Zacks Small-Cap Research

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InVivo Therapeutics, Hdls Corp. (NVIV-OTC)

NVIV: HDE Pathway Could Greatly Speed Path To Market For InVivo…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (05/15/12)	$2.31
Target Price	**$4.50**

UPDATE

We are maintaining our 'Outperform' rating and $4.50 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. In our previous reports we have laid out our valuation methodology. We have conducted a discounted cash flow (DCF) analysis and arrive at a target of $4.50. We have also looked at 20 previous deals in the spine market. Applying the average take-out multiple of 6.1x revenues to our 2016 forecast for revenues of $243 million, discounted back to present day at 20%, yields a target price of $7.50 per share.

SUMMARY DATA

52-Week High	**$3.10**
52-Week Low	**$0.60**
One-Year Return (%)	**N/A**
Beta	**0.12**
Average Daily Volume (sh)	**104,320**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$147**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
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)
2011	0 A	0 A	0 A	0 A	0 A
2012	0 A	0 E	0 E	0 E	0 E
2013					1.0 E
2014					1.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.02 A	-$0.03 A	$0.06 E	-$0.70 A	-$0.67 A
2012	$0.05 A	-$0.06 E	-$0.06 E	-$0.07 E	-$0.14 E
2013					-$0.23 E
2014					-$0.37 E

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WHAT'S NEW

Financial Position

On May 15, 2012, InVivo Therapeutics reported financial results for the first quarter 2012. The company reported no revenues in the quarter, as expected. Net income in the quarter was $3.1 million, or 5 cents per diluted share. Included in results were non-cash derivative gains of $5.6 million, reflecting decreases in the fair value of the derivative warrant liability. Exclusive of the non-cash derivative gain, the pro forma net loss for the first quarter 2012 was $2.5 million, or 4 cents per diluted share.

InVivo exited the first quarter 2012, ended March 31, 2012, with $20.5 million in cash, restricted cash, and equivalents. The cash balance was increased by an underwritten public offering of approximately 9.5 million shares at $2.10 per share, to raise net proceeds of $18.1 million in February 2012. The company also issued approximately 0.64 million shares of common stock upon the exercise of stock options and warrants, which raised net proceeds of approximately $0.3 million. We find the current cash balance to be sufficient to fund operations well in 2013.

We remind investors that there were a total of 17.9 million warrants outstanding as of March 31, 2012. This includes 14.7 million warrants currently exercisable at $1.40 per share, and 2.9 million warrants currently exercisable at $1.00 per share, and the 0.3 million noted above exercisable at $3.06 per share. We expect that additional warrants will be exercised over the course of the year. In total, all outstanding in-the-money warrants could supply an additional $23.5 million in cash.

HDE Pathway Saves Time & Money

In April 2012, InVivo Therapeutics announced significant news relating to the advancement of the company's biopolymer scaffolding device to treat acute spinal cord injury. Management recently met with the U.S. FDA to discuss the Investigational Device Exemption (IDE) and the planned human clinical study. Talks focused on the inclusion / exclusion criteria, along with defining the starting and stopping points for the trial. This is a first of its kind program, and one that we believe could be a potentially revolutionary for the treatment of acute spinal cord injury.

To our surprise and in our view an enormous positive to InVivo, the FDA plans to regulate the biopolymer scaffolding device under the Humanitarian Use Device / Humanitarian Device Exemption (HUD/HDE) pathway. This dramatically reduces both the cost and time necessary to bring the InVivo's product to the market. HDE is similar in both form and content to a Pre-Market Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

HUD/HDE allows InVivo to conduct a small - perhaps five to ten patient open-label program - demonstrate probably benefit, and submit the data back to the FDA to potential market approval in an acute or limited population. InVivo can then collect additional data under this limited FDA approval, at a profit, to expand the indication to a wider patient population. Essentially, under the HDE pathway, the PMA trial for a full label in spinal cord injury can be conducted as a post-approval program. HDE also conveys seven years of market exclusivity. So if approved in 2013, InVivo will have a lock on the market until 2020.

However, before human clinical studies can begin, the FDA must approve the finalized design of the HDE program. We expect that InVivo and the FDA will be working closely over the next few months to finalize the design of the trial. Again, we are expecting five to ten patients, open-label, looking at signs of improvement below the level of the spinal cord injury. Based on preclinical data from the company's three primate studies, we are optimistic on this program. Previously completed primate data has been published in the Journal of Neuroscience Methods, and won the prestigious 2011 Apple Award from the American Spinal Injury Association recognizing excellence in SCI research. The total time of the trial should be around three to four months. We expect that InVivo will spend the next few months working on scale-up manufacturing for the device. We are expecting the trial to start in the third quarter 2012 and cost around $1.5 million. Data should be available early 2013, which would put InVivo in position to receive HDE approval mid-2013, about 2 years earlier than our previous forecast.

Hydrogel Up Next

In the meantime, management is working with the FDA to submit additional data around the company's drug releasing hydrogel for SCI. Ideally, the hydrogel will be regulated as a device by the FDA, allowing InVivo to move into an IDE programs in spinal cord injury and peripheral nerve pain in 2013. This will be followed by larger PMA trials in 2014. The company is preparing the rodent and primate data for submission to the agency and seeks to file an IDE during the second half of 2012. This trial should begin in 2013. If positive, we expect management to expand into a larger PMA program in 2014

On January 17, 2012, management announced collaboration with the Geisinger Health System to conduct a preclinical study using the injectable hydrogel for the treatment of chronic pain caused by peripheral nerve compression. The study will be conducted jointly in the Tapinos Lab of Molecular Neuroscience at the Weis Center for Research and the Slotkin Lab of Spinal Cord Injury Research at the Geisinger Clinic's Neurosciences Institute. The endpoint of the study will be the effectiveness of using injectable hydrogels for the controlled release of drugs to alleviate chronic pain resulting from compression-induced peripheral nerve damage looking at both molecular and behavioral impact in rodents. The study is planned to have four arms: 1) injectable scaffold with drug therapy, 2) the injectable scaffold alone, 3) injectable drug therapy alone, and 4) a control group receiving no injection.

We see an enormous opportunity for the injectable hydrogel. The acute and chronic spinal cord injury market is estimated at $20 to $25 billion in the U.S. alone. For peripheral nerve pain, there are an estimated 3.2 million nerve block injections done in the U.S. each year. It's an estimated $15 billion market. Existing treatment options are limited and only curb pain for as little as one week. A localized injection using the hydrogel to provide time-released anti-inflammatory therapies like methylprednisolone could provide pain relief for up to twelve months with limited systemic side-effects.

Remaining Bullish On InVivo

We are maintaining our 'Outperform' rating and $4.50 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.

In our previous reports we have laid out our valuation methodology. We have conducted a discounted cash flow (DCF) analysis and arrive at a target of $4.50. We have also looked at 20 previous deals in the spine market. Applying the average take-out multiple of 6.1x revenues to our 2016 forecast for revenues of $243 million, discounted back to present day at 20%, yields a target price of $7.50 per share.

INVESTMENT THESIS

Making The Case For InVivo

In July 2011, we initiated coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with spinal cord injury (SCI). Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons. These include speed to market, simplicity of the idea, intellectual property protection, and strong animal model data.

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. It is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery. We think this is a model that lends itself well to clinical trials. Regulation of BSD will be as a medical device, not a biologic or a pharmaceutical product, which should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for later in the year under the Humanitarian Device Exemption (HDE) pathway.

Longer-term, upside to the story comes from gaining approval for the injectable Hydrogel formulation, which can be used with pharmaceutical products like methylprednisolone sodium succinate (MPSS). This will then be followed by applications for use of BSD in-combination with stem cells. We think this has the potential to turn BSD into a potential blockbuster for the treatment of SCI because it opens up the opportunity to heal stalled SCI wounds in the 250,000 to 300,000 patients in the U.S. currently living with SCI. If we look outside the U.S., and include Canada and Western Europe, and the number grows to 400,000 chronic SCI patients in these markets. Including Asia, Australia, and Latin America, and the number of chronic SCI patients is around 2.0 million worldwide. Beyond SCI, management is looking at the potential to file an IDE into peripheral nerve damage with the injectable Hydrogel. There are an estimated 3 million nerve block procedures done in the U.S. each year. Existing medications work only as long as one week and require frequent follow-ups to maintain pain suppression. InVivo is working on injectable Hydrogel formulations that can block nerve damage pain for up to twelve months.

…Key Attributes…

Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons:

- ✓ BSD will be regulated as a medical device. Management filed the IDE to the U.S. FDA in July 2011. The proposed indication is to protect and support spinal tissue and prevent secondary injury, including inflammation and glial scarring, following traumatic spinal cord injury. We think this initial, simpler approach to treating SCI provides investors with a quicker and lower risk path to market than the traditional pharmaceutical or biologics.

- ✓ Strong scientific rationale. InVivo's technology for the BSD was born out of the labs of Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. Dr. Langer has written over 1,100 articles, holds approximately 760 issued and pending patents worldwide that have been licensed or sublicensed to over 220 pharmaceutical, chemical, biotechnology and medical device companies. InVivo's CEO, Frank Reynolds, having suffered a paralyzing injury to his spine in December 1992, has spent years gaining subject matter expertise on the spine and spinal cord.

- ✓ Intellectual property protection is strong. Ultimately, we believe combination therapy will become the standard of care for SCI. InVivo's owns the patent rights to use of all biopolymer scaffolding products which serve as an extracellular matrix for cell therapy, or in in combination with pharmaceutical products or biologic growth factors. These patents also protect the use of time-release drugs, design and manufacture of materials for use in SCI that mimics the natural cellular architecture of the inner grey and outer white matter of the spinal cord. We believe this creates significant barriers to entry for competitors and provides for meaningful licensing and partnering opportunities in the future for InVivo.

- ✓ Animal data has been very encouraging. Although we have only seen data in African Green monkeys, we note the physiological anatomy and neurophysiology characteristics between how the spinal cord works and functions these primates and humans is nearly identical. African Green Monkeys are an acceptable regulatory indicator of potential hazards and research supports translation to humans, Nature Medicine, Vol-13,No.5:561-566, May 2007. The genomic similarity to humans is over 98%. The preclinical data from InVivo has been published in the Journal of Neuroscience Methods, and won the prestigious 2011 Apple Award from the American Spinal Injury Association recognizing excellence in SCI research.

…A Simple Concept…

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. As discussed above, it is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery.



We think this is a model that lends itself well to clinical trials. As noted above, regulation as a Class 3 medical device should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for the second half of 2012 under the HDE pathway. We could see data from this program in early 2012.

HUD/HDE allows InVivo to conduct a small - perhaps five to ten patient open-label program - demonstrate probably benefit, and submit the data back to the FDA to potential market approval in an acute or limited population. InVivo can then collect additional data under this limited FDA approval, at a profit, to expand the indication to a wider patient population. Essentially, under the HDE pathway, the PMA trial for a full label in spinal cord injury can be conducted as a post-approval program. HDE also conveys seven years of market exclusivity. So if approved in 2013, InVivo will have a lock on the market until 2020.

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PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2010 E	2011 A	Q1 A	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**	**$43.7**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$1.0**	**$1.5**	**$1.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$1.0**	**$51.5**	**$45.2**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-	-	-
R&D	$1.7	$4.1	$0.9	$1.0	$1.4	$1.8	$5.1	$10.0	$10.0	$10.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$1.7	$4.6	$1.5	$1.5	$1.5	$1.6	$6.1	$7.0	$8.0	$15.7
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($8.7)	($2.5)	($2.5)	($2.9)	($3.4)	($11.3)	($16.0)	$33.5	$19.5
Operating Margin	*0.0%*	-	-	-	-	-	-	-	-	-
Net Other Income	($4.5)	($26.1)	$5.6	($1.0)	($1.0)	($1.0)	$2.6	$0.0	$0.0	$0.0
Pre-Tax Income	($7.9)	($34.8)	$3.1	($3.5)	($3.9)	($4.4)	($8.7)	($16.0)	$33.5	$19.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$5.8	$4.9
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*17.4%*	*24.9%*
Net Income	($7.9)	($34.8)	$3.1	($3.5)	($3.9)	($4.4)	($8.7)	($16.0)	$27.7	$14.6
Net Margin	*0.0%*	-	-	-	-	-	-	-	*53.7%*	*32.3%*
Reported EPS	**($0.24)**	**($0.67)**	**$0.05**	**($0.06)**	**($0.06)**	**($0.07)**	**($0.14)**	**($0.23)**	**$0.37**	**$0.18**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	33.4	51.9	58.0	62.5	62.5	62.5	61.4	70.0	75.0	80.0

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

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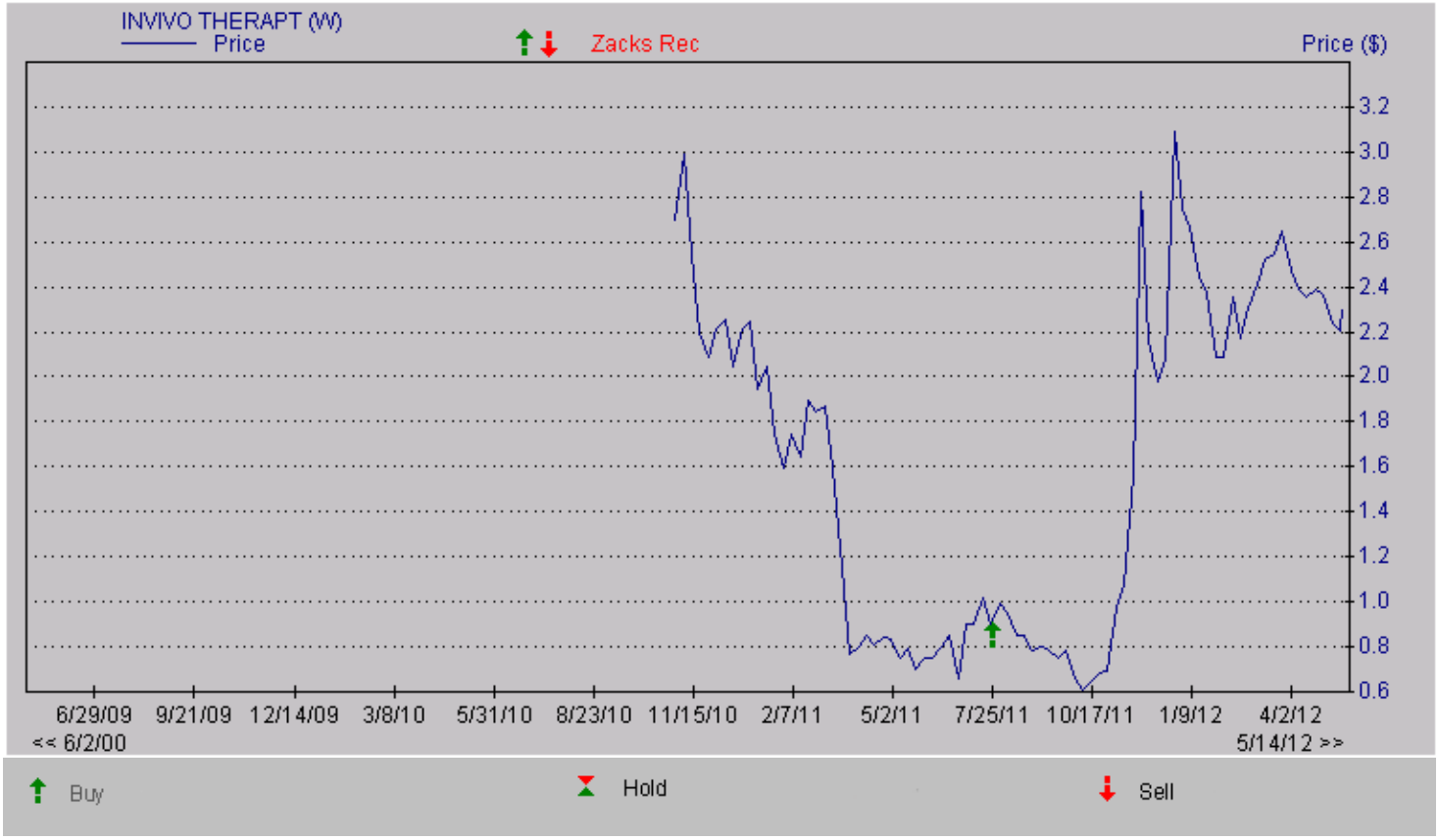
HISTORICAL ZACKS RECOMMENDATIONS



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