Biodesix Announces New Data Presentation at CHEST 2024 Annual Meeting and the Launch of a Complementary Clinical Study

October 7, 2024

Analysis of 35,000 patients tested with Nodify Lung® Nodule Risk Assessment in a real-world setting to be presented at CHEST 2024 and launch of a new clinical study designed to expand data package

LOUISVILLE, Colo.--(BUSINESS WIRE)--Oct. 7, 2024-- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostic solutions company with a focus in lung disease, today announced that new data will be presented at the CHEST Annual Meeting 2024 in Boston, Massachusetts on Tuesday, October 8 at 10:20 am ET. The presentation will detail the experience of healthcare providers using the Nodify Lung® Nodule Risk Assessment in over 35,000 patients consecutively tested in a real-world clinical setting.

Guidelines recommend that clinicians assess the risk of lung cancer in patients with new nodules to inform the next steps for the patient. Up to 80% of patients are assigned a low to moderate risk, or a 5-65% risk of lung cancer, where next steps are unclear. Biodesix Nodify Lung testing, comprised of the Nodify CDT® and Nodify XL2® blood-based lung nodule tests, is designed to reclassify the risk of lung cancer to a high (>65% risk) or very low (<5% risk) category to better clarify the optimal next steps.

At the CHEST conference, **"Use of a blood-based biomarker for indeterminate nodules in community settings,"** will be presented by Kathryn Long, MD of the Medical University of South Carolina. It will describe clinical use patterns and national reclassification rates consistent with prior studies, highlighting the high proportion of results that up- or down-classify patients into actionable risk categories with clear, guideline-recommended, diagnostic plans.

The company also announced a new clinical study, CLARIFY, that will collect patient outcomes and other clinical information on a subset of the patients featured in the CHEST presentation by Dr. Long. CLARIFY is designed to confirm performance of the Nodify CDT and Nodify XL2 tests in diverse patient subgroups through a retrospective chart review of up to 4,000 patients that were tested in a real-world clinical setting. The study's intent is to expand the extensive evidence characterizing the validation and utility of Nodify Lung testing.

"Nodify Lung testing has changed the standard of care for characterizing risk of malignancy in lung nodules over the past four years and we are thrilled to share the aggregate experience of healthcare providers using Nodify Lung testing in clinical practice," said Scott Hutton, Chief Executive Officer of Biodesix. "CLARIFY represents the opportunity to supplement this dataset with further clinical outcomes analysis and increase healthcare providers' confidence in clinical decision-making across distinct patient populations, in various practice settings."

In addition, on Wednesday, October 9 at 10:30 am ET, Sonali Sethi, MD, FCCP, Cleveland Clinic and D. Kyle Hogarth, MD, FCCP, University of Chicago will discuss the **"Patient impact and case studies: the real-world value of biomarkers in lung nodule management"** at Learning Theater 4. This presentation will review Nodify Lung case studies and the impact that the results have on the patient experience and shared decision-making.

About Biodesix

Biodesix is a leading diagnostic solutions company with five Medicare-covered tests available for patients with lung diseases. The blood-based Nodify Lung® Nodule Risk Assessment evaluates the risk of malignancy in pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. The blood-based IQLung™ test portfolio for lung cancer patients integrates the GeneStrat® targeted ddPCR™ test, the GeneStrat NGS® test, and the VeriStrat® test to support treatment decisions across all stages of lung cancer and expedite personalized treatment. In addition, Biodesix collaborates with the world's leading biopharmaceutical companies to provide biomarker discovery, diagnostic test development, and clinical trial support services. For more information, 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 backlog and the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital including under the term loan facility, expectations regarding revenue and margin growth and its impact on profitability, and the impact of a pandemic, epidemic, or outbreak, including the COVID-19 pandemic, on Biodesix and its operations and financial performance. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. The Company's ability to continue as a going concern could cause actual results to differ materially from those contemplated in this press release and additionally, other 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 most recent annual report on Form 10-K, filed March 1, 2024. 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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