



Bionano Genomics Announces Launch of CLIA-Certified Bionano Laboratories, and Expands its Clinical Testing Menu with Launch of First OGM-Based LDT for FSHD

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SAN DIEGO, Sept. 23, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the launch of Bionano Laboratories, a new organization that combines Bionano's optical genome mapping (OGM) data services with the clinical testing services previously offered by Lineagen, and the launch of Bionano Laboratories' first OGM-based laboratory developed test (LDT). Bionano Laboratories recently received CLIA-certification for its lab in San Diego. This certification will enable Bionano Laboratories to offer services to customers seeking to implement OGM into their diagnostic routines and for research applications with hospitals, pharmaceutical companies, and other parties that may desire a more robust regulatory structure for their projects.

A key strategic objective of Bionano Laboratories' CLIA lab is to develop a menu of LDTs based on OGM. The first OGM-based LDT developed by Bionano Laboratories is a test for facioscapulohumeral muscular dystrophy (FSHD), which is the second leading cause of muscular dystrophy and an important marker in the evaluation of muscular disorders.

"We are excited to launch Bionano Laboratories, which will enable the ability to scale OGM LDT and research services to meet increasing market testing demands. We believe our CLIA-certified lab will help streamline the diagnostic odyssey for clinicians and their patients, as it will have the potential to detect many different types of genomic variants in a single diagnostic environment. This launch is an important milestone for Bionano, and something we have been working towards since our acquisition of Lineagen," commented Dr. Alka Chaubey, chief medical officer of Bionano Genomics.

Erik Holmlin, PhD, president and chief executive officer of Bionano Genomics added, "We want to congratulate Alka along with her outstanding team for all the work they've done. The development of LDTs will allow Bionano Laboratories to introduce OGM-based assays to interested physicians and to seek reimbursement from insurance companies for these testing services. We believe our ability to offer CLIA-certified services will enable us to execute our growth strategy and to fulfill our vision of changing the way the world sees the genome."

More details on Bionano Laboratories is available at: <https://bionanolaboratories.com/>

About Bionano Genomics

Bionano Genomics 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 OGM solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. For more information, visit www.bionanogenomics.com, www.lineagen.com or www.biodiscovery.com

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "potential," "believe" 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 these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the utility of OGM-based LDTs, and the ability of Bionano Laboratories to be successful in the market development of OGM-based LDTs. Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: the impact of the COVID-19 pandemic on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; failure OGM-based LDTs to provide meaningful diagnostic utility; failure of clinicians or researchers to add OGM-based LDTs into their diagnostic routine; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; 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, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2021 and in other filings subsequently made by us with the Securities and Exchange Commission. 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.

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