Zacks Small-Cap Research

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Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

InVivo Therapeutics (NVIV-OTC)

NVIV: Waiting For The Human Trial To Start, Uplisting Hits A Snag…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	07/23/2013
Current Price (08/09/13)	$4.45
Target Price	**$4.50**

UPDATE

We continue to wait for the initiation of the first human clinical trial with the company's biodegradable scaffolding, now expected to start this fall 2013. Shareholders have been waiting almost two years for the initiation of this trial. It has been a frustrating delay. In July, came an equally frustrating delay on uplisting to a major exchange. Yet, the stock has performed well over the past several months, no doubt because investors know if the trial is successful, InVivo may be on the market with its device late 2015 or early 2016 thanks to a recent HUD designation.

We have recently reduced our rating to Neutral given the significant run-up in the shares and lack of visibility on the start of the long-awaited HDE trial. Nevertheless, we remain optimistic on the future prospects of InVivo. In fact, our price target remains $4.50 per share, unchanged from our initiation over two years ago.

SUMMARY DATA

52-Week High	**$5.67**
52-Week Low	**$1.28**
One-Year Return (%)	**83.88**
Beta	**0.07**
Average Daily Volume (sh)	**731,507**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**$312**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**28**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	0 A	0 A	0 A	0 A	0 A
2013	0 A	0 A	0 E	0 E	0 E
2014					0 E
2015					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$0.05 A	$0.03 A	$0.12 A	-$0.13 E	$0.07 E
2013	-$0.20 A	-$0.20 A	-$0.07 E	-$0.07 E	-$0.23 E
2014					-$0.27 E
2015					-$0.37 E

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WHAT'S NEW

Financial and Business Review

On August 8, 2013, InVivo Therapeutics reported financial results for the second quarter 2013. The company did not record any revenue in the quarter. This was in-line with expectations. Total operating expenses in the quarter were $5.1 million, consisting of $2.6 million in R&D and $2.5 million in G&A. Both line-items were higher than we had modeled, although we note the company did have $1.6 million in stock-based compensation in the quarter and we do not model significant stock-based compensation to continue in the third and fourth quarter 20143. Net loss for the quarter totaled $14.3 million, or -$0.20 per share. We note that loss included a non-cash charge of $8.4 million for revaluation of the outstanding derivative liability. This is the last quarter we expect the company to report outstanding derivative liability given the warrant call that took place in May and June 2013. We note despite reporting a net loss of $14.3 million in the second quarter, cash burn from operating activities totaled only about $3.1 million. The company exited the second quarter with $22.2 million in cash and investments, and another $0.6 million in restricted cash.

We believe the company remains committed to uplisting its shares to a major exchange, either the NASDAQ-CM or NYSE-MKT. However, on July 30, 2013, the company filed an 8K noting the process to up-list the company's common stock to a national securities exchange has been postponed indefinitely due to issues related to corporate governance. We believe this issue relates to the independence of the Board of Directors. We spoke briefly with management about this issue and they are working to resolve it and hope to have it resolved shortly. Although we are disappointed in the delay, the fact that management identified the corporate governance issue is a sign that the uplisting process began. We believe once completed, listing on a national exchange with a market capitalization over $400 million should allow for significantly improved institutional ownership – something InVivo's stock is sorely missing.

We are anticipating the start of the human clinical trial (discussed below) this fall.

INVESTMENT OVERVIEW

HUD / IDE Approvals

In April 2013, the company went two-for-two on regulatory applications. On April 4th, InVivo announced that the U.S. FDA had approved the company's request for a Humanitarian Use Device (HUD) designation for its biopolymer scaffolding product. The next day, on April 5th, the FDA granted approval allowing the start of the first human trials with the device.

…Who Can Be Treated…



Approval of the HUD grants the biopolymer scaffolding orphan status for the treatment of recent complete spinal cord injury with no motor or sensory function (i.e. ASIA-A) that does not involve penetrating injury (e.g. a gunshot wound) or complete severing of the spinal cord. This pathway allows for commercialization under a Humanitarian Device Exemption (HDE) rather than a Pre-Market Approval (PMA) pathway, saving InVivo an estimated 2-3 years and tens of millions in clinical trials prior to its first authorized sale. HDE applications are exempt from the effectiveness requirement of PMA, and only need to demonstrate reasonable assurance of safety.

The first human trial that InVivo will conduct will be in patients with thoracic injury, but HUD designation allows InVivo to treat all ASIA-A complete injury patients, not just thoracic. According to the National Spinal Cord Injury Statistical Center (NSCISC), an estimated 12,000 individuals will become fully or partially paralyzed each year due to spinal cord injury. NSCISC data show that approximately 46% of these individuals (Table-61) will have complete ASIA-A impairment. With respect to the planned clinical trial, 75% of spinal cord injuries are thoracic (Table-63), so we believe InVivo should have no problem enrolling 5 patients in this open-label study to start in the next few months.

If we assume that 75% of the population does not have a penetrating injury or the complete severing of the spinal cord (Table-26), investors can see the market opportunity here is just under 4,000 patients.

HUD guidelines, allow InVivo to sell its biopolymer scaffolding device up to an annual distribution number. The annual distribution number is defined as: the number of such devices reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States. To be clear, HUD limits the number of devices sold under the annual distribution number to treat, diagnose, or cure 4,000 patients. The patient population is the gate-keeper here, not the number of devices sold.

We briefly spoke with the FDA in preparation for this report. There is no restriction on the number of devices per patient. Take stents for example. A patient may require two or three stents to be treated. In that case, the annual distribution number could be two or three times 4,000. For InVivo's case, we assume one device per patient, but investors need to be aware that under the new FDASIA law, it's the patient population that is monitored and capped, not the actual device sales. Could a patient with a severe spinal cord injury require two devices? Perhaps!

Additionally, the annual distribution number can be modified based on additional information - e.g. new clinical trial data. The new HUD guidelines under the revised FDASIA law improve the market dynamics greatly from the old HUD/HDE guidelines set into place back in 2007. The old guidelines make it clear that the annual distribution number was pretty firm, and capped at 4,000 devices no matter what. New FDASIA guidelines seems to suggest flexibility in the number of devices, with upside to the originally agreed upon figure if treatment (or cure) is working. Does anyone honestly believe the FDA is going to tell InVivo to stop treating complete spinal cord injury with its device at 4,000 patients if this thing truly works?

...What Can InVivo Charge…

Data from the NSCISC shows that the average cost to care for a spinal cord injury patient in the first year of the injury ranges between $335,00 and $1,025,00. For a 25-year old with complete tetraplegia, the lifetime cost of care is an estimated $4.5 million. For a complete paraplegic, it's an estimated $2.2 million. This would seem to suggest that InVivo can charge upwards of $100,000 or more for its device.

Under the new FDASIA law, "*Manufacturers of HDE devices would be allowed to profit on devices intended for a condition or disease that does not occur (or only rarely occurs) in pediatric patients, so long as it meets certain other specified conditions.*" These specified conditions include three circumstances: 1) the disease / disorder / event occurs in pediatric patients and the device includes a pediatric label, or 2) the disease / disorder / event occurs in pediatrics but it is not feasible to test (via clinical trials) the device in a pediatric population, or 3) the disease / disorder / event does not occur in pediatric patients (e.g. some subset of Alzheimer's or Parkinson's disease, or post-menopausal...).

It's pretty clear that spinal cord injury does occur in pediatric patients (0-15 years old). According to statistics from the NSCISC (Table-17), one can see that only 3.3% of all spinal cord injury events occur in pediatric patients. That's only 400 patients per year. If we further narrow down that number to only ASIA-A, as defined under the HUD, and then consider only those with thoracic injury as cleared under the IDE, investors can see the number of target pediatric patients in around 135. We suspect that management will petition the Office of Orphan Products Development (OOPD) for a waiver on the pediatric requirement.

Therefore, for the sake of building a model, we assume InVivo charges a price of $65,000 (unrestricted profit) for the biopolymer scaffolding up to the target population outlined above (roughly 3,840 patients), and then recoups cost at around $10,000 per patient thereafter.

Doing The Math

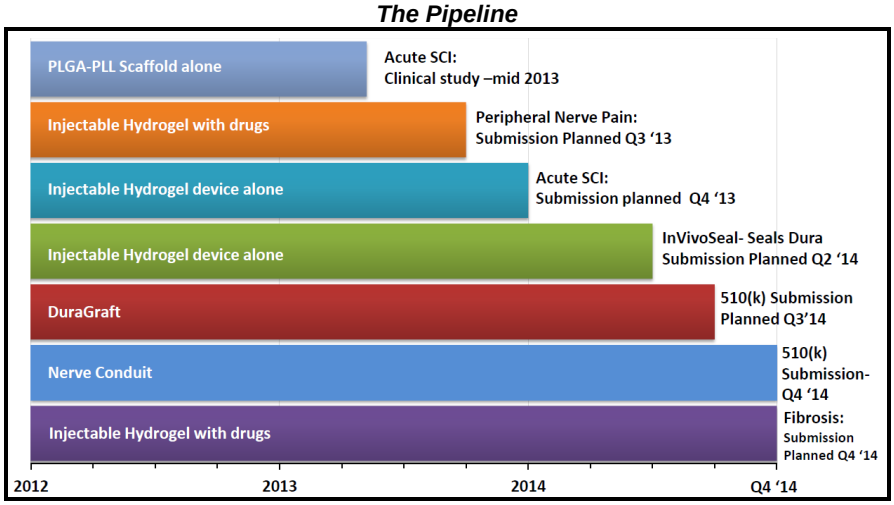
Below is a snap-shot of our model built to project sales of the device using the above assumptions. We started with 12,000 spinal cord injury patient in the U.S., narrowed by 46% to include only those with complete ASIA-A injury, then narrowed again by 75% to include only those with non-penetrating injury. The result is around 3,840 patients (in 2013). We then grew the overall population by 1.5% each year, arriving at just under 4,500 patients by 2023.

We modeled the launch of the device under HDE in 2016, at an unrestricted price of $70,000 per treatment. We believe InVivo can penetrate 50% of the target population by 2019. Subsequently, we assume modest off-label use of the device in patients with incomplete or penetrating injury. We assume only 7.5% market penetration in this category, and assume InVivo can only "recoup cost" on the marketing of the device until full Pre-Market Approval (PMA) in 2019. At that time, we shift the model to capture full price for the device, which we forecast will grow to $88,000 at that time. We forecast 15% market penetration in this population after PMA approval. Under these assumptions, we see the market opportunity for InVivo with its biopolymer scaffolding device under HDE at $262 million by 2023. We see the off-label use as another $106 million opportunity.

InVivo Therapeutics	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Americans with NEW SCI	12,000	12,180	12,363	12,548	12,736	12,927	13,121	13,318	13,518	13,721	13,926
Percent with Complete ASIA-A	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*
Percent Non-Penetrating	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
HUD Population	3,864	3,922	3,981	4,041	4,101	4,163	4,225	4,288	4,353	4,418	4,484
Market Share	*0%*	*0%*	*0%*	*5.0%*	*25.0%*	*40.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*
Treated Patients	0	0	0	202	1,025	1,665	2,113	2,144	2,176	2,209	2,242
Price Per Procedure	$0	$0	$0	$70,000	$76,300	$81,641	$88,172	$95,226	$101,892	$109,024	$116,656
Sales Under HDE	**$0**	**$0**	**$0**	**$14**	**$78**	**$136**	**$186**	**$204**	**$222**	**$241**	**$262**
Non-HUD Population	8,136	8,258	8,382	8,508	8,635	8,765	8,896	9,030	9,165	9,303	9,442
Percent Non-Penetrating	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
Off-Label Use	5,695	5,781	5,867	5,955	6,045	6,135	6,227	6,321	6,416	6,512	6,610
Market Share (pre-PMA)	*0%*	*0%*	*1.0%*	*2.5%*	*5.0%*	*7.5%*	*0%*	*0%*	*0%*	*0%*	*0%*
Market Share (post-PMA)	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*10.0%*	*15.0%*	*15.0%*	*15.0%*	*15.0%*
Treated Patients	0	0	59	149	302	460	623	948	962	977	991
Price Per Procedure	$0	$0	$0	$10,000	$10,800	$11,448	$88,172	$92,581	$97,210	$102,070	$107,174
Non-HDE Sales (pre/post PMA)	**$0**	**$0**	**$0**	**$1**	**$3**	**$5**	**$55**	**$88**	**$94**	**$100**	**$106**
Biopolymer Scaffold (Device Only)	**$0**	**$0**	**$0**	**$16**	**$81**	**$141**	**$241**	**$292**	**$315**	**$341**	**$368**

We note our model assumes no other revenue opportunities for the company. That's nothing for the hydrogel alone, or the hydrogel + methylprednisolone for spinal cord injury or peripheral nerve pain, nothing for seeding the scaffolding device with human neural stem cells, and nothing for the company's DureGraft, InVivoSeal, or Nerve Conduit products, which management tells us will be filed under U.S. 510(k) applications in 2014 (see pipeline graph below). We will begin to add additional products once the company receives clearance to start human clinical trials on these programs later in 2013 or in 2014. We've stated in the past, the hydrogel product alone has billion-dollar potential in spinal cord injury and peripheral nerve pain. Management is particularly optimistic on its DuraGraft and InVivoSeal programs. These offer only upside to the investment story.

The Pipeline



If investors turn their attention back to the revenue model built above, the next logical question is - what will it cost InVivo to obtain these revenues? Below is a snap-shot of the discounted cash flow analysis on those revenues. It includes a cost of goods sold on the device at around $10,000. It includes continuing R&D to support the PMA studies with the scaffolding at around $15 million per year, as well as work to move the hydrogel, DuraGraft, InVivoSeal, and Nerve Conduit programs forward. It includes InVivo maintaining operational overhead at levels consistent with 2013, with modest growth thereafter, plus hiring a 25 person sales force to promote the scaffolding device to the 75+ Level-1 trauma centers around the U.S. starting in 2015.

It includes modest sub-license and royalty payments to the company founders. It includes a fully-adjusted tax rate of 33% starting in 2019. Based on all this information, with a 17.5% discount rate, we believe InVivo is worth $391 million in value. Based on 86.4 million fully-diluted share count, this equates to roughly $4.50 per share.

InVivo Therapeutics	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Biopolymer Scaffold (Device Only)	**$0**	**$0**	**$0**	**$16**	**$81**	**$141**	**$241**	**$292**	**$315**	**$341**	**$368**
CoGS	*$0*	*$0*	*$1*	*$4*	*$13*	*$22*	*$28*	*$31*	*$32*	*$32*	*$33*
R&D	*$9*	*$13*	*$13*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*
SG&A	*$8*	*$10*	*$16*	*$19*	*$25*	*$31*	*$41*	*$46*	*$49*	*$51*	*$54*
Sublicense Payments	*$0*	*$0*	*$0*	*$1*	*$4*	*$7*	*$12*	*$15*	*$16*	*$17*	*$18*
EBIT	($17)	($23)	($29)	($23)	$24	$66	$145	$185	$204	$225	$248
Depreciation and amortization	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*
EBITDA	**($18)**	**($24)**	**($30)**	**($24)**	**$23**	**$65**	**$144**	**$184**	**$203**	**$224**	**$247**
Cash Taxes	$0	$0	$0	$0	$0	$0	($46)	($59)	($65)	($72)	($79)
Tax Rate	-	-	-	-	-	-	*33.0%*	*33.0%*	*33.0%*	*33.0%*	*33.0%*
NOL		*$26.5M Fed / $23.3M MA as of Dec. 31, 2012*									
Discounted Cash Flow											
Net Income	($18)	($24)	($30)	($24)	$23	$65	$98	$125	$138	$152	$168
Depreciation and amortization	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1
Net Cash Changes	$1	$2	$3	$4	$5	$6	$7	$8	$9	$10	$11
Post-Tax Operating Cash Flow	**($16)**	**($21)**	**($26)**	**($19)**	**$29**	**$72**	**$106**	**$134**	**$148**	**$163**	**$180**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**($16)**	**($21)**	**($26)**	**($19)**	**$29**	**$72**	**$106**	**$134**	**$148**	**$163**	**$180**

Assumptions	
Equity Risk Premium:	6.0%
Risk Free Rate:	2.0%
Terminal Growth:	3.0%
Discount Rate:	**17.5%**

Valuation	
10-Year Model:	$154
Terminal Value:	$217
Cash - Debt:	$20
Firm Value:	**$391**

Price Target	
Basic Outstanding:	78.6
Warrants & Options:	7.9
Fully Diluted:	86.4
Target Price:	**$4.52**

Source: Zacks Investment Research, Inc. Jason Napodano, CFA

PROJECTED FINANCIALS

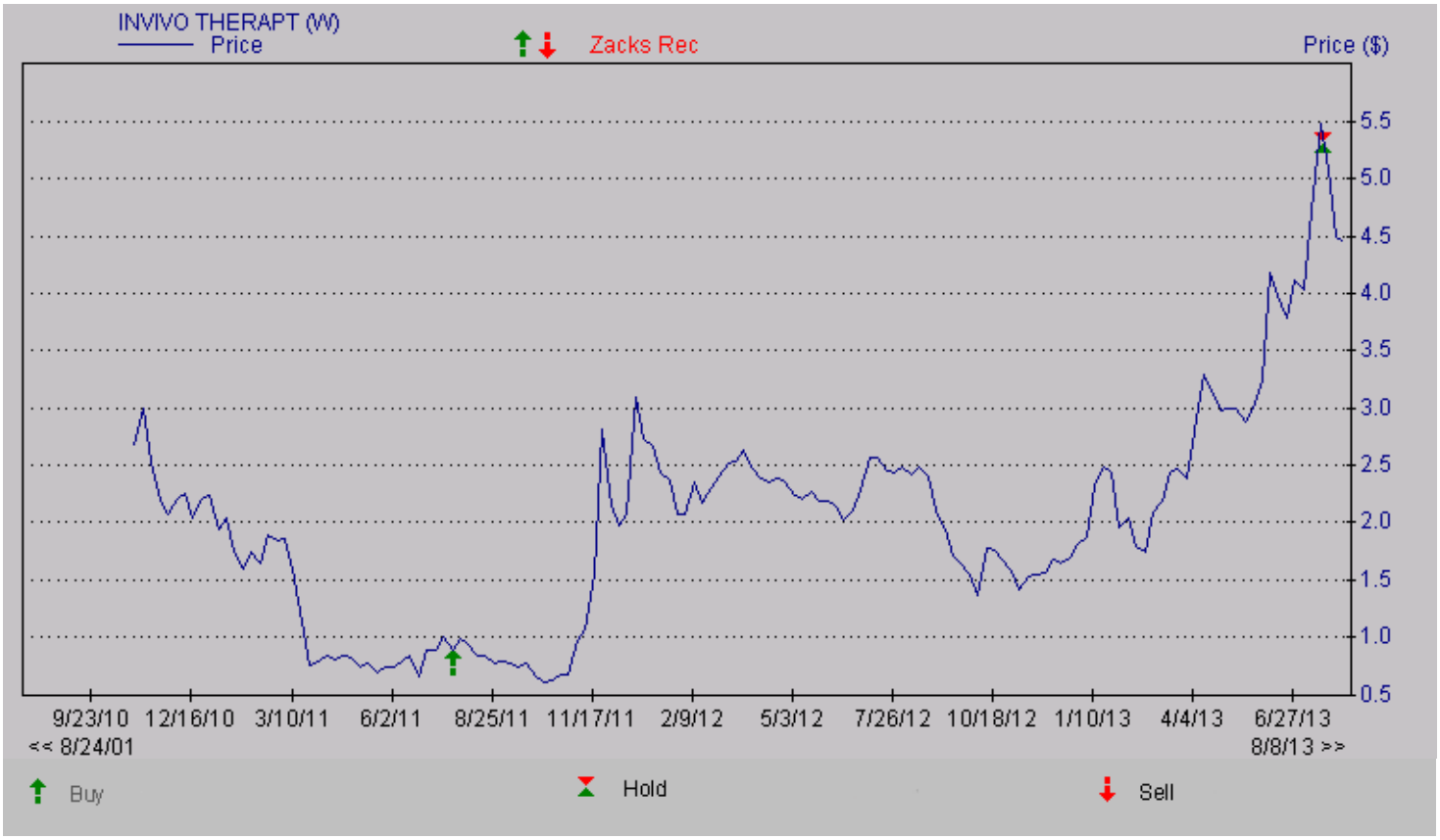
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2011 A	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.6
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$4.1	$6.4	$1.2	$2.6	$2.3	$2.7	$8.8	$12.5	$12.5
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$4.6	$6.4	$1.6	$2.5	$2.0	$2.1	$8.2	$10.0	$16.3
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($8.7)	($12.8)	($2.9)	($5.1)	($4.3)	($4.8)	($17.0)	($22.5)	($29.3)
Operating Margin	-	-	-	-	-	-	-	-	-
Net Other Income	($26.1)	$17.4	($10.5)	($9.2)	($1.0)	($1.0)	$0.0	$0.0	$0.0
Pre-Tax Income	($34.8)	$4.7	($13.3)	($14.3)	($5.3)	($5.8)	($17.0)	($22.5)	($29.3)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*0.0%*
Net Income	($34.8)	$4.7	($13.3)	($14.3)	($5.3)	($5.8)	($17.0)	($22.5)	($29.3)
Net Margin	-	-	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*
Reported EPS	**($0.67)**	**$0.07**	**($0.20)**	**($0.20)**	**($0.07)**	**($0.07)**	**($0.23)**	**($0.27)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	51.9	63.2	66.0	72.4	78.6	79.0	74.0	82.5	85.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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