Zacks Small-Cap Research

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InVivo Therapeutics (NVIV-NASDAQ)

2Q:16 results, 22 Clinical Sites and FDA Expansion of Trial Size Support Enrollment Completion by Year-End.

Based on our DCF model and a 15% discount rate, NVIV is valued at approximately $16.00 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 (8/5/2016)	$6.37
Valuation	**$16.00**

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	**$14.50**
52-Week Low	**$3.50**
One-Year Return (%)	**-54.7**
Beta	**3.55**
Average Daily Volume (sh)	**223,490**
Shares Outstanding (mil)	**31.9**
Market Capitalization ($mil)	**$203.6**
Short Interest Ratio (days)	**12.9**
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 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	-$0.16 A	-$0.19 E	-$0.20 E	-$0.78 E
2017					-$0.86 E
2018					$0.44 E

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WHAT'S NEW

InVivo Reports 2Q:16 Financial Results

InVivo Therapeutics Holdings Corp. (NASDAQ: NVIV) released second quarter 2016 financial results and an operational update for the three month period ending June 30, 2016. Loss per share of ($0.16) was better than our estimate of ($0.20) due to lower research & development and general & administrative expenses. A $600 thousand derivative gain also reduced the loss by approximately two cents. During this period, no revenues were reported. Operating expenses for the second quarter were $5.8 million, which was flat with the second quarter of the prior year.

Research and development expenses, which are primarily amounts spent on contract research organization services and payroll were $2.8 million and rose by $0.3 million or 10% compared to 2Q:15. This was less that the $3.0 million we expected but up on a sequential basis. The year over year increase was due to higher salaries, the addition of new clinical trial sites and patients, and other miscellaneous expense category increases.

General and administrative expenses of $3.0 million fell 7% in the second quarter due to lower legal expenses, exchange filing fees partially offset by higher stock compensation expense compared to 2Q:15. Our estimates called for a modest increase in G&A expenses to $3.5 million.

2Q:15 net Interest expense was $7 thousand in the quarter and InVivo experienced a derivative gain of $0.6 million due to the decline in the stock price over the quarter.

Our target price is reduced as we update for balance sheet items, new shares issued and increases in warrants and options outstanding. Our previous target moves from $17.00 per share to $16.00 per share, which at current prices represents an approximate 150% upside.

Please review our prior reports including the one issued on May 2, 2106 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.

Since our previous report on May 9, InVivo has added two new clinical sites and received approval from the Canadian authorities to enroll patients in Canada. InVivo also received a Notice of Allowance for its patent entitled "Methods and Compositions for the Treatment of Open and Closed Wound Spinal Cord Injuries"

Also since our last report, the FDA provided its critically important consent to expand the INSPIRE trial to 20 patients. During the period of discussions with the FDA, InVivo chose to delay updates related to the study and enrollment of new patients as there were several minor modifications related to protocol and informed consent documents. This caused a several week delay which was necessary to implement the changes for new enrollees. As part of the review, the FDA recommended that a control arm be added as part of the study design. Being a control arm, and given the lack of alternative therapy, it is possible that existing data may be used to satisfy this requirement. However, at this time the determination of how to approach the recommended control arm has not been made and InVivo is still in discussions with the FDA to determine the best way to satisfy this recommendation.

In conjunction with the FDA output, NVIV also announced the 9th and 10th patients implanted with the Neuro-Spinal Scaffold. Unfortunately, the 10th patient died from a stroke several days after the implantation and the cause of death was determined to not be related to the NSS or the implantation procedure. Currently there are eight active implanted patients who have received the NSS, of which four have seen an improvement in AIS grade of one or more levels.

Estimates

We anticipate that InVivo will launch the Neuro-Spinal Scaffold (NSS) in 2018 following a successful approval of the device in 2017. Currently, the company expects to approach full enrollment in the trial by the end of the year. Concurrent with the approval process for the complete thoracic indication, InVivo 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.

Other Material Events Year to Date 2016

- On July 13, 2016, InVivo received approval from Health Canada to begin clinical studies in Canada. The following day, the company welcomed approval for Toronto Western Hospital to serve as a clinical site for the INSPIRE study. Michael Fehlings, M.D., Ph.D., will serve as the principal investigator. Dr. Fehlings presents a strong resume and is currently Director of the Spinal Program at Toronto Western Hospital at the University Health Network, Professor in the Department of Surgery, full member of the Institute of Medical Sciences School of Graduate Studies, a Scholar in the McLaughlin Centre of Molecular Medicine, a Scientist in the McEwen Centre for Regenerative Medicine, a Senior Scientist at the Krembil Research Institute, Director of the University of Toronto Neuroscience Program, Co-Director of the University of Toronto Spine Program, and Krembil Chair in Neural Repair and Regeneration. Dr. Fehlings has published over 400 peer-reviewed articles principally in the area of spinal cord injury and complex spinal surgery.

- 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.

- 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.

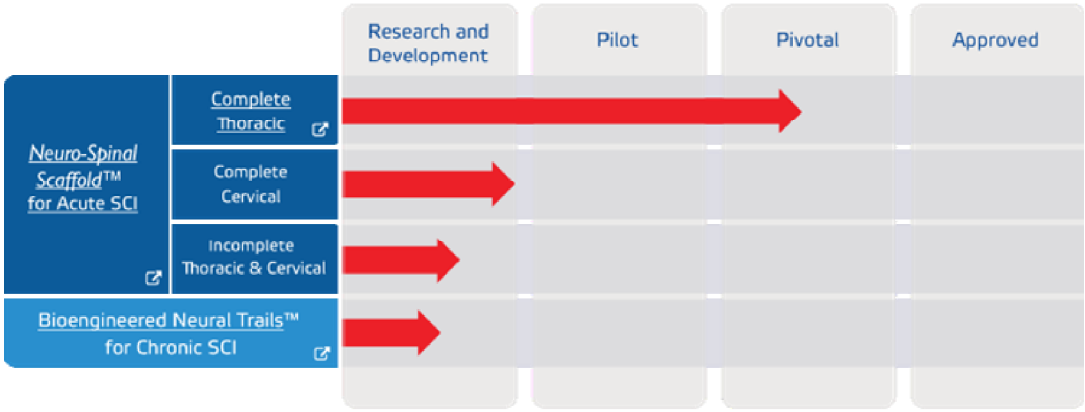
- The company has been fortunate to attend and announce attendance at a number of conferences, presenting to both investors and practitioners. So far in 2016, this includes the Biotech Showcase, the Cowen Health Care Conference, the Spine Summit, American Spinal Injury Association (ASIA) Annual Scientific Meeting, the Committee Roundtable on Biomedical Engineering Materials and Applications (BEMA), the American Association for Neurological Surgeons (AANS) and the Annual Symposium of the National Neurotrauma Society.

- InVivo has added several new clinical trial locations so far this year and now has 22 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
    - May 11, Hospital of the University of Pennsylvania, Philadelphia, PA
    - July 14, Toronto Western Hospital, Toronto, Canada
    - July 18, Ben Taub Hospital/Baylor College of Medicine, Houston, TX

- We anticipate that the complete thoracic program (the INSPIRE study) will complete 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 third quarter and is still in conversations with the FDA in terms of trial design. 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. 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 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.

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	4/26/2016 reports move from AIS A to AIS B
7	Mar-16	T3	Remains AIS A at 3 months
8	Apr-16		Died from injuries 2 days after implant
9	May-16	T3	In follow-up
10	May-16		Died from stroke several days after implant

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 patients to date 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 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 year end, however, they will have to accelerate their run rate to achieve this goal. With the addition of two sites in July, the probability of improving the number of patients increases.

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 June 30, 2016, InVivo held $42 million in cash on hand. The company, in our opinion conservatively, believes that the funds will meet operating and capital requirements through the end of 2017. We anticipate the $1.4 million monthly cash burn rate to increase slightly through the end of the year as new patients are added to the trial.

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, our target price declines slightly to $16 per share from $17 due to an increase in dilution from warrants and options and a decline in cash on the balance sheet. The DCF model applies 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 A	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	$2.8	$3.0	$3.2	$11.6	$15.0	$18.0
G&A	$12.3	$3.0	$3.0	$3.5	$3.7	$13.2	$16.0	$17.0
Operating Income	($22.4)	($5.6)	($5.8)	($6.5)	($6.9)	($24.8)	($31.0)	$16.5
Operating Margin	-	-	-	-	-	-	-	-
Net Other Income	($10.9)	($1.1)	$0.6	$0.0	$0.0	($0.5)	$0.0	$0.0
Pre-Tax Income	($33.3)	($6.6)	($5.2)	($6.5)	($6.9)	($25.2)	($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)	($5.2)	($6.5)	($6.9)	($25.2)	($31.0)	$16.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.26)**	**($0.24)**	**($0.16)**	**($0.19)**	**($0.20)**	**($0.78)**	**($0.86)**	**$0.44**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	26.5	28.2	31.9	34.4	35.0	32.4	36.0	37.0

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

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