## **THERAPEUTICS**<sup>™</sup>

## InVivo Therapeutics Announces Presentation of Twelve-Month Results from the INSPIRE Study of the Investigational Neuro-Spinal Scaffold<sup>™</sup> in Acute Thoracic Complete Spinal Cord Injury

April 17, 2019

- E-poster Presented at the 2019 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting -

CAMBRIDGE, Mass. (April 17, 2019) – InVivo Therapeutics Holdings Corp. (Nasdaq: NVIV) ("InVivo" or the "Company") today announced the presentation of the twelve-month results from the company's single-arm INSPIRE study (InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold<sup>™</sup> for Safety and NeurologidRecovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury). The findings were presented at the 2019 AANS Meeting in San Diego, CA through an e-poster titled, "Twelve Month Results from the INSPIRE Study of the Investigational Neuro-Spinal Scaffold<sup>™</sup> in Acute Thoracic Complete Spinal Cord Injury", co-authored by Kee Kim, M.D., Department of Neurosurgery, UC-Davis, Sacramento, CA, K. Stuart Lee, M.D., Division of Neurosurgery, Vidant Health, Greenville, NC, Lee, Domagoj Coric, M.D., Carolina Neurosurgery and Spine, Charlotte, NC, Nicholas Theodore M.D., Department of Neurosurgery, Johns Hopkins Hospital, Baltimore, MD, and Richard Toselli, M.D., President and Chief Executive Officer of InVivo.

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). Of the seven patients who reached the six-month primary endpoint visit, six patients were later evaluated at the 12-month exam and one patient was lost to follow-up before the 12-month exam. All six patients who were examined at the 12-month exam and had previously converted at the six-month exam remained converted at the 12-month exam. Further, two of those six patients were assessed to have AIS B spinal cord injury (SCI) at the six-month primary endpoint but were later assessed to have improved to AIS C SCI at the 12-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 SCI reported in the literature.

Dr. Toselli commented, "In addition to focusing on enrollment in the INSPIRE 2.0 Study, we look forward to continuing to follow this cohort of INSPIRE patients through their 24-month follow up visit, and we remain encouraged by the continued stability of the AIS conversion rates."

## **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<sup>™</sup>. The publicly traded company is headquartered in Cambridge, MA. For more details, 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. 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 expected timing for enrollment in the Inspire 2.0 Study and expectations regarding continued follow up with patients in the INSPIRE Study. 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 ability to successfully open additional clinical sites for enrollment and to enroll additional patients; 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, 2018, and its other filings with the SEC, including the Company's Form 10-Qs and current reports on Form 8-K. The Company does not undertake to update these forward-looking statements.