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# Viveve Medical (VIVE-NASDAQ)

## 12-Month SUI Feasibility Study Data Further Supports Compelling Efficacy Signal

We use a 10-year DCF model to value VIVE. We have revenue growing from $15M in 2017 to $33M in 2020 and to approximately $92M 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 $4.75/share.

| | |
|---|---|
| Current Price (12/21/18) | $1.20 |
| **Valuation** | **$4.75** |

## OUTLOOK

Earlier this month Viveve announced 12-month results of its feasibility study evaluating their Viveve System technology for the treatment of women with mild-to-moderate stress urinary incontinence (SUI). The following week, results were presented at a SUI-focused KOL symposium sponsored by Viveve. The data, we believe, largely confirms the compelling efficacy signal seen at six months, which was announced in June. And while it appears, as might be expected, that there was somewhat of a deterioration of effectiveness from the six-month to the twelve-month follow up, with results of the 1-hour pad weight test continuing to show substantial improvement from baseline, we think this latest data further bolsters the likelihood of eventual success of the pivotal LIBERATE SUI studies.

We are already anxiously awaiting data from LIBERATE – and particularly from the U.S. study – which we do think is likely to successfully navigate the IDE process. If this recent compelling 12-month feasibility study data can be replicated (or at least strongly supported) in a pivotal U.S. study, we think it could be a substantial value inflection event for VIVE. The relatively massive size of the SUI market (~30M women) and current lack of effective, non-invasive and affordable treatment options means adoption of Viveve treatment in this indication could be quite rapid and potentially dwarf that of use for vaginal laxity/sexual function.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$5.22** |
| **52-Week Low** | **$1.04** |
| **One-Year Return (%)** | **-79.57** |
| **Beta** | **-0.34** |
| **Average Daily Volume (sh)** | **292,349** |
| **Shares Outstanding (mil)** | **45** |
| **Market Capitalization ($mil)** | **$54** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **46** |
| **Insider Ownership (%)** | **3** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **167.7** |
| **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** | **High,** |
| **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 | 4821 A | 3807 E | 17852 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 | -$0.39 A | -$0.32 E | -$1.53 E |
| 2019 | | | | | -$1.02 E |
| 2020 | | | | | -$0.94 E |

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

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**12-Month SUI Data, FDA OKs VIVEVE 2 To Progress, LIBERATE U.S. Start-Date Pushed Back**
It has been a busy few weeks for Viveve. In addition to raising nearly $19M (net) via the sale of common shares, they recently announced compelling 12-month results from their n=36 SUI feasibility study and got the green light from FDA to forge ahead with VIVEVE II (their pivotal U.S. study in sexual function). Below we discuss these, as well as other updates on the ongoing clinical programs in both sexual function and SUI.

**12-Month SUI Feasibility Study Data Further Supports Compelling Efficacy Signal…**
Earlier this month Viveve announced 12-month results of its feasibility study evaluating their Viveve System technology for the treatment of women with mild-to-moderate stress urinary incontinence (SUI). The following week, results were presented at a SUI-focused KOL symposium sponsored by the company. The data, we believe, largely confirms the compelling efficacy signal seen at six months, which was announced in June. And while it appears, as might be expected, that there was somewhat of a deterioration of effectiveness from the six-month to the twelve-month follow up, with results of the 1-hour pad weight test continuing to show substantial improvement from baseline, we think this latest data further bolsters the likelihood of eventual success of the pivotal LIBERATE SUI studies.

In mid-June Viveve announced what we characterized as potentially compelling 6-month data from its SUI 12-month feasibility study. Results at six-months and our accompanying commentary are available in our Appendix. And, for ease of reference, we have also included them in our 12-month results table below.

At the time of the 6-month data release we noted that while given that this was a small single-arm study with data only through 6 months, we could not draw concrete conclusions in terms of efficacy. But, we also noted that combined with positive data of the prior n=10 pilot study, results certainly appeared to support the hypothesis that the Viveve system may have real clinical utility in improving SUI symptoms. Further, we explained that from a regulatory standpoint, efficacy through 12 months is what is important - we expected to know a lot more in terms of the potential utility of the Viveve system in SUI when 12-month results of this study were available.

**Results:** *72% Experience Reduction in Pad Weight Resulting in 56% Mean Reduction. Response Particularly Strong in More Severe SUI*

While intended enrollment was 36, 28 patients completed follow-up through six months and 25 through 12 months. On a side note, this ~30% drop out rate may actually be quite indicative of some of the difficulty in effectively treating SUI with non-surgical therapy such as pelvic floor muscle exercises. Specifically, non-compliance (due to busy lives or other reasons) results in less effective outcomes. It is also suggestive of some of the potential appeal of Viveve SUI therapy – that is, a single, non-invasive treatment does not require rigid compliance (which is in addition to the benefits to surgical options).

- **1-hour pad weight test:** this is the primary endpoint in LIBERATE International (through six months) and is expected to also serve as the primary endpoint in LIBERATE U.S. (through 12 months). As measured by the 1-hour pad weight test, average aggregate urine leakage decreased by 56% from baseline (7.3g vs 3.2g) and 72% (18 of 25) of women experienced improvement.

  For reference, FDA recommends (for the design of pivotal SUI studies) defining 'clinically meaningful improvement' as a reduction in urine leakage of 50% or more. On this measure, 52% of all patients showed a clinically meaningful improvement. And perhaps even more compelling, is that 67% of those patients (n=10) diagnosed as having moderate (that is, more severe) SUI, had a clinically meaningful reduction in leakage. Additionally (as it relates to the 1-hour pad weight test), 60% and 50% of all women and women with moderate SUI, respectively, met the clinically meaningful definition of 'dryness' - which is defined as urine leakage of one gram or less.

  Given the particularly robust effectiveness in ‘moderate’ SUI patients, VIVE expects to power their U.S. LIBERATE study with similarly diagnosed severity – which should further enhance the chances of success of that study – which would further enhance eventual likelihood of U.S. label expansion for SUI.

- Secondary endpoints: while detailed results of the PRO secondary endpoints were not discussed in detail, Viveve noted in the data release that clinically meaningful benefit was achieved at 12 months across all patient reported outcome measures. The results are also included in the table below.

**Efficacy on 1-Hour Pad Weight Test (i.e. primary endpoint in LIBERATE studies) Holds Up through 12 months**

| | | 1-hour Pad Weight | Daily Incontinence Episodes | UDI-6 | IIQ-7 | ICIQ-UI-SF |
|---|---|---|---|---|---|---|
| **Baseline Scores;** | re: @ 6-month look (n=29) | 6.2 g | 2.0 (n=28) | 44 | 36 | 10.9 |
| | re: @ 12-month look (n=35) | 7.3 g | 2.2 | 47 | 39 | 11.3 |
| **Scores at;** | 6-months (n=29) | 1.7 g | 1.0 (n=28) | 21 | 18 | 6.8 |
| | 12-months (n=25) | 3.2 g | 0.8 | 29 | 20 | 7.8 |
| **% reduction from (respective) baseline;** | 6-months (n=29) | 72.6% | 50% (n=28) | 53.6% | 49.2% | 38.0% |
| | 12-months (n=25) | 56.1% | 63.5% | 37.4% | 48.7% | 30.7% |
| **Responder rate (relative to respective baseline);** | 6-months (n=29) | 82.8% | 78.6% (n=28) | 82.8% | 69.0% | 86.2% |
| | 12-months (n=25) | 72.0% | 64.0% | 68.0% | 72.0% | 76.0% |

**Given the particularly strong efficacy signal seen in more severe SUI, VIVE expects to power LIBERATE U.S. with a 'moderate SUI' population**

| Baseline Pad Weight | 12-Month Data: % of patients with > 50% reduction in pad weight from baseline | | | | Cure Rate (i.e. 1 ≥ g leakage) | |
|---|---|---|---|---|---|---|
| | 1 month | 4 months | 6 months | 12 months | 6 mths | 12 mths |
| All Patients 7.3 g (n=35) | 56%, 2.2 g | 73%, 1.3 g | 69%, 1.7 g | 52%, 3.2 g | 66% | 60% |
| Moderate SUI 17.5 g (n=10) | 89%, 3.4 g (n=9) | 100%, 1.2 g (n=9) | 86%, 2.7 g (n=7) | 67%, 4.8 g (n=6) | 29% | 50% |
| Mild SUI 3.2 g (n=25) | 44%, 1.7 g (n=25) | 63%, 1.3 g (n=24) | 64%, 1.4 g (n=22 | 47%, 2.7 g (n=19) | 77% | 68% |

We think this data affirms the efficacy signal witnessed through six months and further bolsters the likelihood of eventual success of both LIBERATE studies. During the KOL symposium presentation management also provided updates relative to VIVIVE II, LIBERATE International and LIBERATE U.S.

***As it relates to the LIBERATE studies….***

In August VIVE announced commencement LIBERATE-International, which (if successful) is expected to be used as primary support for SUI regulatory filings seeking marketing clearance in Canada and Europe. To-date, ~76 patients (of 99 total) have been enrolled across eight active sites. Another 19 have been screened and enrollment could complete within the next few weeks. Management is currently estimating that full results could be available in Q3 2019 (slightly delayed from prior ~mid-2019 expectation).

Meanwhile, in September VIVE made an IDE filing seeking approval to commence its U.S. SUI pivotal study, LIBERATE-U.S. While the hope had been that LIBERATE-U.S. could begin by late-2018/early-2019, that looks like it will not happen. During the SUI KOL symposium presentation management noted that, after a couple of rounds of questions from FDA regarding VIVE's IDE application, the agency requested that the company conduct a sheep safety study. VIVE further noted that this is very similar to what was required of them for final support of their VIVEVE IDE – which was eventually approved.

Given the demonstrated safety to-date in SUI (including acceptable safety/tolerability in the latest 12-month results) as well as in sexual function/vaginal laxity indications, coupled with the fact that this sheep study may effectively be a repeat of what was just successfully conducted, we have little concern that this will be problematic towards eventual IDE approval. But, it does push back anticipated timelines for LIBERATE U.S. Management hopes to

have the sheep study completed in 1H'19. They will then need to file an IDE supplement and, if all goes well, be in a position to start LIBERATE U.S. in the back half of next year. If that happens, management thinks they could have full 12-month data in late-2020/early-2021.

We are already anxiously awaiting data from LIBERATE – and particularly from the U.S. study – which we do think is likely to successfully navigate the IDE process. If this recent compelling 12-month feasibility study data can be replicated (or at least strongly supported) in a pivotal U.S. study, we think it could be a substantial value inflection event for VIVE. The relatively massive size of the SUI market (~30M women) and current lack of effective, non-invasive and affordable treatment options means adoption of Viveve treatment in this indication could be quite rapid and potentially dwarf that of use for vaginal laxity/sexual function.

***VIVEVE II Update***

As a reminder, VIVE received IDE approval of VIVEVE II in March 2018 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). FDA did another safety review once another 25 patients had been followed for one-month and 3-month data was available on a total of 50 patients. Management noted on the Q3 call (in November) that they expected to file this safety data, accompanied with an IDE application requesting to enroll the remaining 150 patients, by the end of November.

Apparently that happened as Viveve announced on December 20th that FDA approved enrollment to continue through to the total of 250. This approval was important given that it was a gatekeeper to finishing the study but, as we noted in our prior update, we think it may also play a role in re-accelerating domestic sales growth given that it is further evidence supporting the safety of Viveve treatment. If so, it is possible that FDA's green-lighting of the final enrollment cohort to proceed could resonate with potential purchasers of the system that may have been hesitant to do so due to the unfortunate halo effect of FDA's warning letter.

Management noted during the SUI KOL symposium that 19 sites are currently actively enrolling and now expects that final results of VIVEVE II could be available sometime in Q1 2020 (largely unchanged from prior expectations).

**Cash position**

VIVE beefed up their cash position through the recent sale of 13.3M common shares at $1.50/share for gross and net proceeds of $20.0M and ~$18.8M, respectively. With average quarterly operating burn of ~$11M and $20M cash on the balance sheet as of the close of Q3, we estimate current cash position is ~$30M. We think this should be sufficient to fund operations through at least mid-2019 and quite possibly through Q3 of next year.

**Valuation**

While our calculated fair value remains at approximately $215M, the increase in outstanding share count moves our per-share price target from $6.75 to $4.75.

## FINANCIAL MODEL

Viveve Medical, Inc

| | 2016 A | 2017 A | Q1A | Q2A | Q3A | Q4E | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|---|
| Total Revenues | $7,141.0 | $15,288.0 | $3,699.0 | $5,525.0 | $4,821.0 | $3,806.8 | $17,851.8 | $24,525.3 | $32,711.9 |
| YOY Growth | 393.5% | 114.1% | 21.6% | 79.6% | 18.5% | -25.4% | 16.8% | 37.4% | 33.4% |
| Cost of Goods Sold | $4,612.0 | $7,844.0 | $2,352.0 | $2,711.0 | $3,327.0 | $2,524.9 | $10,914.9 | $12,934.7 | $15,682.4 |
| Gross Income | $2,529.0 | $7,444.0 | $1,347.0 | $2,814.0 | $1,494.0 | $1,281.9 | $6,936.9 | $11,590.6 | $17,029.6 |
| Gross Margin | 35.4% | 48.7% | 36.4% | 50.9% | 31.0% | 33.7% | 38.9% | 47.3% | 52.1% |
| SG&A | $12,868.0 | $28,831.0 | $8,931.0 | $9,437.0 | $9,114.0 | $9,707.3 | $37,189.3 | $43,041.9 | $49,231.4 |
| % SG&A | 180.2% | 188.6% | 241.4% | 170.8% | 189.0% | 255.0% | 208.3% | 175.5% | 150.5% |
| R&D | $8,365.0 | $12,343.0 | $3,756.0 | $3,672.0 | $3,442.0 | $3,715.4 | $14,585.4 | $11,674.0 | $9,879.0 |
| % R&D | 117.1% | 80.7% | 101.5% | 66.5% | 71.4% | 97.6% | 81.7% | 47.6% | 30.2% |
| Operating Income | ($18,704.0) | ($33,730.0) | ($11,340.0) | ($10,295.0) | ($11,062.0) | ($12,140.9) | ($44,837.9) | ($43,125.3) | ($42,080.9) |
| Operating Margin | -261.9% | -220.6% | -306.6% | -186.3% | -229.5% | -318.9% | -251.2% | -175.8% | -128.6% |
| Total Other Income (Expense) | ($1,407.0) | ($3,229.0) | ($1,080.0) | ($1,063.0) | ($1,110.0) | ($1,147.5) | ($4,400.5) | ($4,368.8) | ($4,531.8) |
| Pre-Tax Income | ($20,111.0) | ($36,959.0) | ($12,420.0) | ($11,358.0) | ($12,172.0) | ($13,288.4) | ($49,238.4) | ($47,494.1) | ($46,612.7) |
| 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) | (158.0) | (132.0) | 0.0 | (539.0) | 0.0 | 0.0 |
| Net Income (continuing ops) | ($20,111.0) | ($36,959.0) | ($12,669.0) | ($11,516.0) | ($12,304.0) | ($13,288.4) | ($49,777.4) | ($47,494.1) | ($46,612.7) |
| YOY Growth | 61.8% | 83.8% | 117.7% | -42.7% | 83.8% | 27.5% | 34.7% | -4.6% | -1.9% |
| Net Margin | -281.6% | -241.8% | -342.5% | -208.4% | -255.2% | -349.1% | -278.8% | -193.7% | -142.5% |
| EPS (continuing ops) | ($2.18) | ($2.12) | ($0.49) | ($0.37) | ($0.39) | ($0.32) | ($1.53) | ($1.02) | ($0.94) |
| YOY Growth | -12.2% | -3.1% | -10.3% | -83.1% | -31.9% | -40.9% | -27.8% | -33.1% | -7.8% |
| Diluted Shares O/S | 9,215 | 17,470 | 25,847 | 31,305 | 31,491 | 41,795 | 32,609 | 46,525 | 49,550 |

Brian Marckx, CFA

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## APPENDIX

**Refresher on Compelling SUI Feasibility Study 6-Month Data:** *Meaningful Improvement On All Endpoints…*

In mid-June Viveve announced what we characterized as potentially compelling 6-month data from its SUI 12-month feasibility study.

**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 June 2018 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 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, 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.

**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.

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