InVivo Therapeutics Announces Complete 12-Month Data from the INSPIRE Study of the Investigational Neuro-Spinal Scaffold™ in Acute Thoracic Complete Spinal Cord Injury

August 28, 2018

CAMBRIDGE, Mass. (August 28, 2018) – InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV) today announced the complete 12-month results from the company's single-arm The **INSPIRE** study (**In**Vivo Study of Probable Benefit of the Neuro-**Spi**nal Scaffold™ for Safety and Neurologic **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury).

As previously announced by InVivo, 7 of 16 (44%) patients who reached the six-month primary endpoint visit in the INSPIRE study had an ASIA Impairment Scale (AIS) conversion at 6 months, which is the primary endpoint of the trial (defined as improvement in AIS grade from baseline for all evaluable patients at the six-month visit). The Objective Performance Criterion (OPC) (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.

Patients are scheduled to have full follow up visits at 12 and 24 months, and the visits include AIS conversion assessments. All patients evaluated at the 12-month visit who had converted an AIS grade at the 6 month visit remained converted at the 12 month visit. One patient was lost to follow up after the 6-month visit and was not assessed at a 12-month visit. Altogether, 19 patients have been implanted with the Neuro-Spinal Scaffold in the INSPIRE study. As previously disclosed, three patients died within two weeks of implantation.

Richard Toselli, M.D., President and Chief Executive Officer of InVivo, commented, "We will continue to follow this cohort of patients as they progress through their 24-month follow up visit and remain encouraged by the continued stability of the AIS conversion rate past the six-month primary endpoint visit."

InVivo has officially closed the INSPIRE study and has received supplemental Investigational Device Exemption (IDE) approval from the US Food and Drug Administration (FDA) for a second pivotal clinical study of the company's Neuro-Spinal Scaffold™ in patients with acute SCI. The 20-patient (10 subjects in each study arm), randomized, controlled trial, or INSPIRE 2.0, is designed to enhance the existing clinical evidence for the Neuro-Spinal Scaffold™ from the company's single-arm INSPIRE study. InVivo is currently focused on the initiation of the INSPIRE 2.0 study.

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 January 2018, the company announced updated clinical evidence, including improvements in patients with acute spinal cord injury (SCI), from its INSPIRE study of the Neuro-Spinal Scaffold™. 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 future clinical investigation of the Company's Neuro-Spinal Scaffold. 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: successfully decreasing costs and spending and successfully opening additional clinical sites for enrollment and enrolling additional patients if such trial is initiated; the timing of the Institutional Review Board process; the company's ability to obtain FDA approval to commercialize its products; 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 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 Annual Report on Form 10-K for the year ended December 31, 2017 and its other filings with the SEC, including the company's quarterly reports on Form 10-Q and current reports on Form 8-K. The company does not undertake to update these forward-looking statements.