Biodesix DeSoto Laboratory Receives both ISO 13485:2016 Certification and Accreditation from the College of American Pathologists

August 25, 2021

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 25, 2021-- Biodesix, Inc. (Nasdaq: BDSX). Today Biodesix announced that the Accreditation Committee of the College of American Pathologists (CAP) and British Standards Institute (BSI) on behalf of International Organization for Standardization (ISO) recently awarded both CAP accreditation and ISO 13485:2016 certification to the Biodesix Laboratory located in DeSoto, Kansas, based on results of two independent inspections conducted by CAP and BSI inspectors.

The CAP advised Biodesix of the impressive national recognition and congratulated the laboratory for its excellence in the services being provided. The U.S. federal government recognizes the CAP Laboratory Accreditation Program, begun in the early 1960s, as being equal-to or more-stringent-than the government's own inspection program.

"Biodesix demonstrates leadership, innovation, and a passionate commitment to standards of excellence while providing the highest quality services, ultimately for patients," said Richard M. Scanlan, MD, FCAP, chair of the CAP's Council on Accreditation. "The CAP congratulates Biodesix on its recent CAP Accreditation."

ISO 13485:2016 is an internationally recognized quality standard specific to the medical device industry that is intended to ensure the quality of medical device design, development, and production. ISO 13485 is recognized by the Global Harmonization Task Force (GHTF) and has become the model QMS standard for the medical industry, and in major markets around the world (US FDA (Food and Drug Administration), Europe, Australia, Canada, Japan). To receive certification, organizations must demonstrate that their Quality Management Systems deliver medical devices and related services that consistently meet customer and regulatory requirements.

Biodesix Chief Executive Officer, Scott Hutton, upon learning of the laboratory's new accreditation and certification, said, "My deep appreciation extends to the Biodesix Quality and Laboratory teams for these significant accomplishments that further demonstrate our mission and commitment to high-quality patient care. Effectively implementing and maintaining this globally harmonized standard is strategic and essential to the continued growth and capabilities Biodesix can provide. The accreditations from both CAP and ISO 13485 confirm the quality of our processes and show our commitment to a high standard of work practices. It is this dedication to quality that our patients, physicians and biopharma partners expect from Biodesix."

About the College of American Pathologists

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. For more information, read the CAP Annual Report at cap.org.

About Biodesix

Biodesix is a leading data-driven diagnostic solutions company with a focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer seven non-invasive tests for patients with lung diseases. Biodesix launched the SARS-CoV-2 ddPCR™ test, the Platelia SARS-CoV-2 Total Ab, and the cPass ™ SARS-CoV-2 Neutralization Antibody test (cPass™ Neutralization Test Kit, GenScript, Inc,) in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 36 hours, expediting time to treatment. The blood based Nodify Lung® nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT™ tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. Biodesix also leverages the proprietary and advanced Diagnostic Cortex® AI (Artificial Intelligence) platform, to collaborate with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. For more information about Biodesix, visit biodesix.com.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Biodesix has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions. Forward-looking statements may include information concerning the impact of the COVID-19 pandemic on Biodesix and its operations, it is possible or assumed future results of operations, including descriptions of its revenues, profitability, outlook, and overall business strategy. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release can be found in the Risk Factors section of Biodesix's most recent annual report on Form 10-K, filed March 16, 2021, or subsequent quarterly reports on Form 10-Q during 2021, if applicable. Biodesix undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

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