INVIVO THERAPEUTICS HOLDINGS CORP.
Form 8-K
April 13, 2017

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

April 13, 2017

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))

Item 7.01. Regulation FD Disclosure.

On April 13, 2017, InVivo Therapeutics, Inc. (the Company) posted an updated corporate presentation in the Investor Relations section of its website at *www.invivotherapeutics.com*.

Item 8.01. Other Events.

On April 13, 2017, the Company announced that it intends to amend its protocol for The INSPIRE Study to include an additional arm (the Benchmark Arm) in order to gather baseline and outcome measures on thoracic, complete spinal cord injury patients. The Company plans to include those patients who have presented at INSPIRE sites since January 1, 2016 but who were excluded from The INSPIRE Study because they did not meet all inclusion criteria or who presented before the sites opened or were enrolling patients. The Company estimates that 20 to 40 additional patients will participate in the Benchmark Arm, and does not expect the Benchmark Arm to impact the timeline for The INSPIRE Study. The Company plans to submit the amended protocol to the United States Food and Drug Administration in the second quarter of 2017.

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, expect, designed to, potentially, and similar expressions, and include statements regarding the Company s plans with respect to the protocol for The INSPIRE Study, its ability to amend such protocol, and the ability of the Company to enroll patients in the Benchmark Arm. 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 enroll patients in The INSPIRE Study, including the Benchmark Arm; the timing of the Institutional Review Board process; the impact of any amendments to The INSPIRE Study protocol on the FDA approval process, including whether the Benchmark Arm will be acceptable to the FDA and sufficient to support the Company s humanitarian device exemption (HDE) application; 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, 2016, and its other filings with the SEC. The Company does not undertake to update these forward-looking statements.

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: April 13, 2017

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