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Viveve Medical (VIVE-NASDAQ)

Q4 Preannouncement, 2019 Guidance / Strategic Restructuring

Based on our DCF model, VIVE is valued at approximately $4.75/share.

Current Price (01/18/19)	$1.20
Valuation	**$4.75**

OUTLOOK

Earlier this week Viveve preannounced expected Q4 revenue of ~$4.4M (~16% ahead of our since-revised estimate), issued initial 2019 revenue guidance of $20.0M (~17% below our since-revised estimate) and outlined an already-underway operational restructuring plan aimed at slashing expenses and refocusing sales efforts at the physician (i.e. non-aesthetic)/SUI-interested segment. The restructuring plan includes significant cuts to the workforce. Per the 8-K, VIVE's headcount will be slashed by 36% to 68 FTEs (from an implied 106) by January 22nd. While VIVE will take a severance-related charge of $900k, we expect this to result in a significant reduction of operating expenses. Assuming a slightly lower proportional reduction to SG&A, we think total operating expenses (assuming flattish R&D) could fall by as much as $12M or more from 2018 to 2019. If that happens and VIVE can hit their $20M revenue guidance, we think operating loss could improve from ~$46M (estimated in FY2019) to under $32M in 2019.

While the reasoning behind the restructuring largely rests on cutting costs, we think the timing is also somewhat prescient given the not-so-subtle shift in focus that has been ongoing from sexual function over to the (much larger) SUI market. It appears that management is now more fully embracing that shift – while we expect the aesthetic/sexual function market to remain an important component of VIVE's business, we think SUI may soon represent the majority of the company's opportunity for accelerating growth.

SUMMARY DATA

52-Week High	**$4.93**
52-Week Low	**$0.93**
One-Year Return (%)	**-76.25**
Beta	**0.62**
Average Daily Volume (sh)	**314,235**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**47**
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 2019 Estimate	**N/A**
P/E using 2020 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	4419 E	18464 E
2019					19400 E
2020					25162 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	-$0.34 E	-$1.56 E
2019					-$0.77 E
2020					-$0.63 E

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

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Q4 Preannouncement, 2019 Guidance / Strategic Restructuring

Earlier this week Viveve preannounced expected Q4 revenue of ~$4.4M (~16% ahead of our since-revised estimate), issued initial 2019 revenue guidance of $20.0M (~17% below our since-revised estimate) and outlined an already-underway operational restructuring plan aimed at slashing expenses and refocusing sales efforts at the physician (i.e. non-aesthetic)/SUI-interested segment.

Q4 numbers (vs our estimates) are 57 (vs 55 E) unit sales, including 48 (vs 40 E) in the U.S. and 9 (vs 15) OUS and 4,600 (vs 5,047 E) consumable treatment tips. The ~$4.4M in expected Q4 revenue implies declines of 13% from Q4'17 and 8% from Q3'18. But, it's at the top-end of management's prior FY2018 revenue guidance, which implied Q4 revenue in the range of $3.4M - $4.4M, and well ahead of our $3.8M estimate. Perhaps even more encouraging is that, based on our calculations, it looks like it also implies relatively healthy pricing – while we do not have any particular insight, we think this suggests ASPs of U.S. consoles may have returned to more normalized levels (and benefitted from the new-gen 2.0 system).

The restructuring plan includes significant cuts to the workforce. Per the 8-K, VIVE's headcount will be slashed by 36% to 68 FTEs (from an implied 106) by January 22nd. While VIVE will take a severance-related charge of $900k, we expect the cuts to result in a significant reduction of operating expenses. Assuming a slightly lower proportional reduction to SG&A, we think total operating expenses (assuming flattish R&D) could fall by as much as $12M or more from 2018 to 2019. If that happens and VIVE can hit their $20M revenue guidance, we think operating loss could improve from ~$46M (estimated in FY2018) to under $32M in 2019.

While the reasoning behind the restructuring largely rests on cutting costs, we think the timing is also somewhat prescient given the not-so-subtle shift in focus that has been ongoing from sexual function over to the (much larger) SUI market. It appears that management is now more fully embracing that shift – while we expect the aesthetic/sexual function market to remain an important component of VIVE's business, we think SUI may soon represent the majority of the company's opportunity for accelerating growth. Given the relatively massive size of the target population (30M in U.S.) and compromise to quality of life among those suffering from the condition, an SUI indication for the Viveve System could prove a more potent revenue driver than that of sexual function.

In addition, FDA's July 2018 warning letter to other energy-based manufacturers appears to have created a stiffer and longer than expected headwind to Viveve's sales – which we think provides additional rationale to accelerate their shift from aesthetics to gynecologists and urologists which are seeking non-invasive SUI therapeutic alternatives.

And, with more and more data showing the effectiveness of the Viveve System in SUI, this should act as a catalyst to help drive awareness and adoption for use in that indication. An IDE seeking approval to commence LIBERATE U.S., the company's proposed U.S.-based FDA pivotal study, is expected to be filed following conclusion of a sheep safety study. Successful completion of the safety study, which we have little concern about (see our discussion below), would get them one important step closer to an FDA label for use in SUI – it should also help drive physician awareness about the technology.

And VIVE has already successfully completed SUI studies. As a reminder, in December VIVE announced 12-month results of its feasibility study evaluating their Viveve System for the treatment of women with mild-to-moderate stress urinary incontinence. 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.

In addition to those results, LIBERATE International, their pivotal OUS SUI study, is expected to read out later this year. If all goes well, VIVE could have CE Marking and Health Canada approval for an SUI indication shortly afterwards.

So, given the opportunity in SUI, we think VIVE's strategic reorganization, including what appears to be a more determined shift with its direct sales efforts from sexual function to SUI, makes sense. And while SUI is where we have as of recently begun to believe where much of the upside growth potential lies, we do think sexual function will remain an important part of the company's overall focus. With VIVEVE II enrolling rapidly, the final patient could run through in the next two or three months – and with a 12-month follow-up, this means topline data could be available sometime in 1H of next year.

Depending on what the data shows and assuming positive results from LIBERATE U.S. (in SUI), we think VIVE could be in an even more potent position – including potentially looking at on-label use in the U.S. for both sexual function and SUI. At that point their strategic options may once more be reevaluated and could include a re-expansion of their sexual function/aesthetic channel focus and complement their SUI/physician strategy. In the meantime, with VIVE's direct reps now detailing to gyns and urologists, we expect they will look to broaden their third-party distribution capabilities to fill in gaps in the aesthetic space in both the U.S. and internationally.

As a refresher, in December VIVE 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…
In December 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.

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).

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	$4,419.0	$18,464.0	$19,400.1	$25,161.6
YOY Growth	393.5%	114.1%	21.6%	79.6%	18.5%	-13.4%	20.8%	5.1%	29.7%
Cost of Goods Sold	$4,612.0	$7,844.0	$2,352.0	$2,711.0	$3,327.0	$2,894.7	$11,284.7	$10,693.3	$12,486.3
Gross Income	$2,529.0	$7,444.0	$1,347.0	$2,814.0	$1,494.0	$1,524.3	$7,179.3	$8,706.8	$12,675.3
Gross Margin	35.4%	48.7%	36.4%	50.9%	31.0%	34.5%	38.9%	44.9%	50.4%
SG&A	$12,868.0	$28,831.0	$8,931.0	$9,437.0	$9,114.0	$10,402.3	$37,884.3	$24,521.7	$27,929.4
% SG&A	180.2%	188.6%	241.4%	170.8%	189.0%	235.4%	205.2%	126.4%	111.0%
R&D	$8,365.0	$12,343.0	$3,756.0	$3,672.0	$3,442.0	$4,312.9	$15,182.9	$15,714.1	$11,222.1
% R&D	117.1%	80.7%	101.5%	66.5%	71.4%	97.6%	82.2%	81.0%	44.6%
Operating Income	($18,704.0)	($33,730.0)	($11,340.0)	($10,295.0)	($11,062.0)	($13,190.9)	($45,887.9)	($31,529.0)	($26,476.2)
Operating Margin	-261.9%	-220.6%	-306.6%	-186.3%	-229.5%	-298.5%	-248.5%	-162.5%	-105.2%
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)	($14,338.4)	($50,288.4)	($35,897.8)	($31,008.0)
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)	($14,338.4)	($50,827.4)	($35,897.8)	($31,008.0)
YOY Growth	61.8%	83.8%	117.7%	-42.7%	83.8%	37.5%	37.5%	-29.4%	-13.6%
Net Margin	-281.6%	-241.8%	-342.5%	-208.4%	-255.2%	-324.5%	-275.3%	-185.0%	-123.2%
EPS (continuing ops)	($2.18)	($2.12)	($0.49)	($0.37)	($0.39)	($0.34)	($1.56)	($0.77)	($0.63)
YOY Growth	-12.2%	-3.1%	-10.3%	-83.1%	-31.9%	-36.2%	-26.3%	-50.5%	-18.9%
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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HISTORICAL STOCK PRICE



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