Zacks Small-Cap Research

March 18, 2014
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InVivo Therapeutics (NVIV-OTCQB)

NVIV: Weighing The Pros and Cons Of Investing In InVivo…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	07/23/2013
Current Price (03/18/14)	$2.48
Target Price	**$2.00**

UPDATE

On a fully-diluted basis, the market value is roughly $200 million. We struggle with this valuation given the lack of visibility around the start of the IDE trial with the scaffold and need for cash at some point in the next few months. Manufacturing, liquidity, and intellectual property concerns keep us on the side lines for now. Effectiveness of the new management remains to be seen. That being said, the scaffolding product has clear and meaningful market potential, as does the hydrogel. InVivo is a bit of an enigma, dogged by the ridiculously overly optimistic guidance and promotional efforts of the previous inept management, but buoyed by a potential new treatment paradigm for spinal cord injury and the visions of once paralyzed monkeys dancing in cages.

SUMMARY DATA

52-Week High	**$5.67**
52-Week Low	**$1.10**
One-Year Return (%)	**4.20**
Beta	**1.23**
Average Daily Volume (sh)	**132,016**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$195**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**28**
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 E	0 E	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	-$0.08 E	-$0.08 E	-$0.08 E	-$0.08 E	-$0.32 E
2015					-$0.31 E
2016					-$0.30 E

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WHAT'S NEW

Financial Results & Business Update

On March 17, 2014, InVivo Therapeutics (NVIV) reported financial results for the fourth quarter and full year ended December 31, 2013. The company did not report revenues during the fourth quarter or full year 2013. This was in-line with expectations. Net loss in the fourth quarter totaled $5.7 million, driven by $3.7 million in R&D and $2.0 million in SG&A expense. For the full year, net loss totaled $38.8 million, drive by $10.5 million in R&D, $8.5 million in SG&A, and $18.9 million in non-cash accounting charges associated with the outstanding derivative liability. This liability was removed in June 2013 when the company successfully completed a $16.1 million warrant call.

From a cash burn standpoint, InVivo use $15.7 million in cash from operating and investing activities in 2013, with approximately $4.3 million of that total coming in the fourth quarter. Operating and investing burn over the last three quarters has totaled $4.2, $4.1, and $4.3 million. The company funded operations in 2013 through $16.8 million in financing activities, primarily through the aforementioned $16.1 million warrant call in the second quarter 2014. InViVo exited 2013 with $14.0 million in cash and investments. Based on the current burn rate of approximately $4.2 million per quarter, we see the current balance as enough to fund operations into October 2014.

CON ➔ InVivo is in a precarious financial position. The current cash balance is enough to fund operations to October 2014. This is consistent with language in the Form 10K, but that includes status quo in operating activities. The company is guiding to finally starting its IDE trial with the scaffolding in the second quarter 2014. We believe this will increase operating burn in the second and third quarter. As a result of this increased burn, we believe the current cash balance may not take the company as far as October. We also believe it would be irresponsible of management to initiate the IDE trial without enough funds to complete the program. Therefore, we believe the company must raise cash before this trial starts, which means in the next two months.

There are 3.283 million warrants outstanding, 2.940 million of which are currently in-the-money based on today's price. This equates to $3.58 million in gross proceeds to the company if exercised. Approximately $3.50 million in value of these warrants will expire in December 2015. It will be interesting to see if the company can pull in enough cash over the next two months through warrant exercising to delay the offering until after the IDE trial starts, assuming they feel comfortable they can fully-fund the trial.

With respect to that IDE trial, it seems the delay is a result of manufacturing issues. According to the Form 10K, InVivo has only begun manufacturing the scaffold on a small scale for use in the pilot clinical study. The scaffolding is made of a biodegradable poly-l-glutamic acid/poly-l-lysine (PLGA-PLL) material. If the company is unable to scale up manufacturing to meet requirements for both the pilot and pivotal clinical studies, management may be forced to rely on contract manufacturers. This wouldn't necessarily be a game-over type event, but we remind investors that InVivo just moved into its new 21,000 square foot manufacturing facility in September 2012. The facility, located in Cambridge, MA, houses two ISO 14644-1 Class ISO-7 (Class 10k) and Class ISO-8 (Class 100k) validated cleanrooms. PP&E on the balance sheet as of December 31, 2013 values these assets at $2.337 million. Future minimum rent commitments total roughly $1.2 million each year through 2018, for a total of $6.058 million. Therefore, it would be a significant financial hit if the company had to outsource its manufacturing.

CON ➔ We previously believed the company's new manufacturing facility was a nice core asset and provided opportunity for operating leverage once the scaffolding became approved; however, with lingering manufacturing issues noted in the Form 10K, this nice asset could turn into a significant anchor.

Manufacturing issues notwithstanding, company planning for the IDE trial continues. We remind investors that back in April 2013 the company received two very positive approval letters from the U.S. FDA. The first granted the scaffolding a Humanitarian Use Device (HUD) designation, which is essentially the medical device equivalent of an orphan drug designation. The HUD designation noted potential use of the scaffolding for treatment of recent complete spinal cord injury with no motor or sensory function (i.e. ASIA-A) that does not involve penetrating injury (e.g. a gunshot wound) or complete severing of the spinal cord. This pathway allows for commercialization under a Humanitarian Device Exemption (HDE) rather than a Pre-Market Approval (PMA) pathway, saving InVivo an estimated 2-3 years and tens of millions in clinical trials prior to its first authorized sale. HDE applications are exempt from the effectiveness requirement of PMA, and only need to demonstrate reasonable assurance of safety.

The second FDA letter in April 2013 approved the start of the company's Investigation Device Exemption (IDE) clearing the way to start the first-in-human clinical trial. InVivo's goal is to implant the scaffold and assess feasibility in five subjects with acute thoracic injuries as defined by under the HUD in an open-label design. Enrollment will be conducted under a stage plan, with a three month waiting period between each subject to allow for the monitoring of initial investigational product safety and resorption. Therefore, at a minimum, the trial will take 15-18 months, with a cost of $1.5 to $2.5 million. This brings us back to our first concern, the cash position. InVivo has cash for the next six months.

The company's goal is to conduct the pilot study in as many as six sites across the U.S. All sites will be level one trauma centers. We have previously reported to investors that one site will be the Massachusetts General Hospital (MGS) in Boston or Geisinger Medical Center (GMC) in Philadelphia. One site has already received Institutional Review Board (IRB) approval and a second site is expected to receive approval soon. The primary outcome of the study will be to assess signs of improvement below the level of the spinal cord injury. InVivo will use standardized American Spinal Injury Association (ASIA) scoring to assess efficacy over a year-long period. Following study design consideration discussions with the FDA, if the first pilot study is successful, the company will conduct a second larger pivotal clinical study in acute spinal cord injury patients.

Although this is all pretty standard on the costs and timeline front, it's a far cry from what the previous management had been telling investors. Former CEO, Francis M. Reynolds, who is currently locked in litigation with the company, was telling investors back in 2011 that the company would be generating revenues from the first sale of its scaffolding product in 2014. Former CFO, Sean F. Moran, would tell us every time we called to discuss the status of the trial that it would start, "Very soon." It's incredible how far from reality these comments truly were.

Past guidance aside, we continue to believe the science behind the scaffolding remains exciting and has meaningful commercial potential. We remind investors of the impressive animal data in acute spinal cord injury generated over the past several years. A series of studies in African green monkeys found that implantation of the bioresorbable polymer scaffold device resulted in an increase in remodeled tissue in the region of the hemisection compared to non-implant controls, and improved recovery of locomotion in subjects with full unilateral hemisection lesions. A manuscript describing the results from these studies is in preparation.

PRO ➔ The opportunity in acute spinal cord injury, even has defined under the HUD, is significant. The InVivo animal data looks very good, specifically with respect to the African green monkey data. The rat data does not look as good as the monkey data, which clearly creates risk, but since humans are primates and physiologically more similar to monkeys than rats, we feel pretty good about the development pathway for the scaffolding.

Below we have modeled out sales of the scaffolding product under both the HUD and non-HUD populations. We have built the modeling using only the proposed indication approved under the IDE from April 2013. We start with an estimated 12,000 acute complete ASIA-A spinal cord injuries in the U.S. each year. We have not broken out location of injury even though InVivo will focus solely on thoracic injury for the pilot study. Approximately 46% of patients will admit with an initial assessment as ASIA-A, with 70% of these injuries classified as non-penetrating. Our statistics are pulled from a 2011 report prepared by the National Spinal Cord Injury Statistical Center (NSCISC).

As for price of the device, we have chosen $65,000. 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 $65,000 is fair (and 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. Therefore, within the HUD indication, we think the company can capture 40% market share. Within the non-HUD indication, we think the company can capture 20% market share. Again, we are using aggressive numbers 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 designed to specifically incorporate advancing regenerative medicine technologies.

InVivo Therapeutics	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Americans with NEW SCI	12,000	12,180	12,363	12,548	12,736	12,927	13,121	13,318	13,518	13,721	13,926
Percent with Complete ASIA-A	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*
Percent Non-Penetrating	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
HUD Population	3,864	3,922	3,981	4,041	4,101	4,163	4,225	4,288	4,353	4,418	4,484
Market Share	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*	*15.0%*	*25.0%*	*30.0%*	*40.0%*	*40.0%*
Treated Patients	0	0	0	0	0	208	634	1,072	1,306	1,767	1,794
Price Per Procedure	$0	$0	$0	$0	$0	$65,000	$70,200	$75,114	$80,372	$85,998	$92,018
Sales Under HDE	**$0**	**$0**	**$0**	**$0**	**$0**	**$14**	**$44**	**$81**	**$105**	**$152**	**$165**
Non-HUD Population	8,136	8,258	8,382	8,508	8,635	8,765	8,896	9,030	9,165	9,303	9,442
Percent Non-Penetrating	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*	*70%*
Off-Label Use	5,695	5,781	5,867	5,955	6,045	6,135	6,227	6,321	6,416	6,512	6,610
Market Share (post-PMA)	*0%*	*0%*	*0%*	*0%*	*0%*	*5.0%*	*10.0%*	*15.0%*	*15.0%*	*20.0%*	*20.0%*
Treated Patients	0	0	0	0	0	307	623	948	962	1,302	1,322
Price Per Procedure	$0	$0	$0	$0	$0	$65,000	$68,250	$71,663	$75,246	$79,008	$82,958
Non-HDE Sales (pre/post PMA)	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$43**	**$68**	**$72**	**$103**	**$110**
Biopolymer Scaffold (Device Only)	**$0**	**$0**	**$0**	**$0**	**$0**	**$33**	**$87**	**$148**	**$177**	**$255**	**$275**

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

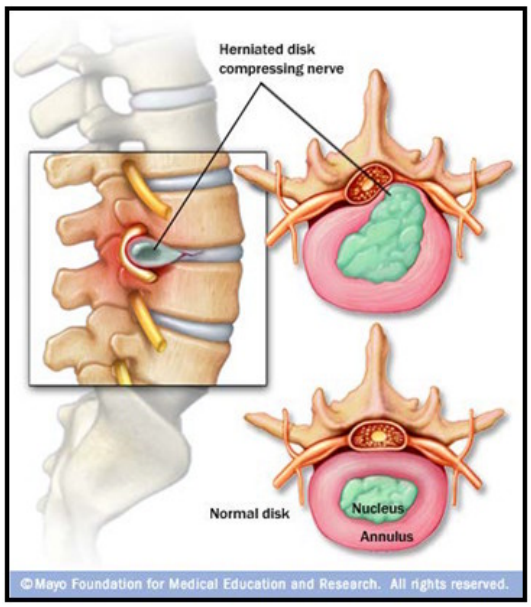
Our modeling pegs U.S. sales of the scaffolding device at $275 million in ten years. Investors may scoff at this forecast, believing that InVivo's device holds blockbuster potential. That might be the case, but not under the HUD population, which is all we can realistically base our forecasts on at this stage in the game. Upside to this forecast could come with expanding the potential indication to include any of the 54% of non-ASIA-A acute injuries, any of the 30% of penetrating injuries, or any of the 300,000 chronic spinal cord injury patients living in the U.S. It's the chronic injury market where the combination of the scaffolding and neural stem cells may have the brightest future for patients and blockbuster sales for InVivo. One final point to mention, our modeling assumes sales in only the U.S., as we have yet to see regulatory filings outside this country.

Of course, modeling sales out ten years from today is a risky endeavor, and assumes that InVivo maintains its intellectual property protection. According to the company's Risk Factors section of its annual Form 10K SEC filing, the company relies on a combination of patents, licenses, trade secrets and non-disclosure agreements to develop, protect and maintain the intellectual property. InVivo holds an exclusive worldwide license to a broad suite of patents co-owned by Massachusetts Institute of Technology (MIT) and Children's Medical Center Corporation (CMCC) covering the use of a wide range of biopolymers to treat spinal cord injury, and to promote the survival and proliferation of human stem cells in the spinal cord.

The CMCC License covers 7 issued U.S. patents and 23 issued international patents expiring between 2014 and 2026, and two pending U.S. patents and 13 pending international patents. The CMCC License has a 15-year term, or as long as the life of the last expiring patent right, whichever is longer. In connection with this agreement, InVivo has submitted to CMCC and MIT a 5-year plan with certain targets and projections that involve the timing of product development and regulatory approvals. The company is required to meet the objectives in the plan, or else notify CMCC and revise the plan. As of December 31, 2013, InVivo is in compliance with this plan. However, if manufacturing delays linger or cash constraints impede clinical progress, CMCC has the right to terminate the agreement.

CON ➔ InVivo does not own the intellectual property around the scaffolding. It has an exclusive agreement, with stipulations from MIT and CMCC. If all goes well, all stays well. However, if CMCC or MIT deems InVivo to be non-compliant with the proposed plan, the company's intellectual property protection around the scaffolding can vanish. If things start to go downhill, they could go downhill very quickly.

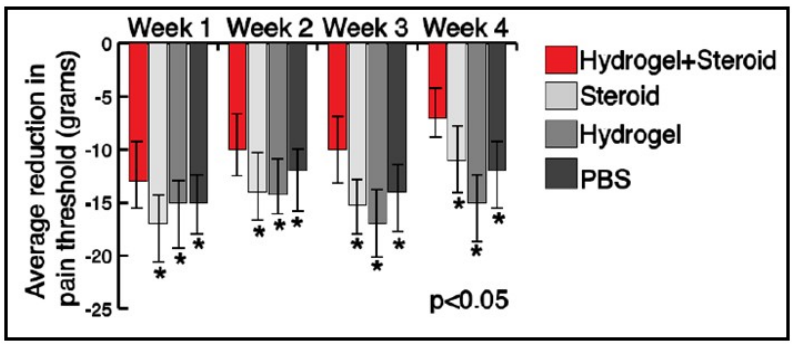
With respect to the hydrogel, the company is current looking for development partners and non-dilutive capital to push forward. According to the Form 10K, the company is looking at potential acquisitions that will maximize the value of this technology in combination with approved and developmental therapeutics. The hydrogel platform encompasses a broad design space with highly tunable chemical and physical properties that allow for precise control of gel formation/degradation and drug release rates. Management is exploring the use of this platform in several clinical indications including neurotrauma, postoperative pain, radicular pain, and oncology. Furthermore, there are several opportunities being explored in the neurotrauma space for which the hydrogel technology could be developed as a device only (e.g. dural sealants, dural grafts, adhesion barriers). For example, the primary application for the hydrogel in neurotrauma might be in treating peripheral nerve pain and in acting as a dural sealant following spinal and cranial surgery requiring the opening of the dura mater.



Disk herniation and radiculopathy are two major causes of peripheral nerve pain. In lumbar radiculopathy, pain or numbness of the buttock and leg is typically caused by compression of the lumbar spinal nerve root (sciatica). Disc herniation, stenosis, osteophyte formation, spondylolithesis, and other degenerative disorders all lead to this type of pain. Existing treatment options include NSAIDs and epidural steroid injections. However, these injections are short-lived and carry risk of side effects. The hydrogel is designed to function as a therapeutic drug delivery depot that provides sustained local release of drugs that provide pain relief, such as glucocorticoid or corticosteroids, for weeks beyond existing depot formulations.

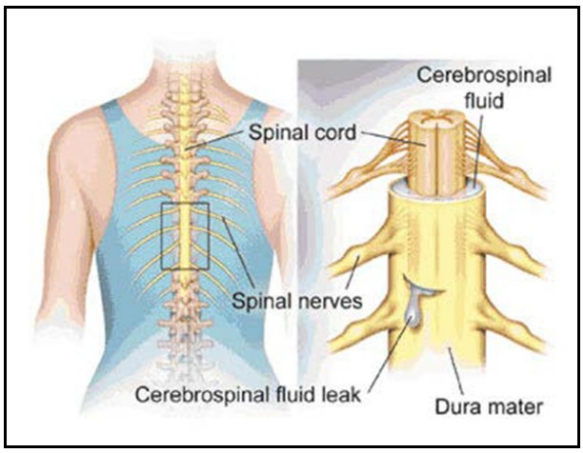
Lots of companies have injectable sustained release pain medications. This is not a revolutionary approach. However, InVivo believes its proprietary poly-ethylene glycol (PEG) formulation Hydrogel has a number of unique advantages over conventional sustained-release depot formulations based on control and residence time, pharmacokinetics and pharmacodynamic properties, and, most importantly, a lack of swelling post injection (more on that below). Treatment for peripheral nerve pain is a pretty sizable market opportunity in the U.S., as 3-4% of the population suffers from chronic lower back pain. InVivo estimates there were nearly 9 million epidural steroid injections in the U.S. in 2010. It's a $300 billion dollar market! Conventional injections last four to six weeks, at best. InVivo's could last 3 months.

PRO ➔ The data here looks very good. InVivo has presented preclinical data conducted by Geisinger in rodent sciatic nerve ligation model. The four week study compared InVivo's hydrogel plus methylprednisolone to the hydrogel alone, methylprednisolone alone, and a control (phosphate buffered saline). Results can be seen in the figure below comparing four groups to baseline "pre-ligation". Results show a clear and statistically significant move back to baseline "no pain" for the combination hydrogel + MPSS product vs. all other components. What's very interesting is that MPSS, the current standard of care, really offers no statistically significant difference from the PBS control. Thus investors can get a sense of the opportunity here for InVivo – the standard of care is pretty terrible but still generates billions in sales. With a clearly superior alternative, InVivo's combination hydrogel + MPSS product could become the new standard of care and generate pretty significant sales.



In use of the Hydrogel as a dural sealant, InVivo would be going squarely up against existing dural sealant products, for example Covidien's DuraSeal. During neurosurgical procedures, preventing the leakage of cerebrospinal fluid (CSF) is essential to reduce potential adverse events such as infection and to ensure positive patient outcomes. To achieve a watertight closure, surgeons can use a product like DuraSeal. The product is approved as an adjunct to suturing – and it's approved as a medical device (not a therapeutic). Covidien describe the product as an innovative synthetic (PEG) absorbable hydrogel sealant that lasts 4 to 8 weeks. CSF leak is a major complication following spinal or cranial surgeries. According to Covidien, there are 1.5 million spinal surgeries performed in the U.S. each year, about 10% of which require a dural sealant. This complicating alone can add $15,000 in additional costs to the healthcare system.

An issue with DuraSeal is potential swelling of the gel post-injection. This is a very tricky situation given the tight location of the spinal cord and potential neurological or physical impact that swelling or added pressure could have on the patient. InVivo believes their proprietary formulation of PEG could offer similar efficacy to DuraSeal but with less risk of complications resulting from swelling. We were unable to peg an exact sales number for DuraSeal at Covidien, but with an estimated 150,000 spinal surgeries with CSF leak per year, we see a pretty meaningful opportunity here.



CON ➔ Unfortunately, the current management thinks that a third party holds intellectual property, including patent rights that may be important or necessary to the development and commercialization of certain hydrogel products. Accordingly, it may be necessary for InVivo to use the patented or proprietary technology of third parties to commercialize its hydrogel products, in which case management would be required to obtain a license from such third parties or acquire such intellectual property rights. Frank never mentioned this in our conversations.

Investors have often asked why we do not model sales of the hydrogel product similarly to how we have mapped out sales of the scaffolding above. There are three reasons: Firstly, we have yet to see any regulatory applications in the U.S. from the company seeking approval to begin clinical studies with the hydrogel. Secondly, the company must secure intellectual property around the hydrogel. Until we see IP secured and applications filed, we believe it is safe to assume the hydrogel remains squarely on the back-burner for InVivo. Lastly, even if the company secures the necessary IP and files an IDE to begin human studies with the hydrogel, with cash to October 2014, InVivo simply does not have the financial capability to push the hydrogel forward without a development partner.

Conclusion

As of March 5, 2014, InVivo's basic share count stood at 78.994 million. There are another 3.661 million vested options and 2.940 million warrants in-the-money. On a fully-diluted basis, the market value is roughly $200 million. We struggle with this valuation given the lack of visibility around the start of the IDE trial with the scaffold and need for cash at some point in the next few months. Manufacturing, liquidity, and intellectual property concerns keep us on the side lines for now. Not to mention, the company has been largely radio-silent over the past six months, having not even updated its investor presentation since the Aegis Capital Healthcare Conference in September 2013. Effectiveness of the new management remains to be seen. That being said, the scaffolding product has clear and meaningful market potential, as does the hydrogel. InVivo is a bit of an enigma, dogged by the ridiculously overly optimistic guidance and promotional efforts of the previous inept management, but buoyed by a potential new treatment paradigm for spinal cord injury and the visions of once paralyzed monkeys dancing in cages.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2013 A	Q4 E	Q4 E	Q4 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	$3.8	$4.0	$4.5	$5.0	$17.3	$20.0	$20.0
SG&A	$8.5	$2.4	$2.2	$2.3	$2.5	$9.4	$11.0	$13.0
Operating Income	($19.0)	($6.2)	($6.2)	($6.8)	($7.5)	($26.7)	($31.0)	($33.0)
Operating Margin	-					-	-	-
Net Other Income	($19.8)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($38.8)	($6.2)	($6.2)	($6.8)	($7.5)	($26.8)	($31.1)	($33.1)
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)	($6.2)	($6.2)	($6.8)	($7.5)	($26.8)	($31.1)	($33.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.52)**	**($0.08)**	**($0.08)**	**($0.08)**	**($0.08)**	**($0.32)**	**($0.31)**	**($0.30)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	74.0	79.0	80.0	90.0	90.0	84.8	100.0	110.0

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

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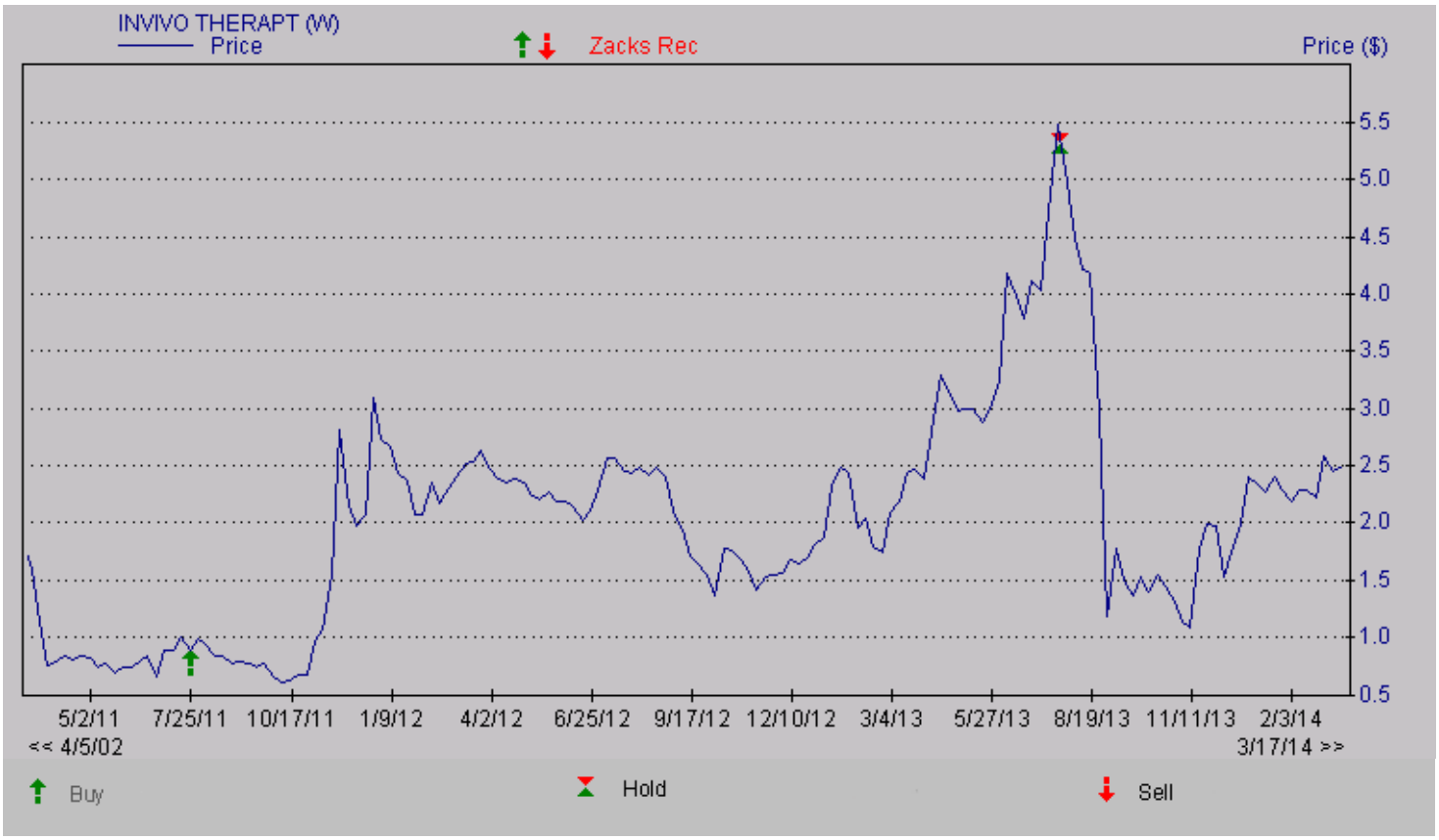
HISTORICAL ZACKS RECOMMENDATIONS



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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- 17.7%, Hold/Neutral- 74.6%, Sell/Underperform – 7.1%. Data is as of midnight on the business day immediately prior to this publication.