Zacks Small-Cap Research

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

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

InVivo Therapeutics (NVIV-OTCQB)

NVIV: Human Trial Seeks First Patient…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	07/23/2013
Current Price (08/07/14)	$0.80
Target Price	**$2.00**

UPDATE

On August 6, 2014, InVivo Therapeutics reported financial results for the second quarter ended June 30, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $3.6 million, driven by $3.1 million in R&D and $1.7 million in SG&A expense. These were both slightly lighter than our expectations.

On April 28, 2014, InVivo Therapeutics announced something that investors have been waiting on for a very long time – the biocompatible polymer scaffolding has finally entered human clinical trials for the treatment of acute spinal cord injury. We are awaiting enrollment of the first patient.

SUMMARY DATA

52-Week High	**$5.60**
52-Week Low	**$0.95**
One-Year Return (%)	**-81.37**
Beta	**1.12**
Average Daily Volume (sh)	**162,659**
Shares Outstanding (mil)	**93**
Market Capitalization ($mil)	**$88**
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 E	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	-$0.06 E	-$0.07 E	-$0.20 E
2015					-$0.23 E
2016					-$0.22 E

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WHAT'S NEW

Financial & Business Update

On August 6, 2014, InVivo Therapeutics (NVIV) reported financial results for the second quarter ended June 30, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $3.6 million, driven by $3.1 million in R&D and $1.7 million in SG&A expense. These were both slightly lighter than our expectations. Cash as of June 30, 2014 totaled $20.8 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 was 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 $3.6 million in cash from operating and investing activities during the second quarter 2014. Operating burn for the previous four quarters came in at $4.2, $4.1, $4.3, and $4.2 million, so operations trimmed while the company prepared to initiate its first human clinical trial with the neuro-spinal scaffolding. In June 2014 the company announced a 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. Resources currently deployed towards InVivo's hydrogel drug delivery program will be eliminated. This was not surprising considering the company could not find a suitable partner for the hydrogel platform.

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 $20.8 million will be sufficient to support its planned activities into the first quarter 2016.

…Expanded Management…

In accordance with the recent reduction in workforce, InVivo has appointed a new Chief Financial Officer (CFO) and provided new management responsibilities for the senior management.

- On June 19, 2014, InVivo appointed Steven McAllister as CFO. Mr. McAllister had been serving as the company's interim CFO since December 2013. Mr. McAllister previously served as Vice President, Finance and Administration for Biomet Spine and Bone Healing Technologies (a private equity-owned medical device company) from 2007–2013, where he was responsible for all accounting, finance, IT, facilities, and insurance operations activities in addition to leading the company's strategic planning initiatives. Mr. McAllister received his BS in Accounting from Fairleigh Dickinson University.

- William D'Agostino, PE, has been appointed Senior Vice President, Operations. Mr. D'Agostino previously served as the company's Vice President, Manufacturing & Engineering since September 2012. Previously, he held the position of Vice President, Engineering at Angiotech Pharmaceuticals which included running all product development and engineering activities across their international facilities. Mr. D'Agostino also worked for Covidien for fifteen years where he gained extensive experience with the development, synthesis and clinical production of bioabsorbable polymers. He is a Licensed Professional Engineer (PE) and holds an MBA from the University of Dallas and a BS in both Chemical Engineering and Materials Engineering from the University of Connecticut.

- Kristin Neff has been appointed Vice President, Clinical Operations & Project Management. Previously, she held the position of Vice President, Clinical Operations. Kristin joined InVivo in August 2013 from TARIS Biomedical where she served as Senior Director, Clinical Operations. Ms. Neff has an MS in Biomedical Engineering from Boston University and a BS in Electrical Engineering from UMass, Amherst.

- Lisa Crockett has been appointed Vice President, Regulatory Affairs & Reimbursement Planning. Previously, she held the position of Vice President, Regulatory Affairs since in June of 2013. Ms. Crockett joined InVivo from Genzyme, where she most recently served as Associate Director of Regulatory Affairs. She holds an MS in Regulatory Affairs from Northeastern University and a BS from Johnson and Wales University.

- On July 1, 2014, InVivo announced Christopher McNulty has assumed the expanded role of Vice President, Business Development & Investor Relations. Before coming to InVivo, Mr. McNulty served as Senior Director of Business Development at Repligen Corporation, where his responsibilities included out-licensing programs for rare neurodegenerative diseases. Previously, he was Director of Corporate Development at Seventh Sense Biosystems and Associate Director of Business Development and Alliance Management at Genzyme Corporation. Mr. McNulty has also held technical roles at Transform Pharmaceuticals and Cereon Genomics. He has an MBA from Harvard Business School, and BS and MEng degrees from MIT.

IDE Trial Finally Starts

On April 28, 2014, InVivo Therapeutics announced something that investors have been waiting on for a very long time – the biocompatible polymer scaffolding has finally entered human clinical trials for the treatment of acute spinal cord injury. We remind investors that implantation of the Neuro-Spinal Scaffold (NSS-) device in preclinical rodent and primate studies resulted in functional recovery for previously paralyzed animals. Recall some of the impressive videos the company made available in 2011 and 2012 from these studies. The company is hoping these results transition over to humans with the start of this potential revolutionary trial.

The pilot study is designed to evaluate whether the NSS- is safe and feasible for the treatment of complete functional spinal cord injury. This will be determined by no degradation in paralysis level or sensory motor neurological function beyond that typically seen in the ASIA-A subject. We believe this is "low-hanging fruit" in terms of the primary outcome. However, the study will also gather preliminary evidence of clinical effectiveness, to be determined by improvement of ASIA Impairment Scale, sensory scores, motor scores, bladder and bowel function, neurological tests, and The Spinal Cord Independence Measure III.

A total of five patients will be enrolled in this initial pilot study. 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. The injury must be a non-penetrating contusion injury no less than 4 mm diameter and limited to 2 contiguous vertebral levels.

…Enrolling The Right Patients…

According to 2013 data from the National Spinal Cord Injury Statistical Center, there are an estimated 12,000 acute spinal cord injuries in the U.S. each year. Data from a 2011 annual statistical report created for the Spinal Cord Injury Model Systems shows that 46% of these individuals will be classified as ASIA-A upon admittance to the hospital. Roughly 90% survive one-week post injury. Approximately 35% of all spinal cord injuries are in the thoracic region on the spin (32% between T3-T12). Approximately 70% of these injuries are non-penetrating. Approximately 60% of the patients are between the ages of 18 and 55. This population, approximately 1,600 individuals, is the target market for InVivo's pilot study.

The pilot study is designed to take place at six sites around the U.S. The initial clinical site will be at The University of Arizona Medical Center in Tucson, AZ under the direction of principal investigator, Ali A. Baaj, MD, Assistant Professor of Surgery and Director of the Spinal Neurosurgery Program at The University of Arizona Medical Center. Two additional sites have been cleared to begin enrolling patients:

- Carolinas Medical Center in Charlotte, NC is now open for enrollment under Dom Coric, MD, of Carolina Neurosurgery & Spine Associates, Chief of Neurosurgery at Carolinas Medical Center. Dr. Coric is a Co-Principal Investigator. William L. Bockenek, MD, Chief Medical Officer of Carolinas Rehabilitation, part of the Carolinas HealthCare System, and Chairman of the Department of Physical Medicine and Rehabilitation at Carolinas Medical Center, is also a Co-Principal Investigator.

- Barrow Neurological Institute in Phoenix, AZ is now open for enrollment for patients. BNI at St. Joseph's Hospital and Medical Center is the largest dedicated neurosurgical center in the world and is a recognized leader in neurosurgical training, research, and patient care. More operative neurosurgical procedures take place at BNI than at any other institution in the United States. Nicholas Theodore, MD, Professor of Neurosurgery, Director of Neurosurgery Spine Program, and Director of Neurotrauma at BNI will be the study's Principal Investigator.

We believe opening up additional clinical sites, especially one in the northeast, is extremely important for timely patient recruitment. After the first patient has been enrolled, 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.

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. Although the initial inclusion criteria for the pilot study are strict, we believe if the NSS- works, neurosurgeons will use the device in almost all non-penetrating spinal cord injuries, regardless of thing 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 design 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

Announcing the start of the pilot study is clearly a positive event for InVivo. It has been over three years since the filing of the first IDE application. The next step for the company is to find and enroll the first patient. This will be 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.

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 $75 million today ($100 million fully-diluted). We think a valuation inflection may come upon the public release of the three-month safety and initial efficacy data from this pilot study. Unfortunately, it has been four months since the trial opened for enrollment and we are still waiting for the first patient to undergo the surgery. We are optimistic on the InVivo story, but believe the shares will remain under pressure until the first patient is enrolled, treated, and the data becomes available. We encourage investors to stay tuned for the next update.

PROJECTED FINANCIALS

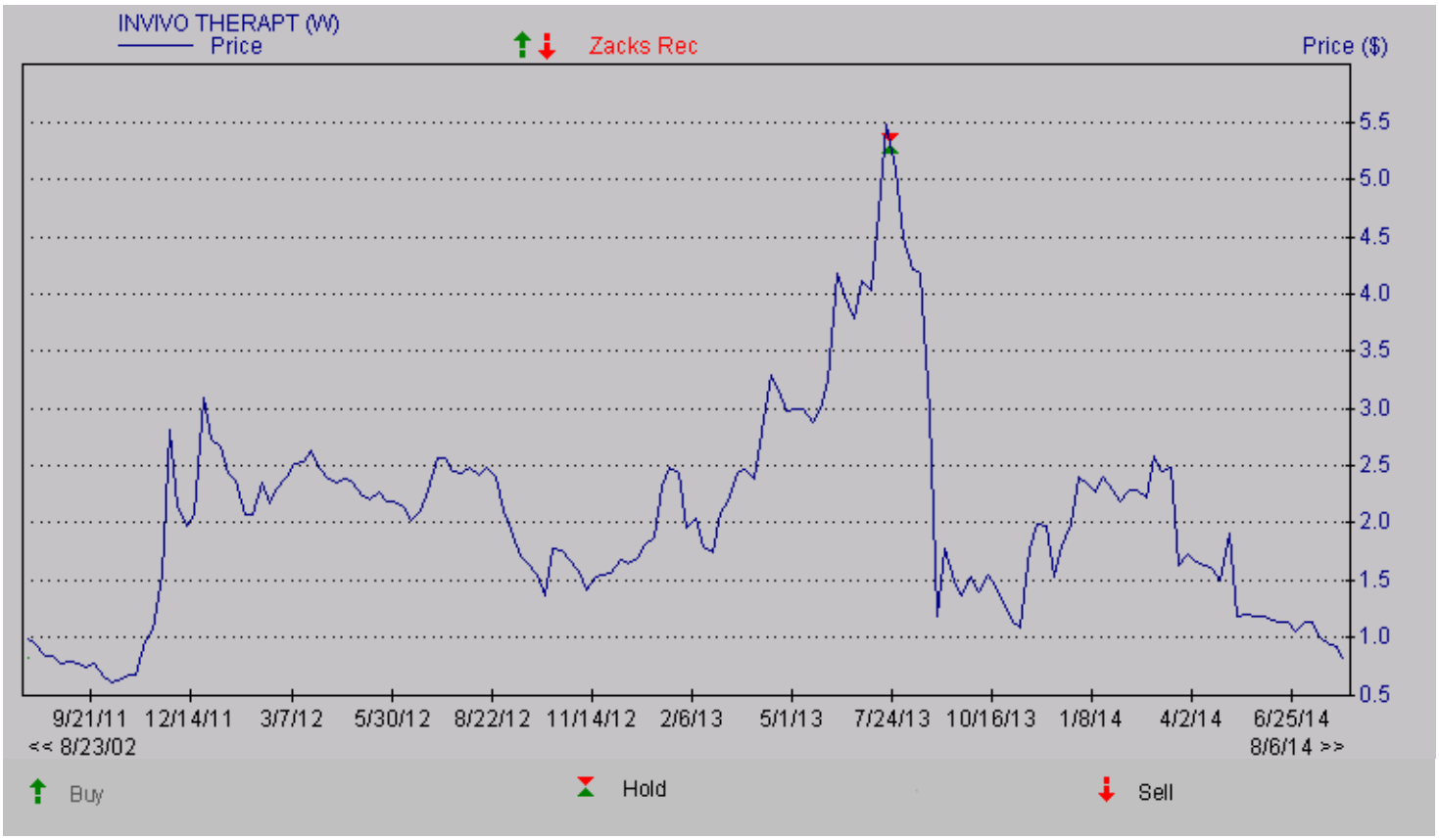
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2013 A	Q1 A	Q2 A	Q3 E	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	$3.3	$3.5	$13.1	$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)	($5.1)	($5.3)	($20.2)	($22.5)	($24.0)
Operating Margin	-					-	-	-
Net Other Income	($19.8)	($0.0)	$1.1	($0.0)	($0.0)	$1.0	($0.1)	($0.1)
Pre-Tax Income	($38.8)	($5.1)	($3.6)	($5.1)	($5.3)	($19.2)	($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)	($5.1)	($5.3)	($19.2)	($22.6)	($24.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.52)**	**($0.07)**	**($0.04)**	**($0.06)**	**($0.06)**	**($0.20)**	**($0.23)**	**($0.22)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	74.0	74.2	87.3	90.0	95.0	96.0	100.0	110.0

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

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