

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 8-K

November 21, 2013

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

November 21, 2013

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)

000-52089
(Commission
File Number)
One Kendall Square, Suite B14402

36-4528166
(IRS Employer
Identification No.)

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 November 21, 2013, InVivo Therapeutics Holdings Corp. (the Company) submitted a filing to the FDA containing proposed changes to its FDA-approved protocol and supporting documents for its scaffold program to treat spinal cord injuries. An FDA guidance document provides that the agency will try to respond to such filings within thirty days. The Company believes that approval of the proposed changes would accelerate the progress of its clinical trial for the scaffold product by eliminating barriers to enrollment and by expanding the number of sites from at least three to as many as six.

Safe Harbor Statement

Any statements contained in this Form 8-K that do not describe historical facts may constitute forward-looking statements within the meaning of the federal securities laws. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties, and include statements regarding the Company's expectations with respect to the impact that the revised protocol would have on the progress of the clinical trials. The 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 obtain FDA approval of its revised protocol and the timing thereof; the identification of appropriate clinical sites; the Institutional Review Board process; the Company's ability to enter into partnerships; the Company's ability to obtain FDA approval 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 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 filings with the SEC, including the Company's Form 10-K and 10-Qs and its current reports on Form 8-K. 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: November 21, 2013

By: /s/ Michael J. Astrue
Michael J. Astrue
Interim Chief Executive Officer