Zacks Small-Cap Research

April 8, 2013
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

InVivo Therapeutics (NVIV-OTC)

NVIV: HUD and IDE Approved!

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (04/08/13)	$3.13
Target Price	**$5.00**

UPDATE

InVivo may finally be getting close to initiating its first human clinical trial in the second quarter 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	**$2.80**
52-Week Low	**$1.28**
One-Year Return (%)	**17.16**
Beta	**0.05**
Average Daily Volume (sh)	**137,986**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$185**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**30**
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 E	0 E	0 E	0 E	0 E
2014					0 E
2015					16.3 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	-$0.08 E	-$0.10 E	-$0.09 E	-$0.09 E	-$0.31 E
2014					-$0.43 E
2015					-$0.24 E

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

InVivo Goes Two For Two!

FDA Grants HUD…

InVivo Therapeutics had a busy week last week with respect to FDA approvals and clearances. On April 4, 2013, 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. InVivo requested the agency grant its 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. Approval under HUD 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.

We note devices eligible for HUD designations are developed to treat rare diseases or conditions that affects fewer than 4,000 individuals in the U.S. per year. 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 22% of these individuals will have complete tetraplegia and 25% will have complete paraplegia. That would bring the proposed population down to 5,640 individuals. If we assume that half of this population does not have a penetrating injury or the complete severing of the spinal cord, investors can see that InVivo is well below the 4,000 maximum eligible population. On a side-note, we fully expect that if approved with the proposed label, InVivo's device will be used, and could even be approved, for a much wider patient population than just medically plausible subset outlined in the HUD request.

…And Approves The IDE

In July 2011, InVivo Therapeutic filed an Investigational Device Exemption (IDE) application for its biocompatible polymer scaffolding (BPS) device to treat acute spinal cord injuries. It's been almost two years since the original IDE application, but the agency finally granted approval allowing the start of the first human trial with the BPS on April 5, 2013. We remind investors that in April 2012, the agency confirmed that the BPS will be regulated as a Class III medical device.

The proposed study will seek to enroll five patients with acute thoracic injuries in an open-label design to take place at two level one trauma centers, one in Boston at Massachusetts General Hospital (MGS) and the other in Philadelphia. The primary outcome of the study will be to assess signs of improvement below the level of the spinal cord injury. InVivo will use standardized American Spinal Injury Association (ASIA) scoring to assess efficacy over a year-long period. We expect enrollment and treatment to take approximately two to three months, with data beginning to dribble out a month later thanks to the open-label design. Patient follow-up will last twelve months. The cost will be around $1.5 million.

InVivo believes that all data will be in hand roughly 15 months after initiation. Assuming the trial begins in the next few months, that means we should have final results late 2014, allowing for the HDE filing hopefully before the end of the year 2014. The FDA would then review the HDE application and have 75 days to respond. If all goes well, InVivo would be in position to start marketing its biocompatible polymer scaffolding product for acute spinal cord injury as early as the second quarter 2015.

We expect InVivo to look to duplicate positive results in patients with cervical injury. If the product is approved by the FDA, we suspect that InVivo will need to expand manufacturing capacity, and establish sales, marketing and distribution channels to sell the product. InVivo plans to market and sell the product through a direct sales force in the U.S. on its own. Approval under the HDE pathway will also protect InVivo from competition with a similar device for seven years.

Warrant Exchange To Facilitate Uplisting

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 2012 with $13.4 million in cash and equivalents and $16.1 million in total assets. Total liabilities at year end 2012 were $18.4 million, thus resulting in negative stockholders' deficit of $2.3 million. However, we note of the $18.4 million in total liabilities, $14.6 million was a non-cash derivative warrant liability resulting from approximately 15.3 million warrants outstanding at year end 2012 with anti-dilution provisions. 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. Therefore, when InVivo files its Form 10Q for the first quarter 2013, we expect this non-cash liability to be above $20.0 million, further reducing the stockholders' equity number and keeping InVivo from uplisting to the NASDAQ or NYSE-MKT.

On April 8, 2013, InVivo announced an offer to exchange the roughly 15.0 million warrants ("2010 warrants") that remained outstanding as of March 31, 2013 for new warrants that no longer have the anti-dilution provision. The anti-dilution provision allows 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 new warrants would not have an anti-dilution provision. In return, InVivo would expend the duration of the warrants by two years so that they all expire in the fourth quarter of 2017 instead of 2015.

Warrants Subject To Exchange Offer

	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		

The exchange period will remain active until May 6, 2013. Given the stock price is currently above $3.00 per share, the odds of the anti-dilution provision being activated are low, especially now that InVivo has been granted HUD and the IDE has been cleared for the biopolymer scaffolding. Thus, we think the exchange is attractive to the "2010 warrant" holders and expect greater than 90% tender. Plus, the ultimate goal of the exchange is to facilitate an uplisting to a national exchange, something that both share and warrant holders clearly would like to see.

If we remove all derivative liability from the balance sheet as of today, stockholders' equity would be positive to the tune of around $12.5 million. 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. As of March 6, 2013, the basic share count stood at 66.1 million, putting the basic market capitalization over $200 million. Listing on a national exchange with a market capitalization over $200 million should allow for significantly improved institutional ownership – something InVivo's stock is sorely missing.

Stock Remains Attractive

We see the opportunity in acute thoracic spinal cord injury, as defined under the HUD application, as a peak $240 million opportunity. This includes treating the maximum 4,000 patients at a price of roughly $60,000 per treatment. We think InVivo could actually charge more for the BPS device. 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 $2.5 million. We remind investors that if the IDE trial succeeds, InVivo could be on the market selling its BPS device into this estimated $250 million opportunity as soon as mid-2015.

Now the upside to the story: The hydrogel and the BPS-hNSC. With the hydrogel for SCI, we estimate that nearly all of the 12,000 acute injury patients per year could be eligible for treatment. With a premium price of $75,000 per surgery, InVivo is looking at an estimated $900 million opportunity. In peripheral nerve pain, above we note an estimated 3.2 million procedures per year. With as little as 5% market share and a yearly price of only $10,000, InVivo is looking at another $1.6 billion market. That alone makes InVivo an interesting long-term investment.

But what really gets us excited is the potential for use of the BPS seeded with autologous human neural stem cells. There are an estimated 200,000 chronic spinal cord injury patients in the U.S. If InVivo can treat just 20% of these patients, with an estimated price of around $100,000 per surgery, the market opportunity would be approximately $4.0 billion.

PROJECTED FINANCIALS

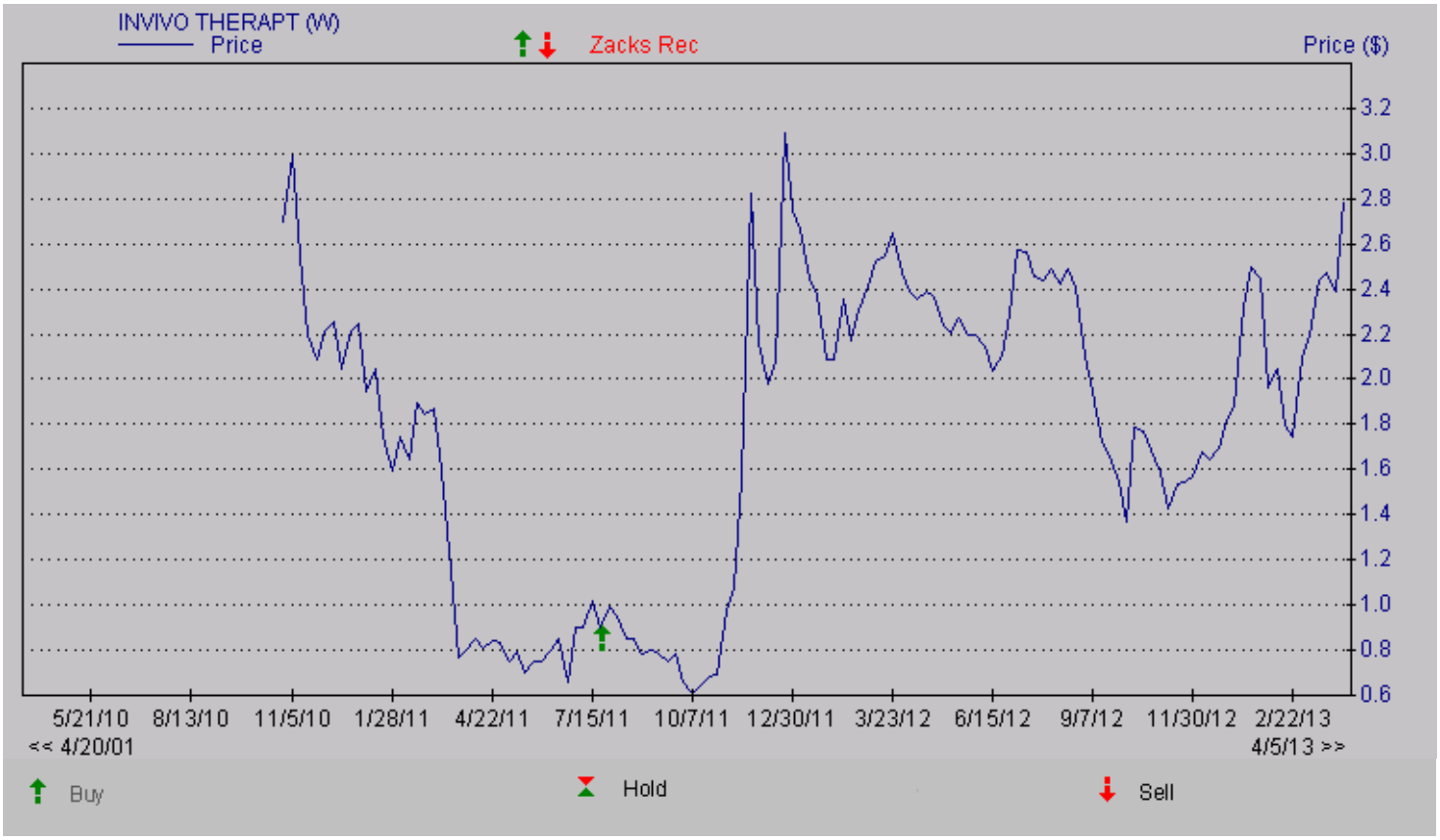
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2010 E	2011 A	2012 A	Q1 E	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$16.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**	**$16.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0	$0.8	$2.6
Product Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	$1.7	$4.1	$6.4	$2.5	$3.5	$3.5	$3.5	$13.0	$15.0	$15.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$1.7	$4.6	$6.4	$2.0	$2.1	$2.1	$2.3	$8.5	$16.3	$17.9
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($8.7)	($12.8)	($4.5)	($5.6)	($5.6)	($5.8)	($21.5)	($32.1)	($19.2)
Operating Margin	*0.0%*	-	-	-	-	-	-	-	-	-
Net Other Income	($4.5)	($26.1)	$17.4	($1.0)	($1.0)	($1.0)	($1.0)	$0.0	$0.0	$0.0
Pre-Tax Income	($7.9)	($34.8)	$4.7	($5.5)	($6.6)	($6.6)	($6.8)	($21.5)	($32.1)	($19.2)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*0.0%*
Net Income	($7.9)	($34.8)	$4.7	($5.5)	($6.6)	($6.6)	($6.8)	($21.5)	($32.1)	($19.2)
Net Margin	*0.0%*	-	-	-	-	-	-	-	*#DIV/0!*	*-117.4%*
Reported EPS	**($0.24)**	**($0.67)**	**$0.07**	**($0.08)**	**($0.10)**	**($0.09)**	**($0.09)**	**($0.31)**	**($0.43)**	**($0.24)**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	33.4	51.9	63.2	66.5	68.0	70.0	72.0	69.1	75.0	80.0

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

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

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1009 companies covered: Buy/Outperform- 14.8%, Hold/Neutral- 78.4%, Sell/Underperform – 6.4%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.