Zacks Small-Cap Research

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Viveve Medical (VIVE-NASDAQ)

VIVE: Sub-Analysis Data Provides Additional Confidence in Eventual Success of VIVEVE II

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 (12/08/17)	$4.99
Valuation	**$11.00**

OUTLOOK

Sub-analysis of the VIVEVE I data showed that patients which underwent a single treatment with the Viveve System experienced greater improvement on all six domains of the sexual-functioning FSFI measure versus patients given sham treatment. Improvement (versus sham) on three of the six domains was statistically significant. Additionally, mean FSFI total score of patients treated with Viveve improved from "sexually dysfunctional" to "sexually functional" while mean FSFI total score of the sham cohort remained at "sexually dysfunctional". The manuscript was published online in late November in the Journal of Women's Health and will be subsequently published in the print version.

Further parsing the VIVEVE I patient population by incorporation of a sexual dysfunction inclusion criterion appears to provide additional supporting evidence of the efficacy of Viveve treatment in improvement of sexual function as measured by FSFI. As design of VIVEVE II is expected to incorporate FSFI score $\leq$ 26.5 as an inclusion criteria and use mean change in total FSFI score as the primary endpoint, this sub-analysis data should provide additional confidence in the eventual success of Viveve's FDA pivotal study.

SUMMARY DATA

52-Week High	**$11.16**
52-Week Low	**$3.75**
One-Year Return (%)	**-18.62**
Beta	**1.04**
Average Daily Volume (sh)	**163,944**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**81**
Insider Ownership (%)	**8**
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	5210 E	15397 E
2018					23046 E
2019					29721 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	-$2.07 E
2018					-$1.53 E
2019					-1.25 E

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

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New Sub-Analysis Further Supports Efficacy of Viveve Treatment on Sexual Functioning:

Effect of Single-Session, Cryogen-Cooled Monopolar Radiofrequency Therapy on Sexual Function in Women with Vaginal Laxity: The VIVEVE I Trial[1], a sub-analysis of the VIVEVE I (i.e. initial U.S. randomized study) data, showed that patients which underwent a single treatment with the Viveve System experienced greater improvement on all six domains of the sexual-functioning FSFI measure versus patients given sham treatment. Improvement (versus sham) on three of the six domains was statistically significant. Additionally, mean FSFI total score of patients treated with Viveve improved from "sexually dysfunctional" to "sexually functional" while mean FSFI total score of the sham cohort remained at "sexually dysfunctional" (i.e. unchanged). The manuscript was published online in late November in the Journal of Women's Health and will be subsequently published in the print version.

As a refresher on VIVEVE I, this was the largest sham-controlled study evaluating the Viveve System for the treatment of vaginal laxity. Inclusion criteria were;

- 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

Note that the FSFI sub-analysis of VIVEVE I also had as inclusion criteria 'baseline FSFI total score of ≤ 26.5' while VIVEVE I did not include that criteria. An FSFI score ≤ 26.5 is clinically considered as having "sexually dysfunction" so this sub-analysis specifically evaluated the ability of Viveve therapy in improving sexual function.

VIVEVE I's primary efficacy endpoint, which related to vaginal laxity (as measured by the "Viveve System Questionnaire"), was met. Per topline results announced in April 2016, 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.

Secondary efficacy endpoints included 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.

Female Sexual Function Index (FSFI)…

As this discussion is in the context of FSFI, we will contain our analysis to that measure. 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]

FSFI was used as both a primary and secondary endpoint in the phase III trials used to support FDA approval of Sprout Pharmaceuticals' drug, Addyi (fibanserin), also sometimes referred to as the "female Viagra". It is also expected to be the primary endpoint in VIVEVE II.

Refresher of FSFI Results of VIVEVE I…

In VIVEVE I (i.e. not the sub-analysis), 103 (71 active, 32 sham) patients were included in the FSFI per-protocol population. Top-line results were announced in April 2016. Of the six domains, two (sexual arousal and orgasm) were statistically different favoring the active arm (arousal and orgasm could 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

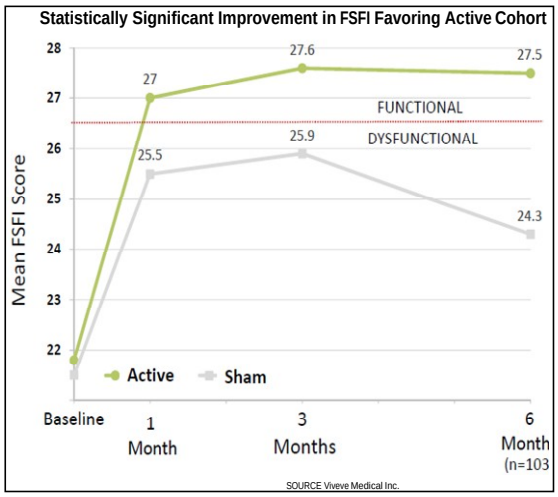
[1] Krychman MD, M. et al. Effect of Single-Session, Cryogen-Cooled Monopolar Radiofrequency Therapy on Sexual Function in Women with Vaginal Laxity: The VIVEVE I Trial. J. Women's Health. Nov. 2017

[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.

- 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 (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.

VIVEVE I Total FSFI

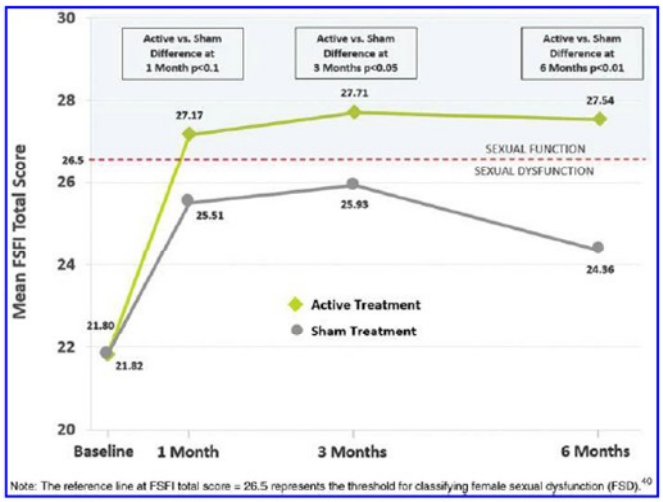


Sub-Analysis Further Supports Efficacy of Viveve Treatment on Sexual Function
The sub-analysis, as mentioned above, further parsed the evaluable patient cohorts by incorporation of a baseline FSFI score ≤ 26.5 criteria. So, of the original cohorts, only those patients which FSFI clinically defined as having sexual dysfunction (prior to treatment) were evaluated in the sub-analysis.

A total of 108 (73 active, 35 sham) patients met the baseline FSFI score ≤ 26.5 criteria (as well as the original inclusion/exclusion criteria) and were evaluable at the predetermined 6-month follow-up (i.e. primary endpoint follow-up in VIVEVE I). Per the investigators, all baseline characteristics (i.e. age, co-morbidities, maternal history, etc.) were similar between active and sham arms. Patients were evaluated at months 1, 3 and 6.

Results further supported efficacy of Viveve treatment on sexual function as measured by FSFI. Mean FSFI total score of the active group improved from sexually dysfunctional to functional at all evaluation timepoints (i.e. 1, 3 and 6 months) while mean FSFI score of the sham group did not improve to functional at any of the 1, 3 and 6-month timepoints (manuscript did not specify whether any of the timepoint differences were statistically significant).

FSFI Sub-Analysisof VIVEVE I



Relative to the six individual FSFI domains, patients treated with Viveve showed greater improvement on all six domains versus those receiving sham treatment. In addition, the difference in improvement on three of the six domains was statistically significant (at 95% CI) and favoring the active group. These were arousal (p=0.004), lubrication (0.040) and orgasm (0.007). (Desire, with p-value of 0.053 just barely missed statistical significance). Note that the domains which exhibited the biggest difference between the two arms was arousal and orgasm – which were also the two domains in VIVEVE I (i.e. the non-subanalysis data) in which the difference between active and sham groups was statistically significant.

FSFI Domains from Sub-Analysis of VIVEVE I

TABLE 2. FEMALE SEXUAL FUNCTION INDEX DOMAINS OF SEXUAL FUNCTION: MEAN VALUES AND ADJUSTED MEAN CHANGE AT BASELINE AND 6 MONTHS POSTINTERVENTION

FSFI domains	*Treatment group*	*Baseline*[a] *mean*	*6-Month mean*	*Adjusted*[b] *mean change*	p-*value*[c]
Desire	Active	2.92	3.72	0.82	0.053
	Sham	2.90	3.33	0.42	
Arousal	Active	3.12	4.39	1.27	0.004[c]
	Sham	3.30	3.80	0.62	
Lubrication	Active	3.78	5.07	1.30	0.040[c]
	Sham	3.90	4.59	0.77	
Orgasm	Active	3.07	4.23	1.24	0.007[c]
	Sham	3.18	3.53	0.51	
Satisfaction	Active	3.65	4.60	1.04	0.124
	Sham	3.35	4.14	0.66	
Pain	Active	4.85	5.14	0.27	0.083
	Sham	4.79	4.72	−0.13	

[a]The baseline FSFI assessment was conducted before the intervention.
[b]The adjusted mean change was estimated from individual ANCOVA models (for each domain), which included the baseline domain score and treatment group as independent variables.
[c]*p*-value deemed statistically significant as ≤0.05.
ANCOVA, analysis of covariance; FSFI, Female Sexual Function Index.
SOURCE: Krychan, et al.

A secondary measure, minimal clinically important differences (MCID) at 6-month follow-up, was also used to help evaluate efficacy of Viveve therapy on sexual function. MCID score is based on each patients' perception of what the minimal amount of change that is important. It helps to quantify a threshold of efficacy. On all six of the FSFI domains, a higher percentage of patients in the active group had perception of achieving meaningful benefit as compared to the sham group. Desire (3.01x greater chance of achieving MCID), arousal (2.73x) and orgasm (2.58x) were domains in which the greatest difference between active and sham arms was observed and the differences were statistically significant.

MCDI of FSFI Domains from Sub-Analysis of VIVEVE I

TABLE 3. MINIMAL CLINICALLY IMPORTANT DIFFERENCE ANALYSES AT THE 6-MONTH TIME POINT FOR EACH FEMALE SEXUAL FUNCTION INDEX DOMAIN OF SEXUAL FUNCTION

FSFI domains	*Treatment*	*MCID value*[a]	N	*≥MCID N′ (%)*		*MCID odds ratio*[b]	*95% CI*	p-*value*[c]
Desire	Active	0.7	73	37.9965	52.1	3.01	1.11–8.17	0.031[c]
	Sham		35	11.998	34.3			
Arousal	Active	1.0	73	44.9972	61.6	2.73	1.06–7.04	0.037[c]
	Sham		35	14	40.0			
Lubrication	Active	1.0	73	41.9969	57.5	1.58	0.57–4.35	0.376
	Sham		35	15.9985	45.7			
Orgasm	Active	0.5	73	48.9976	67.1	2.58	1.08–6.18	0.034[c]
	Sham		35	16.9995	48.6			
Satisfaction	Active	0.9	73	35.0035	48.0	1.53	0.57–4.13	0.400
	Sham		35	14.413	41.2			
Pain	Active	0.1	73	26.0026	35.6	2.17	0.52–8.98	0.286
	Sham		35	11.0005	31.4			

N′ = number of subjects who achieved at least the MCID value.
[a]The MCID value was determined for each FSFI domain of sexual function at the 6-month time point. This value represents the smallest change (6-month value and baseline value) that a subject would identify as clinically important.
[b]MCID odds ratios were estimated using multivariable logistic regression with treatment group and baseline score as independent variables.
[c]*p*-value deemed statistically significant as ≤0.05.
CI, confidence interval; FSFI, Female Sexual Function Index; MCID, minimal clinically important difference.

SOURCE: Krychan, et al.

Our Comments

Further parsing the VIVEVE I patient population by incorporation of a sexual dysfunction inclusion criterion appears to provide additional supporting evidence of the efficacy of Viveve treatment in improvement of sexual function as measured by FSFI. As design of VIVEVE II is expected to incorporate FSFI score $\leq$ 26.5 as an inclusion criteria and use mean change in total FSFI score as the primary endpoint, this sub-analysis data should provide additional confidence in the eventual success of Viveve's FDA pivotal study.

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	$5,210.0	$15,397.0	$23,046.2	$29,720.7	$36,000.2
YOY Growth	393.5%	136.8%	97.7%	120.1%	112.5%	115.6%	49.7%	29.0%	21.1%
Cost of Goods Sold	$4,612.0	$1,619.0	$1,837.0	$2,059.0	$2,714.0	$8,229.0	$11,019.4	$12,370.1	$12,873.2
Gross Income	$2,529.0	$1,422.0	$1,239.0	$2,011.0	$2,496.0	$7,168.0	$12,026.8	$17,350.6	$23,126.9
Gross Margin	35.4%	46.8%	40.3%	49.4%	47.9%	46.6%	52.2%	58.4%	64.2%
SG&A	$12,868.0	$5,450.0	$6,862.0	$7,369.0	$8,138.1	$27,819.1	$31,665.5	$35,991.8	$38,520.2
% SG&A	180.2%	179.2%	223.1%	181.1%	156.2%	180.7%	137.4%	121.1%	107.0%
R&D	$8,365.0	$2,388.0	$3,440.0	$3,464.0	$3,042.7	$12,334.7	$12,606.3	$8,797.3	$7,272.0
% R&D	117.1%	78.5%	111.8%	85.1%	58.4%	80.1%	54.7%	29.6%	20.2%
Operating Income	($18,704.0)	($6,416.0)	($9,063.0)	($8,822.0)	($8,684.7)	($32,985.7)	($32,244.9)	($27,438.5)	($22,665.3)
Operating Margin	-261.9%	-211.0%	-294.6%	-216.8%	-166.7%	-214.2%	-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)	($9,404.6)	($36,139.6)	($35,816.4)	($31,781.3)	($27,170.0)
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)	($20,111.0)	($6,695.0)	($10,425.0)	($9,615.0)	($9,404.6)	($36,139.6)	($35,816.4)	($31,781.3)	($27,170.0)
YOY Growth	61.8%	82.1%	-16.1%	134.2%	76.9%	79.7%	-0.9%	-11.3%	-14.5%
Net Margin	-281.6%	-220.2%	-338.9%	-236.2%	-180.5%	-234.7%	-155.4%	-106.9%	-75.5%
EPS (continuing ops)	($2.18)	($0.57)	($0.54)	($0.50)	($0.48)	($2.07)	($1.53)	($1.25)	($1.01)
YOY Growth	-12.2%	7.1%	-78.3%	-9.6%	-26.4%	-5.2%	-26.0%	-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

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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

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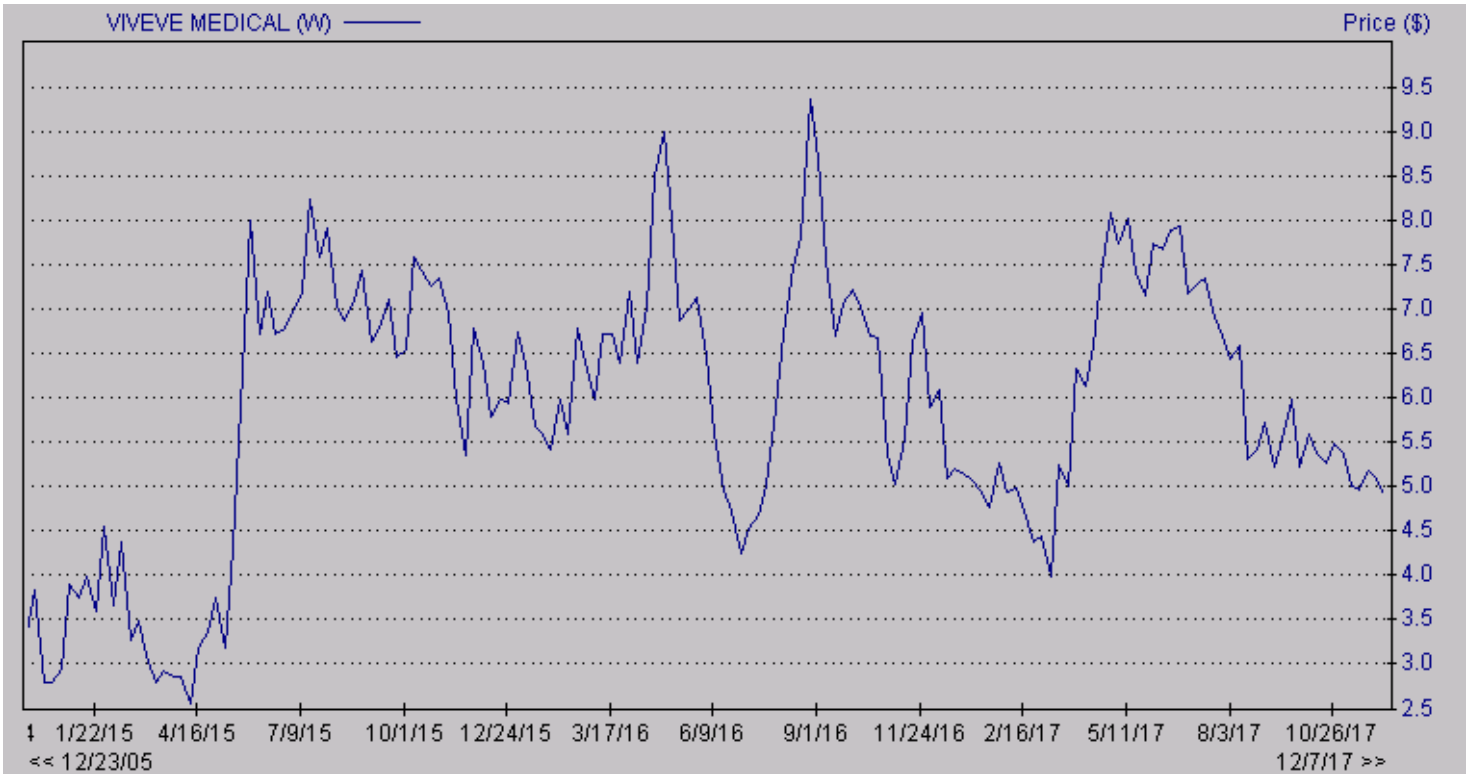

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