

**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

July 12, 2016

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))

Item 7.01. Regulation FD Disclosure.

On July 12, 2016, InVivo Therapeutics, Inc. (the "Company") issued a press release announcing an update on its INSPIRE study of the *Neuro-Spinal Scaffold™* as well as FDA approval of expansion of the INSPIRE study to 20 evaluable patients. A copy of this press release is attached hereto as Exhibit 99.1. In addition, on July 12, 2016, the Company posted an updated corporate presentation in the "Investor Relations" section of its website at www.invivotherapeutics.com.

The information included in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated July 12, 2016 (furnished and not filed for purposes of Item 7.01)

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: July 12, 2016

By: /s/ Tamara Joseph

Name: Tamara Joseph

Title: SVP, General Counsel & Chief Compliance Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 12, 2016 (furnished and not filed for purposes of Item 7.01)

**CONTACT:**

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InVivo Therapeutics Announces Update on the INSPIRE Study and FDA Approval of Expansion of the Study to 20 Evaluable Patients

CAMBRIDGE, Mass. (July 12, 2016) — **InVivo Therapeutics Holdings Corp. (NVIV)** today provided an update on the INSPIRE study of the *Neuro-Spinal Scaffold*™.

Patient Enrollments

InVivo announced that the 9th and 10th patients have been implanted with the *Neuro-Spinal Scaffold* in the INSPIRE study. The 9th patient was implanted at Vidant Medical Center, a Level 1 trauma center located in Greenville, North Carolina. The implantation was performed by Vidant Medical Group neurosurgeons Stuart Lee, M.D., the Principal Investigator at the site, and Hilal Kanaan, M.D., approximately 40 hours after the injury occurred. Dr. Lee said, "The implantation procedure went smoothly and the patient is doing well. We are excited to be a part of the INSPIRE study and look forward to following the patient's progress."

The 10th patient was implanted approximately 18 hours after the injury by Domagoj Coric, M.D., of Carolina Neurosurgery and Spine Associates, Chief of Neurosurgery at the Carolinas Medical Center and a member of the INSPIRE Study Steering Committee. Dr. Coric and Dr. William Bockenek, Chief Medical Officer at Carolinas Rehabilitation, are Co-principal Investigators at this site. Regrettably, the 10th patient died from a stroke several days after the implantation procedure. The cause of death was deemed by Dr. Coric and the Chairman of the DSMB to be unrelated to the *Neuro-Spinal Scaffold* or the implantation procedure.

Mark Perrin, InVivo's Chief Executive Officer and Chairman, said, "We express our condolences to the family of the patient who passed away. Each loss of an individual with a spinal cord injury strengthens our resolve to develop and bring to market new treatments that will improve the lives of patients with these devastating injuries."

Expansion of INSPIRE Study

As previously communicated, the INSPIRE study was approved originally to enroll 12 patients pending review of six-month safety data from the first five patients implanted with the *Neuro-Spinal Scaffold*. In addition to the 10 implanted patients, two patients were screen failures, which means that the patients consented to participate in the study but failed to meet all of the inclusion and exclusion criteria of the study. Although these two screen failure patients were not implanted with the *Neuro-Spinal Scaffold*, they were technically enrolled into the INSPIRE study. Therefore, the study had enrolled 12 patients by the end of May (when the 10th patient was implanted by Dr. Coric) and the enrollment of additional patients required action from the FDA.

After reviewing the six-month safety data, the FDA requested minor modifications to the INSPIRE study protocol and informed consent documents. These modifications are being incorporated, and the FDA has approved the enrollment of additional patients to allow for 20 evaluable patients (with six months of follow up data) in the INSPIRE study. Because of the frequent interactions with the FDA over the last several weeks regarding relatively minor modifications, InVivo chose to postpone updates on the INSPIRE study until there was clarity regarding the path forward. "We are pleased that the FDA has approved expansion of the INSPIRE study that clears the way for enrolling all 20 evaluable patients," Mr. Perrin said. "While the pause in enrollment for the last several weeks was unfortunate, this approval is an important step toward our goal of approaching full enrollment of the INSPIRE study by the end of the year."

During the interactions regarding the expansion of the INSPIRE study, the FDA also recommended that InVivo include a control arm in the study as part of a Study Design Consideration. Mr. Perrin said, "As is typical of the regulatory process, we have addressed a number of Study Design Considerations regarding the INSPIRE study and its pilot precursor study over the last two years. We have begun a constructive discussion with the FDA regarding this Study Design Consideration, and we will provide an update if substantial changes are made to the study protocol. We continue to believe that our current study design is sufficient to demonstrate safety and probable benefit in support of a Humanitarian Device Exemption (HDE) application for marketing approval. Given the encouraging results that we have observed to date, we look forward to working with the FDA to complete the INSPIRE study as efficiently as possible."

About The INSPIRE Study

The **INSPIRE Study: InVivo Study of Probable Benefit of the *Neuro-Spinal Scaffold*™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury**, is designed to demonstrate the safety and probable benefit of the *Neuro-Spinal Scaffold*™ for the treatment of complete T2-T12/L1 spinal cord injury in support of a Humanitarian Device Exemption (HDE) application for approval. For more information, refer to <https://clinicaltrials.gov/ct2/show/study/NCT02138110>.

About the *Neuro-Spinal Scaffold*™ Implant

Following acute spinal cord injury, surgical implantation of the biodegradable *Neuro-Spinal Scaffold* within the decompressed and debrided injury epicenter is intended to support appositional healing, thereby reducing post-traumatic cavity formation, sparing white matter, and allowing neural regeneration across the healed wound epicenter. The *Neuro-Spinal Scaffold*, an investigational device, has received a Humanitarian Use Device (HUD) designation and currently is being evaluated in the INSPIRE pivotal probable benefit 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.

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 safety and effectiveness of the Neuro-Spinal Scaffold, the pace of enrollment and anticipated completion of enrollment of additional patients in the INSPIRE study. 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; whether the company will be required to include a control arm in the INSPIRE study and any resulting impact on the timing and completion of the INSPIRE study and approval of any HDE application; the expected timing of completion of enrollment in the INSPIRE study and submission of a HDE application; the timing of the Institutional Review Board process; the company’s ability to obtain FDA approval of a HDE application for its Neuro-Spinal Scaffold; 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, 2015, 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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