Zacks Small-Cap Research

November 6, 2015
Nisha Hirani, MD
312-265-9442 / nhirani@zacks.com
David Bautz, PhD
312-265-9471 / dbautz@zacks.com

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

InVivo Therapeutics (NVIV-NASDAQ)

NVIV: Enrolls Patients 4 & 5; FDA Approves Pilot Expansion to 10 Patients…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	01/15/2015
Current Price (11/06/15)	$7.72
Target Price	**$24.00**

UPDATE

On November 4, 2015, InVivo Therapeutics (NVIV) announced financial results for the third quarter of 2015. The company reported a net loss of $2.3 million, or $0.09 per share. Cash burn for the quarter was $3.8 million, and the company exited the quarter with $22.1 million in cash and cash equivalents.

InVivo enrolled the last two patients of the planned five-patient pilot study and recently announced that the FDA approved expansion of the study to permit enrollment of ten patients. The company also announced plans to transition the pilot study into a pivotal probable benefit study and use this single study as the basis for a Humanitarian Device Exemption (HDE) application. We should be hearing more regarding the finalized pivotal probable benefit study design and associated timelines before the end of the year.

In our opinion, InVivo remains on track, and at the current price, we view InVivo shares as meaningfully undervalued, and as providing significant long-term upside potential. We are maintaining our price target of $24 per share, and continue to rate the stock a 'Buy'.

SUMMARY DATA

52-Week High	**$17.78**
52-Week Low	**$3.86**
One-Year Return (%)	**99.26**
Beta	**1.16**
Average Daily Volume (sh)	**253,498**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$217**
Short Interest Ratio (days)	**11.30**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**2**
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 A	0 A	0 A	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	-$0.28 A	-$0.17 A	-$0.05 A	-$1.49 A	-$0.83 A
2015	-$0.64 A	-$0.39 A	-$0.09 A	-$0.22 E	-$0.87 E
2016					-$0.90 E
2017					-$0.91 E

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WHAT'S NEW

Financial Update

On November 4, 2015, InVivo Therapeutics reported financial results for the third quarter of 2015 that ended September 30, 2015. As expected, the company did not report any revenues. Net loss totaled $2.3 million and consisted of $2.4 million in R&D and $3.4 million in G&A expense, which were generally in-line with our expectations. Included in the net loss was a non-cash gain of $3.6 million from a re-valuation of warrant liability.

The company burned $3.8 million during the quarter but also received $0.925 million from the exercise of warrants issued from the company's May 2014 public offering. Operating burn for the previous four quarters was $4.2, $2.9, $4.2, and $3.2 million, thus it has been fairly consistent over the past year. InVivo exited the quarter with $22.1 million in cash on the books. We believe the current cash should fund activities for the next twelve months.

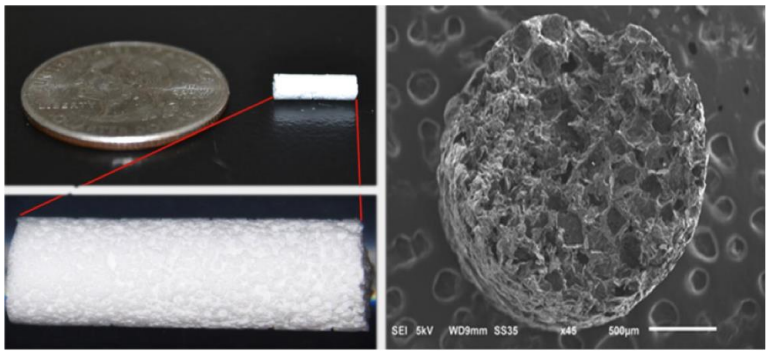
Investigational Pilot Study of Neuro-Spinal Scaffold Update

InVivo is currently conducting an early feasibility pilot study of the Neuro-Spinal Scaffold (NSS) under an approved Investigational Device Exemption (IDE) application for the treatment of complete traumatic acute spinal cord injury (SCI). This FDA approved study is intended to capture data on the safety and feasibility of using the NSS along with gathering preliminary evidence of clinical effectiveness. The pilot study was initially approved to enroll five patients, but InVivo recently announced that the FDA approved expansion of the study to permit enrollment to ten patients. Thus far, there are fourteen clinical sites open and five patients have been enrolled in the study and implanted with the NSS.

InVivo plans to transition the pilot study into a pivotal probable benefit study and to use this single study as the basis for a Humanitarian Device Exemption (HDE) application, which would dramatically reduce clinical trial timelines and time to potential approval and commercialization. InVivo is currently in discussions with the FDA, if the study design is approved, the company expects that the pivotal study will begin in 2016, with an estimated completion date in 2017. If all goes well, we believe this supports obtaining FDA approval to commence commercialization under a HDE.

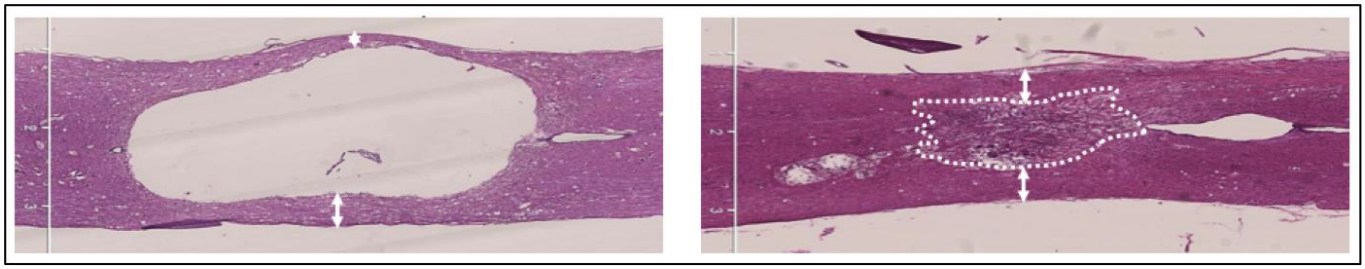
Brief Background on the NSS

The NSS is a porous, biodegradable polymer scaffold comprised of poly(lactic-co-glycolic acid), or PLGA, and poly-L-lysine, or PLL. PLGA is utilized in a number of FDA approved therapeutic devices based on the fact it is both physically strong and biodegradable (Makadia *et al*., 2011). For purposes of the NSS, PLGA serves as a scaffold upon which cellular growth can occur. PLL is utilized for the positive charge it confers to the device, which promotes electrostatic interactions between negatively charged ions of the cell membrane and the positively charged NSS leading to enhanced cellular adhesion. In addition, the device provides structural support to injured spinal tissue, thus allowing the healing/repair processes to proceed without risk of bleeding and inflammation that could lead to the creation of scar tissue around the injury and inhibition of signal transmission along the spinal cord. InVivo management believes its device preserves healthy spinal tissue, increasing the chance for functional recovery. The following picture shows the size of the NSS in relation to a quarter, along with what the device looks like under magnification.



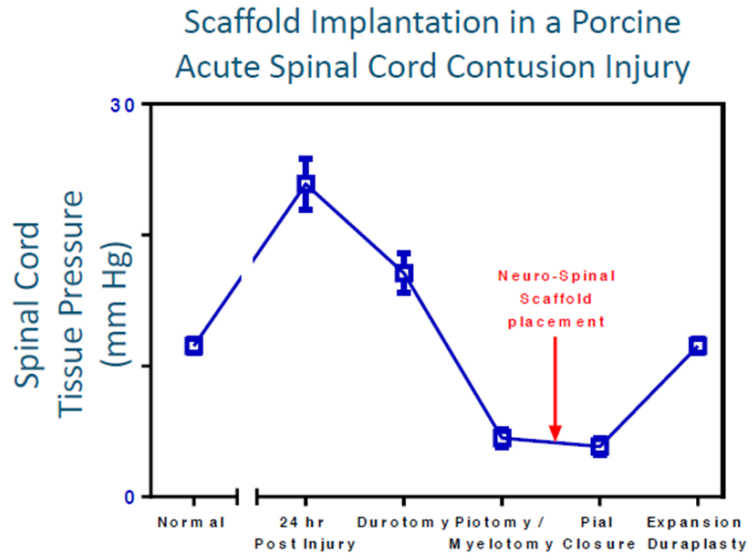
Source: InVivo Therapeutics

A number of preclinical studies have been performed that show the ability of the NSS to aid in remodeling tissue around a spinal cord injury. The following figure shows what occurs to the spinal cord in a rat contusion model both with and without the implantation of the NSS. On the left is the spinal cord from a control rat showing the development of a cyst, leaving a "hole" inside the spinal cord. On the right is the spinal cord from a rat implanted with the NSS showing remodeled tissue and evidence of decreased cyst formation.



Source: Layer *et al.*, 2015

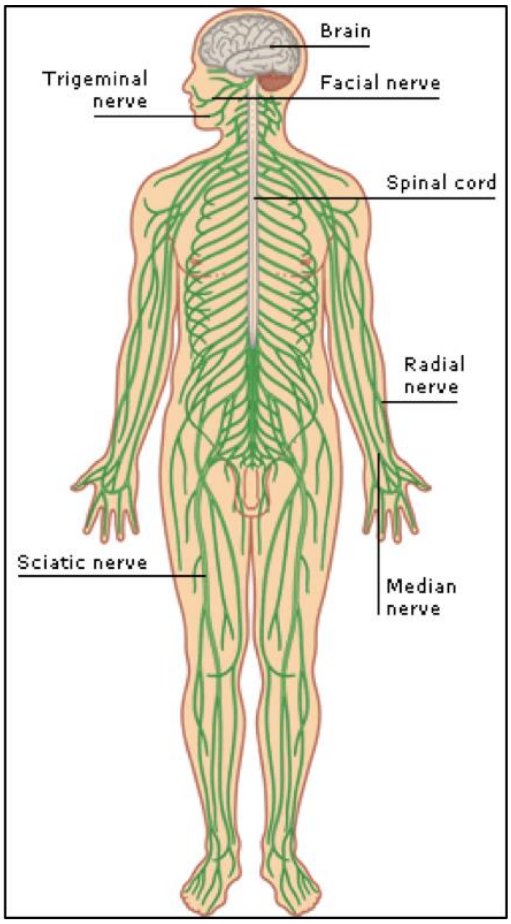
Another aspect of the NSS has to do with the implantation procedure itself. Following a traumatic injury, increased spinal cord tissue pressure leads to secondary damage including ischemia (Leonard *et al.*, 2015). Decreasing spinal cord tissue pressure may enhance spinal cord blood flow and increase tissue oxygenation (Werndle *et al.*, 2014). Preclinical data from a porcine acute spinal cord injury model shows that there is a significant rise in spinal cord pressure following an acute injury and that the pressure is reduced following a myelotomy and implantation of the NSS.



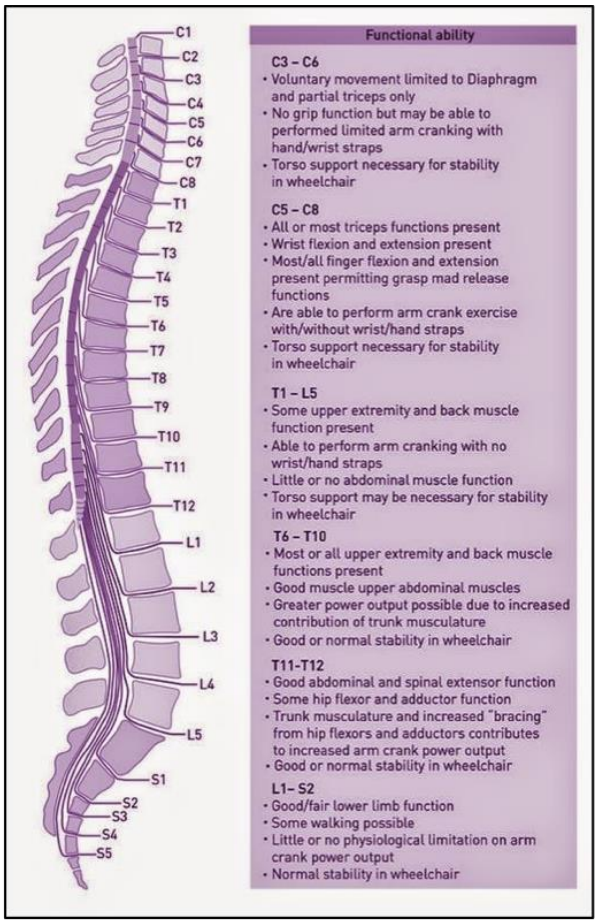
Source: InVivo Therapeutics

Brief Background on Spinal Cord Anatomy

In order to understand spinal cord injuries in humans, it is important to understand how the spinal cord functions with the peripheral nerves in the body. The site of a spinal cord injury is not geographically associated with physiological control because there are sensory root ganglion that branch off from the central canal containing peripheral nerve cells that travel down the body to the pelvis, hips, legs, and feet. There are peripheral nerves that travel down the legs and attach to the central cord at regions all along the spine. The following figures depict the peripheral nerves and the different groups of vertebrae that control various regions of the body. For example, an injury at the C8 level just below the base of the neck will cause a loss of sensory and motor control to the chest, abdomen, pelvis, legs, and feet. However, the patient may still be able to move their fingers because this is controlled by peripheral nerves and dorsal root ganglia that attach at the C7 region of the spine. Injuries below the C8 level will likely leave arm and hand function unharmed. An injury at the L3 vertebra, located just below the belly button, will likely still allow a patient to roll their hips and contract their quadriceps muscles, as these are controlled by nerves that connect at the L1 and L2 region.



Source: aviva.co.uk



Source: Michael Feger Paralysis Foundation

Assessment of Spinal Cord Injuries

The American Spinal Injury Association (ASIA) impairment scale (AIS) describes a person's functional impairment as a result of their spinal cord injury. It is based on neurological responses, touch and pinprick sensations tested in each dermatome (area of the skin), and strength of the muscles that control ten key motions on both sides of the body, including hip flexion (L2), shoulder shrug (C4), elbow flexion (C5), wrist extension (C6), and elbow extension (C7). Traumatic spinal cord injury is classified into five categories on the ASIA Impairment Scale:

A = Complete. No sensory or motor function is preserved in the sacral segments S4-S5.

B = Sensory Incomplete. Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5 (light touch, pin prick at S4-S5: or deep anal pressure (DAP)), AND no motor function is preserved more than three levels below the motor level on either side of the body.

C = Motor Incomplete. Motor function is preserved below the neurological level, and more than half of key muscle functions below the single neurological level of injury (NLI) have a muscle grade less than 3 (Grades 0-2).

D = Motor Incomplete. Motor function is preserved below the neurological level, and at least half (half or more) of key muscle functions below the NLI have a muscle grade > 3.

E = Normal. If sensation and motor function are graded as normal in all segments, assuming the patient had prior deficits, then the AIS grade is E.

Its important to remember that someone without an initial SCI does not receive an AIS grade, so while AIS-E is considered "normal" sensory and motor control, this does not mean no injury is present. Also, for an individual to receive a grade of C or D, i.e. motor incomplete status, they must have either (1) voluntary anal sphincter contraction or (2) sacral sensory sparing with sparing of motor function more than three levels below the motor level for that side of the body. The standards at this time allows even non-key muscle function more than 3 levels below

the motor level to be used in determining motor incomplete status (AIS-B vs. -C). When assessing the extent of motor sparing below the level for distinguishing between AIS-B and -C, the motor level on each side is used; whereas to differentiate between AIS-C and -D (based on proportion of key muscle functions with strength grade 3 or greater) the single neurological level is used.

The key takeaway from the ASIA Impairment Scale is the heavy focus on the sacral region S4-S5 in moving from AIS-A to AIS-B. As noted above, any injured subject with no sensory or motor function in the sacral segment S4-S5, which includes the sphincter muscle and region around and inside the anus, is classified as AIS-A. To move from AIS-A to AIS-B, the subject must demonstrate, at a minimum, sensory function of the S4-S5 region as assessed by light touch, pin prick, or deep anal pressure. The key gating factor in moving from AIS-B to AIS-C is motor control.

Patient Updates

Thus far, five patients have been enrolled in the pilot study for the NSS. We provide an update on each of the patients below.

Patient #1 (Jordan):

The first patient to enroll in the NSS study was involved in a dirt bike accident on October 13, 2014. The injury was classified as AIS-A and graded as complete (total paralysis) at T11 and below. On October 16, 2014, InVivo announced the NSS was successfully implanted in the patient (the surgery took place approximately 8 hours following the accident).

On January 21, 2015 InVivo announced a positive safety update at three months post-injury. At that time the injury was graded as "incomplete" and Jordan was reclassified to AIS-C from AIS-A, with motor, sensory, bowel, and bladder functional improvements compared to baseline.

On May 14, 2015 InVivo announced that between the three-month and six-month post-injury assessment Jordan had regained partial function of knee extensors and remained classified as AIS-C with a motor incomplete spinal cord injury.

On October 23, 2015, InVivo announced that between the six-month and twelve-month post-injury assessment, Jordan continued to demonstrate motor improvement with an additional 8 points gained on the AISA impairment scale. He demonstrated further bilateral improvements in the motor function of hip flexors and knee extensors, and also demonstrated first time bilateral contractions of the ankle dorsiflexors and ankle plantar flexors. Jordan remains classified as AIS-C. As per the company, a large natural history database shows that patients with similar T10-T12 level injuries have an average increase of lower extremity motor scores between 6 and 12 months of fewer than 2 points.

Patient #2 (Jesi):

The second patient to enroll in the NSS was struck by a car while riding on the back of a motorcycle on January 18, 2015. Her injury was classified as AIS-A impairment and graded as complete at T6 with total paralysis at T8 and below. On January 22, 2015, InVivo announced that the NSS was successfully implanted, however due to the severity of the patient's injuries the doctors had to wait two days after her accident to perform the surgery.

On March 26, 2015, InVivo announced re-opening of enrollment in the pilot study, signifying success with respect to the safety endpoint at 30-days post-surgery for Jesi.

On May 14, 2015, InVivo announced a positive safety and efficacy update on Jesi at three months post-injury. Despite a return of some sensory and motor function, including appreciable improvement in trunk stability, self-care, mobility, and bowel and bladder function at the three-month post-implant assessment, Jesi remained classified as AIS-A on the impairment scale due to a lack of consistent and profound sensory and motor function at the sacral S4-S5 region.

On July 6, 2015, InVivo announced a six-month post-implant assessment that showed Jesi had marked improvement in sensory function with partial sensation present five dermatome levels lower on the right side compared to the three-month assessment. This translates to regaining partial sensation from the lower ribs to the hip on the right. In addition, Jesi continues to make meaningful progress in activities of daily living.

Patient #3 (Roger):

On June 4, 2015, InVivo announced that the third patient was enrolled in the pilot study. The NSS was implanted three and a half days after the high-level T4 injury occurred at Carolinas Medical Center in Charlotte, NC. Roger, a 55-year-old construction worker, fell out of a deer stand and was left with a damaged spinal cord with no sensation from the middle of his chest down.

On July 6, 2015, InVivo announced that in the time between implantation and the one-month post-injury assessment, the third patient improved from a complete AIS-A spinal cord injury to an incomplete AIS-B spinal cord injury and that the patient regained sacral sensation with improved bladder function. In addition, there were no reported serious adverse events associated with the NSS.

As per the company presentation at the 2015 Stem Cell Meeting on the Mesa and updated InVivo fact sheet, we gather that Roger had regained partial sensation from the mid-chest to mid-abdomen at the three-month assessment.

Patient #4

On August 20, 2015, InVivo announced that the fourth patient was enrolled in the pilot study. The NSS was implanted 53 hours after the T3 injury occurred at the UC Davis Medical Center in Sacramento, CA. No other follow-up data has been reported to date.

Patient #5

On September 8, 2015, InVivo announced that the fifth patient was enrolled in the pilot study. The NSS was implanted 69 hours after the T8 injury occurred at Keck Hospital of University of Southern California (USC) in Los Angeles. No other follow-up data has been reported to date.

Once is a Fluke, Twice is a Coincidence, Three Times is a Trend…

To summarize what has been seen thus far in the pilot study of the NSS:

- Patient #1 has gone from AIS-A to AIS-C in one month, which occurs in fewer than 5% of AIS-A patients with a T10-T12 injury, and has lower limb motor and sensory improvement in addition to regained bowel function and improved bladder function.

- Patient #2 remains AIS-A but has seen improvement in trunk stability, self-care, mobility, bowel and bladder function, and has regained partial sensation from the lower ribs to the hip on the right side of her body.

- Patient #3 went from AIS-A to AIS-B in the first month after his accident, which is observed in fewer than 4% of patients with a T4 injury, and has sensory improvement from mid-chest to mid-abdomen.

- There is no follow-up data reported on Patients #4 and #5 to date.

- Perhaps most importantly of all, since this is first and foremost a safety study, is that there have been no serious adverse events due to the NSS or the surgical procedure.

Looking at the results thus far, it appears as though a trend is developing in regards to the safety and efficacy of the NSS. Even though this is only a safety study, and InVivo still has five more patients to enroll in the pilot study, it's hard not to be impressed with the level of efficacy seen thus far with the first three patients.

The Path Forward

InVivo will continue to follow all of the patients enrolled in the pilot study for the rest of their lives. Jordan has completed his twelve-month assessment and Jesi has completed her six-month assessment. Patient #3 has completed his three-month exam, and Patients #4 and #5 are now enrolled. We believe that the pilot study will continue to enroll patients until it has reached ten as per the recently FDA approved expansion of the study. We should have a better sense of the adjusted timelines for study completion dates by the end of the year.

Following successful completion of the pilot study, InVivo expects to conduct a pivotal probable benefit 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. Some investors have been asking about the potential for InVivo to file for approval after the pilot study through the FDA's Expanded Access (EA) program. We did not think that safety data from five patients would be enough to convince the FDA to allow approval through the EA program and that the company would need to show safety data from more patients, and thus the company recently receiving approval to expand the study to enroll up to ten patients does not surprise us. The probable benefit study is likely to commence in 2016, however we won't have a clear picture of what the endpoints for that study will be until after all data from the pilot study are collected and the company has had a chance to sit down with various KOLs and the FDA to plan the pivotal study. As mentioned above, we should have a better sense of the pivotal probable benefit study design and associated timelines before the end of the year.

The Potential For the NSS is Enormous

We continue to believe the NSS is a potential $750 million product just in acute spinal cord injury. We also believe after HDE approval, neurosurgeons will be able to use the device in almost all non-penetrating spinal cord injuries, regardless of things like AIS-A impairment level and injury location. In three months, Jordan (Patient #1) 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. At twelve months, Jordan continues to gain additional points on the AISA impairment scale with lower limb motor and sensory improvement in addition to regained bowel function and improved bladder function. In two months, Jesi (Patient #2) went from being completely paralyzed to being able to move her leg, and at six months, has regained partial sensation from the lower ribs to the hip on the right side of her body. In one month, Roger (Patient #3) went from complete AIS-A to incomplete AIS-B with regained sacral sensation and improved bladder function, and now at three months, has regained partial sensation from the mid-chest to mid-abdomen. We suspect that with additional physical therapy and time, all three patients will continue to progress in the right direction. We are hoping to see similar results in Patients #4 and #5 as well as in future patients that will be enrolled in the pilot study.

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

Conclusion

Despite there being a stream of news that indicates that InVivo's remains on the right track, the stock continues to languish. In August 2015, InVivo's common stock was transferred from the Nasdaq Capital Market to the Nasdaq Global Market, following an announcement that the company has been added to the Russell Global, Russell 3000®, Russell 2000®, and Russell Microcap indexes. We believe that being listed on the Global Market allows for greater visibility for InVivo, but as of yet has not helped support the share price. Additionally, we believe the broad sell-off in the biotechnology and pharmaceutical sectors has impacted the small cap names even more so than the larger cap companies. We believe the recent pullback presents investors with an interesting long-term buying opportunity.

InVivo's basic market capitalization is approximately $210 million. We think peak sales of the NSS device alone under HUD could reach close to $750 million. The market for the NSS more than triples in size under a Premarket Approval (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, which represents a 25-fold increase.

We are continuing to maintain a probability of approval of 33%, even under HUD. The reason for this is that approval will be contingent upon showing safety and probably benefit in a larger number of patients, and while we think that a trend has certainly been established with the first three patients we would like to see additional safety and recovery data before increasing the probability of approval. That being said, the company looks to have gone "3 for 3" with respect to improving function for the first three patients in the pilot study. We are interested in reviewing patient updates on patients 4 and 5, as well as learning more about the additional patients that will be enrolled as per to the recently announced FDA approved expansion of patient enrollment.

InVivo plans to announce the finalized pivotal probable benefit study design and associated timelines before the end of the year. If the pivotal probable benefit study commences in 2016 and is completed in 2017, InVivo could likely apply for approval under HUD in 2018 and receive approval in 2019. We should have a better sense of the

timeline by year-end. We have built a detailed financial model forecasting sales of NSS under both HUD and a full PMA clearance. Using a 15% discount rate we think the shares are worth $24. Accordingly, we recommend the stock for long-term investors. Once all the safety data has been collected for the pilot study, we anticipate raising our odds of success if there continues to be no serious adverse events and similar impressive gains continue to be seen.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp. - Income Statement

InVivo Therapeutics	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 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	$10.3	$2.3	$2.5	$2.4	$2.6	$9.9	$12.0	$15.0
SG&A	$7.6	$3.2	$3.2	$3.4	$3.3	$13.2	$14.0	$16.0
Operating Income	($17.8)	($5.5)	($5.8)	($5.9)	($5.9)	($23.0)	($26.0)	($31.0)
Operating Margin	-					-	-	-
Net Other Income	($0.5)	($10.3)	($4.7)	$3.6	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($18.3)	($15.8)	($10.4)	($2.3)	($5.9)	($23.0)	($26.0)	($31.0)
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	($18.3)	($15.8)	($10.4)	($2.3)	($5.9)	($23.0)	($26.0)	($31.0)
Net Margin	-					-	-	-
Reported EPS	**($0.83)**	**($0.64)**	**($0.39)**	**($0.09)**	**($0.22)**	**($0.87)**	**($0.90)**	**($0.91)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	22.1	24.9	26.5	27.0	27.4	26.4	29.0	34.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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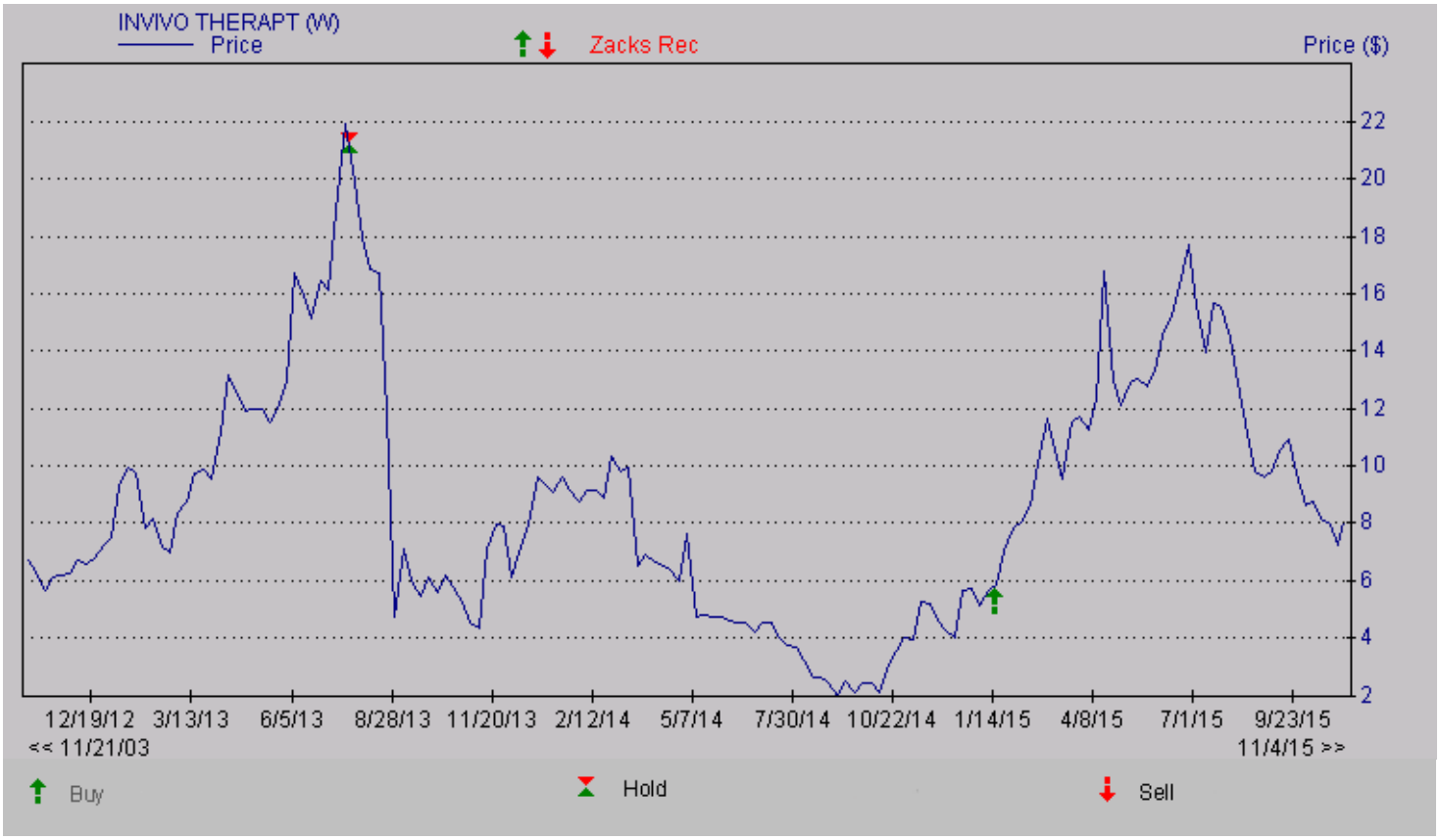
HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution is as follows: Buy/Outperform- 24.8%, Hold/Neutral- 53.9%, Sell/Underperform – 17.5%. Data is as of midnight on the business day immediately prior to this publication.