness may be at least partially a result of manufacturing delays. As aesthetic procedure volume is typically seasonally softer in Q3, we think sales may dip sequentially into next quarter but continue to look for a strong finish to the year. Importantly, management reiterated FY'18 revenue guidance of $22M - $24M. While we have only slightly increased our full-year revenue estimates (from $21.2M to $21.5M), we may be erring on the side of too-conservative given the (more) rapid (than previously expected) reintegration of the sales force and the recent addition of Aesthetic Management Partners (AMP) as a complementary sales channel. We also think FDA's recent action, warning against off-label marketing by certain energy-based device manufacturers (which did not include VIVE), should provide additional opportunity for VIVE's domestic business.

SUMMARY DATA

52-Week High	**$6.00**
52-Week Low	**$1.60**
One-Year Return (%)	**-44.10**
Beta	**-0.53**
Average Daily Volume (sh)	**452,132**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$99**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**64**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**141.2**
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	5525 A	4912 E	7353 E	21489 E
2019					33949 E
2020					43667 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	-$0.37 A	-$0.37 E	-$0.35 E	-$1.56 E
2019					-1.18 E
2020					-0.98 E

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

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Q2 Results: *Sales Force Realignment Appears To Be Paying Dividends As U.S. Systems Sales Crush Prior Record…*

Viveve reported Q2 2018 financial results and provided a business update. Relative to the financials, revenue was very strong, well-ahead of our estimate and better than the prior record by more than 8%. While international sales faltered, falling 18% from the prior year, that overseas weakness was much more than offset by extraordinarily robust domestic sales.

Strength of the U.S. business, which also saw big gains on treatment tip ASPs and resultant widening of related margins, was attributed to increased production following the sales force realignment. While that caused a disruption to domestic sales activity in the first quarter, it appears that the hoped-for benefits may have already begun to materialize. The 69 U.S. system sales in Q2 was more than 2.5x that in the prior year period and 21% more than VIVE had sold in any previous quarter. Unfortunately, sales of consumables were not nearly as robust and actually rather disappointing – although the weakness may be at least partially a result of manufacturing delays.

As aesthetic procedure volume is typically seasonally softer in Q3, we think sales may dip sequentially into next quarter but continue to look for a strong finish to the year. Importantly, management reiterated FY'18 revenue guidance of $22M - $24M. While we have only slightly increased our full-year revenue estimates (from $21.2M to $21.5M), we may be erring on the side of too-conservative given the (more) rapid (than previously expected) reintegration of the sales force and the recent addition of Aesthetic Management Partners (AMP) as a complementary sales channel.

The major news on the operational front includes FDA green-lighting VIVEVE II next-phase enrollment (i.e. safety looks good), positive results of the second U.S. SUI pilot study (which should bolster the LIBERATE U.S. SUI RCT IDE – filing of which is expected any day now), initiation of LIBERATE International (for SUI), and FDA's warning letter to several energy-based device manufacturers (Viveve was not one of them) to stop (illegally) marketing for off-label use in vaginal procedures including vaginal rejuvenation, sexual function and SUI. As we explain below, we think FDA's recent action should provide additional opportunity for VIVE's domestic business.

Q2 total revenue was $5.5M, up 80% yoy, up 49% sequentially and 15% higher than our $4.8M estimate. Console placements totaled 85 units (vs. 64 E) including 69 U.S. (43 E) and 16 OUS (21 E). Treatment tips shipped totaled 2,750 (6,059 E), approximately 125 (5%) of which were provided free as a result of the launch of the practice management team (which commenced in Q1).

Revenue (proportional contribution) per geographic territory:

	Q2 '18	%Ttl	+/- yoy	1H '18	%Ttl	yoy	Q2 '17	%Ttl	1H '17	%Ttl	FY '17	%Ttl
North America	$4,552	(82%)	140%	$7,158	(78%)	89%	$1,895	(62%)	$3,790	(62%)	$11,083	(72%)
Asia Pacific	$630	(11%)	-9%	$1,521	(16%)	6%	$690	(22%)	$1,433	(23%)	$3,178	(21%)
Europe & Middle East	$329	(6%)	-28%	$531	(6%)	-7%	$456	(15%)	$569	(9%)	$667	(4%)
Latin America	$14	(0%)	-60%	$14	(0%)	-96%	$35	(1%)	$325	(5%)	$360	(2%)
Total	$5,525	(100%)	80%	$9,224	(100%)	51%	$3,076	(100%)	$6,117	(100%)	$15,288	(100%)

North America not only continues to represent the most significant contributor to total revenue but it's overall contribution also continues to grow. Accounting for 72% of total revenue through FY'17, North America contributed 82% in Q2 and 78% in 1H '18. Despite VIVE's regular expanding international reach (the Viveve System is now cleared for sale in 66 countries) and the relatively recent launch in the U.S. (Q4 '16 was the first period of U.S. revenue), the domestic market has quickly become the major driver of, and contributor to, total revenue. .

The 69 U.S. console placements is up 155% from 27 in Q2 '17. Through 1H'18, 107 systems have been sold in the U.S., compared to 56 (+91%) from the prior year period. VIVE noted on the call that their sales force currently consists of 49 total sales team members (up from 27 on Jan 1, 2018) which includes; 23 capital reps, 10 associate sales reps, 10 practice development managers, 3 regional sales directors and 1 practice development strategic partnership director – all report to a V.P. of sales.

The capital rep count remained approximately flat from May 2018 (n=24) This implies average sales production of 1 console placement per rep per month (PPM) in Q2, which is significantly improved from the 0.6 (or less) during Q1 of this year. PPM averaged approximately 0.7 through 1H'18. So, while PPM is improving and reached what is often considered a minimum production goal of 1 PPM in Q2, we would hope to see this continue to increase over time.

In July VIVE announced a capital sales partnership with Aesthetic Management Partners, Inc., which provides aesthetic device manufacturers with a complementary domestic sales channel. Under the agreement, the Viveve System will be added to AMP's product offerings and, through their 20 capital reps, provide the opportunity to bundle sales with that of other (unrelated) aesthetic devices marketed by AMP. Management indicated that this channel is geared mostly to providers that are new to the aesthetic market, want to purchase more than one modality and can benefit from bundling one or more simultaneous system purchases. Launch via AMP is expected in early Q4.

As it relates to consumables, 2,750 were recognized as sales, although ~125 were given away free as VIVE's practice managers made their field introductions. Management also noted that they had expected to book another ~1k treatment tips in Q2 but that, due to the large order in the previous quarter, that these were back-logged. Q2 consumable sales implies a utilization rate, with and without the backlog and excluding the 125 freebies, of 2.1 and 1.5 treatment tips per system per month. Through 1H'18 utilization averaged approximately 2.9, compared to ~3.2 in 1H'17. While we think this is an informative metric, particularly with trend-analysis over longer periods of time, as we have noted in the past, 'utilization' calculation is not necessarily indicative of spot-related demand given variability in ordering patterns and inherent skew from significant growth in the installed base. We continue to look for this utilization rate to stabilize (over time) to close 3.0.

So while treatment tip unit sales were not at the level we had hoped in Q2, it appears that consumables pricing was much better than we had modeled. In fact management noted ASP on treatment tips was up 2.5x – which was attributed sales efforts of the newly launched practice management team. The ASP benefit showed up in gross margin, which at 50.9% was 1060 bps better than the prior year period and well ahead of our estimate. Gross margin, per comments on the call, are expected to remain near these levels through the remainder of 2018 (although we continue expect some short-term fluctuations).

Operational Update:

VIVEVE II: FDA OKs Safety, Next-Phase of Enrollment…
VIVE received IDE approval of VIVEVE II in March and in mid-May 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 is using 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 means a safety review must be conducted on the initial patients before additional subjects can enter the study. In early August VIVE announced that, following one-month safety review of the first 25 patients, that FDA approved enrollment to continue up to 100 (i.e. second stage). The second safety review will occur once another 25 patients have been followed for one-month and 3-month data is available on a total of 50 patients. Following that review, VIVE will be required to submit an IDE supplement, approval of which will be required in order to expand to the intended n=250. Per VIVE's current timeline (i.e. as of the Q2 call), they hope to have the study fully enrolled by current year-end (of course that assumes ongoing successful safety reviews and supplemental IDE approval). Importantly, the 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 LIBERATE Studies:
Viveve's SUI clinical programs have moved relatively very rapidly. In June they announced compelling 6-month data from their ongoing (Canada-based) 12-month randomized (n=36) SUI feasibility study – see our discussion below. Then earlier this month they announced commencement of one (of two) of their LIBERATE SUI studies, which (if successful) are expected to be used as primary support for SUI regulatory filings in the U.S., Canada and Europe.

LIBERATE International is now off and running. VIVE announced on August 14h that LIBERATE International, which will be conducted at up to 10 sites in Canada, has now commenced. VIVE anticipates making their IDE filing for LIBERATE U.S. in the very near-term - mentioning on the Q2 earnings call that they hope to file by the end of Q3 (we note that this is a slight delay from prior expectations of 'the end of June or early July'). See our Appendix for a refresher on the LIBERATE study designs and our discussion on SUI

Compelling SUI Feasibility Study 6-Month Data: *Meaningful Improvement On All Endpoints, Will Support IDE Filings…*
In mid-June Viveve announced what we would characterize as potentially compelling 6-month data from its ongoing SUI 12-month feasibility study. As a refresher, this is the second formal pilot/feasibility study assessing the Viveve

System in the treatment of mild-to-moderate SUI (see below for refresher on the first). Listed under clinicaltrials.org Identifier: NCT03066180 (http://bit.ly/2k3OX9p), the single-arm, 36-subject study is being conducted at Dr. Bruce Allan's Allan Centre (Dr. Allan was also the principal investigator for the VIVEVE I vaginal laxity/sexual function study) in Calgary, Canada. Protocol allowed for one (just following baseline) or two (6 – 12 weeks later) Viveve treatments.

While only a single-arm feasibility study, it was clearly designed to be consistent with FDA's recommendations for SUI-device pivotal studies (FDA's guidance (http://bit.ly/2Iy2orT) for *Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence).* This includes the inclusion and exclusion criteria as well as the choice of primary and secondary endpoints. Relative to SUI severity, inclusion criteria included diagnosis of mild-to-moderate SUI as determined by one-hour pad weight test (using International Continence Society definitions; mild = 1-10g, moderate = 11-50g, severe = > 50g). (See our Appendix for a more in-depth review of FDA's guidance on SUI endpoints).

Primary endpoint is reduction in 1-hour pad weight versus baseline. Secondary measures are the 7-day bladder voiding diary and composite scores from three quality-of-life oriented questionnaires; UDI-6 (Urogenital Distress Inventory-Short Form), IIQ-7 (Incontinence Impact Questionnaire) and ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form).

Results: *83% Response Rate on Primary Endpoint, 73% Average Reduction of Urine Leakage…*
Of the 36 enrolled participants, 28 completed full follow-up (i.e. were assessed on all endpoints) through 6 months and one completed full follow-up except for the 7-day voiding diary through 6 months. Management mentioned on the call that while the two-treatment protocol was used with a few women, that there was not an obvious difference in efficacy as compared to a single treatment (a single treatment will be employed in upcoming studies). Results, which are also in the table below (from VIVE's press release), were;

- **1-hour pad weight test:** the 1-hour pad weight test is also expected to serve as the primary endpoint in the two anticipated upcoming SUI LIBERATE studies. As measured by the 1-hour pad weight test (i.e. primary endpoint), average aggregate urine leakage decreased by 73% from baseline (6.2g vs 1.7g) and 83% (24 of 29) of women experienced improvement. For reference (and discussed in more detail below), FDA recommends (for the design of pivotal SUI studies) defining 'clinically meaningful improvement' as a reduction in urine leakage of 50% or more. Additionally (as it relates to the primary endpoint), 66% (19 of 29) of women met the clinically meaningful definition of 'dryness' - which is defined as urine leakage of one gram or less.
- **7-day voiding diary**: the 7-day voiding diary, along with the 1-hour pad weight test, are two measures that FDA recommends using as primary endpoints for pivotal SUI device studies. Based on the 7-day voiding diary, VIVE's feasibility study showed that, through 6 months (n=28), average aggregate incontinence episodes decreased by 50% from baseline (2.0 vs 1.0) and 79% (22 of 28) of women experienced an improvement in incontinence episodes. For reference, FDA recommends defining 'clinically meaningful improvement' for the 7-day voiding diary as greater than 50% reduction in incontinence episodes compared to baseline. While VIVE did not report on 'dryness' as measured by the 7-day voiding diary (defined in our endpoints discussion below), that may be included in the 12-month data (which, potentially could be available late this year or early 2019).
- **QoL questionnaires**: VIVE reported that, through 6 months, 'clinically meaningful' improvement was achieved on the composite scores of the three QoL questionnaires. Additionally, 69%, 83% and 86% of women reported improvement based on the IIQ-7, UDI-6 and ICIQ-UI-SF questionnaires. We discuss QoL measures for SUI device studies in more detail below.

SUI Feasibility 6-month Results

	1-HOUR PAD WEIGHT	DAILY INCONTINENCE EPISODE FREQUENCY	UDI-6	IIQ-7	ICIQ-UI-SF
BASELINE SCORES (N=29)	6.2 g	2.0 (N=28)	44	36	10.9
SCORES AT 6 MONTHS (N=29)	1.7 g	1.0 (N=28)	21	18	6.8
% REDUCTION FROM BASELINE AT 6 MONTHS (N=29)	72.6%	50.0% (N=28)	53.6%	49.2%	38.0%
RESPONDER RATE AT 6 MONTHS (IMPROVEMENT FROM BASELINE) (N=29)	82.8%	78.6% (N=28)	82.8%	69.0%	86.2%

SOURCE: Viveve Medical June 18, 2018 press release

- **Safety**: as has largely been the case with Viveve treatment of vaginal laxity, there were no device-related adverse events through 6 months in this SUI feasibility study.

While, given this was a small single-arm study with data only through 6 months, we cannot draw concrete conclusions in terms of efficacy. But, combined with positive data of the prior n=10 pilot study (see Appendix), results to-date certainly appear to support the hypothesis that the Viveve system may have real clinical utility in improving SUI symptoms. Given that from a regulatory standpoint, efficacy through 12 months is what is important - we should know a lot more in terms of the potential utility of the Viveve system in SUI when 12-month results of this study are available.

FDA Warning Letter Should Weed-Out Imposters and Benefit VIVE

On July 30th FDA issued a Safety Communications letter warning against the use of "Energy-Based Devices to Perform Vaginal 'Rejuvenation' of Vaginal Cosmetic Procedures". The purpose of the letter is to "alert patients and health care providers that the use of energy-based devices to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established."

FDA notes that they are aware of certain device manufacturers that may be marketing for these purposes – none of which are approved for those indications. FDA warns that if these devices are used for 'vaginal rejuvenation' (which includes vaginal laxity/sexual function) that they could cause vaginal burns, scarring, pain during intercourse, and recurring/chronic pain.

FDA has contacted those manufacturers that they believe may be marketing for these unapproved indications and notes that they will be monitoring claims about uses of their products. The manufacturers have 30 days to respond to FDA requests for;

- FDA clearance or approval number for the [name of device] for the additional claims referenced above [i.e. vaginal rejuvenation/sexual function/vaginal laxity or related to]

- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the [name of device] for the additional claims referenced above

FDA's letters to each of the manufacturers can be found here. The following are the companies that FDA contacted – **importantly, Viveve was not one of them**;

Manufacturers contacted by FDA for inappropriately marketing their products related to vaginal rejuvenation/sexual function/vaginal laxity/urinary incontinence:

Manufacturer	Device	FDA-approved/cleared for;
BTL Industries, Inc	Exilis	primary treatment of dermatologic and general surgical procedures for non-invasive treatment of w rinkles and rhytids
Cynosure, Inc.	DEKA SmartXide2 Laser System (MonaLisa Touch)	incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery
Alma Lasers	Alma Lasers Pixel CO2 Laser System (FemiLift),	surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiat1y, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee)
Sciton, Inc.	JOULE Multi-Platform System	for multiple general uses
Thermigen, Inc.	THERMIva	use in dermatological and general surgical procedures for electrocoagulation and hemostasis and to create lesions in nervous tissue w hen used in combination w ith Neuro Therm (previously Smith&Nephew) thermal/coagulation probes
BTL Aesthetics	Venus Fiore RF Ablation System	?
Inmode MD Ltd	FormaV and FractoraV lasers	?

Besides warning providers and women not to use energy-based devices for the unapproved uses related to vaginal rejuvenation, it essentially puts manufacturers on notice that FDA is watching and that they need to cease and

desist with any off-label marketing for these uses. While off-label use of medical devices (and drugs) is generally allowed and based on the providers' discretion, off-label marketing is not. This inappropriate marketing by manufacturers of energy-based devices for sexual function/vaginal laxity/rejuvenation/SUI has long been a major impetus to VIVE's focus on obtaining FDA approval for these indications (specifically, sexual function and SUI) as it would draw a clear and distinct line between the proven benefits (and safety) of the Viveve System and all the rest. This warning letter should almost certainly benefit VIVE in this regard as 'all of the rest' do not have FDA approval for those indications and VIVE is (by far) the furthest along towards obtaining marketing approval.

Viveve was not contacted by FDA regarding this. The Viveve System has also been evaluated in several human clinical studies in for both sexual function and SUI indications. It completed three human clinical studies (and recently began a fourth) related to sexual function/vaginal laxity, including VIVEVE I (multi-site U.S./Canada, RCT, n=174), which was used as support for their IDE application for VIVEVE II. VIVEVE II (multi-site, RCT, n=250) is expected to be (assuming positive results) the pivotal study that supports an eventual FDA filing seeking improvement in sexual function. Viveve received FDA IDE approval to conduct the study in March of this year – IDE approval inherently means that FDA believes any safety risks of using the Viveve System for vaginal procedures in this study are acceptable. Moreover, IDE approval was a fairly drawn-out process in which FDA, at several points, asked VIVE to provide additional information regarding safety.

Of note is that the FDA required VIVEVE II to use a staged roll-in enrollment approach to further ensure safety. While total enrollment is expected to be 250, this staged roll-in requires safety reviews after a certain number of patients have entered the study. In August FDA OK'd continuance of enrollment after their initial safety review.

The Viveve System has also completed two human studies in SUI, with a third currently ongoing (VIVE announced positive 6-month results of this study in June) and a fourth (LIBERATE International) which just commenced (following Health Canada ITA approval). VIVE expects to submit an IDE to FDA for approval of LIBERATE U.S., a large (n=200), multi-site, RCT in SUI in the very near-term.

The point here is that, it's clear that FDA is concerned about safety of energy-based devices used in vaginal aesthetic procedures and SUI and that, unlike some manufacturers, VIVE is following the appropriate path to be able to (legally) market their device for the indications that they are targeting. By contrast, some other devices have little or no formal human clinical study experience and therefore no verified safety record. Viveve's does – and the FDA would not have approved their IDE had they had overwhelming concerns about risk.

So, while we acknowledge that the headline reaction from FDA's warning letter may be a short-term headwind to VIVE (and a much more significant defeat for the other manufacturers), we think it is also a significant win for the company as it should weed out what are essentially the imposters (i.e. those with little to no formal clinical evidence supporting efficacy/safety in these indications). Further, we think FDA approval of the anticipated IDE supplement for VIVEVE II (as well as the separate IDE application for SUI), if that happens, would provide even more validation of the substantive separation between the Viveve System and all other energy-based devices.

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. Recent addition of practice development managers appears to be already benefitting domestic sales as well as ASPs. AMP provides complementary sales channel
- 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, start of VIVEVE II and successful initial safety review are major milestones and could further promote awareness and adoption. Indications are that SUI data, from the initial pilot study and randomized feasibility study, are already benefitting uptake in this indication. Initial data from LIBERATE and additional feasibility study data could further promote adoption in SUI. 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 66 countries and others that could come online soon, the geographic footprint continues to rapidly grow. While, unfortunately, geographic expansion has not resulted in recent international sales growth, we think there remains upside for OUS growth

With 16 capital reps as of YE2017, 23 today, build out of the practice management group, productivity gains and addition of AMP, we 128 U.S. placements in 2H'18 (vs 107 in 1H). We have OUS placements tracking at about 30% of the total. We model 306 total console sales in 2018 (vs 227 in 2017), including 235 in the U.S. (vs 160) – this implies slow but consistent productivity gains – which could prove conservative. We estimate consumable sales average ~2.3 per installed console per month in 2H, down slightly from the 2.6 average during 1H.

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 $7.75/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 $43.7M 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. Based on our DCF model, VIVE is valued at approximately $7.75/share (revised down from $8/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	Q2A	Q3E	Q4E	2018	2019	2020
Total Revenues	$7,141.0	$15,288.0	$3,699.0	$5,525.0	$4,912.0	$7,352.8	$21,488.8	$33,948.8	$43,667.1
YOY Growth	*393.5%*	*114.1%*	*21.6%*	*79.6%*	*20.7%*	*44.1%*	*40.6%*	*58.0%*	*28.6%*
Cost of Goods Sold	$4,612.0	$7,844.0	$2,352.0	$2,711.0	$2,374.2	$3,491.6	$10,928.7	$15,314.3	$17,758.5
Gross Income	$2,529.0	$7,444.0	$1,347.0	$2,814.0	$2,537.9	$3,861.2	$10,560.1	$18,634.5	$25,908.6
Gross Margin	*35.4%*	*48.7%*	*36.4%*	*50.9%*	*51.7%*	*52.5%*	*49.1%*	*54.9%*	*59.3%*
SG&A	$12,868.0	$28,831.0	$8,931.0	$9,437.0	$9,588.3	$9,970.3	$37,926.6	$45,559.3	$50,042.5
% SG&A	*180.2%*	*188.6%*	*241.4%*	*170.8%*	*195.2%*	*135.6%*	*176.5%*	*134.2%*	*114.6%*
R&D	$8,365.0	$12,343.0	$3,756.0	$3,672.0	$3,531.8	$3,823.4	$14,783.2	$11,610.5	$9,694.1
% R&D	*117.1%*	*80.7%*	*101.5%*	*66.5%*	*71.9%*	*52.0%*	*68.8%*	*34.2%*	*22.2%*
Operating Income	($18,704.0)	($33,730.0)	($11,340.0)	($10,295.0)	($10,582.2)	($9,932.6)	($42,149.7)	($38,535.3)	($33,828.0)
Operating Margin	*-261.9%*	*-220.6%*	*-306.6%*	*-186.3%*	*-215.4%*	*-135.1%*	*-196.1%*	*-113.5%*	*-77.5%*
Total Other Income (Expense)	($1,407.0)	($3,229.0)	($1,080.0)	($1,063.0)	($1,132.8)	($1,147.5)	($4,423.3)	($4,368.8)	($4,531.8)
Pre-Tax Income	($20,111.0)	($36,959.0)	($12,420.0)	($11,358.0)	($11,715.0)	($11,080.1)	($46,573.0)	($42,904.1)	($38,359.8)
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)	(158.0)	0.0	0.0	(407.0)	0.0	0.0
Net Income (continuing ops)	($20,111.0)	($36,959.0)	($12,669.0)	($11,516.0)	($11,715.0)	($11,080.1)	($46,980.0)	($42,904.1)	($38,359.8)
YOY Growth	*61.8%*	*83.8%*	*117.7%*	*-42.7%*	*75.0%*	*6.3%*	*27.1%*	*-8.7%*	*-10.6%*
Net Margin	*-281.6%*	*-241.8%*	*-342.5%*	*-208.4%*	*-238.5%*	*-150.7%*	*-218.6%*	*-126.4%*	*-87.8%*
EPS (continuing ops)	($2.18)	($2.12)	($0.49)	($0.37)	($0.37)	($0.35)	($1.56)	($1.18)	($0.98)
YOY Growth	*-12.2%*	*-3.1%*	*-10.3%*	*-83.1%*	*-35.0%*	*-34.7%*	*-26.0%*	*-24.4%*	*-17.5%*
Diluted Shares O/ S	9,215	17,470	25,847	31,305	31,400	31,550	30,026	36,250	39,300

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;[1]
- Inclusion:
  - pre-menopausal and ≥ 18 years of age
  - had least one full term vaginal delivery (>37 completed weeks) at least 12 months prior to enrollment date
  - experienced vaginal looseness (i.e. VSQ < 4) during vaginal intercourse
- **Exclusion:**
  - Pregnant or planning to become pregnant within the next 12 months or has had a delivery within the last 12 month
  - currently meets the criteria for a female sexual disorder including DSM V, FSAD, FOD, Genitopelvic Pain, Sexual Aversion, Dyspareunia or Vaginismus and has not been treated for this condition within the past 12 months
  - taking SSNRI or SSRI drugs

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

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

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

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

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

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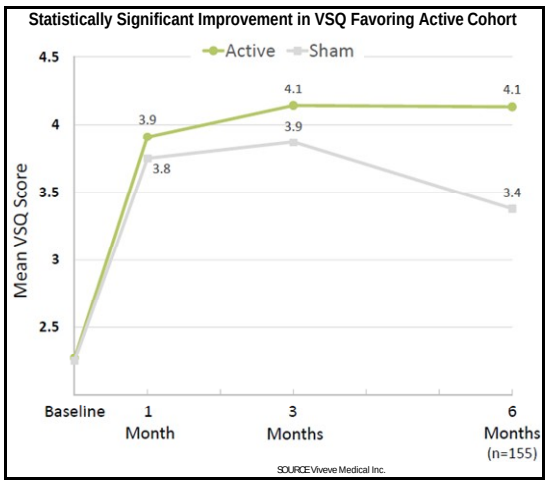
Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity							
					Logistic Regression		
Timepoint	Treatment Group	N	No Laxity n (%)	Chi-Squared p-value	Odds Ratio	95% CI	p-value
Month 6	Active	103	43 (41.7%)	0.005	3.05	(1.37, 6.79)	0.006
	Sham	52	10 (19.2%)				

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

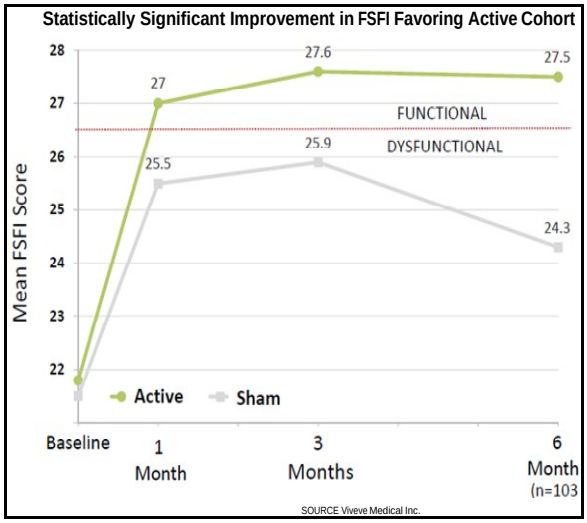
Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total 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 0.007
- satisfaction 0.097
- pain 0.122

[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.

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.[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 ≥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).

STRESS URINARY INCONTINENCE

SUI Pilot Study
N=10, single-arm. Conducted in Calgary, Alberta by Dr. Bruce Allan (Dr. Allan is also the PI of the ongoing n=36 SUI feasibility study and was also one of the PIs 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[5].

While VIVE provided only limited details, they did note (see slide from presentation, below) 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.

N=10 SUI Pilot Study Results at 12 Months

	UDI-6 (n=9)	ICIQ-UI (n=9)
Baseline Score	1567	9.4
12 Mos	767	5.7
% Reduction from Baseline	51%	40%
Responder Rate	100%	89%

SOURCE: Viveve Medical

[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
[5] 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.

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".

LIBERATE Pivotal Registration Trials, International Study Starts, U.S. Study IDE Filing Upcoming…
Success of these LIBERATE studies 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.

Following filing of an Investigational Trial Application (ITA, analogous to IDE in U.S.) to Health Canada, on August 14th VIVE announced that their LIBERATE international study had commenced. The 6-month feasibility study data will be used to support the IDE for approval to commence the U.S. LIBERATE study.

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
    - Secondary: (undisclosed) “other secondary endpoints”
    - Safety: through 12 months
  - Status: currently in the process of reviewing the protocol with Health Canada
- 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

SUI Market
According to the National Women's Health Resource Center[6] (NWHRC), SUI is estimated to effect 30% of all adult women in the U.S. (i.e. ~31M Americans) and of those with SUI, 53% have "slight" incontinence while 17% have severe incontinence. SUI can be a significant hindrance to quality of life. The NWHRC reports that while 75% of women with the condition find it "bothersome" (or worse) and 60% make lifestyle changes as a result of it, as many

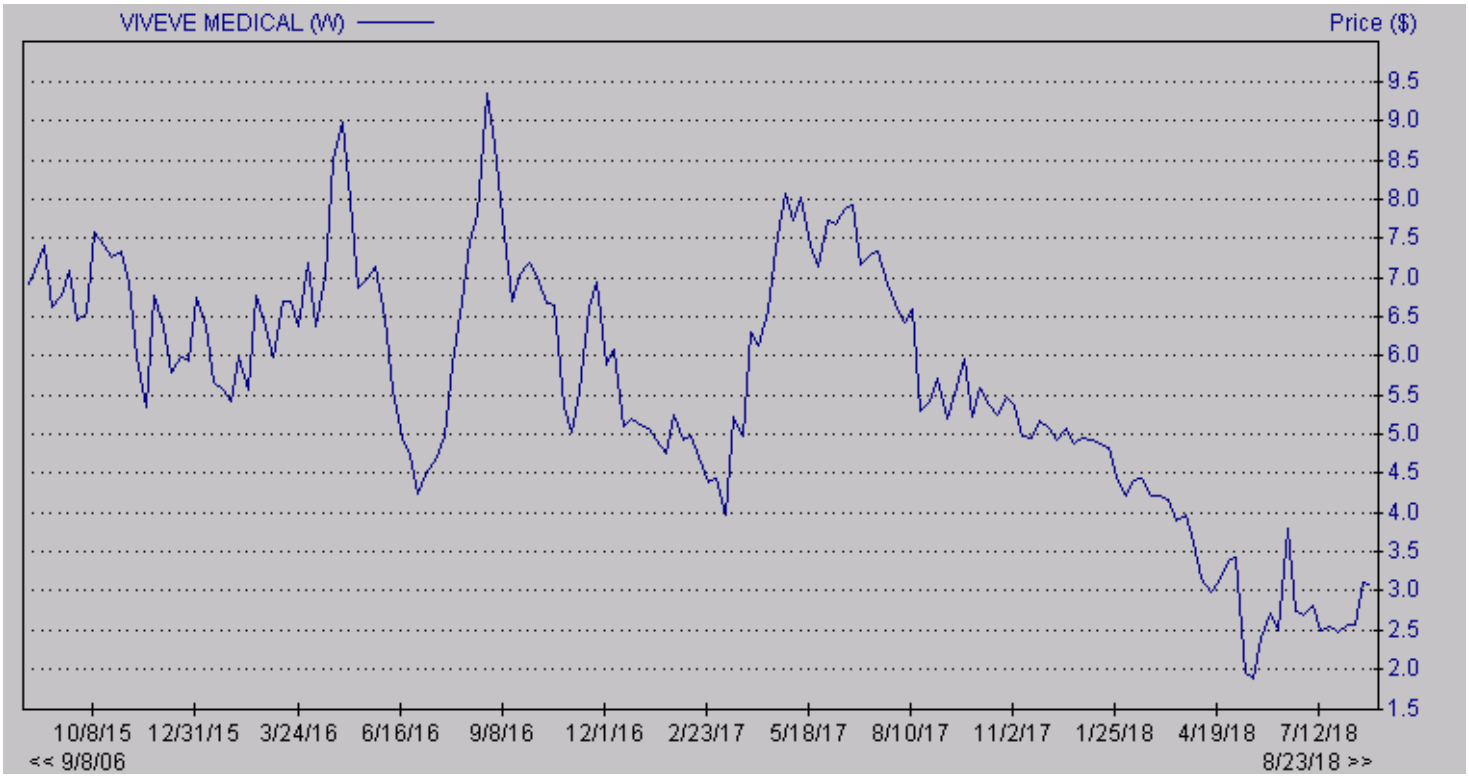
[6] National Women's Health Resource Center. Prevalence and Treatment Patterns of Pelvic Health Disorders Among U.S. Women. The Lewin Group. June 2007

as 50% to 75% of sufferers do not seek treatment (mostly as a result of embarrassment). SUI is more common among women that have had vaginal deliveries.

FDA's guidance on SUI endpoints

- Primary endpoints: FDA recommends that a urinary incontinence device pivotal trial use one or both of the following measures as primary endpoints: urine leakage as assessed by pad weight test and/or reduction in the number of incontinence episodes per day. If only of the two is used as the primary endpoint, FDA further recommends using the other as a secondary endpoint
  - pad weight test: with the 1-hour pad weight test (which can also be performed over a 24-hour period), 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. Relative to the what is considered clinically meaningful (with the objective on dryness) with the one-hour pad weight test, FDA recommends defining 'dryness' as an increase in pad weight of less than 1 gram and defining 'improvement' as a 50% or more decrease in weight from baseline
- Reduction in incontinence episodes: FDA recommends using a standardized voiding diary to document fluid intake and the number of incontinence episodes over seven consecutive days. The average number of incontinence episodes per day is then compared to baseline to determine effectiveness. With the 7-day voiding diary, FDA recommends using 'zero incontinence episodes per day' as the clinically meaningful definition of 'dryness' and 'greater than 50% reduction' (from baseline) as clinically meaningful improvement
- Secondary endpoints: FDA's general guidance relative to stress urinary incontinence clinical trials is to choose secondary endpoints which will provide additional evidence of the efficacy and safety of the device as well as to support performance and labeling. Among the possible secondary endpoints, FDA recommends considering measures related to quality of life (via questionnaires), sexual function, leak point pressure, bladder voiding and patient satisfaction. Specifically as it relates to;
  - QoL: FDA's guidance notes that since UI "is strongly associated with impairment of quality of life," that they recommend using validated QoL measures (as secondary endpoints) such as the Incontinence Quality of Life (I-QOL) questionnaire (as an example of one of many QoL measures that could be employed) and pre-specify the minimum delta that represents a meaningful improvement in QoL. FDA's guidance further recommends that choice of QoL measures should consider the specific populations and settings where they were developed and validated. FDA references The 3rd International Consultation on Incontinence as a source for choosing appropriate QoL measures, which includes the three QoL measures used in VIVE's feasibility study (UDI-6, IIQ-7 and ICIQ-UI-SF). While we may have more discussion on the topic after we know specifics of design of the two LIBERATE studies, we think the most important take-away at this point is that the three QoL measures used in this ongoing feasibility study are definitely validated clinical endpoints
  - Sexual function: based on close proximity to genitalia, FDA recommends consideration of a sexual function related measure (such as a validated sexual function questionnaire)
  - Patient satisfaction: incorporate a validated patient satisfaction questionnaire which asks the participant to rate the improvement (as compared to baseline) on several topics related to how SUI effects their lives and livelihoods

HISTORICAL STOCK PRICE



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