Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

scr.zacks.com

August 1, 2018
Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

10 S. Riverside Plaza, Chicago, IL 60606

Viveve Medical (VIVE-NASDAQ)

VIVE: FDA Warning Letter Should Weed-Out Imposters and Benefit VIVE

We use a 10-year DCF model to value VIVE. We have revenue growing from $15.3M in 2016 to $44M in 2020 and to approximately $100M 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 $7.75/share.

Current Price (08/01/18)	$2.29
Valuation	**$7.75**

OUTLOOK

On July 30th FDA issued a Safety Communications letter warning against the use of "Energy-Based Devices to Perform Vaginal 'Rejuvenation' of Vaginal Cosmetic Procedures". Besides warning providers and women not to use energy-based devices for the unapproved uses related to vaginal rejuvenation, it essentially puts manufacturers on notice that FDA is watching and that they need to cease and desist with any off-label marketing for these uses. **Viveve was not contacted by FDA regarding this.**

This inappropriate marketing by manufacturers of energy-based devices for sexual function/vaginal laxity/rejuvenation/SUI has long been a major impetus to VIVE's focus on obtaining FDA approval for these indications (specifically, sexual function and SUI) as it would draw a clear and distinct line between the proven benefits (and safety) of the Viveve System and all the rest. This warning letter should almost certainly benefit VIVE in this regard as 'all of the rest' do not have FDA approval for those indications and VIVE is (by far) the furthest along towards obtaining marketing approval. We think any short-term headwinds to VIVE will be at least equally (and quite possibly, more than) offset by the longer-term benefits from FDA's warning letter and are maintaining our $7.75/share price target.

SUMMARY DATA

52-Week High	**$7.33**
52-Week Low	**$1.60**
One-Year Return (%)	**-67.78**
Beta	**-0.52**
Average Daily Volume (sh)	**576,797**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$67**
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 (%)	**115.7**
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-Blend**
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	4799 E	5484 E	7235 E	21217 E
2019					34910 E
2020					43478 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	-$0.38 E	-$0.38 E	-$0.37 E	-$1.61 E
2019					-$1.18 E
2020					-$0.98 E

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

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

FDA Warning Letter Should Weed-Out Imposters and Benefit VIVE

On July 30th FDA issued a Safety Communications letter warning against the use of "Energy-Based Devices to Perform Vaginal 'Rejuvenation' of Vaginal Cosmetic Procedures". The purpose of the letter is to "alert patients and health care providers that the use of energy-based devices to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established."

FDA notes that they are aware of certain device manufacturers that may be marketing for these purposes – none of which are approved for those indications. FDA warns that if these devices are used for 'vaginal rejuvenation' (which includes vaginal laxity/sexual function) that they could cause vaginal burns, scarring, pain during intercourse, and recurring/chronic pain.

FDA has contacted those manufacturers that they believe may be marketing for these unapproved indications and notes that they will be monitoring claims about uses of their products. The manufacturers have 30 days to respond to FDA requests for;

- FDA clearance or approval number for the [name of device] for the additional claims referenced above [i.e. vaginal rejuvenation/sexual function/vaginal laxity or related to]

- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the [name of device] for the additional claims referenced above

FDA's letters to each of the manufacturers can be found here. The following are the companies that FDA contacted – **importantly, Viveve was not one of them**;

Manufacturers contacted by FDA for inappropriately marketing their products related to vaginal rejuvenation/sexual function/vaginal laxity/urinary incontinence:

Manufacturer	Device	FDA-approved/cleared for;
BTL Industries, Inc	Exilis	primary treatment of dermatologic and general surgical procedures for non-invasive treatment of w rinkles and rhytids
Cynosure, Inc.	DEKA SmartXide2 Laser System (MonaLisa Touch)	incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery
Alma Lasers	Alma Lasers Pixel CO2 Laser System (FemiLift),	surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiat1y, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee)
Sciton, Inc.	JOULE Multi-Platform System	for multiple general uses
Thermigen, Inc.	THERMIva	use in dermatological and general surgical procedures for electrocoagulation and hemostasis and to create lesions in nervous tissue w hen used in combination w ith Neuro Therm (previously Smith&Nephew) thermal/coagulation probes
BTL Aesthetics	Venus Fiore RF Ablation System	?
Inmode MD Ltd	FormaV and FractoraV lasers	?

Besides warning providers and women not to use energy-based devices for the unapproved uses related to vaginal rejuvenation, it essentially puts manufacturers on notice that FDA is watching and that they need to cease and desist with any off-label marketing for these uses. While off-label use of medical devices (and drugs) is generally allowed and based on the providers' discretion, off-label marketing is not. This inappropriate marketing by manufacturers of energy-based devices for sexual function/vaginal laxity/rejuvenation/SUI has long been a major

impetus to VIVE's focus on obtaining FDA approval for these indications (specifically, sexual function and SUI) as it would draw a clear and distinct line between the proven benefits (and safety) of the Viveve System and all the rest. This warning letter should almost certainly benefit VIVE in this regard as 'all of the rest' do not have FDA approval for those indications and VIVE is (by far) the furthest along towards obtaining marketing approval.

Viveve was not contacted by FDA regarding this. The Viveve System has also been evaluated in several human clinical studies in for both sexual function and SUI indications. It completed three human clinical studies (and recently began a fourth) related to sexual function/vaginal laxity, including VIVEVE I (multi-site U.S./Canada, RCT, n=174), which was used as support for their IDE application for VIVEVE II. VIVEVE II (multi-site, RCT, n=250) is expected to be (assuming positive results) the pivotal study that supports an eventual FDA filing seeking improvement in sexual function. Viveve received FDA IDE approval to conduct the study in March of this year – IDE approval inherently means that FDA believes any safety risks of using the Viveve System for vaginal procedures in this study are acceptable. Moreover, IDE approval was a fairly drawn-out process in which FDA, at several points, asked VIVE to provide additional information regarding safety.

Of note is that the FDA required VIVEVE II to use a staged roll-in enrollment approach to further ensure safety. While total enrollment is expected to be 250, this staged roll-in requirement limits initial enrollment to just 50 patients, at least of 25 of which will need to be treated and assessed for safety purposes (one-month following treatment) before enrollment can be increased. VIVE submitted data on the first 38 patients in early July. At 50, VIVE will then need to submit an IDE supplement, approval of which will be required in order to expand to the intended n=250.

The Viveve System has also completed two human studies in SUI, with a third currently ongoing (VIVE announced positive 6-month results of this study in June). VIVE expects to submit an IDE to FDA for approval of a large (n=200), multi-site, RCT in SUI in the very near-term. They are also seeking Health Canada approval to conduct a similarly-designed study in that country.

The point here is that, it's clear that FDA is concerned about safety of energy-based devices used in vaginal aesthetic procedures and SUI and that, unlike some manufacturers, VIVE is following the appropriate path to be able to (legally) market their device for the indications that they are targeting. By contrast, some other devices have little or no formal human clinical study experience and therefore no verified safety record. Viveve's does – and the FDA would not have approved their IDE had they had overwhelming concerns about risk.

So, while we acknowledge that the headline reaction from FDA's warning letter may be a short-term headwind to VIVE (and a much more significant defeat for the other manufacturers), we think it is also a significant win for the company as it should weed out what are essentially the imposters (i.e. those with little to no formal clinical evidence supporting efficacy/safety in these indications). Further, we think FDA approval of the anticipated IDE supplement for VIVEVE II (as well as the separate IDE application for SUI), if that happens, would provide even more validation of the substantive separation between the Viveve System and all other energy-based devices.

We think any short-term headwinds will be at least equally (and quite possibly, more than) offset by the longer-term benefits from FDA's warning letter and are maintaining our $7.75/share price target.

FINANCIAL MODEL

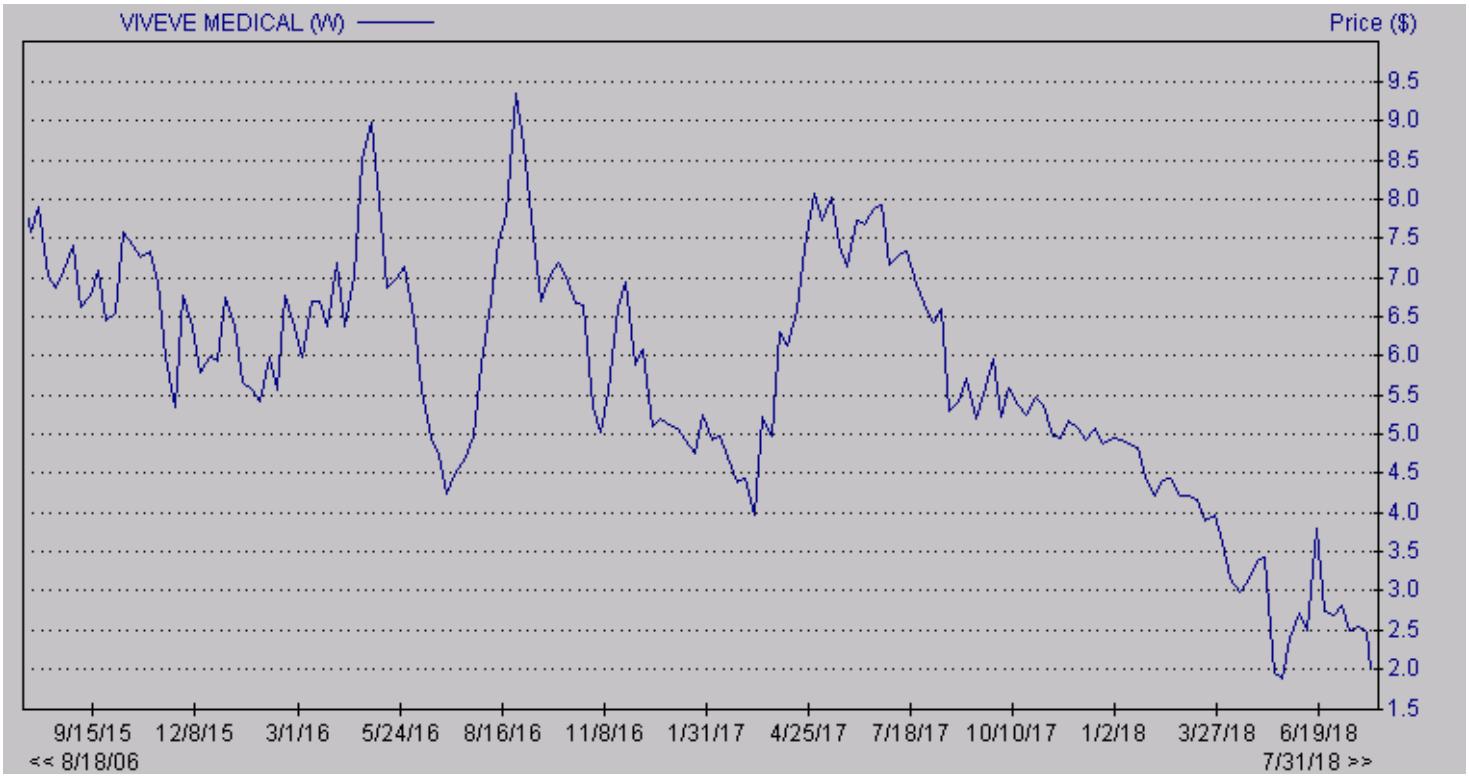
Viveve Medical, Inc

	2016 A	2017 A	Q1A	Q2E	Q3E	Q4E	2018	2019	2020
Total Revenues	$7,141.0	$15,288.0	$3,699.0	$4,799.2	$5,484.4	$7,234.6	$21,217.3	$34,909.7	$43,477.5
YOY Growth	393.5%	114.1%	21.6%	56.0%	34.8%	41.8%	38.8%	64.5%	24.5%
Cost of Goods Sold	$4,612.0	$7,844.0	$2,352.0	$2,676.8	$2,790.9	$3,563.8	$11,383.5	$15,836.2	$17,737.1
Gross Income	$2,529.0	$7,444.0	$1,347.0	$2,122.4	$2,693.5	$3,670.8	$9,833.8	$19,073.5	$25,740.4
Gross Margin	35.4%	48.7%	36.4%	44.2%	49.1%	50.7%	46.3%	54.6%	59.2%
SG&A	$12,868.0	$28,831.0	$8,931.0	$9,176.1	$9,460.7	$9,998.3	$37,566.0	$45,766.6	$49,825.2
% SG&A	180.2%	188.6%	241.4%	191.2%	172.5%	138.2%	177.1%	131.1%	114.6%
R&D	$8,365.0	$12,343.0	$3,756.0	$3,671.4	$3,921.4	$4,268.4	$15,617.2	$11,415.5	$9,652.0
% R&D	117.1%	80.7%	101.5%	76.5%	71.5%	59.0%	73.6%	32.7%	22.2%
Operating Income	($18,704.0)	($33,730.0)	($11,340.0)	($10,725.0)	($10,688.5)	($10,595.9)	($43,349.4)	($38,108.6)	($33,736.8)
Operating Margin	-261.9%	-220.6%	-306.6%	-223.5%	-194.9%	-146.5%	-204.3%	-109.2%	-77.6%
Total Other Income (Expense)	($1,407.0)	($3,229.0)	($1,080.0)	($1,118.2)	($1,132.8)	($1,147.5)	($4,478.5)	($4,368.8)	($4,531.8)
Pre-Tax Income	($20,111.0)	($36,959.0)	($12,420.0)	($11,843.2)	($11,821.3)	($11,743.4)	($47,827.9)	($42,477.4)	($38,268.6)
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)	0.0	0.0	0.0	(249.0)	0.0	0.0
Net Income (continuing ops)	($20,111.0)	($36,959.0)	($12,669.0)	($11,843.2)	($11,821.3)	($11,743.4)	($48,076.9)	($42,477.4)	($38,268.6)
YOY Growth	61.8%	83.8%	117.7%	-41.1%	76.6%	12.6%	30.1%	-11.6%	-9.9%
Net Margin	-281.6%	-241.8%	-342.5%	-246.8%	-215.5%	-162.3%	-226.6%	-121.7%	-88.0%
EPS (continuing ops)	($2.18)	($2.12)	($0.49)	($0.38)	($0.38)	($0.37)	($1.61)	($1.18)	($0.98)
YOY Growth	-12.2%	-3.1%	-10.3%	-82.6%	-34.2%	-30.4%	-24.1%	-26.5%	-16.8%
Diluted Shares O/S	9,215	17,470	25,847	31,250	31,320	31,370	29,947	36,000	39,000

Brian Marckx, CFA

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.