Zacks Small-Cap Research

January 21, 2015
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InVivo Therapeutics (NVIV-OTCQB)

NVIV: Patient No. 1 Shows 'Unexpected' Improvement…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	01/15/2015
Current Price (01/21/15)	$1.47
Target Price	**$3.25**

UPDATE

On January 21, 2015, InVivo Therapeutics (NVIV) provided an update on the status of the first patient enrolled in the company's ongoing pilot study of its investigational Neuro-Spinal Scaffold (NSS) for the treatment of acute spinal cord injury. The primary safety endpoint will be assessed again at six months, 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.

We are buyers of the stock. Our target is $3.25 per share.

SUMMARY DATA

52-Week High	**$2.60**
52-Week Low	**$0.50**
One-Year Return (%)	**-36.03**
Beta	**1.21**
Average Daily Volume (sh)	**460,100**
Shares Outstanding (mil)	**94**
Market Capitalization ($mil)	**$138**
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 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

InVivo Patient No.1 Shows 'Unexpected' Gains

On January 21, 2015, InVivo Therapeutics (NVIV) provided an update on the status of the first patient enrolled in the company's ongoing pilot study of its investigational Neuro-Spinal Scaffold (NSS) for the treatment of acute spinal cord injury. 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. 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

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. This is where it gets interesting, because the results from the first patient, 25-year old Jordan Fallis, are 'unexpected' according to Dr. Theodore.

…The 90-Day Assessment …

On October 15, 2014, InVivo announced the first patient surgery and implantation of NSS took place. 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, 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!

As a reminder, Jordan was 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." Huge!

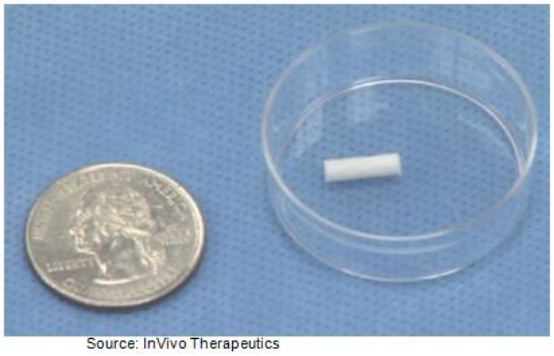
…More Data Needed …

We caution investors into reading too much into the results of one patient. Even Dr. Theodore states, "This is only one patient and we do not want to over-interpret the data." And that's understandable. But we cannot discount the significant improvement in function that Jordan has regained. Again, Jordan was complete AIS-A prior to the surgery. That means he had no sensory or motor function below the injury. Today, neurological assessments categorize Jordan as incomplete AIS-C, which means 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. This is 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 the 3 month data from InVivo's study, they either got really lucky or this thing works!

...What We Think Is Going On…

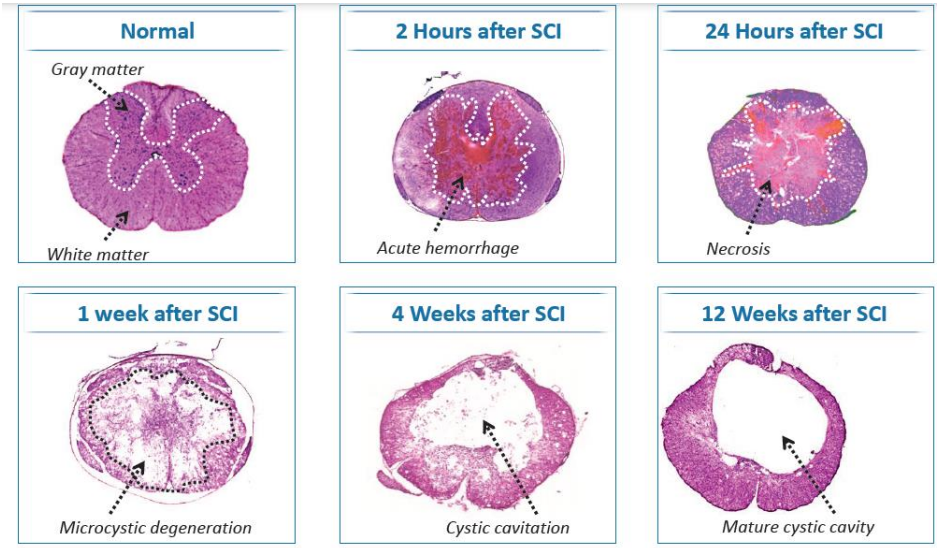
Investors familiar with the InVivo story are aware that the NSS is a porous bioresorbable polymer scaffold comprised of poly ((lactic-co-glycolic acid)-co-poly-(L-lysine)), or PLGA-PLL. The device provides structural support

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.



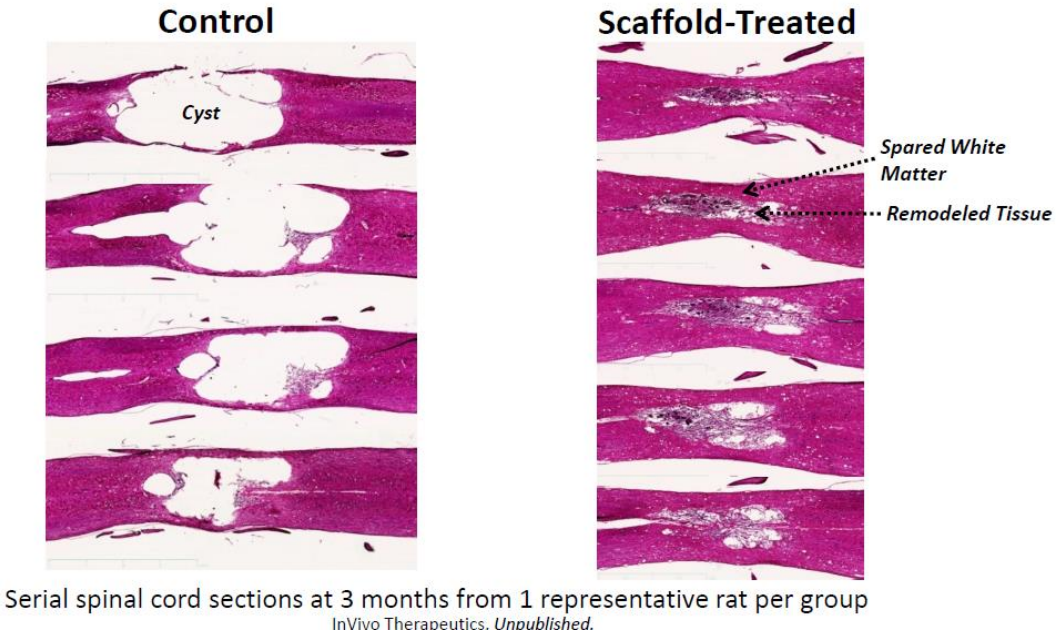
Source: InVivo Therapeutics

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).



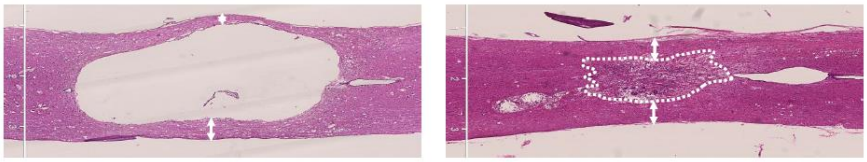
InVivo Therapeutics, unpublished.

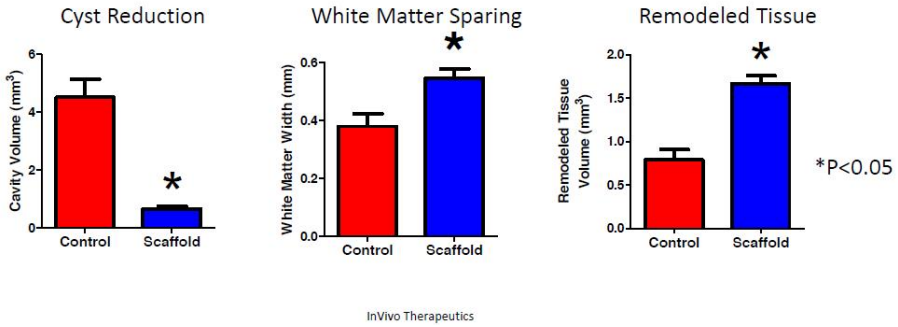
Implantation of InVivo's NSS is designed to prevent cyst formation by providing existing healthy spinal tissue a scaffolding/life preserver. Remodeled tissue forms around the scaffold and then fills the cavity as the device degrades. Preclinical data shows significant spared white matter (see below).



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

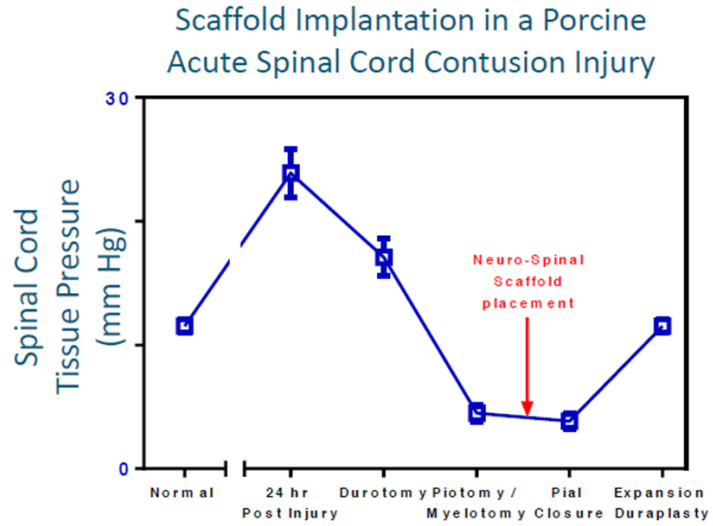
InVivo Therapeutics. *Unpublished.*





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 Jordan for the rest of his life. The next update to investors should come at the six and twelve month marks. However, the pilot study is already seeking patient No. 2 as of early January 2015. We expect patient No. 2 will enroll in the next month. Following a cleared 30-day safety assessment of that patient, the trial will then be opened to enroll patients 3, 4, and 5. As a result of this new accelerated timeline, we are now expecting all five patients to be enrolled in the study by the middle of the year. That means investors will be getting another update on Jordan in three months, and an update on patient No. 2 at the 30-day and 90-day post-surgery time frame. Once patients 3, 4, and 5 enroll, the updates will come almost continuously throughout the second and third quarters. 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…

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 AIS-A impairment level and injury location. 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. We suspect that with additional physical therapy and time, Jordan will progress to AIS-D by this six month or twelve month follow-up. That's incredible!

Under HUD, InVivo can sell up to 4,000 devices per year. That's approximately a third of the total number of acute AIS-A spinal cord injuries on average that occur in the U.S. Upside comes with the approval of NSS under a pre-market approval application, something we suspect that InVivo will do following the HUD pivotal study in 2016.

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. This pegs the peak market under HUD at $600 million, and we think they can get there in only a few years after launch – assuming Jordan was not an outlier and the NSS continues to show similar results in future studies.

Financial Position

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. 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. We see the company's existing funds of $17.6 million as sufficient to support its planned activities through the end of 2015.

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 $25+ million in new cash to the company with no "new" dilution.

Conclusion

I play golf, a lot. InVivo just stood on the first tee and ripped one 300 yards down the center of the fairway. Are they a professional or a 20 handicapper that just got lucky? We will have to wait for the next shot to get a definitive answer, but if we're picking partners based on the drive – I'm with them.

InVivo's basic market capitalization is $169 million. We think peak sales of the NSS, device alone under HUD, is $600 million. The market triples in size under a PMA to $1.8 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 20%. Odd under the PMA are even lower, perhaps 10%. 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. Using a 20% discount rate and a medical device industry average 5x price-to-sales ratio, InVivo should be trading at $3.25 per share. Accordingly, we recommend the stock for long-term investors. We anticipate raising our odds of success if patient No. 2 shows similar impressive gains to the ones made by patient No. 1, Jordan Fallis.

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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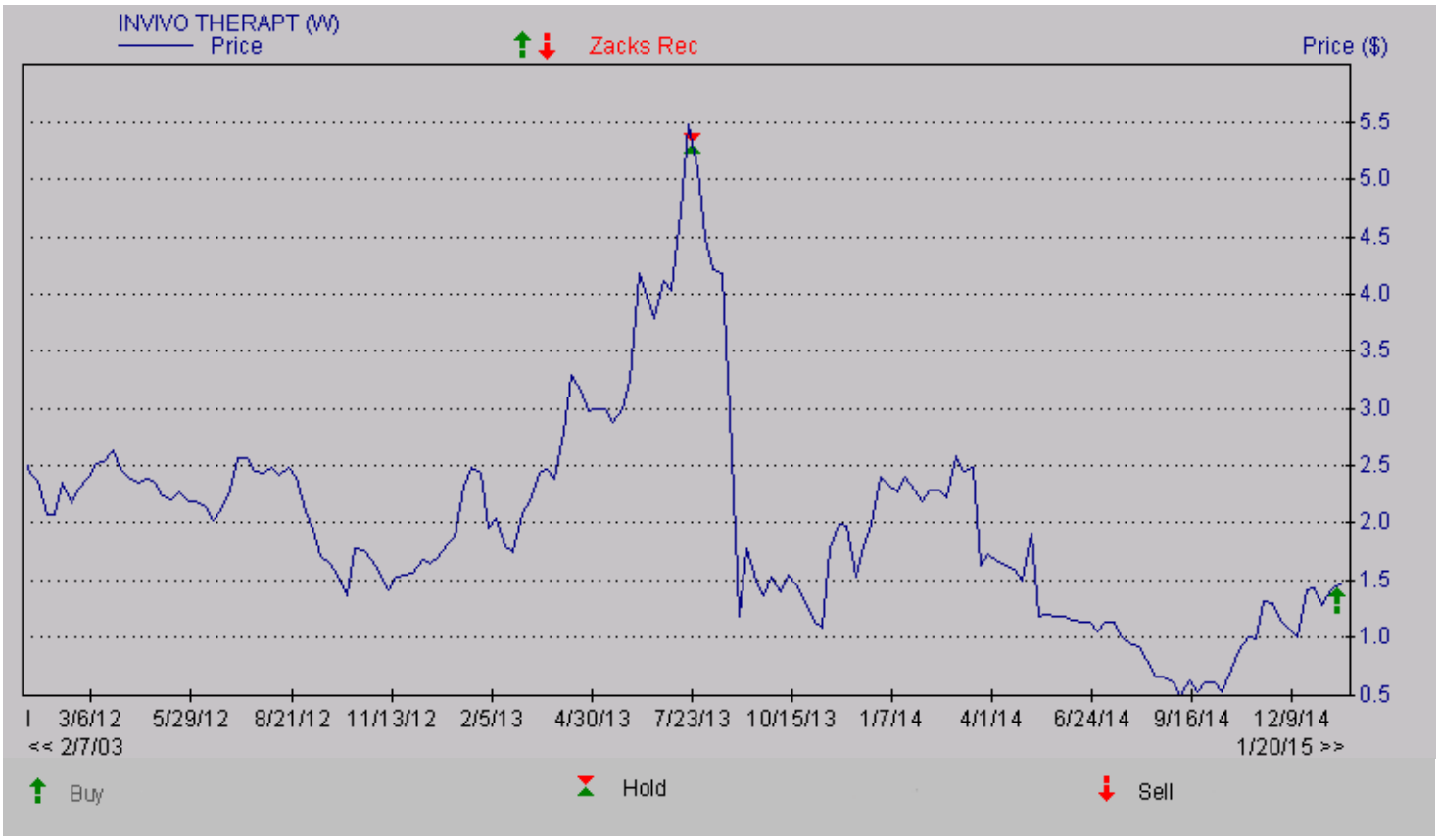

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over 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.