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Viveve Medical (VIVE-NASDAQ)

VIVE: SUI Indication Could Further Enhance Marketing Message, Drive Adoption

We use a 10-year DCF model to value VIVE. We have revenue growing from $7.1M in 2016 to $36M in 2020 and to approximately $95M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVE is valued at approximately $11/share.

Current Price (02/07/18)	$3.92
Valuation	**$11.00**

OUTLOOK

Last week 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 is a relatively common condition among women that have had children.

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

SUMMARY DATA

52-Week High	**$11.16**
52-Week Low	**$3.75**
One-Year Return (%)	**-18.74**
Beta	**-0.79**
Average Daily Volume (sh)	**146,220**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$76**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**67**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**70.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	1284 A	1556 A	1849 A	2452 A	7141 A
2017	3041 A	3073 A	4070 A	5098 E	15285 E
2018					23039 E
2019					29712 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.55 A	-$0.66 A	-$0.46 A	-$0.55 A	-$2.18 A
2017	-$0.57 A	-$0.54 A	-$0.50 A	-$0.48 E	-$2.06 E
2018					-$1.53 E
2019					$-1.25 E

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

VIVE Initiates SUI Program: Expanded Label = Enhanced Marketing Message, Adoption Driver

Last week 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 will serve as exclusive distributor of that company's innovative incontinence therapy devices to U.S. healthcare providers. ICM's product line, sold under the apexM, InTone, InToneMV and Intensity names, mainly focus on female incontinence and pelvic floor muscle stimulation. InTone and InToneMV are used to treat incontinence and require a doctor's prescription. apexM is also an incontinence device but is available without a prescription.

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.

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 (while Geneveve is FDA-cleared for 'general surgical procedures' it is mainly used off-label for vaginal laxity and/or to improve sexual function. An IDE application is outstanding for VIVEVE II, a pivotal FDA RCT (randomized, controlled trial) - positive results of which would provide support for a sexual function indication).

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".

Pivotal Registration Trials Planned, To Kick-Off Following Go-Ahead From Regulators

VIVE hopes to go straight to 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-

[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.

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.

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. Viveve also notes in their PR that the studies will include (undisclosed) secondary endpoints. 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 in VIVE's Jan 31st PR 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"

[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

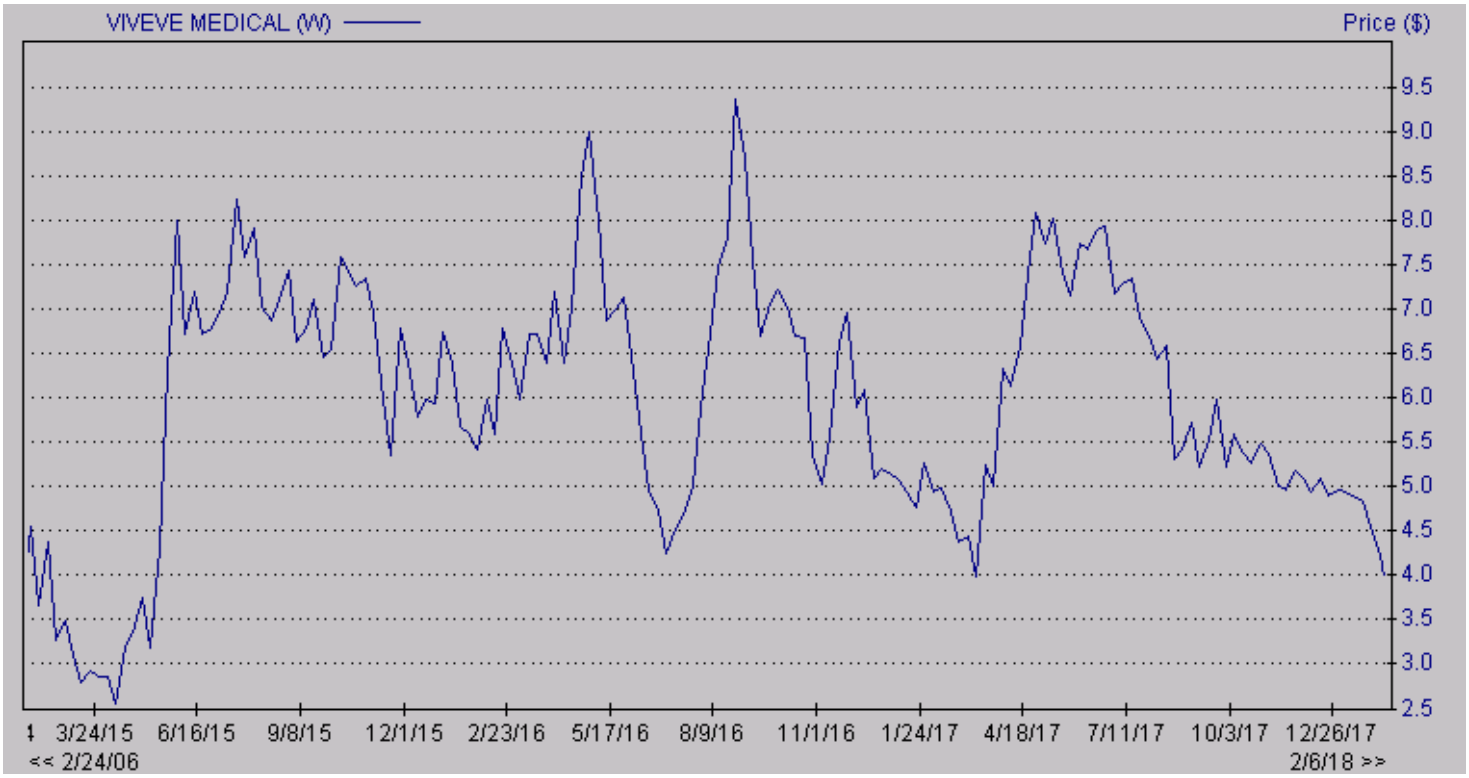
FINANCIAL MODEL

Viveve Medical, Inc

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018	2019	2020
Total Revenues	$7,141.0	$3,041.0	$3,076.0	$4,070.0	$5,098.4	$15,285.4	$23,038.6	$29,711.9	$35,991.1
YOY Growth	393.5%	136.8%	97.7%	120.1%	107.9%	114.1%	50.7%	29.0%	21.1%
Cost of Goods Sold	$4,612.0	$1,619.0	$1,837.0	$2,059.0	$2,642.1	$8,157.1	$11,016.5	$12,367.2	$12,870.6
Gross Income	$2,529.0	$1,422.0	$1,239.0	$2,011.0	$2,456.3	$7,128.3	$12,022.1	$17,344.7	$23,120.5
Gross Margin	35.4%	46.8%	40.3%	49.4%	48.2%	46.6%	52.2%	58.4%	64.2%
SG&A	$12,868.0	$5,450.0	$6,862.0	$7,369.0	$7,963.7	$27,644.7	$31,655.1	$35,981.1	$38,510.5
% SG&A	180.2%	179.2%	223.1%	181.1%	156.2%	180.9%	137.4%	121.1%	107.0%
R&D	$8,365.0	$2,388.0	$3,440.0	$3,464.0	$3,008.0	$12,300.0	$12,602.1	$8,794.7	$7,270.2
% R&D	117.1%	78.5%	111.8%	85.1%	59.0%	80.5%	54.7%	29.6%	20.2%
Operating Income	($18,704.0)	($6,416.0)	($9,063.0)	($8,822.0)	($8,515.4)	($32,816.4)	($32,235.1)	($27,431.1)	($22,660.2)
Operating Margin	-261.9%	-211.0%	-294.6%	-216.8%	-167.0%	-214.7%	-139.9%	-92.3%	-63.0%
Total Other Income (Expense)	($1,407.0)	($279.0)	($1,362.0)	($793.0)	($719.9)	($3,153.9)	($3,571.4)	($4,342.8)	($4,504.7)
Pre-Tax Income	($20,111.0)	($6,695.0)	($10,425.0)	($9,615.0)	($9,235.3)	($35,970.3)	($35,806.6)	($31,773.9)	($27,164.9)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-
Net Income (continuing ops)	($20,111.0)	($6,695.0)	($10,425.0)	($9,615.0)	($9,235.3)	($35,970.3)	($35,806.6)	($31,773.9)	($27,164.9)
YOY Growth	61.8%	82.1%	-16.1%	134.2%	73.7%	78.9%	-0.5%	-11.3%	-14.5%
Net Margin	-281.6%	-220.2%	-338.9%	-236.2%	-181.1%	-235.3%	-155.4%	-106.9%	-75.5%
EPS (continuing ops)	($2.18)	($0.57)	($0.54)	($0.50)	($0.48)	($2.06)	($1.53)	($1.25)	($1.01)
YOY Growth	-12.2%	7.1%	-78.3%	-9.6%	-27.7%	-5.6%	-25.7%	-18.6%	-19.3%
Diluted Shares O/S	9,215	11,664	19,373	19,409	19,420	17,467	23,400	25,500	27,000

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



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