Zacks Small-Cap Research

March 27, 2015
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InVivo Therapeutics

(NVIV-OTCQB)

NVIV: Revolutionizing Treatment For Spinal Cord Injury…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	01/15/2015
Current Price (03/26/15)	$2.87
Target Price	**$6.00**

On March 26, 2015, the U.S. FDA cleared InVivo Therapeutics (NVIV) to allow the open enrollment of patients three, four, and five in the company's ongoing pilot study of its investigational Neuro-Spinal Scaffold (NSS) for the treatment of acute spinal cord injury. We remind investors that this is primarily a safety study (NCT02138110), with the main goal to evaluate whether the NSS is safe and feasible for the treatment of complete functional spinal cord injury. The primary endpoint is incidence of all adverse device effects of any kind/seriousness at six months post-surgery. Safety will be determined by no degradation in paralysis level or sensory motor neurological function beyond that typically seen in the AIS-A subject. However, to gather preliminary evidence of clinical effectiveness of the NSS, study investigators will assess functional improvement of ASIA Impairment Scale, sensory scores, motor scores, bladder and bowel function, neurological tests, and The Spinal Cord Independence Measure III.

UPDATE

SUMMARY DATA

52-Week High	**$3.04**
52-Week Low	**$0.50**
One-Year Return (%)	**65.71**
Beta	**1.15**
Average Daily Volume (sh)	**1,287,657**
Shares Outstanding (mil)	**102**
Market Capitalization ($mil)	**$297**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
Insider Ownership (%)	**32**
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 2015 Estimate	**N/A**
P/E using 2016 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)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 E	0 E	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share
(EPS is operating earnings)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.07 A	-$0.04 A	-$0.01 A	-$0.09 A	-$0.21 A
2015	-$0.04 E	-$0.04 E	-$0.04 E	-$0.05 E	-$0.17 E
2016					-$0.19 E
2017					-$0.21 E

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WHAT'S NEW

InVivo Revolutionizing Spinal Cord Injury

On March 26, 2015, the U.S. FDA cleared InVivo Therapeutics (NVIV) to allow the open enrollment of patients three, four, and five in the company's ongoing pilot study of its investigational Neuro-Spinal Scaffold (NSS) for the treatment of acute spinal cord injury. We remind investors that this is primarily a safety study (NCT02138110), with the main goal to evaluate whether the NSS is safe and feasible for the treatment of complete functional spinal cord injury. The primary endpoint is incidence of all adverse device effects of any kind/seriousness at six months post-surgery. Safety will be determined by no degradation in paralysis level or sensory motor neurological function beyond that typically seen in the AIS-A subject. However, to gather preliminary evidence of clinical effectiveness of the NSS, study investigators will assess functional improvement of ASIA Impairment Scale, sensory scores, motor scores, bladder and bowel function, neurological tests, and The Spinal Cord Independence Measure III.

…Patient No. 1 Shows "Unexpected" Gains…

On October 15, 2014, InVivo announced the first patient surgery and implantation of NSS took place. The subject, then 25 year old Jordan Fallis, 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. On January 21, 2015, InVivo provided an update on the status of the first patient following a safety assessment at 90 days post-surgery. This is where it gets interesting, because Jordan's results are "unexpected"' according to Dr. Theodore.

Before we get into Jordan's gains, it is important to note that in the time between implantation and the 90 day post-injury assessment, there were no reported serious adverse events associated with the NSS. The primary safety endpoint will be assessed again at six months (mid-April 2015), but things look to have gone well with respect to the key gating-factor to moving forward with enrolling more patients in the study.

However, what was unexpected so soon after the surgery was the functional recovery seen to date. According to InVivo's press release, the subject has progressed from a complete AIS-A injury (pre-surgery) to an incomplete AIS-C injury with motor, sensory, bowel, and bladder function improvements. That's huge! Since that time, updates as provided by Mr. Fallis himself suggest increased leg strength and the ability stand with the support of a NMES suit (see pic here).

As a reminder, Jordan was completely paralyzed from the belly-button down following his motorcycle accident. Motor improvement from the pre-surgery assessment to the 3-month visit involved the return of active movement of the hip flexors against gravity (allowing for leg to chest motions) and palpable contractions of the knee extensors. A recent video posted of him on YouTube shows he has regained significant ability. For example, InVivo's press release notes, "Sensory improvement from the pre-surgery assessment to the 3-month visit involved the bilateral return of sensation to two dermatomes extending down the top of the subject's legs and the S4-S5 dermatome. In addition, the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) exam, the Spinal Cord Independence Measure (SCIM III) exam, and additional assessments of bowel and bladder function demonstrated that between hospital discharge and the 3-month visit, the subject has regained bowel function and improved bladder function." Regaining function of bowel and bladder alone leads us to believe InVivo's NSS product has peak sales potential in excess of $500 million.

…Patient No. 2 Showing Similar Improvements…

On January 22, 2015, one day after the company announced the 90-day assessment on Jordan Fallis, the second patient, 22 year old Jesi Stracham, was enrolled into the study. Enrollment took place at Carolinas Medical Center (CMC) in Charlotte, NC under the direction of Dr. Domagoj Coric, Chief of Neurosurgery at CMC, and Dr. William Bockenek, Chief Medical Officers of Carolinas Rehabilitation. Jesi's injury, seemingly more severe than Jordan's, was multi-trauma and required two days of stabilization prior to the implantation of the device.

However, despite what looked to be a more traumatic injury, on March 26, 2015, the U.S. FDA allowed InVivo to open enrollment for patients three, four, and five, suggesting that the 30-day safety assessment on Jesi was clean and that, similar to Jordan, there were no reported serious adverse events associated with the NSS.

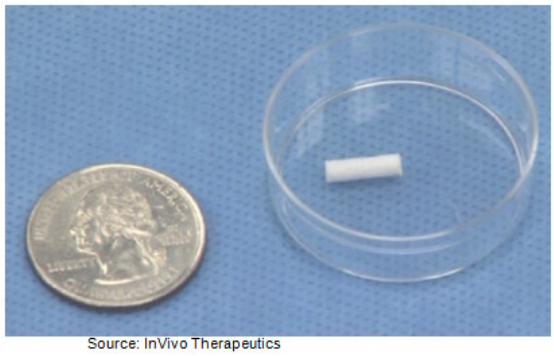
Ms. Stracham has yet to have her 90 day assessment. This will take place late April 2015, with InVivo Therapeutics likely releasing the data shortly thereafter. However, we have seen several updates directly from Jesi over the roughly 60 days post-surgery, the most impressive coming via a YouTube video released on March 23, 2015 showing the 22 year old move her leg without assistance. Wow!

We remind investors that the American Spinal Injury Association Impairment Scale (AIS) is a multi-dimensional approach to categorize motor and sensory impairment in individuals with spinal cord injury. It identifies sensory and motor levels indicative of the most rostral spinal levels demonstrating "unimpaired" function. It's a 5 point ordinal scale, currently on its 6th edition, and classifies individuals from "A" (complete) to "E" (normal sensory and motor function). Patients classified as "AIS A" have no sensory or motor function below the level of injury. This was both Jordan Fallis and Jesi Stracham at time of admittance to the hospital. At 90 days, Jordan has progressed to AIS C. He has regained some motor function below the injury and has voluntary anal sphincter contraction. We suspect in time, as muscle strength returns with physical therapy, Jordan will progress to AIS-D. Based on the YouTube video linked above, Jesi's injury looks to have "healed" to incomplete, likely AIS C or AIS D.

This is truly astonishing and an enormous improvement in such a short timeframe. To put things into perspective, a 1999 analysis by Mario et al found that 10 to 15% of those with initial complete AIS A injuries converted to incomplete injuries at 12 month follow-up. Only 2% will regain strength below the injury level. Based on initial data from both Jordan and Jesi, InVivo is now "2 for 2" in terms of returning both sensory and motor function to two patients previously classified as AIS A at less than 90 days post injury. The probability that InVivo "got unlucky" with both patients having spontaneous recovery is less than 1%.

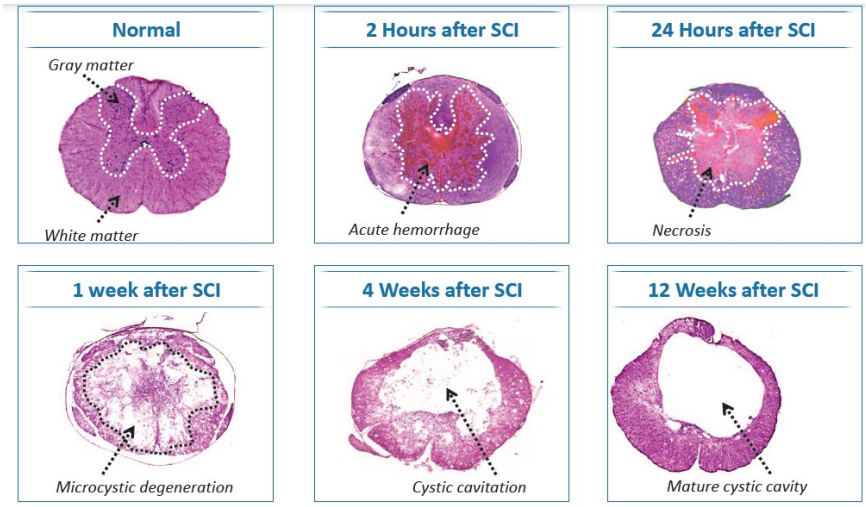
...What We Think Is Going On…

Investors familiar with the InVivo story are aware that the NSS is a porous bioresorbable polymer scaffold comprised of poly ((lactic-co-glycolic acid)-co-poly-(L-lysine)), or PLGA-PLL. The device provides structural support to injured spinal tissue, as well as a supportive matrix for allowing the endogenous healing/repair processes to proceed without risk of bleeding and inflammation creating scar tissue around the injury that might inhibit spinal transmission along the cord. InVivo management believes its device preserves healthy spinal tissue, increasing the chance for functional recovery. NSS is InVivo's proprietary technology and was co-invented by Robert S. Langer, ScD, the David H. Koch Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. The patent rights that are the basis for InVivo's products are under an exclusive, worldwide license from Children's Medical Center Corporation and Massachusetts Institute of Technology.



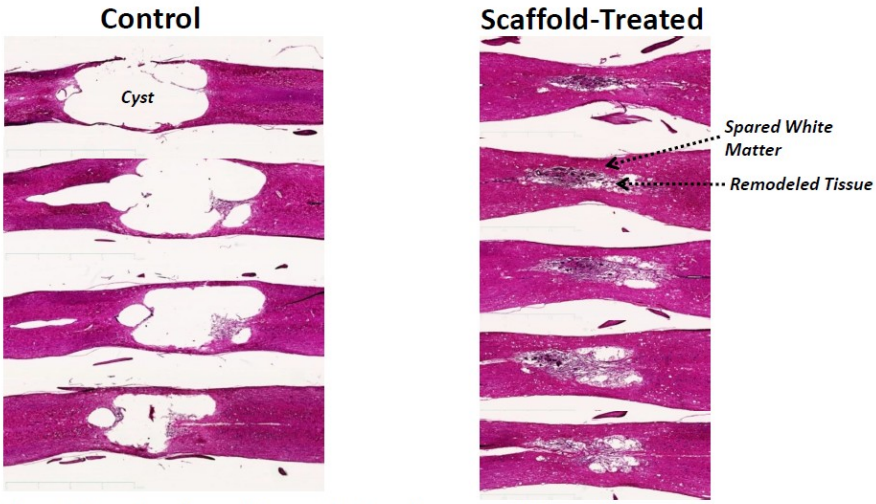
Source: InVivo Therapeutics

The NSS is designed to facilitate the improvement of: 1) Motor control, including the recovery of muscle control, movement, and strength; 2) Sensory function, including reducing neuropathic pain and avoid bed sores, and 3) Autonomic control, including recovery of bowel/bladder control and sexual function. However, there may be secondary benefits not yet fully explored. These include the elimination of cysts, white matter sparing, and pressure reduction. For example, InVivo preclinical data from a rat contusion model shows significant cyst formation inside the spinal cord following an acute hemorrhage representative of a traumatic injury (see below).



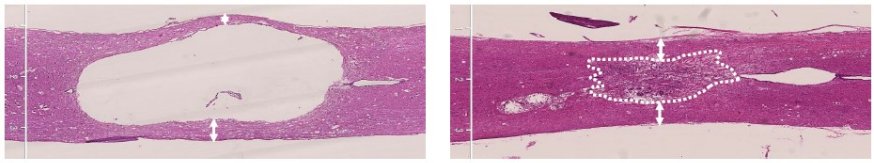
InVivo Therapeutics, unpublished.

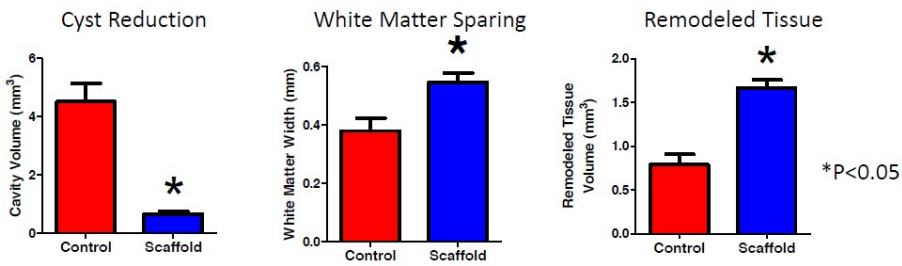
Implantation of InVivo's NSS is designed to prevent cyst formation by providing existing healthy spinal tissue a scaffolding/life preserver. Remodeled tissue forms around the scaffold and then fills the cavity as the device degrades. Preclinical data shows significant spared white matter (see below).



Serial spinal cord sections at 3 months from 1 representative rat per group

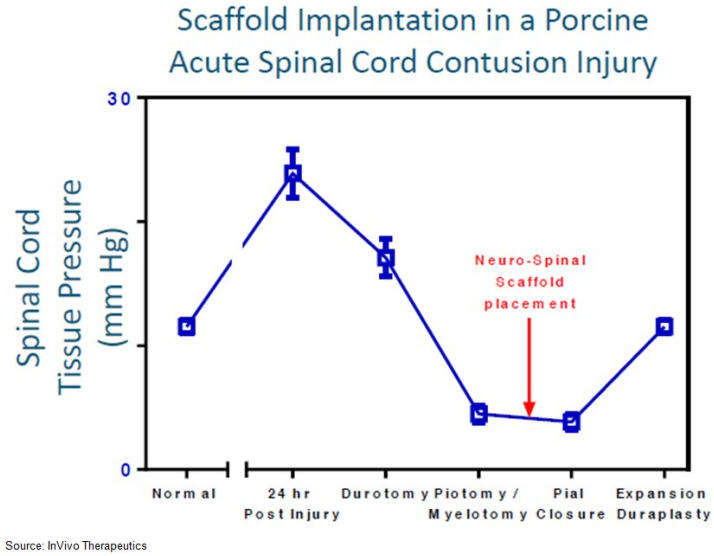
InVivo Therapeutics. *Unpublished.*





InVivo Therapeutics

Beyond the reduction in cyst formation and ability to spare healthy white matter, the implantation procedure of the NSS allows for significant pressure reduction. Following a traumatic injury, increased spinal cord tissue pressure leads to secondary damage including ischemia. Decreasing spinal cord tissue pressure may enhance spinal cord blood flow (Werndle et al, 2014), which leads to tissue oxygenation. It is believed that this leads to neurological recovery. For instance, we had a chance to see a video the implantation of NSS in a porcine acute spinal cord contusion injury model earlier in the month when we sat down for a face-to-face meeting with InVivo management. The pressure reduction inside the spinal cord, as evidenced by substantial leakage of damaged cerebrospinal fluid during the implantation procedure, was profound. InVivo preclinical data shows a significant rise in spinal cord pressure following an acute injury and the reduction of pressure following myelotomy.



Source: InVivo Therapeutics

…What's Next For InVivo…

InVivo will continue to follow both Jordan and Jesi for the rest of their life. The next updates to investors should come in mid-April for Jordan with his six month assessment and in late April with Jesi for her 90 day assessment. The trial is also now open to patients three, four, and five, so investors can expect a very busy summer for the company in terms of providing safety and efficacy assessments on all five patients. We expect the pilot study to wrap up by the end of the year, with 12-month safety assessments of all five patients likely to be completed by the middle of 2016.

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. We remind investors, there are no longer profit restrictions under HUD, only restrictions on the number of devices InVivo can sell per year – which is capped at 4,000 under the existing protocol.

…Reasons To Be Bullish…

We believe the NSS- is a potential $750 million product in acute spinal cord injury. Based on initial signs of efficacy from Jordan and Jesi, we believe if the NSS works. We also believe that neurosurgeons will use the device in almost all non-penetrating spinal cord injuries, regardless of things like AIS-A impairment level and injury location, post HDE approval. In three months, Jordan Fallis went from complete AIS-A with no motor or sensory function below the belly-button to incomplete AIS-C and the ability to control his bowels/bladder. In two months, Jesi went from completely paralyzed to being able to move her leg. We suspect that with additional physical therapy and time, both Jordan and Jesi will progress to AIS-D by this six or twelve month. That's incredible!

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 $150,000 is fair (and actually quite conservative) for our financial modeling.

Financial Position

On March 11, 2015, InVivo Therapeutics reported financial results for the full year ended December 31, 2014. The company did not report revenues during 2014. This was in-line with expectations. Net loss totaled $18.3 million, driven by $10.33 million in R&D and $7.6 million in G&A expense. Net loss included some non-cash items, including re-valuation of warrant liability; so on actual cash basis the company burned $15.3 million. Operating burn for the previous four quarters has been fairly consistent. InVivo exited 2014 with $13.9 million in cash on the books.

In January 2015, the company completed a registered direct offering with two dedicated health care funds, issuing 8.0 million shares at $1.50 per share to net proceeds of $11.1 million. We now believe cash as of March 31, 2015 will be in the area of approximately $21.0 million. We suspect that InVivo will see new cash inflows over the next several quarters as investors exercise currently in-the-money warrants. There are approximately 9.8 million warrants currently in-the-money, 8.5 million exercisable at around $1.40 per share and 1.3 million at $1.00 per share. Exercise of all outstanding warrants currently in-the-money could generate $13.3 million in new cash to the company with no "new" dilution. Nevertheless, thanks to the January 2015 offering, we now believe that InVivo has enough cash to fund operations for the next 18 months.

…Seeking NASDAQ Uplisting…

On March 24, 2015, InVivo announced the company's Board of Directors has approved a 1-for-4 reverse stock split of its issued and outstanding common stock in preparation for the company's planned uplisting to the NASDAQ Capital Market. The company anticipates the reverse stock split to become effective and its common stock to begin trading on a post-split basis at the open of trading on April 8, 2015, contingent upon approval from the Financial Industry Regulatory Authority (FINRA). InVivo's CEO and Chairman of the Board, Mark Perrin, provided investors with his perspective on why the company is undertaking the reverse split and seeking an uplist to the NASDAQ. We agree with the strategy, as being listed on the NASDAQ will provide for significant institutional investor traction, and taking the stock above $10 per share will open up larger healthcare funds that tend to shy away from stocks below $5 per share, as well as minimize volatility and encourage more long-term fundamental investors.

Conclusion

InVivo's basic market capitalization is $294 million. We think peak sales of the NSS device alone under HUD is $750 million. The market more than triples in size under a PMA to $2.5 billion. If the company can strike an alliance with a stem cell supplier and figure out how to seed the NSS with neural-spinal stem cells, then the market opens up from approximately 12,000 acute patients per year to some 300,000 chronic patients. That's a 25-fold increase!

Odds of success at this stage, even under HUD, are still low, perhaps 25%. That being said, the company looks to have gone "2 for 2" with respect to improving function for the first two patients in the pilot study. Odd under the PMA are even lower, perhaps 10%, but so far the data looks outstanding.

We think NSS is likely three years from the market and around six years from peak sales under HUD and 10 years under the PMA. We have built a detailed financial model forecasting sales of NSS under both HUD and a full PMA clearance. Using a 15% discount rate InVivo should be trading at $6 per share. Accordingly, we recommend the stock for long-term investors. We anticipate raising our odds of success if patients No. 3, 4, and 5 shows similar impressive gains to the ones made by the first two patients.

PROJECTED FINANCIALS

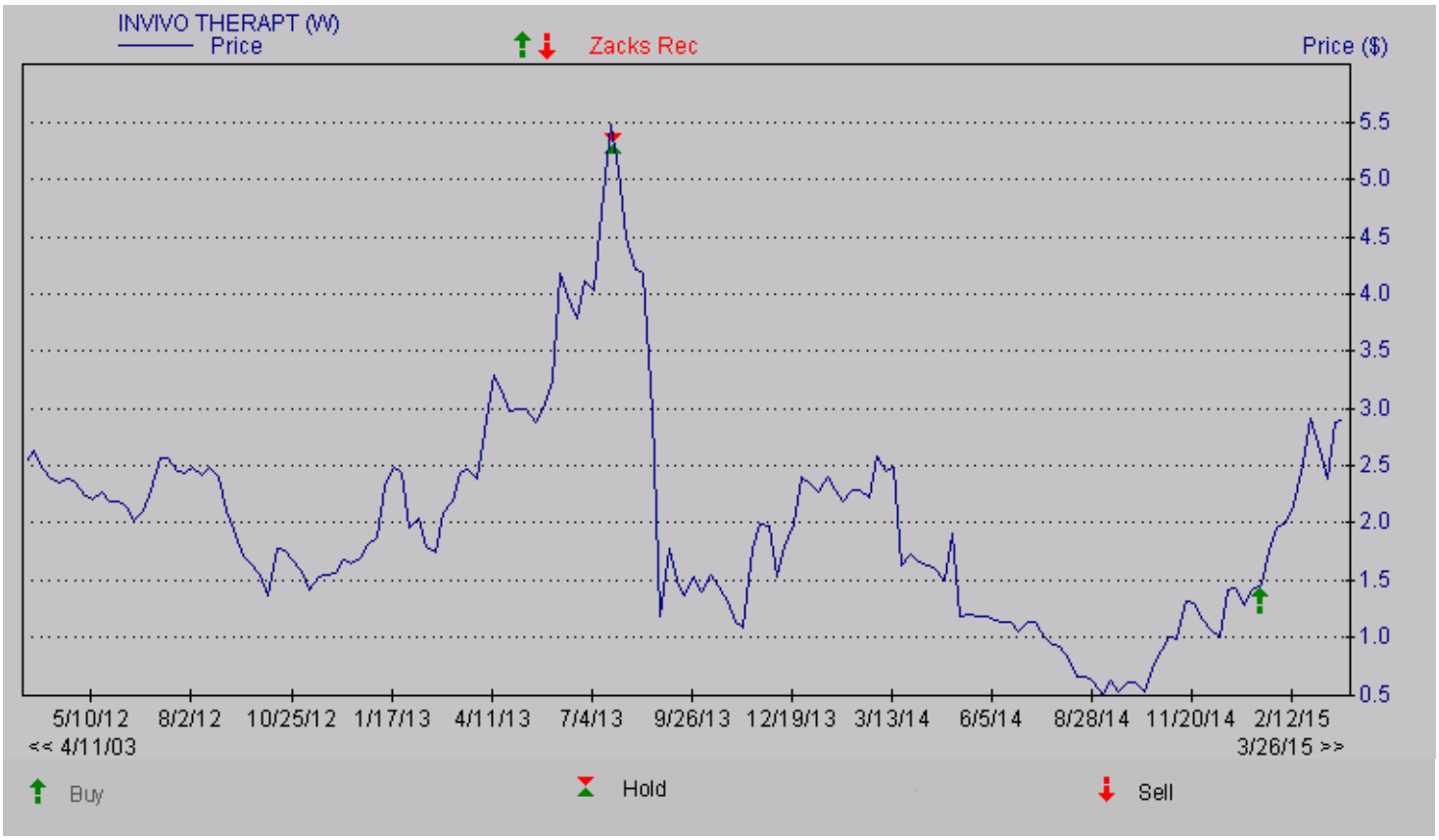
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2013 A	2014 A	Q4 A	Q4 A	Q4 A	Q4 A	2015 E	2016 E	2017 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-					-	-	-
R&D	$10.5	$10.3	$2.0	$2.2	$2.2	$2.5	$8.9	$12.0	$15.0
SG&A	$8.5	$7.6	$1.9	$2.0	$2.0	$2.2	$8.1	$9.0	$10.0
Operating Income	($19.0)	($17.8)	($3.9)	($4.2)	($4.2)	($4.7)	($17.0)	($21.0)	($25.0)
Operating Margin	-	-					-	-	-
Net Other Income	($19.8)	($0.5)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($38.8)	($18.3)	($3.9)	($4.2)	($4.2)	($4.7)	($17.0)	($21.0)	($25.0)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*0.0%*
Net Income	($38.8)	($18.3)	($3.9)	($4.2)	($4.2)	($4.7)	($17.0)	($21.0)	($25.0)
Net Margin	-	-					-	-	-
Reported EPS	**($0.52)**	**($0.21)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.05)**	**($0.17)**	**($0.19)**	**($0.21)**
YOY Growth	-	-					-	-	-
Wt. Ave Shares Outstanding	74.0	88.3	100.0	102.5	103.0	104.0	102.4	110.0	120.0

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

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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 is as follows: Buy/Outperform- 17.2%, Hold/Neutral- 76.6%, Sell/Underperform – 5.5%. Data is as of midnight on the business day immediately prior to this publication.