Zacks Small-Cap Research

November 15, 2011
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# InVivo Therapeutics, Hdls Corp. (NVIV-OTC)

## *NVIV: Moving Into the Clinic With A Revolutionary Device…*

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 07/26/2011 |
| Current Price (11/15/11) | $1.10 |
| **Target Price** | **$4.50** |

## UPDATE

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.

We arrive at our $4.50 price target through DCF, which incorporates an aggressive discount rate. Over the long-term, we see significant upside in shares of NVIV through commercialization partnerships or a take-over.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$1.20** |
| **52-Week Low** | **$0.60** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **0.24** |
| **Average Daily Volume (sh)** | **136,436** |
| **Shares Outstanding (mil)** | **52** |
| **Market Capitalization ($mil)** | **$58** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **2** |
| **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 |
| 2013 | | | | | 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 | -$0.03 E | -$0.13 E |
| 2012 | | | | | -$0.17 E |
| 2013 | | | | | -$0.21 E |

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## WHAT'S NEW

**Third Quarter Financials**

On November 15, 2011, InVivo Therapeutics reported financial results for the third quarter ended September 30, 2011. The company did not report any revenues during the third quarter. This was in-line with expectations. Operating expenses during the quarter totaled $2.2 million. InVivo record a net gain in the quarter of $3.1 million, or $0.06 per diluted share. Gain in the quarter included a non-cash gain of $5.3 million or $0.10 per diluted share, associated with a reduction in the fair value of the derivative warrant liability. InVivo held cash and equivalents of $3.7 million at the end of the third quarter 2011.

**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 seeking to commence a human clinical study in July 2011. InVivo plans to meet with the FDA in December 2011 to finalize the design for the trial. 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 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 are expecting the trial to start in early 2012.

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.

***…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 primate data for submission to the agency and seeks to file an IDE in early 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 by the end of 2012.

***…In Peripheral Nerve…***

Management also seeks to file another IDE around the middle of 2012 for 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 in 2012. There are an estimated 3 million nerve block injections done in the U.S. each year. Existing treatment options are limited and only curb pain for as little as one week. InVivo is formulating its drug-releasing hydrogel to block nerve pain for up to twelve months.

## 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** | **$89.9** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| **Collaborative & Licensing** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0.0** | **$89.9** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Cost of Goods / Services | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $9.0 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - | - |
| R&D | $1.7 | $0.6 | $1.4 | $1.0 | $1.1 | $4.1 | $4.5 | $5.0 | $19.4 |
| *% R&D* | - | - | - | - | - | - | - | - | *21.5%* |
| SG&A | $1.7 | $0.8 | $1.1 | $1.2 | $1.1 | $4.2 | $5.0 | $10.0 | $10.0 |
| *% SG&A* | - | - | - | - | - | - | - | - | *11.1%* |
| Operating Income | ($3.4) | ($1.4) | ($2.5) | ($2.2) | ($2.2) | ($8.3) | ($9.5) | ($15.0) | $51.5 |
| *Operating Margin* | *0.0%* | - | - | - | - | - | - | - | *57.3%* |
| 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) | ($14.9) | $51.7 |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $9.5 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *18.3%* |
| Net Income | ($7.9) | ($1.3) | ($1.4) | $3.1 | ($2.1) | ($1.7) | ($9.4) | ($14.9) | $42.2 |
| *Net Margin* | *0.0%* | - | - | - | - | - | - | - | *47.0%* |
| **Reported EPS** | **($0.24)** | **($0.02)** | **($0.03)** | **$0.06** | **($0.04)** | **($0.03)** | **($0.14)** | **($0.21)** | **$0.56** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Wt. Ave Shares Outstanding | 33.4 | 51.7 | 51.7 | 54.3 | 56.0 | 53.4 | 65.0 | 70.0 | 75.0 |

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

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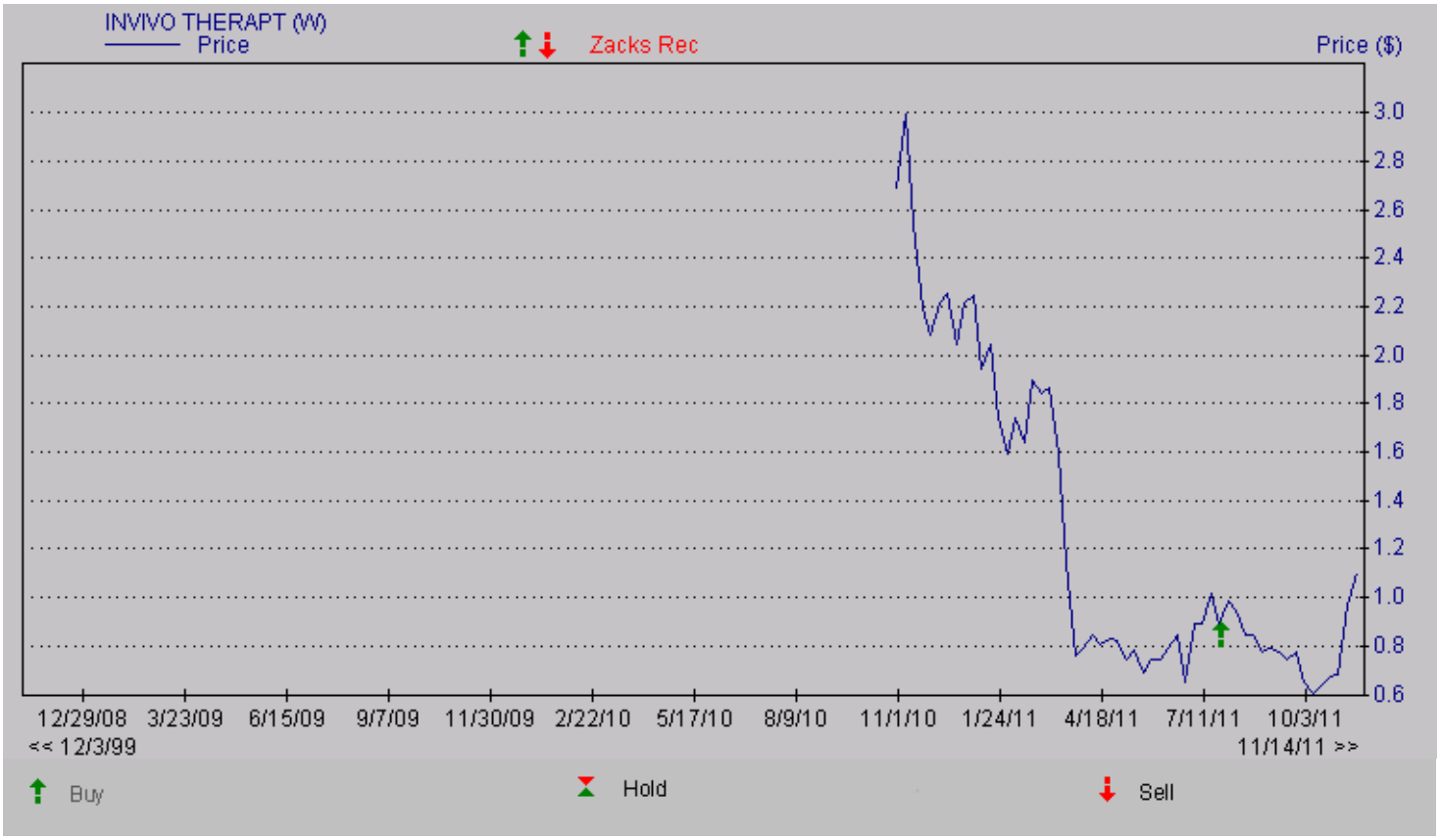
## HISTORICAL ZACKS RECOMMENDATIONS

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