



Bionano Laboratories Receives College of American Pathologists (CAP) Accreditation for its Clinical Laboratory

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SAN DIEGO, Aug. 16, 2023 (GLOBE NEWSWIRE) -- Bionano Laboratories, a laboratory services business of Bionano Genomics, Inc. (Nasdaq: BNGO), today announced that it has received Laboratory Accreditation from the College of American Pathologists (CAP) for its Clinical Laboratory Improvement Amendments (CLIA)-certified reference lab. CAP accreditation is awarded to laboratories that meet stringent requirements and maintain the highest standards for laboratory operations of quality, accuracy, and consistency, as outlined by CAP.

CAP accreditation is often required for a clinical service provider to become part of insurance companies' preferred provider networks for reimbursement. It is also a credential that is frequently sought after by pharmaceutical and biotechnology companies who desire their projects to be conducted under a more robust regulatory structure, especially if the data are intended to be used for a submission to the U.S. Food and Drug Administration.

"I'm proud of the work our team has conducted to first develop CAP and CLIA compliant policies, procedures and practices with the highest level of quality, and then to be able to successfully pass such a rigorous inspection like the one CAP conducts," commented Alka Chaubey, PhD, FACMG, chief medical officer of Bionano.

"I want to congratulate Alka and the team at Bionano Labs for achieving this milestone. I believe it will help us support the proliferation of optical genome mapping (OGM) in a number of markets, including the cell and gene therapy markets where we believe OGM can offer significant value as part of the quality control for cell bioprocessing," added Erik Holmlin, PhD, president and chief executive officer of Bionano.

About Bionano Laboratories:

Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way the world sees the genome. Its clinical services offer a genetic testing experience that combines a comprehensive testing portfolio with thoughtful and accessible support options for the diagnostic journey. Bionano Laboratories also offers direct access to optical genome mapping 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 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. 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. The Company additionally offers nucleic acid extraction and purification solutions using proprietary isotachopheresis technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Except as otherwise specifically identified, Bionano's OGM 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 Private Securities Litigation Reform Act of 1995. Words such as "believe," "can," "will" 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 ability and utility of the CAP accreditation for Bionano Laboratories to result in being added to the preferred provider networks of any insurance companies; the ability and utility of the CAP Accreditation to drive additional business with pharmaceutical or biotechnology companies; whether the CAP accreditation will support the proliferation of OGM in any markets, including the cell and gene therapy markets; and whether OGM will offer significant value as part of the quality control for cell bioprocessing. 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 geopolitical and macroeconomic developments, such as recent and potential future bank failures, the ongoing Ukraine-Russian conflict and related sanctions, and any global pandemics, on our business and the global economy; the failure of the CAP accreditation to impact Bionano Laboratories being added to additional preferred provider networks; the failure of the CAP accreditation to drive additional business with pharmaceutical or biotechnology companies; the expansion and utility of OGM; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts and our ability to continue as a "going concern"; 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, 2022 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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The logo for Bionano Genomics, featuring the word "bionano" in a lowercase, blue, sans-serif font. A small trademark symbol (TM) is located at the top right of the letter "o".

Source: Bionano Genomics