Zacks Small-Cap Research

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InVivo Therapeutics (NVIV-OTCQB)

NVIV: First patient enrolled in pilot study of the Neuro-Spinal Scaffold…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	07/23/2013
Current Price (11/06/14)	$1.01
Target Price	**$2.00**

UPDATE

On November 5, 2014, InVivo Therapeutics reported financial results for the third quarter ended September 30, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $1.2 million, driven by $2.4 million in R&D and $1.8 million in SG&A expense. This quarter's results were favorably impacted by a gain in derivative warrant liability of $3.0 million.

On October 15, 2014, InVivo Therapeutics announced the enrollment of the first patient in the pilot spinal cord injury trial. On October 29, 2014, the company announced the FDA has approved broadening the eligibility criteria for the study as well as expanding the number of clinical sites from six to 20. Both changes should help greatly expedite patient enrollment.

SUMMARY DATA

52-Week High	**$2.60**
52-Week Low	**$0.50**
One-Year Return (%)	**-10.62**
Beta	**1.22**
Average Daily Volume (sh)	**753,564**
Shares Outstanding (mil)	**93**
Market Capitalization ($mil)	**$94**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**1**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share
(EPS is operating earnings)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.20 A	-$0.20 A	-$0.07 A	-$0.07 A	-$0.52 A
2014	-$0.07 A	-$0.04 A	-$0.01 A	-$0.07 E	-$0.16 E
2015					-$0.23 E
2016					-$0.22 E

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WHAT'S NEW

Financial & Business Update

On November 5, 2014, InVivo Therapeutics (NVIV) reported financial results for the third quarter ended September 30, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $1.2 million, driven by $2.4 million in R&D and $1.8 million in SG&A expense. Results were favorably impacted by a gain in derivative warrant liability of $3.0 million. Cash as of September 30, 2014 totaled $17.6 million. We remind investors that on May 9, 2014, InVivo completed an underwritten public offering whereby the company sold 14.0 million shares of common stock at $1.15 per share to raise gross proceeds of $16.1 million. Also included in the transaction were 7.0 million warrants exercisable for five years at $1.44 per share. Aegis Capital Corp. acted as sole book-running manager for the offering.

From a cash burn standpoint, InVivo used $3.2 million in cash from operating and investing activities during the third quarter 2014. Operating burn for the previous four quarters came in at $4.1, $4.3, $4.2, and $3.6 million, so operating burn has been decreasing in the past couple of quarters. This is due to the company's realignment of its R&D strategy to focus its resources on the Neuro-Spinal Scaffold (NSS-) and the Neuro-Spinal Scaffold plus Stem Cells (NSS+SC) program for spinal cord injury.

The reduction in operating expenses noted above resulted from a reduction in headcount of 14 employees, or 28% of its workforce, along with shelving hydrogel R&D activities. The headcount reduction and the shifting of R&D resources is expected to result in annualized savings of approximately $3 million and to reduce cash expenditures by approximately 23% compared to 2013 levels. With these savings, InVivo anticipates that existing funds of $17.6 million will be sufficient to support its planned activities through the end of 2015.

…First patient enrolled in pilot spinal cord injury trial…

On October 15, 2014, InVivo announced the first patient was enrolled in the pilot study of its Neuro-Spinal Scaffold (NSS) for the treatment of complete traumatic spinal cord injury. The subject was enrolled at the Barrow Neurological Institute at St. Joseph's Hospital and Medical Center in Phoenix, AZ. Dr. Nicholas Theodore, Chief of Spinal Surgery, Barrow Neurosurgical Institute and Medical Director of the Neurological Trauma Program performed the surgery and commented that the procedure went smoothly and the patient was doing well following surgery.

A total of five patients will be enrolled in this initial pilot study. Originally, enrollment criteria for the trial stipulated that patients must be between 18 and 55 year old, and have traumatic spinal cord injury along the thoracic region on the spine (T3-T11) with ASIA-A complete impairment confirmed by neurosurgeon, occurring within past 10 days.

On October 29, 2014, InVivo announced that the U.S. Food and Drug Administration (FDA) had approved various changes to the protocol for the pilot study, including expanding the number of allowable clinical sites from six to 20 and broadening the eligibility criteria. These changes should help to expedite patient recruitment into the trial. The new eligibility criteria changes include:

- ✓ The upper end of the age range has been increased from 55 to 65
- ✓ The spinal cord injury level has been expanded from T3-T11 to T3-T12/L1
- ✓ The enrollment window has been extended from 10 to 21 days post injury
- ✓ The Body Mass Index upper limit has been increased from 35 to 39

On Oct. 20, 2014, InVivo announced that the Barnes-Jewish Hospital at Washington University Medical Center in St. Louis, MO, would be the fourth clinical site in the pilot study. Barnes-Jewish Hospital is the largest regional trauma center in St. Louis and is one of the largest clinical spine care practices for the United States. Paul Santiago, MD, an Associate Professor of Neurological Surgery and Orthopedic Surgery at the Washington University School of Medicine in St. Louis, will be the study's Principal Investigator at the Barnes-Jewish Hospital. Barnes-Jewish Hospital joins the University of Arizona Medical Center in Tucson, AZ, Carolinas Medical Center in Charlotte, NC, and Barrow Neurological Institute in Phoenix, AZ as sites eligible to enroll patients in the pilot study. InVivo is anticipating announcing two additional sites in the coming weeks once the final administrative steps of site start-up are complete, with more sites to be added next year now that the number of allowable clinical sites has been expanded to 20.

Now that the first patient has been treated, InVivo will record the safety and efficacy data noted above at 24 hours, 48 hours, one week, time of hospital discharge, one month, three months, six months, and twelve months. InVivo will be working closely with the FDA on data analysis, and if the safety looks good at three months, then the trial will be cleared to allow enrollment of the second patient. After the second patient clears the three month safety assessment, the trial will be allowed to enroll the third patient, and so on and so forth until five patients are enrolled.

As of now, we are not expecting the FDA to allow accelerated enrollment of patients 3-5 based on the safety and efficacy data from the first two patients, but that is certainly a possibility and something the company will aggressively pursue if the data looks good. Remember, this is an open-label study so the company, investors, and the general public (including the media) will be watching the recovery of this patient closely.

However, assuming no accelerated enrollment, the pilot study will take 18 months to complete, with full twelve-month patient data on all five patients coming in roughly 28 to 30 months. Following successful completion of the pilot study, InVivo expects to conduct a pivotal study to obtain FDA approval to commence commercialization under a Humanitarian Device Exemption (HDE). We remind investors that InVivo received a Humanitarian Use Device (HUD) designation for the NSS in April 2013.

…Reasons To Be Bullish…

Management believes the NSS- is a potential $500 million product in acute spinal cord injury. We concur. Even with the expanded inclusion criteria for the study we believe it still remains strict. We believe if the NSS works, then neurosurgeons will use the device in almost all non-penetrating spinal cord injuries, regardless of things like ASIA impairment level and injury location. This brings the market up from roughly 1,600 patients per year to more like 6-8,000 patients per year. Of course, as of now we are excluding the nearly 300,000 American's with injuries greater than 10 days old. In time, InVivo may expand the use of the NSS to these "chronic" patients, perhaps in combination with neural/spinal cord stem cells.

According to the NSCISC's February 2013 report "Spinal Cord Injury Facts and Figures at a Glance," (i) during the first year, average "cost of care" ranges from $340,787 to $1,044,197, depending on the severity of the injury, (ii) the net present value to maintain a quadriplegic injured at age 25 for life is $4,633,137, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,265,584. Because these costs place a tremendous financial burden on families, insurance providers, and government agencies, and because of the HUD designation, we believe a cost of $100,000 is fair (and actually quite conservative).

As for commercialization, according to industry statistics, nearly 80% of all spinal cord injuries are treated at 75 Level 1 trauma centers around the U.S. We believe the company can effectively target these 75 centers with 10 to 20 direct representatives. InVivo's scaffolding is designed to complement the current standard of care for an acute spinal cord injury, not replace it. The sales forced, armed with pivotal human efficacy data and promoting the product under that type of marketing message, should have enormous success.

We are being aggressive here because the scaffolding is designed to be complementary to standard-of-care or new treatment options that might incorporate the use of neural stem cells. We expect next-generations variations of the scaffolding will be designed to specifically incorporate advancing regenerative medicine technologies. As such, $500 million seems easily doable – assuming the NSS works.

Conclusion

Enrolling the first patient in the IDE trial is clearly an important milestone for InVivo. It has been over three years since the filing of the first IDE application. The trial is an open-label design, so we expect that the company will keep investors in the loop as the three, six, and twelve-month data becomes available from this first patient. We would not be surprised to see data begin leaking out over the next several weeks. That first patient was completely paralyzed at the time of the surgery. Any signs of improvement over the next several weeks and we think InVivo's stock soars.

The Neuro-Spinal Scaffold in the HUD population easily looks like a $500 million drug. If that's the case, InVivo's stock is certainly very attractive at a market capitalization of only $100 million today. We think a valuation inflection may come upon the public release of the three-month safety and initial efficacy data from this pilot study.
We are optimistic on the InVivo story, but believe the shares will remain under pressure until the data becomes available from the first patient. We encourage investors to stay tuned for the next update.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-					-	-	-
R&D	$10.5	$3.2	$3.1	$2.4	$3.5	$12.2	$15.0	$16.0
SG&A	$8.5	$1.8	$1.7	$1.8	$1.8	$7.1	$7.5	$8.0
Operating Income	($19.0)	($5.1)	($4.7)	($4.2)	($5.3)	($19.3)	($22.5)	($24.0)
Operating Margin	-					-	-	-
Net Other Income	($19.8)	($0.0)	$1.1	$3.0	($0.0)	$4.0	($0.1)	($0.1)
Pre-Tax Income	($38.8)	($5.1)	($3.6)	($1.2)	($5.3)	($15.3)	($22.6)	($24.1)
Taxes	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*0.0%*
Net Income	($38.8)	($5.1)	($3.6)	($1.2)	($5.3)	($15.3)	($22.6)	($24.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.52)**	**($0.07)**	**($0.04)**	**($0.01)**	**($0.06)**	**($0.16)**	**($0.23)**	**($0.22)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	74.0	74.2	87.3	101.6	95.0	96.0	100.0	110.0

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

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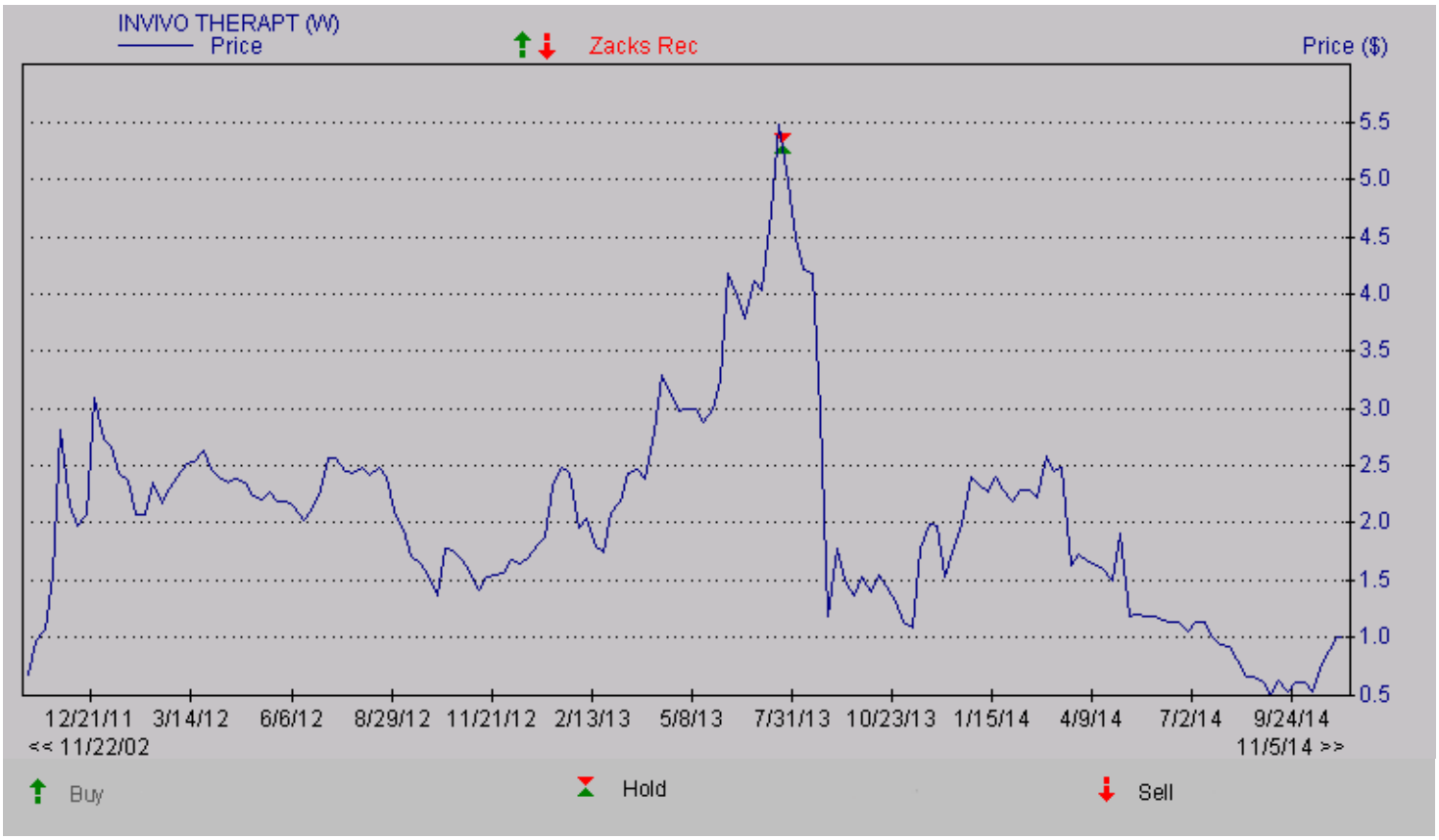

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