# 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 13, 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 13, 2016, InVivo Therapeutics, Inc. (the "Company") issued a press release announcing that Health Canada has approved the Company's Investigational Testing Authorization application to commence clinical studies in Canada. A copy of this press release is attached hereto as Exhibit 99.1. In addition, on July 13, 2016, the Company posted an update to the "CEO's Perspective" section of its website entitled "Epidemiology and Market Opportunity Around the World" at *www.invivotherapeutics.com/about-invivo/ceo-perspective/*.

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 13, 2016 (furnished and not filed for purposes of Item 7.01)
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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.

By: /s/ Tamara Joseph

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

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## EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 13, 2016 (furnished and not filed for purposes of Item 7.01)
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CONTACT: Brian Luque (617) 863-5535 Investor Relations bluque@invivotherapeutics.com

## InVivo Therapeutics Receives Investigational Testing Authorization from Health Canada

**CAMBRIDGE, Mass. (July 13, 2016)** — **InVivo Therapeutics Holdings Corp. (NVIV)** today announced that Health Canada has approved the company's Investigational Testing Authorization application to commence clinical studies in Canada. The authorization will allow the company to enroll Canadian patients into the ongoing INSPIRE study once a Canadian site is open for enrollment. InVivo currently is in late stage conversation with various Canadian Research Ethics Boards and expects to announce its first Canadian site in the coming weeks.

"The Canadian scientific and medical community recognizes spinal cord injury as a significant unmet medical need and has been at the forefront of researching potential therapies for years," Mark Perrin, InVivo's CEO and Chairman, said. "Partnering with countries and institutions that share our commitment to advancing the field is a significant step in furthering the company's global mission: to redefine the life of the spinal cord injury patient."

A new CEO's Perspective discussing spinal cord injury incidence and prevalence around the world, including Canada, can be found on the InVivo Therapeutics website: http://www.invivotherapeutics.com/about-invivo/ceo-perspective/

## About The INSPIRE Study

The **INSPIRE** Study: **In**Vivo Study of Probable Benefit of the *Neuro-Spinal Scaffold*<sup>TM</sup> for Safety and Neurologic **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury, is designed to demonstrate the safety and probable benefit of the *Neuro-Spinal Scaffold*<sup>TM</sup> 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*<sup>™</sup> 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, progress toward achievement of OPC for The INSPIRE Study, the expected timing of full enrollment in the study, the ability of the company to open a site in Canada or enroll patients in Canada, and the timing of the submission of the Humanitarian Device Exemption (HDE). 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; the impact of achieving the OPC on the FDA approval process; the company's roducts and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for the company 's products and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for 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 8-K. The company does not undertake to update these forward-looking statements.