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InVivo Therapeutics Announces Latest Results from INSPIRE and Provides Update on Proposed Clinical Path Forward

January 3, 2018

CAMBRIDGE, Mass. (Jan 3, 2018) – InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV) today announced the latest results from The **INSPIRE Study: InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurological Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury**. The primary endpoint of the study is defined as improvement in ASIA Impairment Scale (AIS) grade from baseline for all evaluable patients at the six-month visit. Nineteen patients have been implanted with the Neuro-Spinal Scaffold. Three patients died within two weeks of implantation. The 16 evaluable patients have now all reached the six-month primary endpoint visit. Seven of the 16 (43.8%) evaluable patients had an AIS grade improvement from baseline at six months. The Objective Performance Criterion (study success definition) for the study was a 25% AIS conversion rate based on the published conversion rates for thoracic spinal cord injury (SCI) reported in the literature.^{1,2}

The most recent patient to reach the primary endpoint visit was assessed to be AIS C (motor incomplete) at six months, meaning that some motor function was detected at the sacral level. Of the seven INSPIRE patients who had AIS improvements at six months, five patients improved from complete AIS A SCI to sensory incomplete AIS B SCI, and two patients improved from complete AIS A SCI to motor incomplete AIS C SCI. Two of the five patients who were assessed to be AIS B at six months later improved to AIS C at 12 or 24 months.

In July 2017, enrollment of patients in the INSPIRE study was placed on hold following the third patient death. Although InVivo and the respective site principal investigators believe these deaths were not related to the Neuro-Spinal Scaffold investigational device, the company is in discussions with the FDA to ensure that these cases have been comprehensively evaluated and to ensure that all appropriate risk mitigation measures have been implemented. As part of those ongoing discussions, InVivo has proposed a randomized controlled trial to supplement the existing clinical evidence for the Neuro-Spinal Scaffold. InVivo does not anticipate reopening enrollment in INSPIRE and expects to provide additional clarity on its clinical path forward in the second quarter of 2018.

"I am pleased to report the latest AIS conversion results from INSPIRE," said Richard Toselli, Acting Chief Executive Officer. "INSPIRE demonstrated the surgical feasibility of Neuro-Spinal Scaffold implantation and produced encouraging data on AIS conversions at six months compared to the Objective Performance Criterion and natural history reported in the literature. We remain in discussions with the FDA regarding the clinical path forward in support of a Humanitarian Device Exemption filing. We are working diligently to provide clarity as expeditiously as possible as we evaluate various strategic and financing options. I look forward to providing more details on our proposed randomized controlled study in the second quarter of 2018."

¹ Zariffa et al., Spinal Cord (2011)

² Lee et al., J. Spinal Cord Med (2014)

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. In 2011, the company earned the David S. Apple Award from the American Spinal Injury Association for its outstanding contribution to spinal cord injury medicine. In 2015, the company's investigational Neuro-Spinal Scaffold™ received the 2015 Becker's Healthcare Spine Device Award. 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," "designed to," "potentially," and similar expressions, and include statements regarding the status of the company's clinical program. 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 discussions and engagement with the FDA; the company's ability to initiate, conduct and complete clinical trials; the expected benefits and

potential efficacy of the company's products and technology in connection with the treatment of spinal cord injuries; the availability of substantial additional funding for the company to continue its operations and to conduct research and development, clinical trials and future product commercialization; and other risks associated with the company's business, research, product development, attainment of regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the company's Quarterly Report of the three months ended September 30, 2017, and its other filings with the SEC, including the company's most recent Form 10-K, its Form 10-Qs and its current reports on Form 8-K. The company does not undertake to update these forward-looking statements.