Zacks Small-Cap Research

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InVivo Therapeutics (NVIV-OTC)

NVIV: Human Trials To Start Hopefully This Summer, Uplisting Goal In Sight…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (05/13/13)	$2.96
Target Price	**$5.00**

UPDATE

InVivo may finally be getting close to initiating its first human clinical trial over the summer of 2013. This is the even that shareholders have been waiting almost two years for. If successful, InVivo may be on the market with its device by the middle of 2015 thanks to a recent HUD designation.

We are maintaining our 'Outperform' rating and $5.00 price target on shares of InVivo. We remain bullish on the company's long-term prospects with the biopolymer scaffolding device and the injectable hydrogel. Opportunities in spinal cord injury (SCI) and peripheral nerve injury are in the hundred-millions of dollars. In fact, both are blockbuster opportunities given the significant size of the market and the lack of effective treatment options.

SUMMARY DATA

52-Week High	**$3.30**
52-Week Low	**$1.28**
One-Year Return (%)	**35.66**
Beta	**-0.02**
Average Daily Volume (sh)	**327,257**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$198**
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 2012 Estimate	**N/A**
P/E using 2013 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 E	0 E	0 E	0 E
2014					0 E
2015					13.5 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	-$0.06 E	-$0.07 E	-$0.07 E	-$0.20 E
2014					-$0.27 E
2015					-$0.23 E

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WHAT'S NEW

Financial Review

On May 9, 2013, InVivo Therapeutics reported financial results for the first 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 $2.85 million, consisting of $1.21 million in R&D and $1.64 million in G&A. Both line-items were lighter than we had modeled, showing that the company has maintained good cost control despite the move to a much larger and state-of-the-art facility in Cambridge, MA just last year. Net loss for the quarter totaled $13.33 million, or -$0.20 per share. We note that loss included a non-cash charge of $10.45 million for revaluation of the outstanding derivative liability.

…Warrant Exchange Turns Into Warrant Call…

InVivo's stated goal is to move from the OTC to a national exchange, either the NASDAQ or NYSE-MKT. To do that, the company must meet certain listing requirements around market value, tangible assets, stock price, and stockholders' equity. As of today, the company meets all requirements for listing on the NASDAQ-CM or NYSE-MKT except stockholders' equity of greater than $4.0 million.

InVivo exited the first quarter (March 31, 2013) with $10.3 million in cash and equivalents and $13.8 million in total assets. Total liabilities at the end of the quarter were $28.2 million, thus resulting in negative stockholders' deficit of $14.3 million. However, we note of the $12.2 million in total liabilities, $24.6 million was a non-cash derivative warrant liability resulting from approximately 15.0 million warrants outstanding at the end of the quarter.

The warrants create a liability because they have an anti-dilution provision allowing for the reset of the exercise price of the warrant to a new lower price if the company raises cash at prices below the exercise price of the warrants. This is the "liability" that must be recorded on the balance sheet. The liability increases as the stock price increases farther above $1.40 per share where the majority of the warrants are exercisable (see schedule below). The warrants are also callable by the company if the stock trades above $2.80 per share for 20 consecutive trading days. The warrant liability is revalued each quarter and increases as InVivo's stock price increases. InVivo's stock closed at $1.74 per share on December 31, 2012. On March 28, 2013, the last day of trading for the first quarter 2013, the stock closed at $2.39 per share – a 37% increase.

Warrants Subject To Anti-Dilutive / Call Option

	Number Outstanding	Exercise Price per Share	Expiration Date
Merger Warrants issued on October 26, 2010	325,000	$ 1.00	10/26/2015
Investor Warrants issued on October 26, 2010	9,521,457	$ 1.40	10/26/2015
Investor Warrants issued on November 10, 2010	1,149,250	$ 1.40	11/10/2015
Investor Warrants issued on December 3, 2010	822,653	$ 1.40	12/03/2015
Placement Agent Warrants issued on October 26, 2010	1,263,408	$ 1.00	10/26/2015
Placement Agent Warrants issued on November 10, 2010	174,336	$ 1.00	11/10/2015
Placement Agent Warrants issued on December 3, 2010	71,325	$ 1.00	12/03/2015
Placement Agent Warrants issued on October 26, 2010	1,409,017	$ 1.40	10/26/2015
Placement Agent Warrants issued on November 10, 2010	247,037	$ 1.40	11/10/2015
Placement Agent Warrants issued on December 3, 2010	26,125	$ 1.40	12/03/2015
Total Eligible Warrants	15,009,608		

On April 8, 2013, InVivo announced an offer to exchange the roughly 15.0 million warrants listed above for new warrants that no longer have the anti-dilution provision. In return, InVivo would extend the duration of the warrants by two years so that they all expire in the fourth quarter of 2017 instead of 2015. This seemed like a fair deal for the warrant holders considering InVivo's stock price on April 8th was around $3.00 per share, and it looked unlikely that the company would raise cash below $1.40 kicking in the anti-dilution reset.

However, on May 3, 2013, InVivo's stock traded above $2.80 per share for 20 consecutive days. Thus, the company terminated the warrant exchange and enacted a call notice for all outstanding warrants listed above. Management noted in the press release that since the start of April 2013, the company has already received $5.7 million from the exercise of Investor some of these warrants. It seems investors were simply exercising in-the-money warrants instead of exchanging them for new warrants. With the remaining warrants now subject to call, InVivo expects to receive an additional $10.4 million by June 3, 2013 (redemption date). Once all warrants have been exercised or called, InVivo will no longer have to record the derivative liability on the balance sheet noted above for these warrants.

Below is a snapshot of the balance sheet as of March 31, 2013, and our forecast for the balance sheet on June 30, 2013. Our forecast assumes operating cash burn of around $3.0 million in the second quarter with no major changes in working capital.

Balance Sheet	March 31, 2013 A	June 30, 2013 E
Cash & Equivalents	$10.3 mil	$23.5 mil
Total Assets	$13.8 mil	$27.0 mil
Derivative Liability	$24.6 mil	-
Current Liabilities	$26.3 mil	$1.8 mil
Total Liabilities	$28.2 mil	$3.6 mil
Stockholder's Equity	($14.3 mil)	$23.4 mil

Based on our model, the company will have positive stockholder's equity of around $23.4 million as of June 30, 2013. This would allow for the company to qualify for listing on either the NASDAQ-CM or NYSE-MKT. We believe once complete, InVivo will look to move quickly with listing on either exchange. Listing on a national exchange with a market capitalization over $250 million should allow for significantly improved institutional ownership – something InVivo's stock is sorely missing.

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

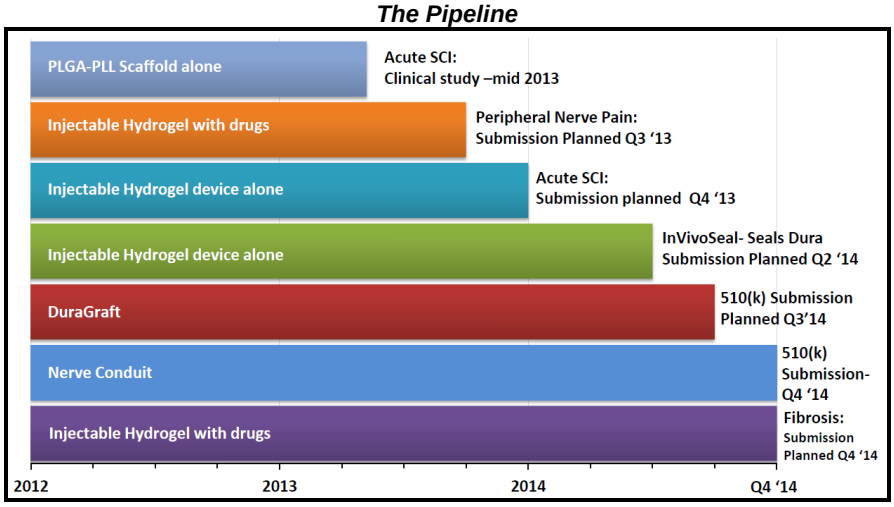
Below is a snap-shot of our model built to project sales of the device using the above assumptions. We started with 12,000 spinal cord injury patient in the U.S., narrowed by 46% to include only those with complete ASIA-A injury, then narrowed again by 75% to include only those with non-penetrating injury. 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 2015, at an unrestricted price of $65,000 per treatment. We believe InVivo can penetrate 50% of the target population by 2018. 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 $91,000 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 $271 million by 2023. We see the off-label use as another $110 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%*	*5.0%*	*20.0%*	*40.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*	*50.0%*
Treated Patients	0	0	199	808	1,640	2,081	2,113	2,144	2,176	2,209	2,242
Price Per Procedure	$0	$0	$65,000	$72,475	$78,998	$84,528	$91,290	$98,593	$105,494	$112,879	$120,781
Sales Under HDE	**$0**	**$0**	**$13**	**$59**	**$130**	**$176**	**$193**	**$211**	**$230**	**$249**	**$271**
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	$10,000	$10,900	$11,772	$12,478	$91,290	$95,854	$100,647	$105,679	$110,963
Non-HDE Sales (pre/post PMA)	**$0**	**$0**	**$1**	**$2**	**$4**	**$6**	**$57**	**$91**	**$97**	**$103**	**$110**
Biopolymer Scaffold (Device Only)	**$0**	**$0**	**$14**	**$60**	**$133**	**$182**	**$250**	**$302**	**$326**	**$353**	**$381**

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 $437 million in value. Based on 89.9 million fully-diluted share count, this equates to roughly $5 per share.

Biopolymer Scaffold (Device Only)	$0	$0	$14	$60	$133	$182	$250	$302	$326	$353	$381
CoGS	*$0*	*$0*	*$3*	*$10*	*$20*	*$26*	*$28*	*$31*	*$32*	*$32*	*$33*
R&D	*$8*	*$13*	*$13*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*	*$15*
SG&A	*$8*	*$10*	*$18*	*$23*	*$31*	*$35*	*$42*	*$47*	*$50*	*$53*	*$55*
Sublicense Payments	*$0*	*$0*	*$1*	*$3*	*$7*	*$9*	*$12*	*$15*	*$16*	*$18*	*$19*
EBIT	($15)	($23)	($20)	$9	$61	$96	$152	$193	$213	$235	$259
Depreciation and amortization	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*	*$1*
EBITDA	**($16)**	**($24)**	**($21)**	**$8**	**$60**	**$95**	**$151**	**$192**	**$212**	**$234**	**$258**
Cash Taxes	$0	$0	$0	$0	$0	$0	($48)	($62)	($68)	($75)	($82)
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	($16)	($24)	($21)	$8	$60	$95	$103	$131	$144	$159	$175
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	**($14)**	**($21)**	**($17)**	**$13**	**$66**	**$102**	**$111**	**$140**	**$154**	**$170**	**$187**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**($14)**	**($21)**	**($17)**	**$13**	**$66**	**$102**	**$111**	**$140**	**$154**	**$170**	**$187**

Assumptions	
Equity Risk Premium:	5.9%
Risk Free Rate:	1.9%
Terminal Growth:	3.0%
Discount Rate:	**17.5%**

Valuation	
10-Year Model:	$214
Terminal Value:	$226
Cash - Debt:	$24
Firm Value:	**$463**

Price Target	
Basic Outstanding:	70.2
Warrants & Options:	19.7
Fully Diluted:	89.9
Target Price:	**$5.15**

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

PROJECTED FINANCIALS

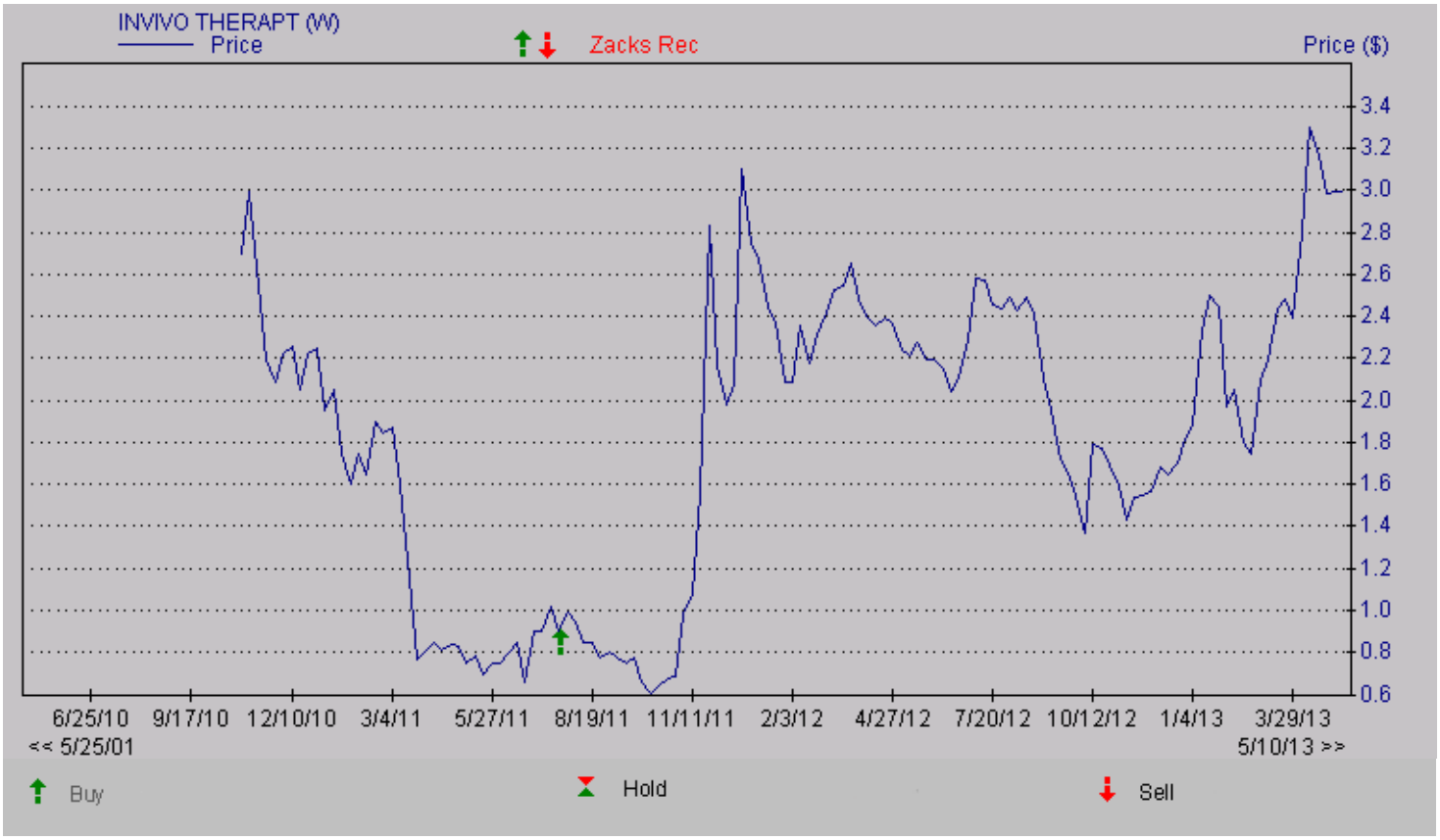
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2011 A	2012 A	Q1 A	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$13.5**
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**	**$13.5**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0.0	$2.6
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$4.1	$6.4	$1.2	$1.6	$2.3	$2.7	$7.8	$12.5	$12.5
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$4.6	$6.4	$1.6	$1.8	$2.0	$2.1	$7.5	$10.0	$17.6
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($8.7)	($12.8)	($2.9)	($3.4)	($4.3)	($4.8)	($15.4)	($22.5)	($19.2)
Operating Margin	-	-	-	-	-	-	-	-	-
Net Other Income	($26.1)	$17.4	($10.5)	($1.0)	($1.0)	($1.0)	$0.0	$0.0	$0.0
Pre-Tax Income	($34.8)	$4.7	($13.3)	($4.4)	($5.3)	($5.8)	($15.4)	($22.5)	($19.2)
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)	($4.4)	($5.3)	($5.8)	($15.4)	($22.5)	($19.2)
Net Margin	-	-	-	-	-	-	-	*#DIV/0!*	*-141.9%*
Reported EPS	**($0.67)**	**$0.07**	**($0.20)**	**($0.06)**	**($0.07)**	**($0.07)**	**($0.20)**	**($0.27)**	**($0.23)**
YOY Growth	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	51.9	63.2	66.0	77.0	78.0	79.0	75.0	82.5	85.0

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

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