

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 8-K

January 04, 2019

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 4, 2019

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)

(Former name or former address, if changed since last report)

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))

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

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.

Item 7.01. Regulation FD Disclosure.

On January 4, 2019, InVivo Therapeutics Holdings Corp. (the “Company”) posted an updated corporate presentation in the “Investor Relations” section of its website at [www.invivotherapeutics.com](http://www.invivotherapeutics.com).

Item 8.01. Other Events.

On January 4, 2019, the Company announced an updated projected clinical timeline, specifically that it anticipates enrolling its first patient in the INSPIRE 2.0 study in the first quarter of 2019.

Safe Harbor Statement

Any statements contained in this Current Report on Form 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” and similar expressions, and include statements regarding enrollment in the INSPIRE 2.0 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 need to raise additional capital, to successfully decrease costs and spend and to successfully open clinical sites for enrollment and to enroll additional patients if such study is initiated; the timing of the Institutional Review Board process; 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 Annual Report on Form 10-K for the year ended December 31, 2017, the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2018 and its other filings with the SEC, including the Company’s quarterly reports on Form 10-Q and current reports on Form 8-K. The Company does not undertake to update these forward-looking statements.

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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.

/a

INVIVO THERAPEUTICS HOLDINGS  
CORP.

Date: January 4, 2019 By: /s/ Richard Toselli  
Name: Richard Toselli  
Title: President and Chief Executive Officer

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