Zacks Small-Cap Research

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

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Viveve Medical (VIVE-NASDAQ)

VIVE: Major Milestone Crossed With U.S. Entry

We use a 10-year DCF model to value VIVMD. We have revenue growing from $5.7M in 2016 to $23.5M 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 (01/30/17)	$4.98
Valuation	**$11.00**

OUTLOOK

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. Approval in Brazil and the U.S., which lead the world in vaginal rejuvenation procedures, came in October. S. Korea represents another high potential territory where Geneveve was recently approved for sale.
Viveve recently crossed what we characterize as a major milestone with the entry of the Viveve System into the U.S. market and the recent announcement last week that they have begun deployment of their initial domestic sales force. While other energy-based devices targeted to the U.S. vaginal laxity market have preceded Viveve's entry, none are FDA-cleared for an indication related to that use. And, more importantly, the Viveve System is the only device that has demonstrated significant efficacy for the improvement in vaginal laxity and/or sexual function. 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 in Q1 2017.

SUMMARY DATA

52-Week High	**$10.00**
52-Week Low	**$4.02**
One-Year Return (%)	**-3.13**
Beta	**1.45**
Average Daily Volume (sh)	**29,619**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$56**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**54**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**15.2**
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 Rank in Industry	**N/A**

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	1849 A	2189 E	6878 E
2017					12303 E
2018					17949 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	-$0.46 A	-$0.46 E	-$2.08 E
2017					-$1.46 E
2018					-$1.10 E

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

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WHAT'S NEW…

Viveve Launches Initial U.S. Sales Force, VIVEVE I Clinical Data Accepted For Publication
Viveve recently crossed what we characterize as a major milestone with the entry of the Viveve System into the U.S. market and the announcement last week that they have begun deployment of their initial domestic sales force. Management laid out their initial U.S. commercialization plans on the Q3 call (November), noting that they expect to detail in the U.S. with ten direct sales people including two regional managers, each of which will be responsible for four territory managers. As the U.S. ranks #1 (per ISAPS data) in the world for the combined number of vaginal rejuvenation and labiaplasty procedures performed each year, we expect U.S. commercialization to offer significant growth opportunity for the company.

The initial formal marketing message in the U.S. will be limited for "use in general surgical procedures for electrocoagulation and hemostasis", the indication for which the Viveve System (recently rebranded as "Geneveve" received FDA clearance in October of last year. However, we expect 'off-label' use related to reduction of vaginal laxity and for the improvement of sexual function – both of which were endpoints in the U.S. VIVEVE I study, to drive demand.

As a reminder, VIVEVE I was a multi-site, randomized, sham-controlled study which showed that just one ~30-minute treatment with the Viveve System resulted in a highly statistically significant difference in vaginal laxity among those patients receiving treatment versus those given sham (i.e. control). In addition, patients receiving Viveve treatment were 3x more likely to report no vaginal laxity at 6-month follow-up compared to control (see our more detailed discussion of the results below). The full study results were recently accepted for publication in the Journal of Sexual Medicine.

While other energy-based devices targeted to the U.S. vaginal laxity market have preceded Viveve's entry, none are FDA-cleared for an indication related to that use. And, more importantly, the Viveve System is the only device that has demonstrated significant efficacy for the improvement in vaginal laxity and/or sexual function. As clinicians look to and often demand robust clinical evidence (i.e. U.S., multi-site, randomized, sham-controlled studies) as a prerequisite to adoption of a particular device, we believe Viveve will have a meaningful competitive advantage.

In The Meantime: Expand U.S. Label and Continue to Grow Int'l Footprint

In the meantime, VIVE will look to **expand the U.S.** label to include an indication related to "improvement in sexual function" (allowing for specific marketing for that purpose). As a reminder, in late September 2016 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. Management noted on the Q3 call in November that FDA had since responded with a request for additional information and that they expected to respond prior to 2016 year-end. Assuming timely approval of the IDE, this study could potentially commence in Q1 2017.

The proposed 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. Primary endpoint is expected to be FSFI. As a reminder, results of the randomized, sham-controlled VIVEVE I study, announced in April, showed 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.

On the international front, VIVE has been aggressively expanding their commercial footprint. In October 2016 they met another significant milestone – gaining regulatory clearance of the Viveve System in Brazil for "the treatment of the vaginal introitus, after childbirth, to improve sexual function". As Brazil ranks #2 to only the U.S. in not only vaginal rejuvenation but in total number of all types of cosmetic/aesthetic procedures, we think that country also offers substantial near-term revenue potential.

And another potential potent catalyst that recently came online was gaining regulatory approval (for general surgical procedures) of Geneveve in S. Korea in August. S. Korea ranks third behind Brazil in total number of cosmetic/aesthetic procedures performed and ranks #1 in the number of procedures performed on a per-capita basis. And it appears Viveve's system has already been well received in that country as management noted on the Q3 call that sales in S. Korea have been brisk. Viveve is looking to further exploit the potential in S. Korea and will seek to expand the label to include the treatment of the vaginal introitus.

The Viveve System is now cleared for sale in at least 51 countries with the most recent regulatory approvals coming within the last few weeks which included Colombia, Costa Rica and Malaysia. In addition, regulatory submissions in approximately 15 other countries are currently pending. Viveve has distribution agreements in place that cover approximately 67 countries.

VIVEVE I: U.S Multi-Site, Randomized Sham-Controlled Study
Results of VIVEVE I showed that just one ~30-minute treatment with the Viveve System resulted in a highly statistically significant difference in vaginal laxity and sexual function among those patients receiving treatment versus those given sham (i.e. control). This also marked the first time that any company was able to demonstrate significant efficacy of their energy-based device in a controlled clinical study.

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 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 >

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

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).

Active Cohort 3x More Likely vs. Sham To Achieve No Vaginal Laxity

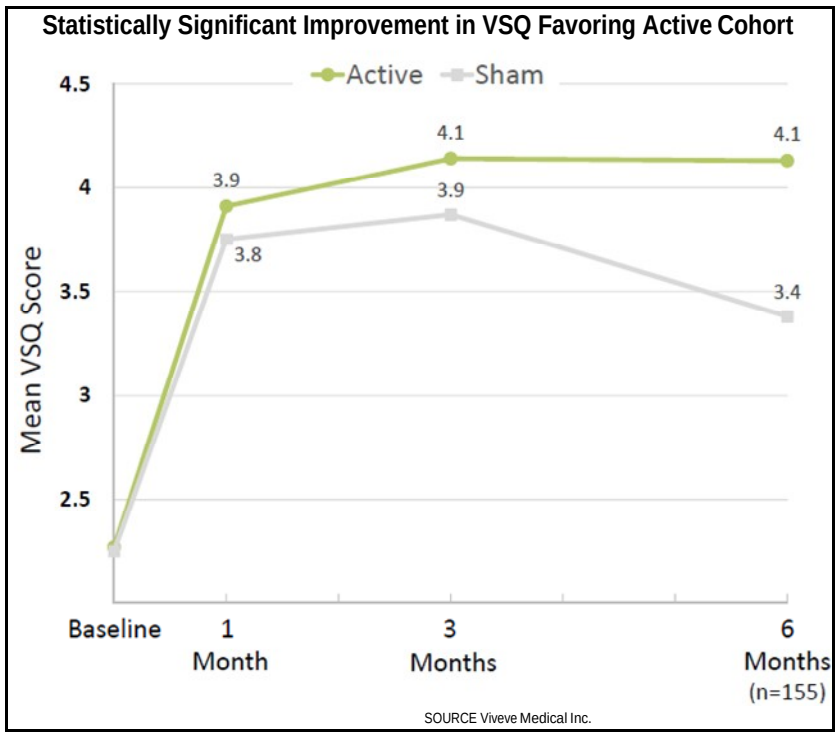
					Logistic Regression		
Timepoint	Treatment Group	N	No Laxity n (%)	Chi-Squared p-value	Odds Ratio	95% CI	p-value
Month 6	Active	103	43 (41.7%)	0.005	3.05	(1.37, 6.79)	0.006
	Sham	52	10 (19.2%)				

SOURCE Viveve Medical Inc.

Mean VSQ scores 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)
    - 6-month mean VSQ score from baseline was 1.9 for active vs. 1.1 for sham

The mean change from baseline of the active (1.9) versus shame (1.1) 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

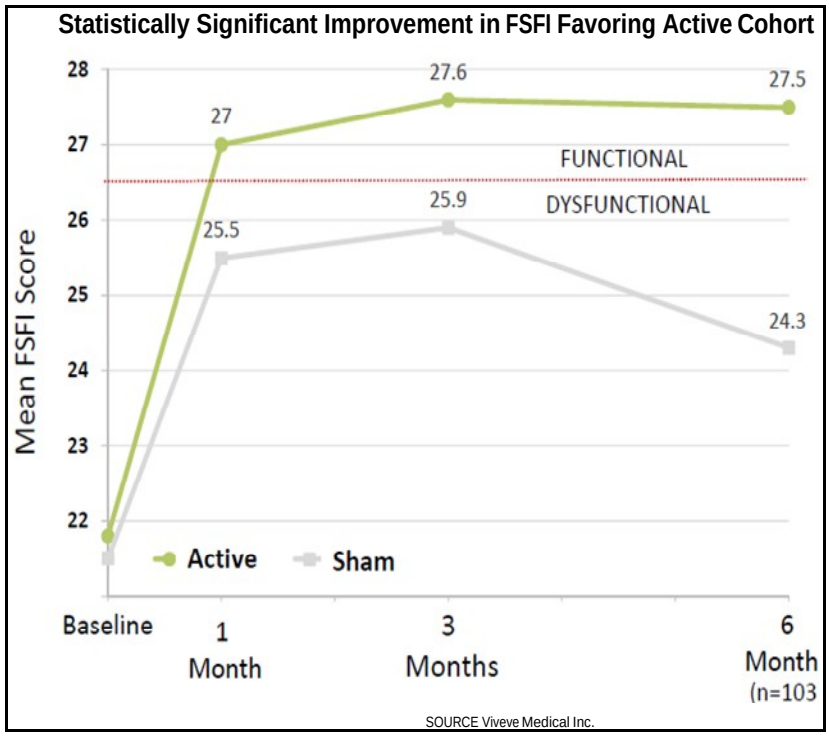
Similar to the two prior studies, VIVEVE I demonstrated that treatment with the Viveve System is associated with a significant increase in sexual function. FSFI is a brief, 19-item self-report measure of female sexual function that provides scores on six domains of sexual function as well as a total 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 (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.



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.

[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.

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; 38 (32.5%) active vs. 20 (35.1%) sham
- related treatment-emergent adverse events; 13 (11.1%) active vs. 7 (12.3%) sham
- serious treatment-emergent adverse events; 0 (0.0%) active vs. 1 (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. Management noted on the Q3 call that FDA had since responded with a request for additional information and the company expected to respond by 2016 year-end. 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.

U.S. Study: assuming IDE approval, VIVE will move towards clinical trial site selection and IRB approvals. Proposed VIVEVE II 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. 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 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. We may know more in the very near term.

FINANCIAL MODEL

Viveve Medical, Inc

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018	2019
Total Revenues	$1,447.0	$1,284.0	$1,556.0	$1,849.0	$2,189.0	$6,878.0	$12,302.6	$17,949.1	$23,523.1
YOY Growth	*1507.8%*	*3278.9%*	*2031.5%*	*216.6%*	*191.1%*	*375.3%*	*78.9%*	*45.9%*	*31.1%*
Cost of Goods Sold	$985.0	$936.0	$1,022.0	$1,158.0	$1,396.9	$4,512.9	$7,342.4	$9,437.2	$10,341.0
Gross Income	$462.0	$348.0	$534.0	$691.0	$792.1	$2,365.1	$4,960.3	$8,512.0	$13,182.0
Gross Margin	*31.9%*	*27.1%*	*34.3%*	*37.4%*	*36.2%*	*34.4%*	*40.3%*	*47.4%*	*56.0%*
SG&A	$7,464.0	$2,548.0	$2,615.0	$3,272.0	$3,440.0	$11,875.0	$15,255.3	$18,667.1	$23,052.6
% SG&A	*515.8%*	*198.4%*	*168.1%*	*177.0%*	*157.2%*	*172.7%*	*124.0%*	*104.0%*	*98.0%*
R&D	$4,988.0	$1,796.0	$2,463.0	$2,054.0	$2,066.0	$8,379.0	$8,615.0	$5,544.0	$4,789.0
% R&D	*344.7%*	*139.9%*	*158.3%*	*111.1%*	*94.4%*	*121.8%*	*70.0%*	*30.9%*	*20.4%*
Operating Income	($11,990.0)	($3,996.0)	($4,544.0)	($4,635.0)	($4,713.9)	($17,888.9)	($18,910.0)	($15,699.2)	($14,659.6)
Operating Margin	*-828.6%*	*-311.2%*	*-292.0%*	*-250.7%*	*-215.3%*	*-260.1%*	*-153.7%*	*-87.5%*	*-62.3%*
Total Other Income (Expense)	($436.0)	($110.0)	($772.0)	($234.0)	($217.5)	($1,333.5)	($741.2)	($513.6)	($178.7)
Pre-Tax Income	($12,426.0)	($4,106.0)	($5,316.0)	($4,869.0)	($4,931.4)	($19,222.4)	($19,651.2)	($16,212.8)	($14,838.2)
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)	($4,869.0)	($4,931.4)	($19,222.4)	($19,651.2)	($16,212.8)	($14,838.2)
YOY Growth	*101.1%*	*135.6%*	*-14.0%*	*92.9%*	*64.1%*	*54.7%*	*2.2%*	*-17.5%*	*-8.5%*
Net Margin	*-858.7%*	*-319.8%*	*-341.6%*	*-263.3%*	*-225.3%*	*-279.5%*	*-159.7%*	*-90.3%*	*-63.1%*
EPS (continuing ops)	($2.48)	($0.55)	($0.66)	($0.46)	($0.46)	($2.08)	($1.46)	($1.10)	($0.96)
YOY Growth	*-75.5%*	*-73.9%*	*-93.5%*	*-58.4%*	*-31.7%*	*-16.2%*	*-30.1%*	*-24.7%*	*-12.6%*
Diluted Shares O/S	5,000	7,493	8,081	10,630	10,700	9,226	13,500	14,800	15,500

Brian Marckx, CFA

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