



## **Biodesix Adds Digital Diagnostics to Lung Pipeline, Creating New Growth Platform Combining Blood and Imaging Biomarkers**

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### **Partnership with Vanderbilt University and Vanderbilt Health accelerates development of the first radiomics-based test for lung nodule risk assessment**

LOUISVILLE, Colo., Oct. 19, 2026 (GLOBE NEWSWIRE) -- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostics solutions company, today announced the addition of Digital Diagnostics to its Lung Diagnostics strategy, establishing the foundation for a multimodal diagnostic platform that combines blood-based biomarkers, imaging biomarkers, and artificial intelligence. The first product, a radiomics-based test for lung nodule risk assessment developed with Vanderbilt University and Vanderbilt Health, is designed to complement the Nodify Lung® portfolio and represents the next phase of innovation in lung diagnostics. Initial data for this new test will be presented at RSNA on December 3, 2026, and commercial availability is anticipated in 2028.

The Digital Diagnostics initiative extends the Biodesix blood-based lung diagnostics franchise into imaging, which is central to clinical evaluation of many pulmonary conditions. Biodesix is uniquely positioned to commercialize multimodal lung diagnostics through its established testing portfolio, national commercial infrastructure, reimbursement expertise, regulatory capabilities, and deep relationships with pulmonary and primary care physicians. By integrating complementary sources of diagnostic information, Biodesix aims to deliver a more comprehensive assessment of lung cancer risk than either modality can deliver alone and to build a scalable platform that can support future products across a broad range of lung diseases.

Millions of patients are evaluated each year for pulmonary nodules and other respiratory conditions. Lung nodule risk assessment in the pulmonology and primary care settings represents the initial commercial application. The same physicians diagnose and manage a broad range of diseases and conditions across the respiratory system, many of which rely on imaging as a central component of clinical evaluation. Biodesix believes its multimodal diagnostics platform has the potential to support future innovation across a broad range of pulmonary diseases, significantly expanding the overall opportunity for the platform.

"We believe the future of lung diagnostics will be multimodal," said Scott Hutton, CEO of Biodesix. "Digital Diagnostics represents a significant expansion of our strategy, bringing blood-based biomarkers, imaging biomarkers, and artificial intelligence (AI) together on one platform. Biodesix has the clinical, commercial, and reimbursement capabilities to translate that innovation into solutions physicians can use in practice. We are starting with lung nodule risk assessment, but our vision is much broader—to build a new diagnostic platform capable of supporting innovations across lung disease."

The initiative is supported by a strategic development partnership with Vanderbilt University and Vanderbilt Health. Biodesix is the first diagnostics company recognized as an Industry Affiliate of the Vanderbilt Lab for Immersive AI Translation (VALIANT), a collaborative program focused on accelerating the translation of advanced artificial intelligence research into clinical applications.

"Every day in my clinic I see patients with pulmonary nodules confronting the possibility of lung cancer and asking what comes next," said Fabien Maldonado, MD, MSc, Executive Medical Director of the Vanderbilt Lung Institute, Professor of Medicine and Thoracic Surgery, and Director of Vanderbilt Interventional Pulmonology Research. "Patients want to know whether they should proceed toward a biopsy or continue with imaging surveillance. Several years ago, our research demonstrated that imaging and blood biomarkers provide complementary information and can meaningfully improve the accuracy of lung cancer risk assessment. The challenge has been translating that science into a practical solution that physicians can use at scale. We are excited to help bring a multimodal diagnostic approach into routine clinical practice."

Biodesix has built a dedicated Digital Diagnostics initiative under the leadership of Michael Kammer, PhD. Since joining Biodesix in 2025, Dr. Kammer has led the company's digital diagnostics roadmap and the team executing a comprehensive program that includes strategic partnerships such as the one with Vanderbilt University and Vanderbilt Health, clinical evidence generation, operational readiness, reimbursement strategy, regulatory planning, and product development.

"What makes this opportunity particularly compelling is the ability to bring together complementary strengths from both organizations," said Michael Kammer, PhD, Head of Radiomics at Biodesix. "Vanderbilt brings world-class expertise in artificial intelligence and imaging science, while Biodesix contributes deep experience in product development, commercialization, reimbursement, and clinical adoption in pulmonary medicine. Together, we are building more than a single diagnostic test. We are creating a multimodal platform designed to support future innovation across a broad range of lung diseases."

#### **The First Product: A Radiomics-based Lung Nodule Risk Assessment Test**

The first product being developed is a radiomics-based digital diagnostic for lung nodule risk assessment that applies artificial intelligence to extract quantitative features from medical images, such as computed tomography (CT) scans. The test is designed for high-specificity and will complement the market-leading Nodify Lung® blood-based test portfolio. By combining novel imaging biomarkers with the established blood-based biomarkers, Biodesix aims to deliver a more comprehensive assessment of lung

cancer risk than either modality alone, helping physicians make more confident clinical decisions.

Biodesix is rapidly progressing towards commercialization of the first digital diagnostic test for lung nodule assessment:

- **Commercial Availability:** Biodesix anticipates commercial availability in 2028, when the integrated multimodal test portfolio is expected to be sold through the company's established commercial channels.
- **Clinical Data:** Initial performance data will be presented at the RSNA 2026 Annual Meeting on December 3, 2026.

**Presenter:** Michael Kammer, PhD, Biodesix Head of Radiomics

**Title:** High-Specificity Lung Cancer Identification from Whole-Field CT with Kernel Harmonization for Pulmonary Nodule Triage.

- **Evidence Generation:** Biodesix has received Institutional Review Board (IRB) approval for STRATIFY ([NCT07858552](#)), a prospective clinical study designed to generate one of the first proprietary matched datasets of blood-based biomarkers, imaging-based biomarkers, and clinical outcomes. This unique dataset is expected to support clinical validation, evidence to support reimbursement, and future multimodal product development efforts. The study is expected to commence in the fourth quarter of 2026.
- **Regulatory:** Biodesix has engaged with the U.S. Food and Drug Administration (FDA) to support an efficient regulatory pathway.
- **Reimbursement:** Biodesix has engaged with Medicare to support future commercialization.
- **Operations:** Biodesix has established an Independent Diagnostic Testing Facility (IDTF) to facilitate clinical testing and future operational scale.

## About Biodesix

Biodesix is a leading diagnostic solutions company, driven to improve clinical care and outcomes for patients. Biodesix Diagnostic Tests, marketed as Nodify Lung® Nodule Risk Assessment and IQLung® Cancer Treatment Guidance, support clinical decisions to expedite personalized care and improve outcomes for patients with lung disease. Biodesix Development Services enable the world's leading biopharmaceutical, life sciences, and research institutions with scientific, technological, and operational capabilities that fuel the development of diagnostic tests, tools, and therapeutics. Visit [biodesix.com](#) for more information.

## 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 possible or assumed future results of operations, including descriptions of our revenues, profitability, outlook, and overall business strategy, the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital, the anticipated impact and benefits of new clinical data, reimbursement coverage and research partnerships, the impact of enhanced U.S. tariffs, import/export restrictions or other trade barriers on the company and its operations and financial performance. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. 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 our most recent Annual Report on Form 10-K, filed February 26, 2026, or subsequent Quarterly Reports on Form 10-Q during 2026, as 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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