Zacks Small-Cap Research

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

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

InVivo Therapeutics, Hdls Corp. (NVIV-OTC)

NVIV: Meeting With Management Confirms Big Plans For 2012…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (01/18/12)	$2.53
Target Price	**$4.50**

UPDATE

We recently sat down with management at InVivo to receive an update on the pipeline and business plans for 2012. We think management has set some aggressive but achievable goals in 2012. The stock continues to look attractive to us.

In July 2011 we initiated coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with spinal cord injury (SCI). Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons. These include speed to market, simplicity of the idea, intellectual property protection, and strong animal model data.

SUMMARY DATA

52-Week High	**$3.10**
52-Week Low	**$0.60**
One-Year Return (%)	**N/A**
Beta	**0.19**
Average Daily Volume (sh)	**352,849**
Shares Outstanding (mil)	**53**
Market Capitalization ($mil)	**$133**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**35**
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 2011 Estimate	**N/A**
P/E using 2012 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)
2010	0 A	0 A	0 A	0 A	0 A
2011	0 A	0 A	0 A	0 E	0 E
2012	0 E	0.1 E	0.2 E	0.2 E	0.5 E
2013					1.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.02 A	-$0.03 A	-$0.03 A	-$0.16 A	-$0.24 A
2011	-$0.02 A	-$0.03 A	$0.06 E	-$0.04 E	-$0.03 E
2012	-$0.04 E	-$0.04 E	-$0.04 E	-$0.04 E	-$0.15 E
2013					-$0.15 E

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WHAT'S NEW

Making Progress Toward The Clinic

…With BSD…

During the third quarter the company took a number of positive steps with respect to bringing its biopolymer scaffold device (BSD) into human clinical trials. InVivo submitted an IDE to the U.S. FDA in July 2011 seeking to commence a human clinical study. InVivo plans to meet with the FDA (CDRH) in April 2012 to finalize the design for the trial. We think talks will center on the inclusion / exclusion criteria. We are expecting this program to be an open-label design, seeking to enroll a total of 10 patients with endpoints in improvement of function one to two levels below the site of injury. We expect the program will enroll 2 patients (Part-A) and offer initial preliminary data in two months after initiation. If positive, the FDA should allow expansion into the next 8 patients (Part-B). The total time of the trial should be around three to four months. We expect that InVivo will spend the next few months working on scale-up manufacturing for the device. We are expecting the trial to start around mid-2012 and cost around $1.5 million.

Strongly positive data should allow management to transition the IDE to a humanitarian device exemption (HDE) pathway and qualify for Orphan designation. The HDE pathways greatly speeds the path to market, whereas the Orphan designation will protect from competing products for seven years post launch. Based on preclinical data from the company's three primate studies, we are optimistic on this IDE program. Previously completed primate data has been submitted to a peer-review journal for publication. We are expecting data from the second primate study to be presented shortly.

…With Drug-Releasing Hydrogel…

In the meantime, management is working with the FDA to submit additional data around the company's drug releasing hydrogel for SCI. The company is preparing the rodent and primate data for submission to the agency and seeks to file an IDE around the middle of 2012. We expect the design of the Hydrogel IDE study will be similar to the IDE program for the BSD discussed above. If positive, we expect management to expand into a larger pre-market approval (PMA) program in 2013.

…In Peripheral Nerve…

Management also seeks to file another IDE around the middle of 2012 for chronic pain due to peripheral nerve damage. Expansion into peripheral nerve damage is a meaningful opportunity for the company. It not only expands the company's focus beyond SCI, but it potentially creates another opportunities to partner or seek non-dilutive funding in 2012.

On January 17, 2012, management announced collaboration with the Geisinger Health System to conduct a preclinical study using the injectable hydrogel for the treatment of chronic pain caused by peripheral nerve compression. The study will be conducted jointly in the Tapinos Lab of Molecular Neuroscience at the Weis Center for Research and the Slotkin Lab of Spinal Cord Injury Research at the Geisinger Clinic's Neurosciences Institute. The endpoint of the study will be the effectiveness of using injectable hydrogels for the controlled release of drugs to alleviate chronic pain resulting from compression-induced peripheral nerve damage looking at both molecular and behavioral impact in rodents. The study is planned to have four arms: 1) injectable scaffold with drug therapy, 2) the injectable scaffold alone, 3) injectable drug therapy alone, and 4) a control group receiving no injection.

We see this as a significant opportunity for InVivo. There are an estimated 3.2 million nerve block injections done in the U.S. each year. It's an estimated $15 billion market. Existing treatment options are limited and only curb pain for as little as one week. A localized injection using the hydrogel to provide time-released anti-inflammatory therapies like methylprednisolone could provide pain relief for up to twelve months with limited systemic side-effects.

New Headquarters In Cambridge

We note that in December 2011, management entered into a multi-year lease for a 21,000 square-foot facility in Cambridge, MA to serve as the company's fully integrated global headquarters. The facility will house InVivo's corporate offices, lab space, a rodent vivarium, and a cGMP cleanroom. Details of the facility include:

- ✓ A chemistry lab for formulations and chemical synthesis of the Company's hydrogel and polymer-based scaffold technologies;
- ✓ A cGMP cleanroom for manufacturing and packaging of the Company's biomaterial devices for clinical studies and early product launch;
- ✓ A rodent vivarium to evaluate the safety and efficacy of various devices and treatment combinations in SCI and other nervous system injury models which the Company believes to be one of the largest dedicated to spinal cord injury research in the world;
- ✓ A biology lab for developing cell therapies used in combination with the Company's biomaterial devices;
- ✓ A surgeon training facility to educate the medical community, prepare for product launch, and engage physicians for research and product development purposes; and,
- ✓ The ability to expand to additional space as the Company grows.

Financial Update

With all the planned clinical and preclinical programs noted above, we expect that InVivo will require significant cash in the next year quarters. The company exited the third quarter 2011 (ended September 30, 2011) with $3.7 million in cash and investments.

…Raised Roughly $3.0 Million In Q4-2011…

On December 21, 2011, InVivo entered into a securities purchase agreement with Ingenieria E Inversiones LTDA (IEI-LTDA) whereby the company sold 0.980 million shares of common stock to IEI-LTDA at $2.04 per share, plus issued 0.343 million warrants to purchase additional common stock over the next five years at $3.06 per share. Net proceeds from the transaction were $1.9 million.

We remind investors that there were a total of 18.8 million warrants outstanding as of September 30, 2011. This included 15.6 million warrants currently exercisable at $1.40 per share and 3.2 million warrants currently exercisable at $1.00 per share. According to management, roughly $1.0 million additional capital was raised in the fourth quarter 2011 from conversion of these warrants. Therefore, we estimate that InVivo exited 2011 with approximately $4.9 million in cash. We find this to be sufficient to fund operations into the third quarter 2012.

…S1 & S3 Active…

Despite the still 17+ million warrants outstanding, InVivo is going to require additional cash either in the second or third quarter 2012 to keep the pipeline on track. On December 16, 2011, the company filed an S1 registering $10 million in maximum aggregate offering. As noted above, roughly $2.0 million was offered a week later. On January 5, 2012, InVivo filed an S3 registering an additional $50 million in potential maximum aggregate offerings. The combination of the S1, S3, and the 17+ million warrants outstanding currently in-the-money put InVivo in an excellent position to raise additional capital in 2012 and beyond.

INVESTMENT THESIS

Making The Case For InVivo

In July 2011, we initiated coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with spinal cord injury (SCI). Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons. These include speed to market, simplicity of the idea, intellectual property protection, and strong animal model data.

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. It is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery. We think this is a model that lends itself well to clinical trials. Regulation of BSD will be as a medical device, not a biologic or a pharmaceutical product, which should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for later in the year.

Longer-term, upside to the story comes from gaining approval for the injectable Hydrogel formulation, which can be used with pharmaceutical products like methylprednisolone sodium succinate (MPSS). This will then be followed by applications for use of BSD in-combination with stem cells. We think this has the potential to turn BSD into a potential blockbuster for the treatment of SCI because it opens up the opportunity to heal stalled SCI wounds in the 250,000 to 300,000 patients in the U.S. currently living with SCI. If we look outside the U.S., and include Canada and Western Europe, and the number grows to 400,000 chronic SCI patients in these markets. Including Asia, Australia, and Latin America, and the number of chronic SCI patients is around 2.0 million worldwide. Beyond SCI, management is looking at the potential to file an IDE into peripheral nerve damage with the injectable Hydrogel. There are an estimated 3 million nerve block procedures done in the U.S. each year. Existing medications work only as long as one week and require frequent follow-ups to maintain pain suppression. InVivo is working on injectable Hydrogel formulations that can block nerve damage pain for up to twelve months.

…Key Attributes…

Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons:

- ✓ BSD will be regulated as a medical device. Management filed the Investigational Device Exemption (IDE) to the U.S. FDA in July 2011. The proposed indication is to protect and support spinal tissue and prevent secondary injury, including inflammation and glial scarring, following traumatic spinal cord injury. We think this initial, simpler approach to treating SCI provides investors with a quicker and lower risk path to market than the traditional pharmaceutical or biologic pathway.

- ✓ Strong scientific rationale. InVivo's technology for the BSD was born out of the labs of Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. Dr. Langer has written over 1,100 articles, holds approximately 760 issued and pending patents worldwide that have been licensed or sublicensed to over 220 pharmaceutical, chemical, biotechnology and medical device companies. InVivo's CEO, Frank Reynolds, having suffered a paralyzing injury to his spine in December 1992, has spent years gaining subject matter expertise on the spine and spinal cord.

- ✓ Intellectual property protection is strong. Ultimately, we believe combination therapy will become the standard of care for SCI. InVivo's owns the patent rights to use of all biopolymer scaffolding products which serve as an extracellular matrix for cell therapy, or in in combination with pharmaceutical products or biologic growth factors. These patents also protect the use of time-release drugs, design and manufacture of materials for use in SCI that mimics the natural cellular architecture of the inner grey and outer white matter of the spinal cord. We believe this creates significant barriers to entry for competitors and provides for meaningful licensing and partnering opportunities in the future for InVivo.

- ✓ Animal data has been very encouraging. Although we have only seen data in African Green monkey's, we note the physiological anatomy and neurophysiology characteristics between how the spinal cord works and functions these primates and humans is nearly identical. African Green Monkeys are an acceptable regulatory indicator of potential hazards and research supports translation to humans, Nature Medicine, Vol-13,No.5:561-566, May 2007. The genomic similarity to humans is over 98%.

…A Simple Concept…

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. As discussed above, it is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery.



We think this is a model that lends itself well to clinical trials. As noted above, regulation as a Class 3 medical device should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for early 2012. We could see data from this program by April or May 2012. The next step following this small pilot study remains to be seen. We see two potential next steps following completion of the IDE study:

1. Traditionally, the next step following the IDE is to conduct a larger Pre-Market Approval (PMA) study in approximately 30-40 patients with SCI. Assuming successfully completion of the PMA program, InVivo should be able to file for approval in the U.S. through the 510(k) pathway.

2. With "Homerun" like data from the IDE study, meaning moving patients off a ventilator or taking a complete tetraplegic and returning bowel function or more, InVivo may be able to file for approval in a narrow patient population. An option is to seek approval under the FDA's Humanitarian Device Exemption (HDE) protocol. HDE is similar in both form and content to a Pre-Market Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The HDE pathway may allow approval for InVivo's BSD in an acute population or in complete tetraplegics.

Longer-term, upside to the story comes from gaining approval for the injectable Hydrogel formulation, which can be used with pharmaceutical products like methylprednisolone sodium succinate (MPSS). This will then be followed by applications for use of BSD in-combination with stem cells. We think this has the potential to turn BSD into a potential blockbuster for the treatment of SCI because it opens up the opportunity to heal chronic SCI in the 250,000 to 300,000 patients in the U.S. currently living with SCI. If we look outside the U.S., and include Canada and Western Europe, the number grows to 400,000 chronic SCI patients in these markets. Including Asia, Australia, and Latin America, the number of chronic SCI patients is around 2.0 million worldwide.

Beyond SCI, management is looking at the potential to file an IDE into peripheral nerve damage with the injectable Hydrogel. There are an estimated 3 million nerve block procedures done in the U.S. each year. Existing medications work only as long as one week and require frequent follow-ups to maintain pain suppression. InVivo is working on injectable Hydrogel formulations that can block nerve damage pain for up to twelve months.

Valuation

…On DCF…

We have performed a discounted cash flow (DCF) analysis to value the shares. We assume that InVivo looks to launch BSD in 2014 at a price of $60,000. We assume 90% gross margin, a sales force of 25 full-time representatives, and ongoing R&D funding the registration programs for Hydrogel and BSD + cells. We model approval of the Hydrogel in 2015 and the combination therapy in 2016. We think management can slowly raise the price towards $100,000, and capture 10% of the 100,000 to 150,000 chronic and acute SCI patients in the U.S. We have used an extremely aggressive discount rate of 20% to account for the early-stage nature of the product. We arrive at a market value of approximately $360 million, or $4.50 per share based on roughly 65 million shares currently outstanding, 6.4 million unregistered shares, and a future dilution of 10 million shares to fund operations in 2012 (adjusted fully diluted share count of 81.6 million).

…On A Takeout…

As noted above, our DCF model assumes InVivo bring BSD to the market alone. However, if BSD is a success, a larger partner will surely come along and make shareholders and offer. Accordingly, we can adjust our valuation to see, "What it could be worth" to a potential larger company on a takeover. We do this so that investors can get a true sense of fair market value for the stock.

Starting with our DCF model, we've increased sales by 20% to account for "overwhelming" promotion of a massive sales force like J&J or Medtronic. We've also removed future dilution and lowered the discount rate to account for a much lower cost of capital. Finally, we've reduce the S&GA expense figuring that a larger company will use representatives already in the field promoting products for spinal surgery, biomaterials, tissue engineering, or neurology. We arrive at a "take-out" value of $525 million, or $7.25 per share. We believe this is a price that a company like J&J or Medtronic could easily pay and still see accretion.

We can also look at previous deals between larger pharmaceutical or medical device companies and see – on average – what multiple of revenue seems fair to pay. We have looked at several previous deals:

Acquirer	Target	Purchase Price	TTM Sales	Price / Sales
Abbott Labs	Spinal Concepts	$210 Million	$27 Million	7.8x
Stryker	BSI Neurovascular	$1.5 Billion	$348 Million	4.3x
Shire Pharma	Advanced Bio	$750 Million	$146 Million	5.1x
Stryker	OrthoVita	$305 Million	$95 Million	3.2x
Medtronic	Salient Surgical	$525 Million	$100 Million	5.3x
J&J	Synthes, Inc.	$19.3 Billion	$3.7 Billion	5.2x
Zimmer Holdings	Abbott Spine	$360 Million	$109 Million	3.3x
Sulzer Medica	Spine-Tech	$595 Million	$58 Million	10.1x
Integra LifeSci	Theken Spine	$75 Million	$34 Million	2.2x
Kinetic Concepts	LifeCell	$1.7 Billion	$190 Million	8.9x
Medtronic	Kyphon	$3.9 Billion	$408 Million	9.6x
"Private Equity"	Biomet	$10.9 Billion	$2.1 Billion	5.4x
Smith & Nephew	Oratec Intervent	$310 Million	$48 Million	6.5x
Smith & Nephew	Orthopaedic Bio	$28 Million	$6 Million	4.6x
Medtronic	Xomed	$800 Million	$91 Million	8.8x
Medtronic	Sofamor Danek	$3.7 Billion	$400 Million	9.2x
J&J	DePuy	$3.5 Billion	$850 Million	4.1x
DePuy	AcroMed	$325 Million	$91 Million	3.6x
Smith & Nephew	Plus Orthopedics	$899 Million	$300 Million	3.0x
			Average Deal P/S Ratio	**6.1x**

By 2015, we expect InVivo's BSD and next-generation products roughly $200 million in sales. If we apply our average P/S multiple of 6.1x, we arrive at a take-out price of $1.2 billion. Based on our fully diluted share count, we arrive at a fair price of $14.75 in 2015. Discounting that back to present day at 20%, we $7.10 per share.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2010 E	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E	2014 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.5**	**$1.0**	**$1.5**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.5**	**$1.0**	**$1.5**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$1.7	$0.6	$1.4	$1.0	$1.1	$4.1	$5.2	$5.5	$10.4
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$1.7	$0.8	$1.1	$1.2	$1.1	$4.2	$4.8	$6.0	$8.0
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($1.4)	($2.5)	($2.2)	($2.2)	($8.3)	($9.5)	($10.5)	($16.9)
Operating Margin	*0.0%*	-	-	-	-	-	-	-	-
Net Other Income	($4.5)	$0.1	$1.2	$5.3	$0.1	$6.7	$0.1	$0.1	$0.2
Pre-Tax Income	($7.9)	($1.3)	($1.4)	$3.1	($2.1)	($1.7)	($9.4)	($10.4)	($16.7)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$4.4
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*26.1%*
Net Income	($7.9)	($1.3)	($1.4)	$3.1	($2.1)	($1.7)	($9.4)	($10.4)	($12.3)
Net Margin	*0.0%*	-	-	-	-	-	-	-	*-821.3%*
Reported EPS	**($0.24)**	**($0.02)**	**($0.03)**	**$0.06**	**($0.04)**	**($0.03)**	**($0.15)**	**($0.15)**	**($0.16)**
YOY Growth	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	33.4	51.7	51.7	54.3	56.0	53.4	61.0	70.0	75.0

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

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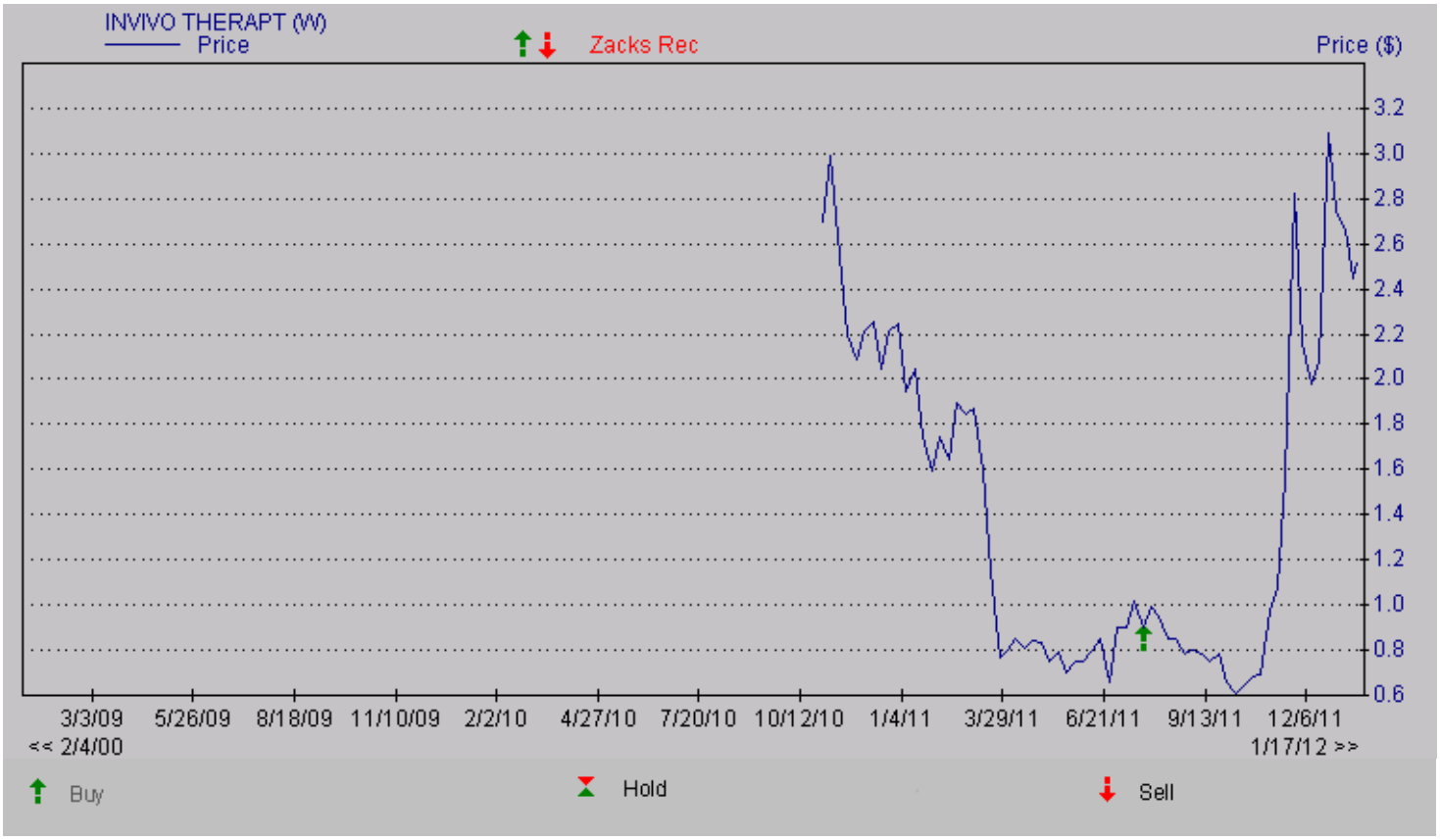
HISTORICAL ZACKS RECOMMENDATIONS



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