Biodesix Advances Two Complementary Approaches to Molecular Residual Disease (MRD) Monitoring

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Biodesix-led tumor-informed and tumor-naïve programs draw on the company's bioinformatics and diagnostics test development expertise

LOUISVILLE, Colo., Sept. 24, 2026 (GLOBE NEWSWIRE) -- Biodesix, Inc. (Nasdaq: BDSX), a leading diagnostics solutions company, today announced strategic progress in two collaborative programs for tumor-informed and tumor-naïve Molecular Residual Disease (MRD) solutions intended to support cancer centers and clinical laboratories. Both solutions detect circulating tumor DNA (ctDNA), the tumor DNA that a cancer sheds into the blood, to assess whether disease remains or is returning after treatment. The tumor-informed solution is the result of a multi-year collaboration with Bio-Rad Laboratories. The tumor-naïve solution is a newly launched program with Thermo Fisher Scientific that extends a collaboration for companion diagnostic validation and other development work. Both approaches will be validated by Biodesix in collaboration with key investigators at Memorial Sloan Kettering Cancer Center (MSK) and are designed to run on partner platforms already installed in laboratories around the world.

"Our approach to MRD reflects a core conviction: sensitivity matters, and so does patient access. We are building ultra-sensitive assays with global collaborators whose platforms can carry those assays to laboratories and patients around the world," said Scott Hutton, Chief Executive Officer of Biodesix. "Offering both tumor-informed and tumor-naïve MRD means the clinical question can drive the testing strategy, rather than forcing a single approach in every situation. We believe this work positions Biodesix to participate in the growth of MRD testing well beyond the patients that can be reached through a centralized laboratory model."

No single MRD approach serves every patient. Tumor-informed testing is generally the most sensitive option when tumor tissue is available, and tumor-naïve testing extends monitoring to patients whose tissue is unavailable or insufficient. Biodesix is advancing both, drawing on its proprietary Diagnostic Cortex® bioinformatics platform, its experience developing, validating, and commercializing diagnostic tests in its CAP-accredited, CLIA- and NYS CLEP-certified laboratory, and its track record in companion diagnostics test validation with global partners. The two programs build on MRD data that Biodesix and its collaborators have presented at scientific meetings over the past two years. Together they represent the first time Biodesix has outlined its MRD strategy as a whole and represents an expansion of the company's focus beyond lung diagnostics into a rapidly growing area of precision oncology.

Tumor-informed MRD

For the tumor-informed solution, Biodesix profiles a patient's tumor tissue using its proprietary Diagnostic Cortex® bioinformatics platform to identify multiple complex genomic changes unique to that individual. Bio-Rad's Droplet Digital™ PCR technology is then used to track those changes in blood over the course of the patient's care, partitioning each sample into thousands of separate reactions so that individual tumor molecules can be counted. The ultra-sensitive informatics and analysis workflows detect ctDNA below 1 part per million (ppm) of the total DNA in a blood sample.

"Detecting molecular residual disease means finding a handful of molecules in a complex background, the precise application for which Droplet Digital PCR has an advantage over other technologies. Our multi-year work with Biodesix has focused on making that sensitivity practical in routine laboratories. We look forward to supporting broad access to these solutions and the positive impact they will have on patient lives," said Steve Kulisch, Vice President of Genomics Product Management, Bio-Rad Laboratories.

Tumor-naïve MRD

The tumor-naïve solution detects methylated ctDNA in blood using rapid next-generation sequencing on the Genexus™ platform from Thermo Fisher Scientific. Biodesix has begun developing and validating this assay in its CAP-accredited, CLIA- and NYS CLEP-certified laboratory as part of the Thermo Fisher Center of Excellence Network. Because the method reads methylation patterns rather than mutations unique to an individual tumor, it requires no tumor tissue. This means the test can potentially help patients who otherwise would not have been eligible for an MRD test because their archived tissue is unavailable or insufficient.

"Methylation carries a rich biological signal, and rapid analytic and informatics workflows make it possible to act on that signal in a clinically relevant timeframe," said Gary Pestano, Ph.D., Chief Scientific Officer of Biodesix. "By providing both tumor-informed and tumor-naïve approaches, Biodesix can reach more of the patients who may benefit from molecular monitoring throughout their cancer journey."

Upcoming presentations

Gary Pestano, Ph.D., Chief Scientific Officer of Biodesix, will join a spotlight panel on the future of MRD at the 5th Annual Roth

Healthcare Opportunities Conference.

Panel Title: The Rise of MRD Monitoring in Solid Tumors and Where it Goes Next
Date and Time: Tuesday, September 29, 2026, 2:00 PM ET
Location: The Metropolitan Club, New York, NY
Panelists:

- Gary Pestano, Ph.D., Chief Scientific Officer, Biodesix, Inc. (Nasdaq: BDSX)
- Amal Thommil, MRD Monitoring Specialist, DeciBio
- Pedram Razavi, M.D., Ph.D., Medical Oncologist, Director of Liquid Biopsy & Cancer Genomics, MSK

Data supporting both MRD programs will be presented at the AMP 2026 Annual Meeting in November 2026 in Seattle, with additional data planned for the San Antonio Breast Cancer Symposium in December 2026. The presentations will feature continued collaborative work with MSK, Bio-Rad Laboratories, and Thermo Fisher Scientific.

Notes and Disclosures:

Memorial Sloan Kettering (MSK) has institutional financial interests related to Biodesix, Inc.

Droplet Digital PCR is a trademark of Bio-Rad Laboratories, Inc.

Genexus is a trademark of Thermo Fisher Scientific.

Nodify Lung, IQLung, and Diagnostic Cortex are registered trademarks of Biodesix, Inc.

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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