# 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): May 16, 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)

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 2.02 Results of Operations and Financial Condition.

On May 16, 2011, InVivo Therapeutics Holdings Corp. (the "Registrant") reported its results of operations for its fiscal quarter ended March 31, 2011. A copy of the press release issued by the Registrant concerning the foregoing results is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The exhibit listed in the Exhibit Index below is furnished 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.

Date: May 16, 2011

By: /s/ Frank M. Reynolds Frank M. Reynolds Chief Executive Officer

### EXHIBIT INDEX

#### Exhibit No. Description

99.1 Press Release of the Registrant, dated May 16, 2011.



Contact:

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#### InVivo Therapeutics Reports First Quarter 2011 Financial Results

CAMBRIDGE, Mass. – May 16, 2011 – InVivo Therapeutics (NVIV.OB), a medical device company focused on the development of groundbreaking technologies for the treatment of spinal cord injuries (SCI), today reported financial results for the first quarter 2011.

For the three months ended March 31, 2011, the Company reported a net loss of \$1,278,000, or \$.02 per share, compared to a net loss of \$454,000, or \$.02 per share, for the quarter ended March 31, 2010. Operating expenses increased by \$1,018,000 in the first quarter of 2011 as compared to the prior year as the Company made investments to expand infrastructure and capabilities to support a planned human clinical trial, and incurred costs associated with public company practices. The Company ended the first quarter of 2011 with \$6,864,000 in cash.

"We are proud that InVivo has been able to maintain a low cost R&D model even after becoming a public company," said Frank Reynolds, InVivo's Chief Executive Officer. "Our first quarter was marked by a number of significant achievements and milestones. We have moved our lead biopolymer scaffolding product closer to commercialization and our management team has been preparing for the commencement of human clinical trials. InVivo's technology holds great promise for SCI patients: in a number of preclinical SCI models our biopolymer scaffolding devices improved functional recovery following paralysis. Today there is no effective treatment for spinal cord injuries, and we estimate the market potential to be over \$10 billion."

#### **Recent Highlights**

#### • Moved forward on biopolymer scaffolding device for SCI.

The Company has been diligently preparing for human studies and has developed a solid clinical protocol. InVivo expects to file an Investigational Device Exemption with the FDA and commence a trial before year-end.

#### • Formed a strategic partnership with The Miami Project To Cure Paralysis to develop novel SCI treatments.

In Vivo's partnership with The Miami Project To Cure Paralysis, the world's most comprehensive spinal cord injury center, will evaluate In Vivo's biopolymer devices synergistically combined with the Miami Project's Schwann cells, other cellular therapies and drugs. The alliance has the potential to expand In Vivo's pipeline with products for the

chronic spinal cord injury population. InVivo has rights to jointly develop any resulting intellectual property and has a first right of offer to license and commercialize any intellectual property developed by the Miami Project.

#### • Received prestigious Apple Award for top publication in SCI research.

The Company was recently selected by the American Spinal Injury Association as the 2011 recipient of the prestigious Apple Award that recognizes excellence in SCI research. InVivo's seminal publication (2010 Journal of Neuroscience Methods, 188,258,269) reported compelling preclinical results with InVivo's lead biopolymer scaffolding device. InVivo made history when it became the first company to demonstrate improvement in functional recovery after paralysis was induced in a non-human primate SCI model.

#### Announced data on novel hydrogel technology.

The Company announced the presentation of data at the 2011 Annual Meeting of the American Association of Neurological Surgeons/Central Nervous System Section on Disorders of the Spine and Peripheral Nerves. Eric J. Woodard, M.D., InVivo Therapeutics Chief Medical Officer and Chief of Neurosurgery, New England Baptist Hospital, co-authored and presented the poster titled "An injectable thiol-acrylate poly(ethylene glycol) hydrogel for sustained release of methylprednisolone sodium succinate for treatment of spinal cord injury and in neurosurgical applications." The laboratory investigation was designed to evaluate the potential of the Company's hydrogel to overcome limitations associated with systemic administration of high-dose methylprednisolone (MP), a steroid commonly used in the treatment of SCI.

For more information about this press release, please visit http://nviv.irnewsroom.com/news-and-media or click here.

#### **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. For more information on InVivo Therapeutics, please visit <u>www.invivotherapeutics.com</u>.

#### 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.

## InVivo Therapeutics Holdings Corp. Consolidated Statements of Operations

		Three Months Ended March 31,	
	2011	2010	
Operating expenses:			
Research and development	\$ 636,323	\$ 157,384	
General and administrative	764,319	224,670	
Total operating expenses	1,400,642	382,054	
Operating loss	(1,400,642)	(382,054)	
Other income (expense):			
Other income	—	—	
Interest income	2,818	87	
Interest expense	(1,513)	(72,021)	
Derivatives gain (loss)	121,347		
Other income (expense), net	122,652	(71,934)	
Net loss	\$ (1,277,990)	<u>\$ (453,988)</u>	
Net loss per share, basic and diluted	\$ (0.02)	\$ (0.02)	
Weighted average number of common shares outstanding, basic and diluted	51,660,942	26,259,515	

## InVivo Therapeutics Holdings Corp, Consolidated Balance Sheets

	As of	
	March 31, 2011	December 31, 2010
	Unaudited	
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 6,864,118	\$ 8,964,194
Restricted cash	105,000	—
Prepaid expenses	461,989	81,166
Total current assets	7,431,107	9,045,360
Property and equipment, net	500,566	280,181
Other assets	52,389	53,639
Total assets	\$ 7,984,062	\$ 9,379,180
LIABILITIES AND STOCKHOLDERS' DEFICIT:		
Current liabilities:		
Accounts payable	\$ 294,036	\$ 336,945
Capital lease payable-current portion	29,620	—
Derivative warrant liability	10,525,843	10,647,190
Accrued expenses	97,025	247,547
Total current liabilities	10,946,524	11,231,682
Capital lease payable-less current portion	58,712	
Total liabilities	11,005,236	11,231,682
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.00001 par value; authorized 100,000,000 shares, issued and outstanding 51,674,712 and		
51,647,171 shares outstanding at March 31, 2011 and December 31, 2010, respectively	516	516
Additional paid-in capital	12,491,459	12,382,141
Deficit accumulated during the development stage	(15,513,149)	(14,235,159
Total stockholders' deficit	(3,021,174)	(1,852,502
Total liabilities and stockholders' deficit	\$ 7,984,062	\$ 9,379,180