Zacks Small-Cap Research

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
Brian Marckx, CFA
312-265-9474 / bmarckx@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

InVivo Therapeutics (NVIV-NASDAQ)

Releases 1Q:15 results, updating valuation to reflect current balance sheet.

Based on our DCF model and a 15% discount rate, NVIV is valued at approximately $17.00 per share. We apply a 65% probability of FDA approval for the Neuro-Spinal Scaffold. The model does not reflect any revenue benefit from the Neural Trails initiative or potential market expansion into the incomplete AIS B or lower market.

Current Price (5/6/2016)	$5.51
Valuation	**$17.00**

OUTLOOK

In January 2016, InVivo Therapeutics received approval of its protocol amendment from the FDA, which converted its ongoing NSS pilot study into a pivotal probable benefit study. The company plans to use this single study as the basis for a HDE application with planned submission in late 2017. In April, NVIV reported that a fourth patient reported improvement to AIS B or better leaving only one additional conversion before the study achieves its primary endpoint.

In December, NVIV announced its treatment for chronic spinal cord injury (SCI) through its Bioengineered Neural Trails Program which may restore neuronal connectivity and promote neurological recovery in patients with chronic SCI. Although currently in a pre-clinical stage, this program may take the baton from the NSS into chronic SCI and address the nearly 300,000 Americans currently suffer from this condition and currently have only limited therapeutic options.

At the current price, we view InVivo shares as meaningfully undervalued, and feel they provide significant long-term upside potential. With sufficient cash to support two more years of operations, we believe the current share price presents investors with an attractive long-term buying opportunity. Our price target reflects material market penetration into the complete AIS A thoracic and cervical market.

SUMMARY DATA

52-Week High	**$17.87**
52-Week Low	**$3.66**
One-Year Return (%)	**-57.5**
Beta	**3.19**
Average Daily Volume (sh)	**442,511**
Shares Outstanding (mil)	**31.9**
Market Capitalization ($mil)	**$176**
Short Interest Ratio (days)	**7.6**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**18**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**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)
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2016	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2017					$0.0 E
2018					$51.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.64 A	-$0.39 A	-$0.09 A	-$0.17 A	-$1.26 A
2016	-$0.24 A	-$0.20 E	-$0.19 E	-$0.20 E	-$0.82 E
2017					-$0.86 E
2018					$0.44 E

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WHAT'S NEW

InVivo Reports 1Q:16 Financial Results

InVivo Therapeutics Holdings Corp. (NASDAQ: NVIV) reported financial results for its 1Q:16 corresponding to the period ending March 31, 2015. Loss per share of ($0.24) was greater than our forecast of ($0.19) entirely due to the derivative loss related to repricing of warrants. During this period, no revenues were reported. Operating expenses for the three-month period were $5.6 million, which was greater than the $5.5 million spent in the first quarter of the prior year.

Research and development expenses of $2.6 million rose by $0.3 million or 12% compared to 1Q:15. This was slightly less that the $2.8 million we expected and down slightly on a sequential basis. Higher salaries from the addition of new personnel, higher clinical trial costs from addition of participants, and new trial sites, as well as a variety of other small items contributed to the year over year difference.

General and administrative expenses of $3.0 million fell 7% in the first quarter due to a $0.6 million decline in legal costs and lower stock compensation expense. Increases in consulting, salary, stock listing, and recruiting fees partially offset the contraction leading to a $0.2 million decline compared to 1Q:15. The decrease varied with our estimate of $3.3 million in G&A expenses.

Net Interest expense was an immaterial $9 thousand in the quarter. Derivative loss was $1.1 million due to adjustments related to anti-dilution provisions.

Our target price is reduced slightly as we update for new shares issued and increases in warrants and options outstanding. Our previous target moves from $18.00 per share to $17.00 per share representing over 200% upside from current levels.

Please review our prior reports for an in-depth discussion of InVivo's Neural Spinal Scaffold and Bioengineered Neural Trails programs and a patient by patient discussion of progress receiving InVivo's promising implant.

Estimates

We anticipate that InVivo will launch the Neuro-Spinal Scaffold (NSS) in 2018 following a successful approval of the device in 2017. The company, concurrent with the approval process for the complete thoracic indication, has announced an intention to begin pivotal trials for a complete cervical indication as well, which we forecast will be completed by 2020. We believe that sales will rise from $51 million in 2018 rising to $600 million over the next ten years. These estimates do not include any revenues from approval of the device related to incomplete thoracic or cervical indications nor do they include any revenues for the Bioengineered Neural Trails initiative.

Public Offering of Shares

On March 14, 2016, NVIV announced that it would offer common shares and warrants through Raymond James & Associates to fund the current and forthcoming clinical trials and support general corporate expenses. The offering, which included 0.5 warrant for every share, was priced at $7.50 per unit for 4.29 million units, which included the 15% over allotment of 0.56 million shares. The 2.15 million separable warrants have an exercise price of $10 and expire after a 5-year term. InVivo received $29.91 million in net proceeds after commissions.

Other Material Events Year to Date 2016

- On February 29, the company received a protocol amendment approval from the FDA to establish the Objective Performance Criterion (OPC) for the INSPIRE study. The OPC was defined as a 25% or higher proportion of the study participants demonstrating a one ASIA Impairment Scale (AIS) grade improvement six months following the procedure. This compares to historical six-month improvement rates in the 12% to 16% range. This is a very positive event for InVivo given their strong conversion rate thus far. We believe that InVivo will be able to surpass the 25% hurdle, providing strong support for eventual approval.

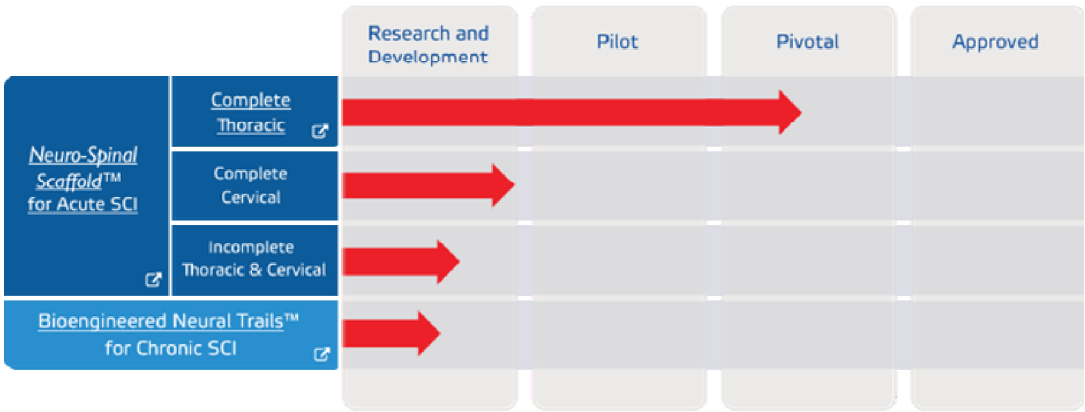
- The company has been fortunate to attend and announce attendance at a number of conferences, presenting to both investors and practitioners. So far in 2016, this includes the Biotech Showcase, the Cowen Health Care Conference, the Spine Summit, American Spinal Injury Association (ASIA) Annual

Scientific Meeting, the Committee Roundtable on Biomedical Engineering Materials and Applications (BEMA) and the American Association for Neurological Surgeons (AANS).

- InVivo has added several new clinical trial locations so far this year and now has 19 sites that are participating in the INSPIRE study. Over the next few quarters we anticipate some additional sites to be opened. Below we list the sites added year to date.

    - February 3, UCSD Medical Center, San Diego, California
    - March 2, Vidant Medical Center in Greenville, North Carolina
    - March 3, University of Louisville Hospital in Louisville, Kentucky
    - March 8, Thomas Jefferson University Hospital in Philadelphia, Pennsylvania
    - April 5, University of Virginia Health System in Charlottesville, Virginia

- NVIV has also updated their pipeline chart, illustrating the current and planned programs for SCI. Currently, we anticipate that the complete thoracic program (the INSPIRE study) will wrap up sometime in early 2017, followed soon after by a filing with the FDA and, if successful, FDA approval in early 2018 and a launch of the NSS shortly after. InVivo plans to begin with the complete cervical trial in the next couple months, which we anticipate will commence as a pivotal trial also using the Humanitarian Device Exemption (HDE) pathway. The population size for the cervical group is similar to the thoracic group at about 2,000 patients and we believe that NVIV will be able to take advantage of the HDE due to the population size and only be required to show probable benefit. No announcement regarding timing for the incomplete thoracic and cervical trial has been made, but we foresee clinical trials beginning in the next few years. However, we note that due to the addressable population size in excess of 12,000 patients annually, the Premarket Approval (PMA) pathway must be used for this group, requiring a statistically significant study to support evidence of effectiveness, which will require a larger trial and potentially greater duration as compared to the complete thoracic and complete cervical efforts. InVivo has not provided detail regarding the clinical development program for the Bioengineered Neural Trails initiative, but has indicated that they are targeting a pre-IND meeting with the FDA by year end 2016. See below for a graphic summary of the current programs.



- NVIV performed three implantations since the beginning of the year; unfortunately one of the patients died due to the injuries sustained in the vehicle accident that damaged their spine. The patient who died will not be included as part of the study as there was no opportunity to observe the outcome of the implantation procedure. We discuss each of the eight patients in more detail later in our report.

Conclusion

There remains a huge unmet need in spinal cord injury as there are currently no commercially approved therapeutics (devices or drugs) to treat SCI. Currently, surgical intervention with rehabilitation is the standard-of-care in dealing with SCI patients.

InVivo's news regarding the successful conversion of four of seven active patients is a strong positive for the stock. While some have postulated that this early success may indicate an early filing for approval due to the one additional conversion needed to achieve the Objective Performance Criterion, we remind investors that the

objective of the pivotal study is to show both probable benefit (which will be supported by surpassing the 25% hurdle) and safety, which may require observation of the full 20 patients throughout the six month term. While it is possible that the company may file early, we do not incorporate this into our expectations.

Shares of InVivo are well below their 12-month high despite continued progress in their pivotal trial. We believe the current price of the shares presents substantial upside as determined by our target price. As of March 31, 2015, InVivo held $46 million in cash on hand including proceeds from the March share offering. The company, in our opinion conservatively, believes that the funds will meet operating and capital requirements through the end of 2017. We anticipate a continued $1.4 million monthly cash burn rate through the end of the year which matches first quarter levels.

Our current model forecasts the completion of the pivotal probable benefit study in 2017, an application for approval under HUD in late 2017 and ultimate approval in 2018. Our financial model assumes the INSPIRE trial reaches full enrollment on time, and that approval will be contingent upon showing safety and probable benefit in a larger number of patients. Based on our estimates and 10-year DCF model, we have determined a price target of $17 which uses a 15% discount rate and a 65% probability of approval.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp. - Income Statement

InVivo Therapeutics	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$51**
YOY Growth	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$51**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$10.1	$2.6	$3.0	$3.0	$3.2	$11.8	$15.0	$18.0
G&A	$12.3	$3.0	$3.5	$3.5	$3.7	$13.7	$16.0	$17.0
Operating Income	($22.4)	($5.6)	($6.5)	($6.5)	($6.9)	($25.5)	($31.0)	$16.5
Operating Margin	-	-	-	-	-	-	-	-
Net Other Income	($10.9)	($1.1)	$0.0	$0.0	$0.0	($1.1)	$0.0	$0.0
Pre-Tax Income	($33.3)	($6.6)	($6.5)	($6.5)	($6.9)	($26.5)	($31.0)	$16.5
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	($33.3)	($6.6)	($6.5)	($6.5)	($6.9)	($26.5)	($31.0)	$16.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.26)**	**($0.24)**	**($0.20)**	**($0.19)**	**($0.20)**	**($0.82)**	**($0.86)**	**$0.44**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	26.5	28.2	33.0	34.4	35.0	32.6	36.0	37.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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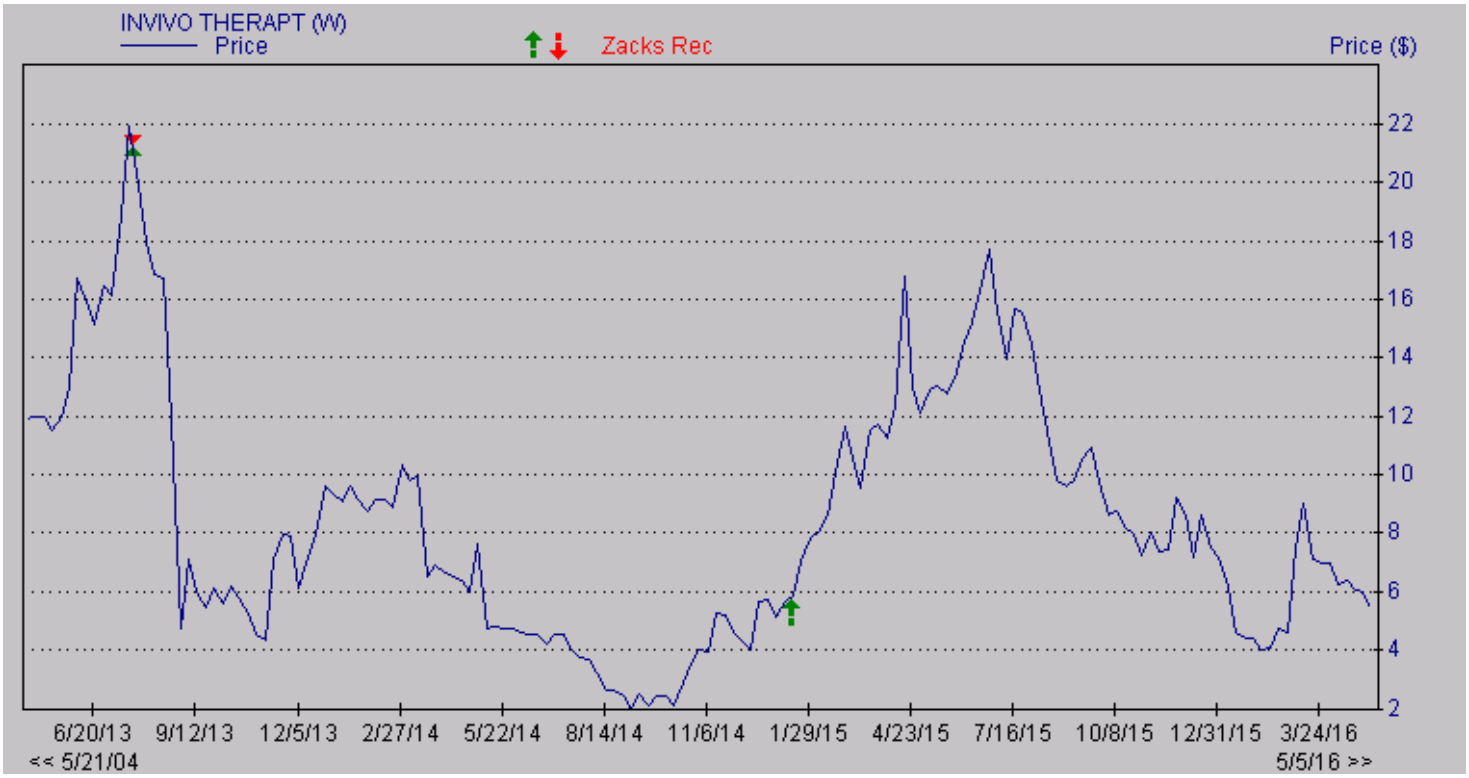
HISTORICAL STOCK PRICE



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