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

June 2, 2022
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):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	NVIV	The Nasdaq Capital Market

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 8.01. Other Events

On June 2, 2022, InVivo Therapeutics Holdings Corp. (the "Company") issued a press release announcing that the Company has completed enrollment in its INSPIRE 2.0 Study for acute spinal cord injury. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 2, 2022, of InVivo Therapeutics Holdings Corp.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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: June 2, 2022

By: /s/ Richard Toselli
Name: Richard Toselli, M.D.
Title: Chief Executive Officer

Exhibit 99.1

InVivo Therapeutics Announces Completion of Enrollment for the INSPIRE 2.0 Acute Spinal Cord Injury Study

Topline data expected to be reported in Q1 2023

CAMBRIDGE, Mass – June 2, 2022 – InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV), a research and clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries, today announced that it has completed enrollment in the INSPIRE 2.0 Study for patients with acute spinal cord injury. The 20-patient study is a randomized, controlled trial featuring 10 subjects in each study arm, designed to enhance the existing clinical evidence for the Neuro-Spinal Scaffold™ from the Company's INSPIRE 1.0 study.

"Reaching full enrollment in our INSPIRE 2.0 study is a significant advancement in our research and development efforts towards a potential treatment for spinal cord injury," said Richard Toselli, M.D., InVivo's President and Chief Executive Officer. "We're grateful to the study participants, as well as the clinicians, investigators, and staff who have worked relentlessly to make this possible, and of course to our team at InVivo. We're very excited to be continuing towards our goal of serving this patient population and expect to present topline data from the study in Q1 of 2023."

Kee Kim, M.D., Professor and Chief of Spinal Neurosurgery at UC Davis, Sacramento, CA, and a Principal Investigator in the INSPIRE 2.0 Study, stated "Completing patient enrollment in the INSPIRE 2.0 Study is a major milestone for the spinal cord injury community, and I am pleased to have had the opportunity to help improve potential treatment options for this underserved patient population."

For more details on the Company's INSPIRE 2.0 Study, please visit this link.

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. 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” and similar expressions, and include statements regarding the company’s expectation regarding the timing for the announcement of topline data and ability to serve the spinal cord injury patient population. 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 obtain additional funding to support the ongoing clinical and potential commercialization program for the investigational Neuro-Spinal Scaffold™, the varied interpretation of clinical data, the timing, cost and expense of regulatory filings, the potential for regulatory authorities granting or delaying approval for our Neuro-Spinal Scaffold, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and in other filings that the company may make with the Securities and Exchange Commission in the future. The company does not undertake to update these forward-looking statements.

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