Bionano Announces Commercial Release of New Kits for its Ionic System featuring New Chemistry for Nucleic Acid Extraction from FFPE and Tumor Tissue

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SAN DIEGO, June 06, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the commercial release of new kits for its Ionic® Purification System featuring new chemistry for nucleic acid extraction from formalin-fixed paraffin-embedded (FFPE) and tumor tissue. These products offer potential improvements in quality and yield of nucleic acid extracted from complex biological samples including those with low cell counts or otherwise challenging sample types, such as FFPE tumor samples.

Most clinical samples used in oncology research are stored as FFPE tissues, which often contain degraded or fragmented nucleic acid. Conventional extraction methods are labor intensive and can further damage nucleic acid during the extraction and purification process. The Ionic Purification System uses isotachophoresis (ITP) to extract, purify and concentrate nucleic acid from biological samples without binding, washing, or stripping from fixed surfaces. Since nucleic acids remain in their native form when using the ITP workflow on the Ionic system, it can be an ideal solution for many sample types, including limited and low-quality solid tumor and homologous recombination deficiency (HRD) samples.

The Ionic® G2 chemistry includes four new kits for use with the Ionic Purification System, including G2 FFPE to DNA, G2 FFPE to RNA, G2 FFPE Complete and G2 Tissue to DNA. Ionic G2 kits enable ITP to provide up to a potential 4.5-fold increase in nucleic acid yield over the leading column-based system, with higher quality sample results and reduced sample processing time. ITP on the Ionic system is currently focused on nucleic acid purification for applications with next-generation sequencing (NGS). Bionano is developing ITP solutions for optical genome mapping (OGM) that are planned to be available in the future.

“Bionano acquired Purigen so we could develop an ITP workflow for ultra-high molecular weight (UHMW) DNA. We’re continuing to support applications of ITP on the Ionic system in other areas, especially for NGS, because we believe it provides us a bridge to the molecular pathology community independent of OGM,” said Erik Holmlin, PhD, president and chief executive officer of Bionano.

More information on the Ionic system can be found here.

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 isotachophoresis (ITP) technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Forward-Looking Statements of Bionano

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “can,” “potential” 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 potential of the Ionic Purification System to offer improvements in quality and yield of nucleic acid extracted from complex biological samples including those with low cell counts or otherwise challenging sample types, such as FFPE tumor samples; the potential of the Ionic G2 kits to enable ITP to improve the quality and yield of nucleic acids when compared to column-based methods; and the potential of the Ionic Purification System and the Ionic G2 kits to be an ideal solution for many sample types, including limited and low-quality solid tumor and homologous recombination deficiency (HRD) samples. 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 bank failures, the COVID-19 pandemic and the ongoing Ukraine-Russian conflict, and related sanctions, on our business and the global economy; the failure of the Ionic Purification System or the Ionic G2 kits to improve the quality and yield of nucleic acid extracted from complex biological samples including those with low cell counts or otherwise challenging sample types, such as FFPE tumor samples, and low-quality solid tumor and homologous recombination deficiency (HRD) samples; the failure of customers to adopt our Ionic Purification System and the Ionic G2 kits for their sample isolation needs; 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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