# 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

Date of Report (Date of earliest event reported): July 7, 2011

# **INVIVO THERAPEUTICS HOLDINGS CORP.**

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation) 000-52089 (Commission File No.) 36-4528166 (IRS Employer Identification No.)

One Broadway, 14th Floor Cambridge, Massachusetts (Address of principal executive offices)

02142 (Zip Code)

(617) 475-1520 (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:

□ 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)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

On July 7, 2011, InVivo Therapeutics Holdings Corp. (the "Registrant") issued a press release announcing that the Registrant submitted an Investigational Device Exemption to the U.S. Food and Drug Administration for a proprietary biopolymer scaffolding device to protect and support spinal tissue and prevent secondary injury following traumatic spinal cord injury. A copy of the press release is filed as Exhibit 99.1 to this current report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The exhibit listed in the Exhibit Index below is filed with this report.

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.

By: /s/ Frank M. Reynolds

Frank M. Reynolds Chief Executive Officer

Date: July 8, 2011

## EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release of the Registrant, dated July 7, 2011.



#### InVivo Therapeutics Submits IDE Application to FDA for Spinal Cord Injury Clinical Trial

**CAMBRIDGE, Mass. (July 7, 2011) – InVivo Therapeutics (OTC/BB: NVIV)** today announced that the Company has submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for a proprietary biopolymer scaffolding device to protect and support spinal tissue and prevent secondary injury, including inflammation and glial scarring, following traumatic spinal cord injury.

The Company has requested permission to initiate an open-label study of 10 patients with acute spinal cord injuries within several days of injury. As currently planned, patients will be enrolled in the pilot trial at sites in Boston and Washington, D.C. under Principal Investigators Eric Woodard, M.D., InVivo's Chief Medical Officer and Chief of Neurosurgery at New England Baptist Hospital, and Jonathan Slotkin, M.D., neurosurgeon at Washington Brain & Spine Institute. Patients will subsequently be transferred to a rehabilitation center and will be followed for one year.

The trial will evaluate safety data as the primary endpoint. Motor and sensory recovery, as determined by the American Spinal Injury Association (ASIA) Impairment Score, will also be assessed as secondary endpoints.

"InVivo's first regulatory submission for human testing is a major step forward in realizing the promise of our technology for spinal cord injury patients," said Frank Reynolds, Chief Executive Officer of InVivo Therapeutics. "While current procedures offer very little hope, we have seen evidence of functional recovery in our preclinical non-human primate studies that supports advancement to human trials. Our goal for this initial study is to safely minimize the secondary injury processes, thereby allowing the body to reorganize locally toward functional recovery through the spared healthy tissue. This process, known as neuroplasticity, may result in partial functional recovery."

The InVivo investigational device is a biopolymer scaffold implant that will be customized by a neurosurgeon to fit the spinal cord lesion, and then implanted into the patient's spinal cord. The scaffold biodegrades within the body at a controlled rate over approximately 12 weeks.

In addition to the scaffold, InVivo is developing and testing its second product, an injectable hydrogel intended as a minimally invasive option to deliver agents locally.

#### **About InVivo Therapeutics**

InVivo Therapeutics Holdings Corp. is a Cambridge, MA medical device company focused on utilizing polymers as a platform technology to develop treatments to improve function in individuals paralyzed as a result of traumatic spinal cord injury. The company was founded in 2005 on the basis of proprietary technology co-invented by Robert Langer, ScD, Professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, MD, who is affiliated with Massachusetts General Hospital in Boston.

#### 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. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and

uncertainties. 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 sell additional shares of common stock, 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, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC, including, our Form 10-K and Form 10-Q and our current reports on Form 8-K. We do not undertake to update these forward-looking statements made by us.

#### **Contact InVivo Therapeutics:**

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