Zacks Small-Cap Research

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# InVivo Therapeutics (NVIV-NASDAQ)

***5th Patient Converts to AIS B or Better; OPC Achieved; Target Price Up.***

Based on our DCF model and a 15% discount rate, NVIV is valued at approximately $18.00 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 (8/22/2016) | $7.77 |
| **Valuation** | **$18.00** |

## 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 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 the stock provides 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** | **$11.80** |
| **52-Week Low** | **$3.50** |
| **One-Year Return (%)** | **-21.0** |
| **Beta** | **3.55** |
| **Average Daily Volume (sh)** | **223,490** |
| **Shares Outstanding (mil)** | **31.9** |
| **Market Capitalization ($mil)** | **$248** |
| **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 Announces Fifth Patient Conversion to Incomplete AIS B**

On August 17, 2016, InVivo Therapeutics Holdings Corp. (NASDAQ: NVIV) announced that patient number nine had converted from a complete AIS A to an incomplete AIS B spinal cord injury in between the second and third month evaluations. This marks the fifth patient to improve at least one AIS grade of eight patients that are currently enrolled in the study. As a result of achieving this milestone, we increase the probability of ultimate FDA approval from 65% to 75% and increase our target price from $16.00 per share to $18.00 per share.

To assess probable benefit, InVivo along with the FDA established the objective performance criteria (OPC) in February of this year. The OPC was set at 25% or more of the patients in the INSPIRE study achieving an improvement of at least one AIS grade by six months post-implantation. This hurdle was established based on data from longitudinal, natural history databases. In large European and U.S. databases [European Multicenter Study about Spinal Cord Injury (EMSCI) - Zaffira *et al*., 2011; Spinal Cord Injury Model System (U.S. database) – Lee *et al*., 2014; Sygen clinical trial in spinal cord injury – Fawcett *et al*., 2007], the published rates of spontaneous improvement of at least one AIS grade for complete (AIS-A), thoracic SCI patients at six months are less than 16%.

Based on the current number of patients converted compared to the total number enrolled, the INSPIRE trial has a current success rate of 62.5%. Examining the target study size of 20 implanted patients, and five conversions, INSPIRE has achieved its OPC. Some investors are hopeful that InVivo may pursue an early approval with the FDA before completing the study with the full 20 patients. While this may be possible, we remind investors that the purpose of the trial is also to evaluate safety of the device. We anticipate that at this point the company will approach the FDA and evaluate their options based on feedback from the regulatory agency. If we continue to see conversions, we anticipate InVivo will have an increasingly stronger argument for an early filing.

**Estimates**

Our earnings and cash flow estimates do not change based on the 5th conversion; however, we do increase the probability that the Neuro-Spinal Scaffold (NSS) will eventually be approved from 65% to 75%. Our models forecasts a 2018 launch of the NSS following a successful approval of the device in 2017. Currently, the company expects to approach full enrollment in the trial by the end of 2016. 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**

- InVivo adds a 23rd clinical site to the INSPIRE study roster. On August 18, the company announced that Northwestern Medicine in Chicago, Illinois will be included in the trial's study locations.

- On August 11th, the company announced the appointment of Pamela Stahl to the role of Chief Commercial Officer. Her background and experience at UnitedHealth Group (NYSE: UNH) is a valuable asset in her efforts to build a comprehensive global commercial strategy for developing the company's sales, reimbursement, and marketing strategies.

- On July 13, 2016, InVivo received approval from Health Canada to begin clinical studies in Canada. The following day, the company added the Toronto Western Hospital to serve as a clinical site for the INSPIRE study.

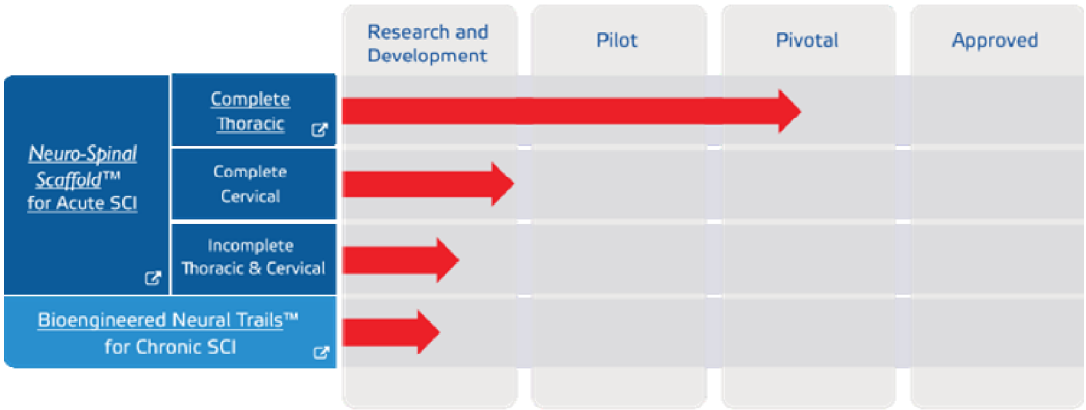
- On March 14, 2016, NVIV announced that it would offer common shares and warrants through Raymond James & Associates to fund the current and forthcoming clinical trials and support general corporate expenses. The offering, which included 0.5 warrant for every share, was priced at $7.50 per unit for 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.

- InVivo has added several new clinical trial locations so far this year and now has 23 sites that are participating in the INSPIRE study.

    - 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
    - August 18, Northwest Hospital, Chicago, IL

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. 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.




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 | 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. While some have postulated that this early success may indicate an early filing for approval due, 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 year end, however, they will have to accelerate their run rate to achieve this goal. With the addition of nine sites so far this year, 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 that the conversion of the fifth patient to AIS B incomplete status is an important milestone and justifies an increase in our target price. We raise the probability of ultimate sales of the NSS to 75% from our previous 65% rate and increase our target price to $18.00 from $16.00. 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, we endorse a price target of $18.00 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 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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