

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934**

**December 1, 2015**

Date of Report (Date of earliest event reported)

**INVIVO THERAPEUTICS HOLDINGS CORP.**

(Exact Name of Registrant as Specified in Charter)

**Nevada**

(State or Other

Jurisdiction of Incorporation)

**001-37350**

(Commission File Number)

**36-4528166**

(IRS Employer

Identification No.)

**One Kendall Square, Suite B14402**

**Cambridge, Massachusetts 02139**

(Address of Principal Executive Offices) (Zip Code)

**(617) 863-5500**

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 5.02      Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On December 1, 2015, the Compensation Committee of the Board of Directors (the "Board") of InVivo Therapeutics Holdings Corp. (the "Company") recommended, and the Board approved, the extension of corporate housing benefits for Mark Perrin, the Company's Chief Executive Officer, for up to an additional 12 months.

**Item 8.01      Other Events.**

On December 3, 2015, the Company issued a press release announcing that it has received conditional approval from the U.S. Food and Drug Administration to convert its ongoing pilot study into a pivotal probable benefit study. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

*Cautionary Note Regarding Forward-Looking Statements*

This Current Report on Form 8-K and the press release filed herewith contain forward-looking statements within the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements" for purposes of these provisions, and include statements regarding conditional approval of the company's pivotal probable benefit study and the expected timing of enrollment in the study and subsequent HDE approval and commercialization. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties that could cause future results to differ materially from current expectations, including company's ability to obtain final approval from the FDA and to successfully open additional clinical sites for enrollment and to enroll additional patients; the timing of the Institutional Review Board process; the company's ability to commercialize its products; the expected benefits and efficacy of the company's products and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for the company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and other risks associated with the company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. Given these uncertainties, investors should not place undue reliance on these forward-looking statements. Additional risk factors are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, and other filings the Company makes with the Securities and Exchange Commission, including quarterly reports on Form 10-Q and current reports on Form 8-K. All forward-looking statements included in this Current Report on Form 8-K and the press release filed herewith are made

as of the date hereof, based on information available to the Company as of the date of this report, and the Company assumes no obligation to update any such forward-looking statements, except as required by law

**Item 9.01            Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 3, 2015.
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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: December 3, 2015

By:            /s/ Tamara Joseph  
Name:        Tamara Joseph  
Title:        SVP, General Counsel & Chief Compliance Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated December 3, 2015.
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InVivo Therapeutics Announces Conditional Approval for INSPIRE Pivotal Probable Benefit Clinical Study of the *Neuro-Spinal Scaffold*™

**CAMBRIDGE, Mass. (Dec 3, 2015) — InVivo Therapeutics Holdings Corp. (NVIV)** announced it has received conditional approval of a study protocol amendment from the U.S. Food and Drug Administration (FDA) that will convert its ongoing pilot study into a pivotal probable benefit study. The approval is conditional solely upon a minor change to the informed consent form that has already been submitted to the FDA. Full approval of the amendment is expected in the next 30 days.

With this transition, the study will be known formally as “The **INSPIRE** Study: **InVivo** Study of Probable Benefit of the *Neuro-Spinal Scaffold* for Safety and Neurologic **R**ecovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury.” The INSPIRE Study is designed to enroll 20 implanted patients, inclusive of the five patients already enrolled. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one ASIA Impairment Scale (AIS) grade at 6 months post-implantation.

The INSPIRE study is conditionally approved to enroll up to 12 patients, but InVivo expects that the FDA will approve the full 20 patients following the review of 6-month safety data for the first five patients. The company plans to submit these data in the second quarter of 2016.

An objective performance criterion (OPC) for the study to support probable benefit using historical benchmarks is under discussion with the FDA. In large European and US databases, the published rates of spontaneous improvement of at least one AIS grade in complete (AIS A), thoracic SCI patients at 6 months are less than 16%. An additional study protocol amendment may be required to establish the OPC.

The inclusion criteria have also been broadened to include patients with T2 injuries (new range T2-T12/L1) and ages 16-17 (new range 16-70). The FDA has also agreed to increase the total number of allowable U.S. sites to 40. In addition to the U.S. sites, the company plans to initiate the study in Canada and the United Kingdom with the intent to include patients enrolled at ex-U.S. sites as part of the 20 patient study.

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“This conditional approval marks one of the most significant corporate milestones the company has achieved to date. Being able to convert our pilot study into a small pivotal probable benefit study provides us with a very efficient path to commercialization,” said Mark Perrin, Chief Executive Officer and Chairman. “We anticipate completing enrollment in the pivotal probable benefit study and submitting an application for Humanitarian Device Exemption (HDE) approval in 2017.”

The company will continue to announce the enrollment of each patient and any conversions of AIS classification as well as any other dramatically positive or negative events. The company will also seek to communicate interim results at various scientific and medical meetings. The company does not consider a patient’s unchanged AIS classification or a medically insignificant adverse event to be material.

The company will discuss the details of the pivotal probable benefit study during tonight’s KOL Event and Company Update webcast, which begins at 5:15PM ET and will be broadly accessible through [lifesci.rampard.com/20151203](http://lifesci.rampard.com/20151203).

### About the *Neuro-Spinal Scaffold*™

Following an acute spinal cord injury, the biodegradable *Neuro-Spinal Scaffold* is surgically implanted at the epicenter of the wound and is designed to act as a physical substrate for nerve sprouting. Appositional healing to spare spinal cord tissue, decreased post-traumatic cyst formation, and decreased spinal cord tissue pressure have been demonstrated in preclinical models of spinal cord contusion injury. The *Neuro-Spinal Scaffold*, an investigational device, has received a Humanitarian Use Device (HUD) designation and is currently being studied in an Investigational Device Exemption (IDE) study for the treatment of patients with complete (AIS A) traumatic acute spinal cord injury.

### About InVivo Therapeutics

InVivo Therapeutics Holdings Corp. is a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries. The company was founded in 2005 with proprietary technology co-invented by Robert Langer, Sc.D., Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, M.D., who then was at Boston Children’s Hospital and who now is affiliated with Massachusetts General Hospital. In 2011, the company earned the David S. Apple Award from the American Spinal Injury Association for its outstanding contribution to spinal cord injury medicine. In 2015, the company’s investigational *Neuro-Spinal Scaffold* received the 2015 Becker’s Healthcare Spine Device Award. The publicly-traded company is headquartered in Cambridge, MA. For more details, visit [www.invivotherapeutics.com](http://www.invivotherapeutics.com).

### Safe Harbor Statement

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as “believe,” “anticipate,” “intend,” “estimate,” “will,” “may,” “should,” “expect,” “designed to,” “potentially,” and similar expressions, and include statements regarding the FDA’s conditional approval of the company’s pivotal probable benefit study, the expected timing of the FDA’s full approval, and the expected timing of completion of enrollment in the study and subsequent application for HDE approval and commercialization. Any forward-looking statements contained herein are based on current expectations, and are subject to

*a number of risks and uncertainties. Factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the company's ability to successfully open additional clinical sites for enrollment and to enroll additional patients; the timing of the Institutional Review Board process;*

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*the company's ability to obtain FDA approval to modify its pilot trial protocol or to conduct a future study; the company's ability to commercialize its products; the company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the company's products and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for the company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and other risks associated with the company's business, research, product development, regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the company's Annual Report on Form 10-K for the year ended December 31, 2014, and its other filings with the SEC, including the company's Form 10-Qs and current reports on Form 8-K. The company does not undertake to update these forward-looking statements.*

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