Bionano Laboratories Announces Proposed Local Coverage Determination (LCD) from MolDX for Genome-Wide Detection of Structural Variants in Hematologic Neoplasms

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SAN DIEGO, Sept. 10, 2026 (GLOBE NEWSWIRE) -- Bionano Laboratories, a wholly-owned subsidiary of Bionano Genomics, Inc. (Nasdaq: BNGO) that offers CLIA-certified laboratory developed test (LDTs), today announced that MolDX, a program that assesses molecular diagnostic technologies on behalf of Medicare Administrative Contractors (MACs), has issued a proposed Local Coverage Determination (LCD) for Genome-Wide Molecular Methodologies for the Detection of Copy Number Alterations and Structural Variants in Hematologic Neoplasms. The LCD would establish Medicare coverage criteria for molecular testing, including optical genome mapping (OGM), in the workup of hematologic neoplasms. The proposed LCD is open for public comment through October 11, 2026.

The draft LCD would provide coverage for genome-wide assays that detect copy number alterations and structural variants when testing informs diagnosis or clinical management in accordance with current expert or professional guidelines. The proposed policy recognizes that these approaches, including OGM, can deliver clinically valid and useful genetic information for hematologic neoplasms that are comparable or superior to traditional methods such as conventional karyotyping and chromosomal microarray. Bionano Laboratories has validated the OGM-Dx™ HemeOne diagnostic test for hematologic malignancy analysis, which would be expected to be eligible for coverage under this proposed LCD once finalized and once the lab satisfies the technical assessment process. The proposed LCD is available here.

This proposed LCD would cover a broad range of suspected hematologic malignancies including leukemias, lymphomas, and myelomas at time of initial diagnosis, progression, or relapse. The draft LCD states that “it has been adequately proven that a single test may provide equivalent or greater clinically valid and useful genetic information as could be achieved by the combination of multiple traditional methodologies (including CBA, FISH, and CMA).”

"Patients with a hematologic malignancy depend on complete, accurate genomic information to guide their diagnosis and care, and this proposed coverage determination is an important acknowledgment that tests, such as our OGM-Dx HemeOne, can deliver that information in a single test," said Alex Hastie, Ph.D., chief scientific officer of Bionano and responsible for overseeing test development at Bionano Laboratories. "We look forward to participating in the public comment process as MolDX moves toward a final determination."

About Bionano Laboratories:
Lineagen, Inc. d/b/a Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way the world sees the genome. Its clinical diagnostics services offer optical genome mapping (OGM) testing that combines a comprehensive testing portfolio with thoughtful and accessible support options. Bionano Laboratories also offers direct access to OGM for applications across basic, translational and clinical research. For more information, visit www.bionanolaboratories.com

About Bionano
Bionano is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company’s mission is to transform the way the world sees the genome through optical genome mapping (OGM) solutions, diagnostic services and software. The Company offers OGM solutions for clinical, translational, medical, and basic research. The Company also offers an industry-leading, platform-agnostic genome analysis software solution, and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also offers OGM-based diagnostic testing services. For more information, visit www.bionano.com

Bionano's products are for research use only and not for use in diagnostic procedures.

Forward-Looking Statements of Bionano Genomics
This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. Words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding market adoption of our products; our commercial prospects and future financial and operating results; and our ability to meet our stated goals and commercial opportunities, including our full year and third quarter 2026 guidance. Each of these forward-looking statements involves risks and uncertainties. Accordingly, investors and prospective investors are cautioned not to place undue reliance on these forward-looking statements as they involve inherent risk and uncertainty (both general and specific) and should note that they are provided as a general guide only and should not be relied on as an indication or guarantee of future performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to: our ability to improve our margins, extend our cash runway and reach a potential pathway to profitability; our ability to continue as a going concern as disclosed in our filings with the SEC, which requires us to manage costs and obtain significant additional financing to fund our strategic plans and commercialization efforts; our ability to execute on our strategy and achieve our objectives; the impact and utility of our cost savings initiative and our recent financing; our ability to continue to drive OGM (as defined above) adoption by potential customers for routine use in genomic analysis; the impact, or lack thereof, of Category I CPT codes to accelerate or increase the adoption of OGM; continued research, presentations and publications involving OGM and its utility compared to traditional

cytogenetics and our technologies; the impact of our Stratys™ system and VIA™ software to increase throughput and simplify analysis of OGM data our ability to drive adoption of OGM and our technology solutions; our ability to further deploy new products and applications for our technology platforms; our expectations and beliefs regarding future growth of the business and the markets in which we operate; our ability to consummate any strategic alternatives including the risk that if we fail to obtain additional financing we may seek relief under applicable insolvency laws; the size and growth potential of the markets for our products, and our ability to serve those markets; the rate and degree of market acceptance of our products; our ability to manage the growth of our business and integrate acquired businesses; the fact that we are limited to "research use only" with respect to many of the materials and components used in our consumable products including our assays; our ability to expand our commercial organization to address effectively existing and new markets that we intend to target; the impact from future regulatory, judicial, and legislative changes or developments in the U.S. and foreign countries; our ability to compete effectively in a competitive industry; the introduction of competitive technologies or improvements in existing technologies and the success of any such technologies; the performance of our third-party contract sales organizations, suppliers and manufacturers; our ability to attract and retain key scientific or management personnel; the accuracy of our estimates regarding expenses, future revenues, reimbursement rates, capital requirements and needs for additional financing; the impact of adverse geopolitical and macroeconomic developments, such as recent and future bank failures, ongoing international conflicts, and related sanctions, regional or global pandemics, inflation, tariffs, increased cost of goods, supply chain issues, and global financial market conditions; on our business and operations, as well as the business or operations of our suppliers, customers, manufacturers, research partners and other third parties with whom we conduct business and our expectations with respect to the duration of such impacts and the resulting effects on our business; our ability to realize the anticipated benefits and synergies of our prior and any future acquisitions or other strategic transactions; our ability to attract collaborators and strategic partnerships; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties described in our filings with the Securities and Exchange Commission ("SEC"), including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2025, any subsequently filed Quarterly Reports on Form 10-Q and in other filings subsequently made by us with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as may be required by law.

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