Zacks Small-Cap Research

August 27, 2013
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

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

# InVivo Therapeutics (NVIV-OTC)

## *NVIV: New CEO Wipes Slate Clean Of Expectations…*

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | Buy |
| Date of Last Change | 07/23/2013 |
| Current Price (08/27/13) | $1.85 |
| **Target Price** | **$2.00** |

## UPDATE

This morning InVivo Therapeutics provided a clinical timeline update in the form of a press release relating to the company's biopolymer scaffolding to treat acute spinal cord injury (SCI). The news is a bit of a disappointment for those long the shares, as the timelines for potential commercialization of the biopolymer scaffolding have been pushed back several years. But the news does not come as a total surprise given the recent management changes that took place at the company last week, and the fact that the U.S. FDA always takes the most cautious approach to new medical technology, regardless of how great the preclinical data looks or how often the CEO campaigns publicly.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$5.67** |
| **52-Week Low** | **$1.28** |
| **One-Year Return (%)** | **83.88** |
| **Beta** | **0.07** |
| **Average Daily Volume (sh)** | **731,507** |
| **Shares Outstanding (mil)** | **70** |
| **Market Capitalization ($mil)** | **$312** |
| **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 2013 Estimate** | **N/A** |
| **P/E using 2014 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) |
|---|---|---|---|---|---|
| 2012 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2013 | 0 A | 0 A | 0 E | 0 E | 0 E |
| 2014 | | | | | 0 E |
| 2015 | | | | | 0 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | $0.05 A | $0.03 A | $0.12 A | -$0.13 E | $0.07 E |
| 2013 | -$0.20 A | -$0.20 A | -$0.07 E | -$0.07 E | -$0.23 E |
| 2014 | | | | | -$0.27 E |
| 2015 | | | | | -$0.37 E |

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

**Reality Check Hits Shares Hard**

This morning InVivo Therapeutics provided a clinical timeline update in the form of a press release relating to the company's biopolymer scaffolding to treat acute spinal cord injury (SCI). The news is a bit of a disappointment for those long the shares, as the timelines for potential commercialization of the biopolymer scaffolding have been pushed back several years. But the news does not come as a total surprise given the recent management changes that took place at the company last week, and the fact that the U.S. FDA always takes the most cautious approach to new medical technology, regardless of how great the preclinical data looks or how often the CEO campaigns publicly.

***New Clinical Timelines***

In December 2012, InVivo filed a request with the U.S. FDA for a Humanitarian Use Device (HUD) designation. The request came after an April 2012 meeting in which InVivo and the FDA discussed the requirements for the HUD designation and the potential for the device to be regulated and distributed under a Humanitarian Device Exemption (HDE). In February 2013, the company provided a brief update to investors, noting that an updated investigation device exemption (IDE)was filed with the FDA seeking to initiate the first human pilot studies with the biopolymer scaffolding.

In April 2013, the company went two-for-two on these regulatory applications. On April 4th, InVivo announced that the U.S. FDA had approved the company's request for a HUD designation, and the next day, on April 5th, the FDA granted approval allowing the start of the first human trials with the device. In the press release noting the FDA approval to start the trial, former CEO, Frank Reynolds, noted the trial would begin in the "next few months" and that all the necessary data to the FDA "by the end of 2014."

The press release this morning now states that the first patient in the 5-patient open-label pilot study will not be enrolled until the first quarter 2014. Additionally, because this is the first human testing of the biopolymer scaffolding, enrollment for the subsequent four patients will be staggered such that each patient will be followed for three months prior to requesting approval to enroll the next patient. Because InVivo must obtain FDA approval to enroll each subsequent patient, the company now anticipates that from the date of the first enrolled patient, it will take at least 21 months to complete enrollment.

If we figure another three months to analyze the data from the final patient, investors are looking to at least two years from the start of the pilot study to submission of the data to the FDA. That's a delay of around 18 months from Frank's previous guidance. However, the real potential bombshell comes with the next sentence in the press release, noting that the FDA will then require InVivo to conduct a pivotal study with a control group to obtain approval to commence commercialization under the HDE.

Former CEO, Frank Reynolds, had always told us that the biopolymer scaffolding would be on the market after the 5-patient pilot study. Now it seems as though the FDA wants a larger, controlled study prior to granted marketing approval of the scaffolding. Assuming this pivotal trial starts around mid-2016, takes approximately two years to complete, with another year for the FDA to accept and review the application, base case scenario pegs approval of the scaffolding under HDE around mid-2019. The figure below gives investors a sense of how things have changed based on today's news.

| Prior Guidance Under CEO Frank Reynolds | | | | |
|---|---|---|---|---|
| 5-person pilot study to being "mid-2013". Study will take 15 months total. | Submit data from 5-person pilot study to the FDA "year-end 2014" | FDA approval of the scaffolding under HUD "mid-2015" | | |
| **New Projected Timelines** | | | | |
| 5-person pilot study to being "Q1-2014". Study expected to take 21-24 months. | Submit data from pilot study to FDA around "early-to-mid-2016". | Begin pivotal program "mid-2016". This should take 24 months from start to finish. | Submit pivotal program data to FDA "mid-to-late 2018". | FDA approval of the scaffolding under HUD "mid-to-late 2019" |

| |
|---|
| Company guidance |
| Zacks estimation |

We want to be clear that the new projected timelines above (boxes in green) are our new predicted timelines, not official company guidance. InVivo is astutely only guiding to the start and enrollment of the pilot study. Beyond that, there are simply too many wildcards.

- ***Better-Case Scenario***: InVivo gets safety and efficacy data back from the first two or three patients (remember the pilot study is of open-label design) and it's fantastic. The company asks the FDA to enroll patients 4 and 5 concurrently to save time, and the FDA agrees. This could shave 3 to 6 months off the start of the pivotal program.
- ***Even Better-Case Scenario***: The open-label pilot study is going so well that not only does the FDA allow the concurrent enrollment of patients 3-4-5, but also allows the company to start the pivotal program before the pilot study ends. This could shave at much as 12-18 months off our base-case scenario noted in the picture above.

- ***Best-Case Scenario***: The open-label pilot study is an absolute home-run (i.e. the scaffolding is not only safe but has demonstrated profound efficacy beyond expected recovery) and the FDA allows InVivo to seek accelerated approval. InVivo would still have to conduct the pivotal program, but potential commercialization under HUD could come as early as late 2016.

At this point it is too difficult for us to accurately predict the outcome of these events. Thus, our 'Neutral' rating on the stock. Under our base-case scenario, our financial model pegs fair-value for the stock around $2.00 per share. Under better and even-better case scenarios valuation of the stock moves to around $3.00 to $3.50 per share. Under the best-case scenario, InVivo is worth $4.50 per share, which is our most recent price target as of our August 9th Zacks report.

**Some Final Thoughts**

Today's press release notes that new interim CEO, Michael Astrue, along with senior management, has undertaken a comprehensive project and timeline review of its hydrogel technologies platform, as well as its application to pain treatment, dural sealants, dural replacements, nerve conduits and fibrosis treatment, and will provide an update as to the status of those programs as data is available. We have all along stated that our valuation analysis of InVivo includes only commercialization of the biopolymer scaffolding. From time of first IDE application (July 7, 2011) to approval of that application (April 5, 2013) took nearly two years. The trial is pegged to begin in the first quarter 2014.

We believe the hydrogel will be regulated as a therapeutic, and thus InVivo will be required to file an investigational new drug (IND) application. To our knowledge, this has not been filed to date. We believe InVivo has learned a great deal over the past year in dealing with the U.S. FDA, so we do not expect a similar two-and-a-half years from the filing of the hydrogel IND to the start of the first human pilot study with the hydrogel in either pain or spinal cord injury. However, at this stage factoring in revenues and earnings for a pre-IND candidate, regardless of how promising the hydrogel sounds, is totally premature. Similarly, we believe the dural sealant, dural replacement, nerve conduits, and fibrosis treatment products are entirely too early-stage to factor into any reasonable valuation metric.

InVivo exited the second quarter ended June 30, 2013 with $22.2 million in cash and investments. We find this to be sufficient to fund operations into 2015. Therefore, the company will require capital to complete the 5-person pilot study with the scaffolding. We believe $20 to $25 million in financing in 2014 is reasonable and easily achievable given the potential for the scaffolding device, even with our base-case scenario timelines noted above.

Uplisting to a major exchange seems to have hit a snag due to an unexpected corporate governance issue. Although we view this as only a minor delay and believe the company remains fully-committed to uplisting to a major exchange by the end of the year. This alone could spark a return of investor interest to the stock despite today's news of a delay on the clinical front. In the end, we view today's far more realistic clinical guidance from the new interim CEO as refreshing. We hope the days of over-promise / under-deliver are a thing of the past.

Nevertheless, considering valuation in the shares ranges between $2.00 and $4.50, we remain on the sidelines until visibility improves. We may be tempted to revise our rating to ‘Buy’ if the shares hit $1.50. At this level, the stock would offer 33% upside to our base-case scenario of $2.00 per share.

## PROJECTED FINANCIALS

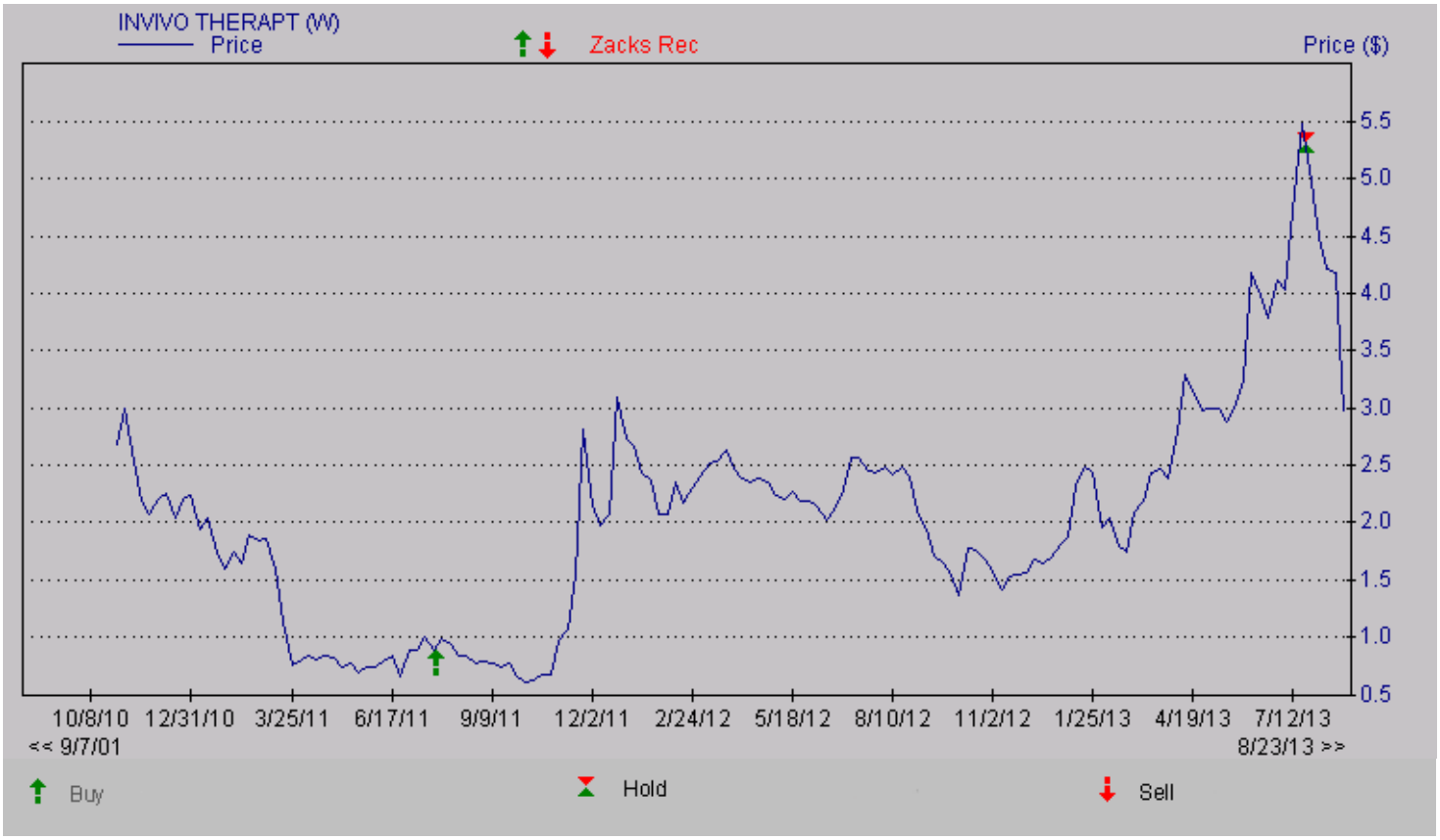
**InVivo Therapeutics Holdings Corp.**
Income Statement

| InVivo Therapeutics | 2011 A | 2012 A | Q1 A | Q2 A | Q3 E | Q4 E | 2013 E | 2014 E | 2015 E |
|---|---|---|---|---|---|---|---|---|---|
| **Product Sales** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *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** | **$0.0** | **$0.0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Cost of Goods / Services | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0.0 | $0.6 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - | - |
| R&D | $4.1 | $6.4 | $1.2 | $2.6 | $2.3 | $2.7 | $8.8 | $12.5 | $12.5 |
| *% R&D* | - | - | - | - | - | - | - | - | - |
| SG&A | $4.6 | $6.4 | $1.6 | $2.5 | $2.0 | $2.1 | $8.2 | $10.0 | $16.3 |
| *% SG&A* | - | - | - | - | - | - | - | - | - |
| Operating Income | ($8.7) | ($12.8) | ($2.9) | ($5.1) | ($4.3) | ($4.8) | ($17.0) | ($22.5) | ($29.3) |
| *Operating Margin* | - | - | - | - | - | - | - | - | - |
| Net Other Income | ($26.1) | $17.4 | ($10.5) | ($9.2) | ($1.0) | ($1.0) | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($34.8) | $4.7 | ($13.3) | ($14.3) | ($5.3) | ($5.8) | ($17.0) | ($22.5) | ($29.3) |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0.0 | $0.0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0.0%* | *0.0%* |
| Net Income | ($34.8) | $4.7 | ($13.3) | ($14.3) | ($5.3) | ($5.8) | ($17.0) | ($22.5) | ($29.3) |
| *Net Margin* | - | - | - | - | - | - | - | *#DIV/0!* | *#DIV/0!* |
| **Reported EPS** | **($0.67)** | **$0.07** | **($0.20)** | **($0.20)** | **($0.07)** | **($0.07)** | **($0.23)** | **($0.27)** | **($0.35)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| Wt. Ave Shares Outstanding | 51.9 | 63.2 | 66.0 | 72.4 | 78.6 | 79.0 | 74.0 | 82.5 | 85.0 |

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

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

## HISTORICAL ZACKS RECOMMENDATIONS




## DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR"), Zacks & Company (ZCO") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned.

ZCO and Zacks SCR are separate legal entities. ZCO is U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority and the Securities Investor Protection Corp. This report is for your information only and is not an offer to sell, or a solicitation of an offer to buy, the securities or instruments through ZCO.

Zacks SCR uses the following rating system for the securities it covers. 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 of Zacks Ratings is as follows on the 1028 companies covered: Buy/Outperform- 14.9%, Hold/Neutral- 78.3%, Sell/Underperform – 5.7%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.