INVIVO THERAPEUTICS HOLDINGS CORP.
Form 8-K
January 03, 2018

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

January 3, 2018

Date of Report (Date of earliest event reported)

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as Specified in Charter)

Nevada	**001-37350**	**36-4528166**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 7.01 **Regulation FD Disclosure.**

On January 3, 2018, InVivo Therapeutics Holdings Corp. (the Company) issued a press release announcing certain updates on its clinical development program, including The INSPIRE Study and a proposed randomized controlled trial. A copy of the press release is furnished herewith. Also on January 3, 2018, the Company posted an updated corporate presentation in the Investor Relations section of its website at www.invivotherapeutics.com. The information contained in this Item 7.01 is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities under that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. **Other Events.**

On January 3, 2018, the Company announced the latest results from 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). The primary endpoint of the study is defined as improvement in ASIA Impairment Scale (AIS) grade from baseline for all evaluable patients at the six-month visit. Nineteen patients have been implanted with the *Neuro-Spinal Scaffold*. Three patients died within two weeks of implantation. The 16 evaluable patients have now all reached the six-month primary endpoint visit. Seven of the 16 (43.8%) evaluable patients had an AIS grade improvement from baseline at six months. The Objective Performance Criterion (study success definition) for the study was a 25% AIS conversion rate based on the published conversion rates for thoracic spinal cord injury (SCI) reported in the literature.

The most recent patient to reach the primary endpoint visit was assessed to be AIS C (motor incomplete) at six months, meaning that some motor function was detected at the sacral level. Of the seven INSPIRE patients who had AIS improvements at six months, five patients improved from complete AIS A SCI to sensory incomplete AIS B SCI, and two patients improved from complete AIS A SCI to motor incomplete AIS C SCI. Two of the five patients who were assessed to be AIS B at six months later improved to AIS C at 12 or 24 months.

In July 2017, enrollment of patients in The INSPIRE Study was placed on hold following the third patient death. Although the Company and the respective site principal investigators believe these deaths were not related to the *Neuro-Spinal Scaffold* investigational device, the Company is in discussions with the United States Food and Drug Administration to ensure that these cases have been comprehensively evaluated and to ensure that all appropriate risk mitigation measures have been implemented. As part of those ongoing discussions, the Company has proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold*. The Company does not anticipate reopening enrollment in INSPIRE and expects to provide additional clarity on its clinical path forward in the second quarter of 2018.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
99.1*	Press release issued by the Company on January 3, 2018

*This exhibit is being furnished and shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Cautionary Note on Forward Looking Statements

Any statements contained in this 8-K 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, e designed to, potentially, and similar expressions, and include statements regarding the status of the Company s clinical program. 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 discussions and engagement with the United States Food and Drug Administration; the Company s ability to initiate, conduct and complete clinical trials; the expected benefits and potential 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 trials and future product commercialization; and other risks associated with the Company s business, research, product development, attainment of regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the Company s Quarterly Report of the three months ended September 30, 2017, and its other filings with the SEC, including the company s most recent Form 10-K, its Form 10-Qs and its current reports on Form 8-K. The Company does not undertake to update these forward-looking statements.

SIGNATURE

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: January 3, 2018

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