Zacks Small-Cap Research

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Viveve Medical (VIVE-NASDAQ)

VIVE: FDA Clearance for GSP, IDE Filed

We use a 10-year DCF model to value VIVMD. We have revenue growing from $5.7M in 2016 to $22.0M in 2019 and to approximately $78M in 2026. Other key inputs to our DCF include a 11% discount rate and 2% terminal growth rate. Based on our DCF model, VIVMD is valued at approximately $11/share.

Current Price (10/13/16)	$6.90
Valuation	**$11.00**

OUTLOOK

Viveve's flagship product, the Viveve System, is used to treat vaginal laxity and sexual function, a condition which is often caused by vaginal childbirth and one in which about 50% of women that have undergone normal vaginal delivery hold as a concern. Other methods exist to address vaginal laxity although they suffer from certain drawbacks.

VIVEVE I large, randomized clinical study results confirmed earlier findings that Viveve System significantly improves sexual function and reduces vaginal laxity. This marketing study, along with data from previous studies and the recent significantly beefed-up distribution is expected to help accelerate the roll-out of the Viveve System. Brazil and U.S., which lead the world in vaginal rejuvenation procedures, could come online in the near term. Next steps are to conduct U.S. study in support of FDA filing for treatment of vaginal tissue to improve sexual function – study could initiate this year. In the meantime, will look to initially commercialize in U.S. under general surgical indication

Our DCF-based valuation values the company at $11/share.

SUMMARY DATA

52-Week High	**$9.38**
52-Week Low	**$4.10**
One-Year Return (%)	**-9.63**
Beta	**1.27**
Average Daily Volume (sh)	**50,824**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$72**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**52**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 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)
2015	38 A	73 A	584 A	752 A	1447 A
2016	1284 A	1556 A	1322 E	1493 E	5655 E
2017					11017 E
2018					16492 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$1.10 A	-$0.68 A	-$0.50 A	-$0.54 A	-$2.48 A
2016	-$0.55 A	-$0.66 A	-$0.39 E	-$0.40 E	-$1.71 E
2017					-$1.94 E
2018					-$1.37 E

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

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FDA Clearance for GSP for Coagulation and Hemostasis, IDE Filed

Viveve continues to make substantive progress towards their quest to commercialize the Viveve System in the U.S. In late September the company submitted an IDE to FDA seeking approval to commence VIVEVE II, a pivotal U.S.-based study expected to support an eventual regulatory filing seeking clearance for an indication related to improvement in sexual function. Assuming timely approval of the IDE, this study could potentially commence in Q1 2017. VIVE's Sept 27 press release notes that the proposed pivotal study will include ~250 patients at up to 25 study sites in the U.S. and Canada which will be randomized 1:1 active/sham. This proposed design is exactly in-line with what we had anticipated as is the FSFI primary endpoint.

Then just last week, VIVE announced the Viveve System received 510(k) clearance for general surgical procedures for electrocoagulation and hemostasis. We expect the company will provide an update on their plans for initial commercialization under this indication in the near-term. As we have noted in the past, we think this indication will provide VIVE will some early revenue opportunity but, perhaps more importantly, it allows for initial awareness building in the U.S. as they pursue a sexual function indication.

VIVE has also made **additional progress on the international commercialization front**. This includes gaining regulatory approval of the Viveve System in Australia (announced Sept 8) and consummating a distribution agreement with Device Consulting for that country and New Zealand. And, most recently, VIVE announced (Sept 15) a distribution relationship with Melon Ltd for Finland. Viveve now has distribution lined up in 69 countries, 30 of which the Viveve System has already gained regulatory clearance.

Refresher on Pathway for FDA Clearance for Improvement of Sexual Function…..

Highly Positive VIVEVE I Study Results…
In April 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

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

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).

Mean VSQ score 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)

The mean difference at 6 months of 0.7 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. 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 0.004
- satisfaction 0.097
- pain 0.122

But while just two of the six individual domains hit statistical significance, the weighted average of the six domains of the active arm (27.5) was statistically different from that of the sham arm (24.3) at the 6-month follow-up. 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

[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.

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 weighted average total score, as opposed to individual domain scores, is what FDA will be looking for as an endpoint in VIVE's proposed pivotal U.S. study. And while it is uncertain as to whether FDA will accept FSFI as a primary endpoint in VIVEVE II, we are encouraged that this is a clinical industry metric which has already been well-validated and documented. We think if accepted by FDA, that these VIVEVE I results, coupled with similarly positive FSFI results in the prior two studies, bode well for chances that VIVEVE II also hits statistical significance on FSFI.

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) or secondary (VSQ) endpoints 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; 32.5% active vs. 35.1% sham
- related treatment-emergent adverse events; 11.1% active vs. 12.3% sham
- serious treatment-emergent adverse events; 0% active vs. 1.8% sham

NEXT STEPS

U.S. IDE: In late September the company submitted an IDE to FDA seeking approval to commence VIVEVE II, a pivotal U.S.-based study expected to support an eventual regulatory filing seeking clearance for an indication related to improvement in sexual function. Assuming timely approval of the IDE, this study could potentially commence in Q1 2017.

VIVE intends to seek an indication for 'the treatment of vaginal tissue to improve sexual function', with (weighted average total) FSFI as the primary endpoint. While 'vaginal laxity' as measured by VSQ (or a version of) was the primary endpoint in all three of Viveve's clinical trials, VSQ is a proprietary metric developed by Viveve and may not be deemed acceptable to FDA without further scrutiny and validation. By contrast, FSFI is a clinical industry metric which has already been well-validated and documented. Management has also previously noted that they hope to incorporate VSQ as a secondary endpoint.

So assuming FDA concurs with a proposed FSFI endpoint and eventual FDA clearance for the treatment of vaginal tissue to improve sexual function indication, the Viveve System would be the only therapy approved for that claim providing significant and substantive difference from all other vaginal laxity-related devices. This, in our opinion, could be a game-changer for Viveve.

Marketing Message: VIVE will also likely look to have the VIVEVE I data published. They will also certainly be incorporated into the current marketing message outside of the U.S. We think this data could be potent – while the two prior studies provided evidence of significant efficacy of the Viveve System in both vaginal laxity and sexual function, the larger size and sham-controlled nature of VIVEVE I should provide clinicians with a much more definitive conclusion to the device's effectiveness.

U.S. Study: assuming IDE approval, VIVE will move towards clinical trial site selection and IRB approvals. VIVE's Sept 27 press release announcing that they had submitted the IDE notes that the proposed pivotal study will include ~250 patients at up to 25 study sites in the U.S. and Canada which will be randomized 1:1 active/sham. And as anticipated, primary endpoint is expected to be FSFI.

We expect additional interaction between VIVE and FDA prior to commencement of the study (assuming the IDE is approved). Discussions should include finalizing clinical trial design including size, endpoints and indications. We note that VIVEVE I was obviously not a U.S. or in any way an FDA-affiliated study – as such, design, size, endpoints and other components of VIVEVE II could differ from that of VIVEVE I, and potentially meaningfully so. We may know more in the coming few months.

APPENDIX

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 $\geq$15 reliably identifies over 90% of women who are currently experiencing sexually related personal distress (Derogatis et al 2008).

Vaginal Introitus Laxity Inventory (VALI)[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).

[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

FINANCIAL MODEL

Viveve Medical, Inc

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018	2019
Total Revenues	$1,447.0	$1,284.0	$1,556.0	$1,322.1	$1,493.0	$5,655.1	$11,016.9	$16,491.7	$21,462.0
YOY Growth	*1507.8%*	*3278.9%*	*2031.5%*	*126.4%*	*98.5%*	*290.8%*	*94.8%*	*49.7%*	*30.1%*
Cost of Goods Sold	$985.0	$936.0	$1,022.0	$856.3	$944.6	$3,758.8	$6,589.8	$8,712.7	$9,355.1
Gross Income	$462.0	$348.0	$534.0	$465.8	$548.4	$1,896.2	$4,427.1	$7,779.0	$12,106.8
Gross Margin	*31.9%*	*27.1%*	*34.3%*	*35.2%*	*36.7%*	*33.5%*	*40.2%*	*47.2%*	*56.4%*
SG&A	$7,464.0	$2,548.0	$2,615.0	$2,555.0	$2,794.0	$10,512.0	$12,228.7	$13,853.0	$14,594.1
% SG&A	*515.8%*	*198.4%*	*168.1%*	*193.3%*	*187.1%*	*185.9%*	*111.0%*	*84.0%*	*68.0%*
R&D	$4,988.0	$1,796.0	$2,463.0	$1,881.0	$1,864.0	$8,004.0	$8,615.0	$5,544.0	$4,789.0
% R&D	*344.7%*	*139.9%*	*158.3%*	*142.3%*	*124.9%*	*141.5%*	*78.2%*	*33.6%*	*22.3%*
Operating Income	($11,990.0)	($3,996.0)	($4,544.0)	($3,970.2)	($4,109.6)	($16,619.8)	($16,416.6)	($11,618.0)	($7,276.3)
Operating Margin	*-828.6%*	*-311.2%*	*-292.0%*	*-300.3%*	*-275.3%*	*-293.9%*	*-149.0%*	*-70.4%*	*-33.9%*
Total Other Income (Expense)	($436.0)	($110.0)	($772.0)	($197.5)	($197.5)	($1,277.0)	($741.2)	($513.6)	($178.7)
Pre-Tax Income	($12,426.0)	($4,106.0)	($5,316.0)	($4,167.7)	($4,307.1)	($17,896.8)	($17,157.8)	($12,131.6)	($7,455.0)
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)	($12,426.0)	($4,106.0)	($5,316.0)	($4,167.7)	($4,307.1)	($17,896.8)	($17,157.8)	($12,131.6)	($7,455.0)
YOY Growth	*101.1%*	*135.6%*	*-14.0%*	*65.1%*	*43.3%*	*44.0%*	*-4.1%*	*-29.3%*	*-38.5%*
Net Margin	*-858.7%*	*-319.8%*	*-341.6%*	*-315.2%*	*-288.5%*	*-316.5%*	*-155.7%*	*-73.6%*	*-34.7%*
EPS (continuing ops)	($2.48)	($0.55)	($0.66)	($0.39)	($0.40)	($1.94)	($1.37)	($0.89)	($0.52)
YOY Growth	*-75.5%*	*-73.9%*	*-93.5%*	*-64.3%*	*-40.4%*	*-21.9%*	*-29.3%*	*-35.5%*	*-41.5%*
Diluted Shares O/S	5,000	7,493	8,081	10,600	10,700	9,218	12,500	13,700	14,400

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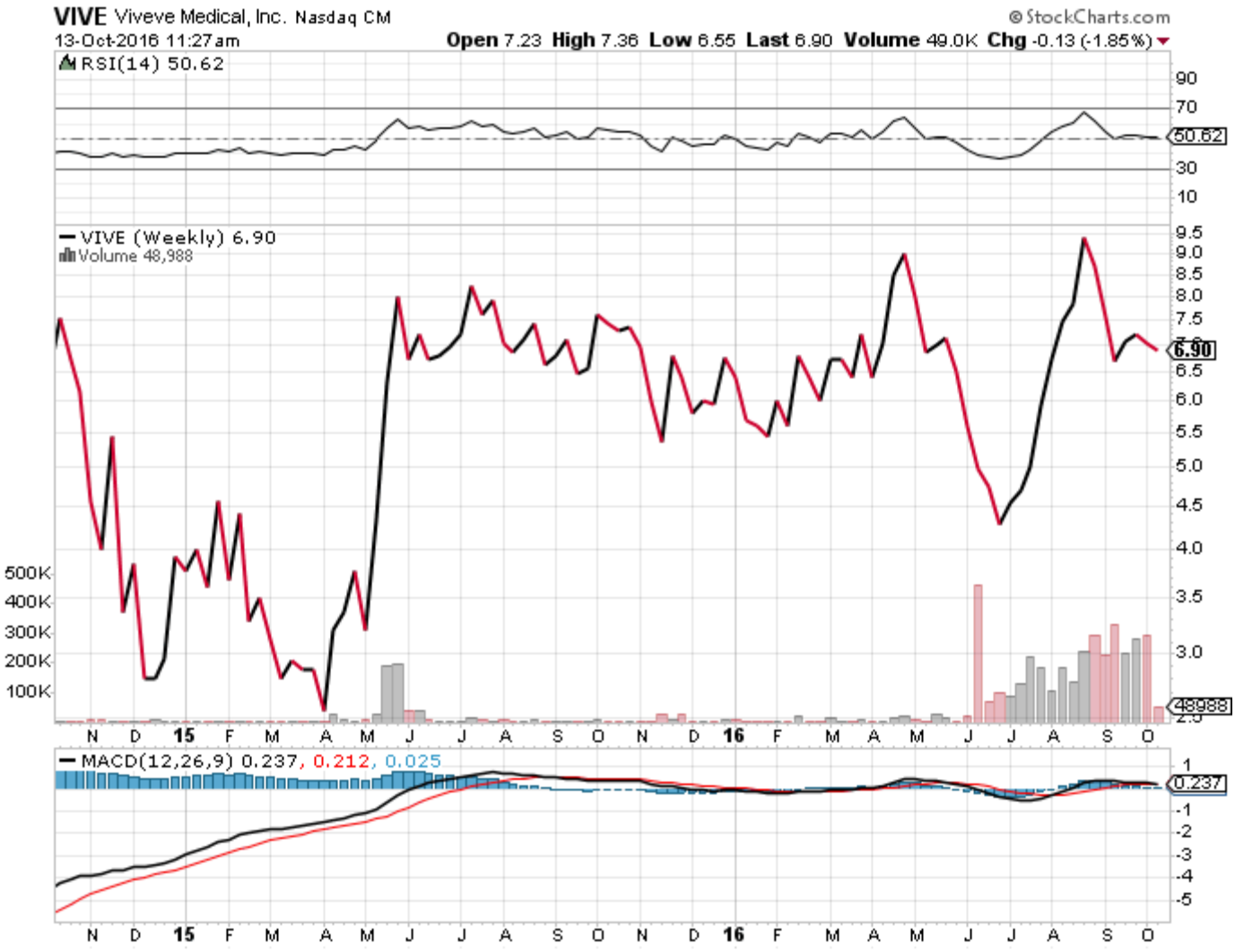

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