Zacks Small-Cap Research

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InVivo Therapeutics (NVIV-NASDAQ)

Slow Enrollment Delays Filing, Approval and Commercialization Forecasts.

Based on our DCF model and a 15% discount rate, NVIV is valued at approximately $15.00 per share. We apply a 75% probability of FDA approval for the Neuro-Spinal Scaffold based on the achievement of the OPC. 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 (11/16/2016)	$5.55
Valuation	**$15.00**

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 August, NVIV reported that the fifth patient reported improvement to AIS B or better thereby achieving the OPC and 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 who currently suffer from this condition and have only limited therapeutic options.

At the current price, we view InVivo shares as undervalued, and feel the stock provides long-term upside potential. With sufficient cash to support seven additional quarters of operations, we believe the 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	**$11.80**
52-Week Low	**$3.50**
One-Year Return (%)	**-24.2**
Beta	**3.38**
Average Daily Volume (sh)	**269,364**
Shares Outstanding (mil)	**32.0**
Market Capitalization ($mil)	**$178**
Short Interest Ratio (days)	**9.65**
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 A	$0.0 A	$0.0 E	$0.0 E
2017					$0.0 E
2018					$0.0 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	-$0.16 A	-$0.19 A	-$0.20 E	-$0.79 E
2017					-$0.69 E
2018					-$0.84 E

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WHAT'S NEW

3Q:16 Financial and Operational Results

On November 4, 2016, InVivo Therapeutics Holdings Corp. (NASDAQ : NVIV) filed its third quarter 10-Q generating a quarterly net loss of ($6.2) million for the three month period ending September 30, 2016. This compares to our estimate of a ($6.5) million loss and the ($2.3) million expended in 3Q:15. On a per share basis the loss was ($0.19) matching our estimate of ($0.19). Our estimates called for a higher share count as compared with actuals, which explains the match between actuals and our estimates on a per share basis. No revenues were reported in the quarter, as expected.

Research and development expense was $3.3 million in the quarter, increasing from the prior year's $2.4 million due to a rise in clinical trial costs from a greater number of enrollees in the INSPIRE trial. Other factors behind the rise are attributable to higher contract service and consulting costs as well as an increase in a variety of other smaller expense categories. The amount was greater than our $3.0 million estimate.

General and administrative costs were $2.6 million, falling sequentially and year over year. Lower legal and stock compensation expenses were the primary factors behind the decline. Other line items including consulting fees, investor relations expenses and depreciation also declined as compared to the prior year period. Our G&A estimates were for expenditures of $3.5 million.

Other income consisted primarily of mark to market derivative fluctuations and consisted of a loss in 3Q:16 compared to a $3.6 million gain in the 3Q:15 period. Net interest income totaled $18,000 in the three-month period compared to net interest expense of $30,000 in the third quarter of 2015.

Invivo consumed $12.4 million in free cash flow for the first nine months of 2016 and $4.1 million for the quarter. The nine month use of free cash was up from the $11.0 million consumed in the same period in 2015. Cash balance declined sequentially from $41.6 million to $38.0 million with an operating burn of $4.1 million in the quarter.

The company announced several key events during the quarter.

- The addition of several new clinical sites for the INSPIRE study since the conclusion of the second quarter, which brings the total number of sites to 27.
    - University of Iowa Hospitals and Clinics in Iowa City, IA
    - Allegheny General Hospital (AGH) in Pittsburgh, PA
    - Beth Israel Deaconess Medical Center (BIDMC) in Boston, MA
    - Foothills Medical Centre in Calgary, Alberta
    - Northwestern Medicine in Chicago, IL
    - Ben Taub Hospital in Houston, TX

- Changes in board and executive positions including:
    - Appointment of Jeffrey Hatfield to the Board of Directors. Mr. Hatfield most recently served as President, Chief Executive Officer, and Board Member for Vitae Pharmaceuticals and previously held executive positions at Bristol-Myers Squibb (NYSE: BMY).
    - Lorianne K. Masuoka, M.D., Chief Medical Officer announced her retirement after 19 months in the role.
    - On August 11th, the company announced the appointment of Pamela Stahl to the role of Chief Commercial Officer. Her background includes experience at UnitedHealth Group (NYSE: UNH) and her focus at InVivo will be to build a comprehensive global commercial strategy for developing the company's sales, reimbursement, and marketing strategies.

- Presentation at scientific and advocacy meetings
    - Alex Aimetti, Ph.D. presented a keynote speech in Neuro Engineering at the 2016 Symposium on Biomaterials Science
    - Dr. Aimetti presented at the 2016 Working 2 Walk Science & Advocacy Symposium
    - Thomas Ulich, M.D. presented at the annual Partnering Forum, part of the Cell & Gene Meeting on the Mesa
    - Michael Fehlings, M.D., Ph.D. presented "Clinical-Pathological Assessment of Severe (AIS A) Traumatic Acute Thoracic Spinal Cord Injury: Post-Durotomy/Myelotomy Observations from the INSPIRE Trial" at the 2016 Congress of Neurological Surgeons (CNS)
    - Nicholas Theodore, M.D. presented at the 2016 Congress of Neurological Surgeons (CNS)
    - Kristin Neff, Vice President of Clinical Operations & Project Management, presented at the 55th International Spinal Cord Society (ISCoS) Annual Scientific Meeting

- Neuro Spinal Scaffold for cervical spinal cord injury
    - On September 30, the FDA disapproved the cervical study pending results from the INSPIRE study
    - InVivo will continue to confer with the FDA to obtain support for moving into cervical SCI
    - Projected pilot study for cervical in Canada in 1H:17
    - Planned expansion into Europe

Review of Invivo Thesis

As a reminder, we adjusted our price target to $15.00 based on our estimates of a 2019 domestic launch of the Neuro-Spinal Scaffold (NSS) for neurologic recovery in subjects with complete thoracic AIS A spinal cord injury, and potentially a later launch which addresses complete cervical and incomplete thoracic and cervical spinal cord injury. While we currently ascribe no value to the company's Bioengineered Neural Trails program, we do believe the optionality of this effort provides additional opportunity following the development of the NSS.

We have been disappointed at the slow rate of enrollment in the INSPIRE trial and despite the 27 clinical sites currently open, no new patients have been added since May 2016. When the trial reached 12 patients that were approved for the study in May, it went into a pre-specified hold at which time the FDA required changes to the protocol which effectively closed all sites until the sites could resubmit the protocol amendments. The sites remained closed until late July at which time, the site count moved upward towards the current 27 as of November 9. Despite these closures, the rate of patient additions has been well below our forecasts and we now move our estimates to 2H:17 for full enrollment to be reached. Following the six month observation period, we anticipate that topline readout from the pivotal study will be available by early 2018. While it is possible that InVivo may seek and receive early approval given the INSPIRE trial has already achieved its objective performance criterion of five converted patients, we believe that the FDA will want to review safety data for the full 20 enrollees.

Estimates

Invivo announced the conversion of a fifth patient on August 17, 2016, which was a distinct positive. While the conversion did not impact our earnings and cash flow estimates, it does increase the probability estimate that the Neuro-Spinal Scaffold (NSS) will eventually be approved from 65% to 75%. However, the rate of enrollment has been very slow and there are currently only eight enrolled patients, and no new patients have been enrolled since May. Based on our updated estimates, our model forecasts a 2019 launch of the NSS following a successful approval of the device in 2018. We believe that sales will rise from $52 million in 2019 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. Approval or advancement of these initiatives would provide upside to our current estimates.

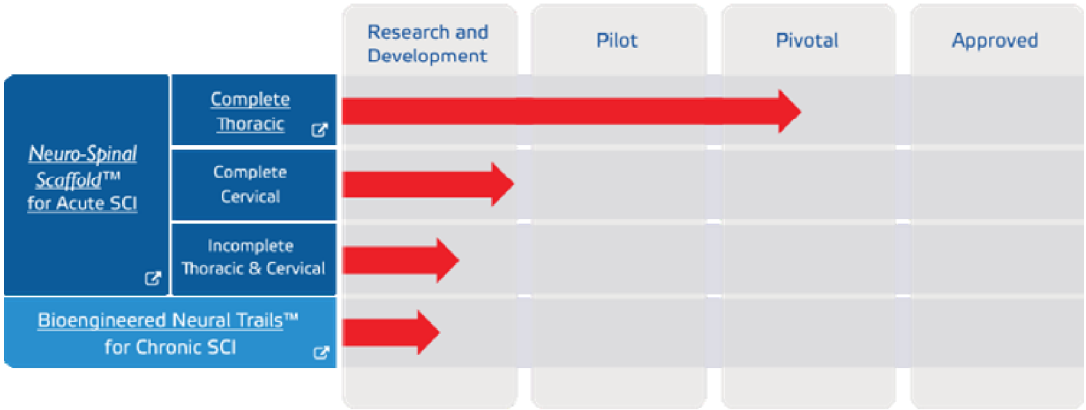
Other Material Events Year to Date 2016

We anticipate that the complete thoracic program (the INSPIRE study) will complete sometime in early 2018, followed soon after by a filing with the FDA and, if successful, FDA approval in late 2018 and a launch of the NSS shortly thereafter. InVivo plans to begin the complete cervical trial have been delayed due to the FDA withholding its approval and requiring additional but as yet unidentified information. When and if approved, we anticipate this

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. Due to the addressable population size in excess of 12,000 patients annually, the Premarket Approval (PMA) pathway must be used for an incomplete thoracic and cervical indication, requiring a statistically significant study to support evidence of effectiveness. This will be a larger trial of potentially greater duration as compared to the complete thoracic and complete cervical indications. 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.

Exhibit I – NVIV Pipeline



NVIV has performed five implantations since the beginning of the year. Unfortunately, two of the patients died due to injuries and complications of those injuries sustained in their accidents. The patients who died will not be included as part of the study as there was no opportunity to observe the outcome of the implantation procedure. Below we summarize the status of the patients currently enrolled in the study.

Exhibit II – Summary of INSPIRE Enrollees

Patient	Implant Date	Injury	Current Status
1	Oct-14	T11	Converted from AIS A to AIS C at Month 1 with substantial ongoing lower limb motor and sensory improvement through Month 12
2	Jan-15	T7	Remains AIS A but with marked bowel and bladder improvement through Month 12
3	Jun-15	T4	Converted from AIS A to AIS B at Month 1 with additional sensory improvement (from midchest to midabdomen) through Month 6
4	Aug-15	T3	Remains AIS A at Month 6
5	Sep-15	T8	3/7/2016 reports move from AIS A to AIS B
6	Feb-16	T10	Coverted to AIS B at 2 months
7	Mar-16	T3	Remains AIS A at 3 months
8	Apr-16		Died from injuries 2 days after implant
9	May-16	T4	Converted to AIS B before 3 months.
10	May-16		Died from stroke several days after implant

Conclusion

There remains a material 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 five patients, thus meeting the OPC, is a strong positive for the stock, however, the slow rate of enrollment since May is a negative. While some have postulated that this early success may indicate an early filing for approval, we remind investors that the objective of the pivotal study is to show both probable benefit (which is supported by surpassing the 25% hurdle) and safety, which may require observation of the full complement of patients throughout the six month term. While it is possible that the company may file early, we do not incorporate this into our expectations. InVivo anticipates completing the enrollment process by 1H:17, however, we shift our forecasts to 2H:17 and see ultimate approval by 2H:18 and launch in early 2019.

Shares of InVivo are well below their 12-month high and we attribute the decline in the stock over the last few months to the low rate of enrollment. Due to the delays and slow rate, we shift first sales of the NSS from 2018 to 2019. Due to the one year delay is sales, we adjust our target price from $18.00 to $15.00. As of June 30, 2016, InVivo held $42 million in cash on hand. The company believes that the funds will meet operating and capital requirements through the end of 2017. It is likely that InVivo will require a capital raise prior to commercializing the device, and we anticipate that this will take place following potential approval by the FDA. We anticipate that the $4 to $5 million per quarter cash burn rate will continue in the coming quarters.

Our current model forecasts the completion of the pivotal probable benefit study in 2018, an application for approval under HUD in late 2018 and ultimate approval in larte 2018 followed by commercialization in early 2019. Based on our estimates and 10-year DCF model, we endorse a price target of $15.00 per share using a 15% discount rate and a 75% probability of approval and sales.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp. - Income Statement

InVivo Therapeutics	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 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	$10.1	$2.6	$2.8	$3.3	$3.2	$11.9	$12.0	$15.0
G&A	$12.3	$3.0	$3.0	$2.6	$3.7	$12.3	$13.0	$16.0
Operating Income	($22.4)	($5.6)	($5.8)	($5.9)	($6.9)	($24.1)	($25.0)	($31.0)
Operating Margin	-	-	-	-	-	-	-	-
Net Other Income	($10.9)	($1.1)	$0.6	($0.3)	$0.0	($0.8)	$0.0	$0.0
Pre-Tax Income	($33.3)	($6.6)	($5.2)	($6.2)	($6.9)	($24.9)	($25.0)	($31.0)
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)	($5.2)	($6.2)	($6.9)	($24.9)	($25.0)	($31.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.26)**	**($0.24)**	**($0.16)**	**($0.19)**	**($0.20)**	**($0.79)**	**($0.69)**	**($0.84)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	26.5	28.2	31.9	32.0	35.0	31.8	36.0	37.0

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

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