Zacks Small-Cap Research

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InVivo Therapeutics (NVIV-OTC)

NVIV: More Primate Data Coming Soon. Human Trials Nearing…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (11/15/12)	$1.65
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 and believe that shares of InVivo are drastically under-valued.

SUMMARY DATA

52-Week High	**$3.10**
52-Week Low	**$1.28**
One-Year Return (%)	**-11.29**
Beta	**0.06**
Average Daily Volume (sh)	**57,533**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**$107**
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 A	0 A	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	$0.03 A	$0.12 A	-$0.06 E	$0.15 E
2013					-$0.23 E
2014					-$0.30 E

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WHAT'S NEW

Financial Position

On November 14, 2012, InVivo Therapeutics reported financial results for the third quarter 2012. The company reported no revenues in the quarter, as expected. Net income in the quarter was $8.0 million, or 12 cents per diluted share. Included in results were non-cash derivative gains of $10.9 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 second quarter 2012 was $2.9 million, or 4 cents per diluted share.

InVivo exited the third quarter 2012, ended September 30, 2012, with $16.2 million in cash, restricted cash, and equivalents. Operating and investing cash burn for the quarter totaled $2.7 million. For the first nine months of 2012, InVivo has burned an estimated $8.0 million from operating and investing activities. The company has raised approximately $19.1 million through financing activities. We find the current cash balance to be sufficient to fund operations into the first quarter of 2014 (current management guidance).

As of November 9, 2012, the basic share count stood at 65.9 million. We remind investors that there are a total of 15.5 million warrants outstanding as of September 30, 2012. This includes 13.5 million warrants currently exercisable at $1.40 per share and 1.9 million warrants currently exercisable at $1.00 per share. Based on comparing the 10Q filing from the first, second, and third quarter 2012, it looks like an estimated 1.1 million warrants were exercised during the quarter. In total, the 13.5 million warrants at $1.40 per share could supply an additional $18.9 million in cash to the company.

In October 2012, the company entered into a loan agreement with the Massachusetts Development Finance Agency (MassDev) from the Commonwealth of Massachusetts's Emerging Technology fund. The loan provides InVivo with a $2.0 million line of credit at an annual fixed interest rate of 6.5%. In October 2012, management drew on the line and received proceeds of $1.144 million, including $0.200 million for working capital purposes and $0.944 million for the purchase of capital equipment.

HDE Trail In SCI To Start In Q2-2013

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 (SCI). Earlier in the year, management 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 revolutionize 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 open-label program designed to 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 an unconstrained 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 say 2014, InVivo will have a lock on the market until 2021.

However, before human clinical studies can begin, the FDA must inspect and approve the company's new manufacturing facility. InVivo is current manufacturing GMP test batches and expects to gain final FDA validation of the facility in the next few months. This should allow the HDE trial to initiate in the second quarter 2013. We are expecting five patients, all with thoracic injury, open-label, looking at signs of improvement below the level of the spinal cord injury. We expect enrollment and treatment to take approximately two to three months, with data beginning to dribble out a month later. Patient follow-up will last twelve months. The cost will be around $1.5 million. We expect InVivo to look to duplicate positive results in patients with cervical injury.

InVivo will use standardized American Spinal Injury Association (ASIA) scoring to assess efficacy over a year-long period. The first update should come in the second quarter 2013. Based on preclinical data from the company's three primate studies, we are optimistic on this program. Previously completed non-human 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. We are expecting InVivo to submit additional data from its preclinical non-human primate studies later in 2012 or in early 2013. Publication of this data could spark investor excitement in the InVivo story.

Hydrogel Up Next

Meanwhile, InVivo is working with the FDA to submit additional data around the company's drug releasing hydrogel for SCI. Management would like to see the hydrogel 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 or 2015. Only before that can take place, the pathway needs to be confirmed and additional preclinical data needs to be submitted to the FDA for review.

The company is preparing the rodent and primate data for submission to the agency and seeks to file an IDE during the first quarter of 2013. This trial should begin shortly thereafter. If positive, we expect management to expand into a larger PMA program. If the U.S. FDA regulates the hydrogel as a drug, we expect InVivo to look to commence a phase 1 study in early 2013.

On January 17, 2012, management announced collaboration with the Geisenger Health System (GHS) 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 Geisenger Clinic's Neurosciences Institute. InVivo paid Geisenger $60,000 upfront and will fund the cost of the study, which is estimate to be $150,000.

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. InVivo expects that this study will be completed by the end of 2012.

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 $22 billion market. Existing treatment options 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.

Preclinical Pipeline

In July 2012, InVivo held the inaugural Langer Summit on Neurotrauma chaired by InVivo co-founder Robert S. Langer, ScD, the David Koch Institute Professor at Massachusetts Institute of Technology. The meeting brought together some of the leading researchers in neurotrauma who shared and discussed recent innovations in the field and the opportunities for InVivo to advance its technologies into the clinic. By all measures, the event was a success, bringing over 30 researchers together to collaborate and create new treatment options for the treatment of neurotrauma. The upside – InVivo will retain intellectual property on any platform technology developed as a result of the summit.

In August 2012, InVivo announced that one of the company's neurosurgeons, Amer Khalil, MD, has been selected as the winner of an MDH Research Award, a grant given by MDHonors, to further InVivo's research on spinal cord injury. Dr. Khalil was awarded a grant of $10,000 for his project titled, "Spinal cord repair using biomaterial-based drug-releasing strategies for reducing scarring and promoting regeneration."

Management sees Dr. Khalil's project as an exciting opportunity to expand its technology into a potential third product for the treatment of fibrosis. InVivo believes its hydrogel can be used to reduce scarring in both reparative surgical and dermatological applications. We believe minimizing scarring after reparative surgery or scarring following plastic surgery procedures is an enormous market opportunity – potentially millions of treatments per day in the U.S.

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.

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 early 2013 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 first half of 2013 under the HDE pathway. We could see data from this program around the middle of 2013.

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 2014, InVivo will have a lock on the market until 2021.

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PROJECTED FINANCIALS

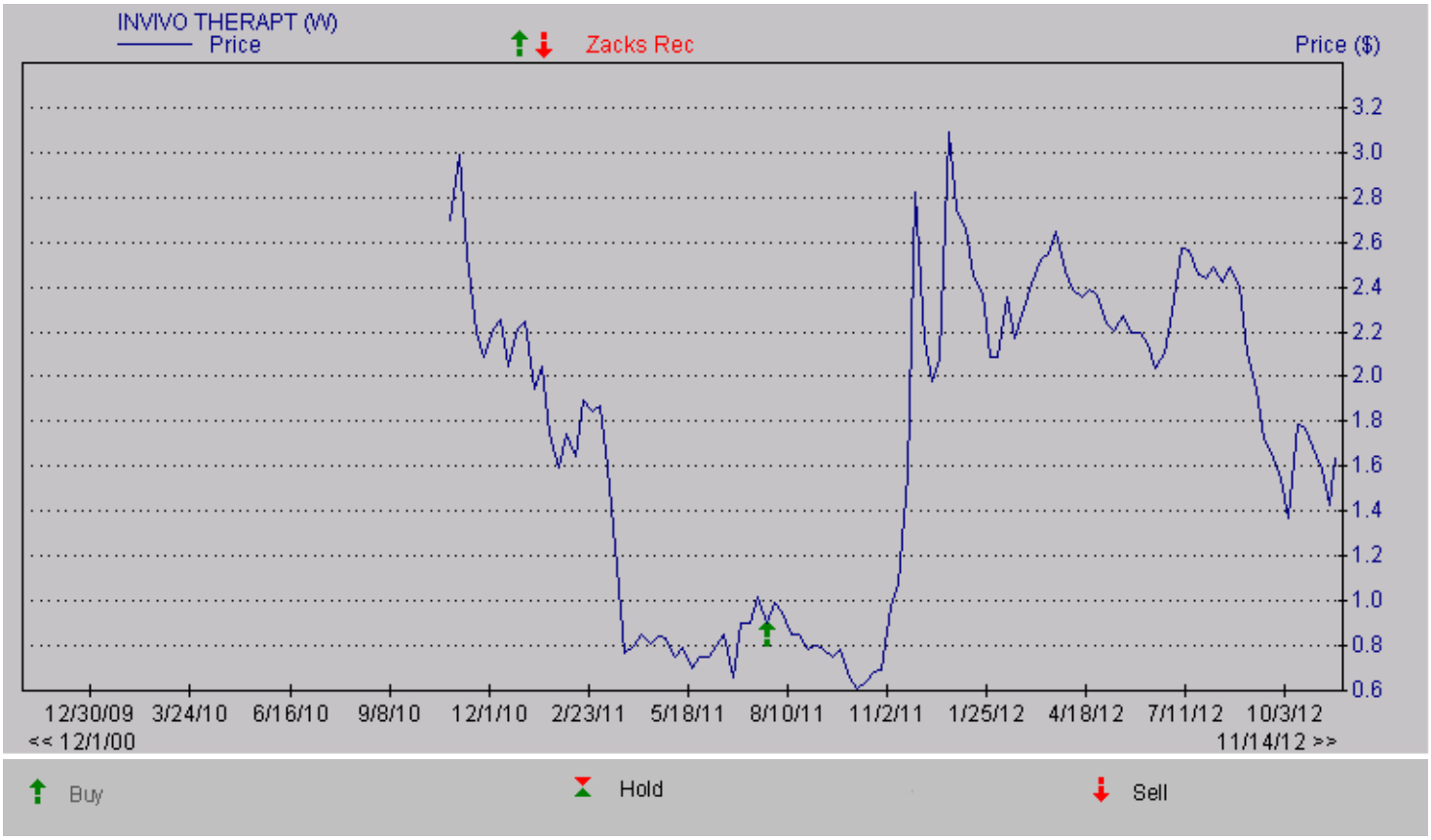
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2010 E	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E	2015 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$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**	**$1.0**	**$1.5**	**$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	$1.3	$1.4	$1.5	$5.1	$10.0	$10.0	$10.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$1.7	$4.6	$1.5	$1.4	$1.5	$1.5	$5.9	$7.0	$8.0	$15.7
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($8.7)	($2.5)	($2.8)	($2.8)	($3.0)	($11.1)	($16.0)	($16.5)	$19.5
Operating Margin	*0.0%*	-	-	-	-	-	-	-	-	-
Net Other Income	($4.5)	($26.1)	$5.6	$5.0	$10.9	($1.0)	$20.4	$0.0	$0.0	$0.0
Pre-Tax Income	($7.9)	($34.8)	$3.1	$2.2	$8.0	($4.0)	$9.4	($16.0)	($16.5)	$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%*	*-35.3%*	*24.9%*
Net Income	($7.9)	($34.8)	$3.1	$2.2	$8.0	($4.0)	$9.4	($16.0)	($22.3)	$14.6
Net Margin	*0.0%*	-	-	-	-	-	-	-	*-1488.0%*	*32.3%*
Reported EPS	**($0.24)**	**($0.67)**	**$0.05**	**$0.03**	**$0.12**	**($0.06)**	**$0.15**	**($0.23)**	**($0.30)**	**$0.18**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	33.4	51.9	58.0	64.1	65.1	66.0	63.3	70.0	75.0	80.0

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

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