

**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

March 9, 2023

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)

N/A

(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))

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 March 9, 2023, InVivo Therapeutics Holdings Corp. (the “Company”) issued a press release announcing initial data from the INSPIRE 2.0 Study for acute spinal cord injury. A copy of the 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 March 9, 2023, of InVivo Therapeutics Holdings Corp.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: March 9, 2023

By: /s/ Richard Toselli

Name: Richard Toselli

Title: President and Chief Executive Officer

INVIVO

THERAPEUTICS

InVivo Therapeutics Announces Topline Data from Pivotal INSPIRE 2.0 Study in Acute Spinal Cord Injury

Study did not achieve primary endpoint of defined improvement on standard impairment scale

InVivo to evaluate full data set and strategic options for the company

CAMBRIDGE, Mass – March 9, 2023 – 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 (SCI), today announced topline results from the company’s INSPIRE 2.0 study, which was designed to evaluate the safety and probable benefit of InVivo’s investigational Neuro-Spinal Scaffold™, a bioresorbable scaffold-based device in development for patients with acute SCI. The study did not meet its primary endpoint, which was assessed by the proportion of treated patients achieving an improvement of at least one American Spinal Injury Association (ASIA) Impairment Scale (“AIS”) grade at six months post-scaffold implantation, versus a control group that received standard of care surgery.

“We are disappointed by the outcome of this study as treatments for spinal cord injury are so urgently needed and we know many in the SCI patient and advocate community wait in hope for therapeutic options. We have rigorously pursued the science and believe that, upon full assessment, the INSPIRE 2.0 data set will provide a significant addition to the clinical literature around the treatment of SCI,” said Richard Toselli, M.D., InVivo’s President and Chief Executive Officer. “I extend our deepest thanks to our patients and clinical sites who have supported InVivo’s work to bring our science to patients, and the InVivo team who have tirelessly pursued our mission.”

InVivo management will conduct a full assessment of the study data set and plans to share its findings in full in a peer-reviewed medical venue at a later date. The company will also evaluate its strategic options and provide an update on corporate direction when appropriate.

About InVivo Therapeutics

InVivo Therapeutics is a clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. The company was founded in 2005 with proprietary technology co-invented by Robert Langer, Sc.D., and Joseph P. Vacanti, M.D. InVivo 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 assessment of the full INSPIRE 2.0 data set and evaluation of strategic options. 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 its ability to identify strategic options and other risks identified and described in more detail in the company's Annual Report on Form 10-K for the year ended December 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.

Contacts

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