Bionano Laboratories Announces New York State Department of Health Approval of Lab Developed Tests Based on Optical Genome Mapping

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New York State Department of Health approval allows clinical use of optical genome mapping (OGM) based lab developed tests (LDTs) for patients with suspected genetic disease, reproductive disorders, and hematologic malignancies at University of Rochester Medicine.

SAN DIEGO, September 8, 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 the New York State Department of Health (NYSDOH) has approved the use of optical genome mapping (OGM)-based LDTs for the clinical evaluation of samples from patients suspected of various genetic disorders including reproductive disorders and hematologic malignancies at University of Rochester Medicine (URochester Medicine), marking a significant milestone in the adoption of OGM for clinical cytogenomics.

The approvals support the clinical implementation of OGM in the laboratory led by **M. Anwar Iqbal, PhD**, Director of the DNA Microarray CGH/OGM Laboratory at URochester Medicine. Previously, LDTs leveraging OGM have been offered by labs in other states and other countries, but the NYSDOH approval allows, for the first time, patients in New York to benefit from this advanced cytogenomic technology.

University of Rochester Medicine has been an early advocate for OGM across disorders in which structural variants play a central role. Dr. Iqbal and his team have collaborated on three clinical studies establishing the clinical validity of OGM in prenatal, postnatal, and hematologic malignancy settings.

Having completed laboratory validation and received NYSDOH approval for diagnostic testing, the medical center now offers these tests to patients. The lab's initial focus was coupled with reproductive disorders, where balanced translocations and other structural variants are a common underlying cause. With recent approval for hematologic cancers, testing has now expanded to cancer patients as well.

Key highlights of the NYSDOH approvals include:

- **Diagnostic test approval at premier academic cancer center in New York:** OGM-based testing is now approved for clinical use in genetic disorders and hematologic malignancies at URochester Medicine Wilmot Cancer Institute, an institution recognized internationally for excellence in cancer genomics and precision medicine.
- **Potential to streamline laboratory workflows**: OGM may reduce reliance on multiple cumbersome cytogenetic assays by providing genome-wide structural variant analysis in a single workflow.
- **Continued momentum for clinical adoption:** The approval represents another step toward broader acceptance of OGM for routine clinical cytogenetic testing of hematologic malignancies.

“New York State Department of Health approval at this respected cancer center is an important milestone and provides support for OGM-based tests being offered and under consideration for development at Bionano Laboratories,” said **Alex Hastie, PhD,** Chief Scientific Officer of Bionano and responsible for overseeing test development at Bionano Laboratories. “The team led by Dr. Iqbal at URochester Medicine has been at the forefront of evaluating and implementing innovative genomic technologies. Their clinical adoption of OGM reflects the growing confidence in this technique and further validates our own efforts to develop and offer OGM-based tests.”

Dr. **Anwar Iqbal** of URochester Medicine commented, “The approval of our OGM-based clinical test by NYSDOH represents an important advancement for patients with suspicion of hematologic cancers. OGM enables a comprehensive assessment of structural genomic alterations and complements our efforts to deliver state-of-the-art genomic diagnostics.”

Bionano Laboratories believes that growing adoption of OGM by leading academic medical centers, comprehensive cancer centers, and other clinical laboratories continues to strengthen the evidence supporting the utility of its current and under consideration offerings. The laboratory remains focused on collaborating with the clinical and research communities to advance genomic technologies that may improve understanding of disease biology and support precision medicine.

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 Genomics

Bionano is a provider of genome analysis solutions that 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. Bionano offers OGM solutions for applications across basic, translational, and clinical research, as well as an industry-leading, platform-agnostic genome analysis software solution and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its 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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