bionano

Bionano Reports Preliminary Fourth Quarter and Full-Year 2023 Results

January 8, 2024

- Preliminary Q4 2023 revenue expected to be between \$10.4 and \$10.7 million, which would represent an estimated increase of 27% to 30% over Q4 2022
- Reached installed base of 326 optical genome mapping (OGM) systems as of YE 2023; increase of 36% over the 240 installed systems as of YE 2022
- Preliminary number of nanochannel array flowcells sold in Q4 2023 expected to be 7,980, which would represent an estimated increase of 67% over the 4,781 flowcells sold in Q4 2022
- Achieved all full-year 2023 ELEVATE milestones

SAN DIEGO, Jan. 08, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today reported certain unaudited preliminary financial and commercial highlights for the fourth quarter and fiscal year ended December 31, 2023. The Company's full results for the fourth quarter and the fiscal year ended December 31, 2023 are not yet available.

"2023 was a year in which we saw consistent progress in our business, and we ended the year with a lot of momentum across all facets of our business," commented Erik Holmlin, PhD, president and chief executive officer of Bionano. "In addition to Bionano's efforts to advance OGM, our user base has independently organized to advocate for OGM as an alternative to traditional cytogenetic methods, with user groups convening across the globe and an international consortium of researchers publishing a framework for the adoption and implementation of OGM. We believe the progress of OGM in 2023, combined with our achievement of our ELEVATE milestones and our cost savings initiatives and financing, have positioned us for success in 2024."

Q4 2023 Preliminary Unaudited Financial and Business Results

- Revenues for the fourth quarter 2023 are expected to be in the range of \$10.4 million to \$10.7 million, an estimated increase of 27% to 30% compared to \$8.2 million in the fourth quarter of 2022.
- Full year 2023 revenue is expected to be in the range of \$35.8 million and \$36.1 million, an estimated increase of 29% to 30% compared to full year 2022.
- Installed base of OGM systems totaled 326 at year-end, which represented a 36% increase over the 240 installed systems reported at the end of 2022.
- Nanochannel array flowcells sold in the fourth quarter is expected to be 7,980, an estimated increase of 67% over the 4,781 flowcells sold in the fourth quarter of 2022.
- Cash, cash equivalents, and available-for-sale securities as of December 31, 2023 were approximately \$102.8 million, of which \$36.1 million is subject to certain restrictions. We raised net proceeds of \$11.0 million from ATM sales during the period of November 14, 2023 through December 31, 2023. An additional \$2.9 million has been raised in net proceeds from ATM sales in 2024 to date.

Achieved All Full-Year 2023 ELEVATE! Milestones

- Released the high throughput OGM instrument, called the Stratys[™] system, as part of an early access program in the fourth quarter of 2023; the full commercial release is expected in early 2024. The Stratys system is expected to enable a four-fold increase in raw data generation rate compared to the Saphyr[®] system and is designed for maximum lab flexibility by enabling up to 12 single access chips, accessible as they complete runs, without the need to batch multiple samples on a consumable.
- Released VIA[™] software, which replaces NClinical[™] software with a simple and integrated workflow for visualization, interpretation, and reporting for OGM, microarray and next-generation sequencing (NGS) data types for enhanced contextualization across multiple variant types and accelerated time to results at a reduced cost. A workflow focused on hematological malignancies was released in June 2023, and in December 2023, the Company announced upgrades to its pipeline for OGM data analysis in VIA software for applications in constitutional genetic diseases.
- Pre-commercial version of the lonic Purification System for isolation of DNA for OGM analysis running in the field with the full commercial launch planned for 2024.
- Launched an OGM laboratory developed test (LDT) for constitutional genetic disease applications through Bionano Laboratories.

- Submitted a dossier to Medicare seeking a local coverage determination (LCD) for OGM coverage.
- Conducted a pre-submission discussion with FDA in connection with the planned clearance of the Stratys system.
- Met or exceeded all previously stated 2023 milestones for prenatal, postnatal, and hematological malignancy clinical trials, including: sample enrollment and data collection for prenatal study; interim publication of the prenatal study; interim publication of the hematological malignancy study; peer-reviewed interim publication from postnatal study; and IRB approval for solid tumor study.

"In 2023, we secured additional financing and announced a series of cost savings initiatives that will continue into this year. We remain focused on financial discipline and implementing actionable processes that we believe will enable us to improve margins and further extend our cash runway. I believe in the power of OGM and that 2024 has the potential to be a tremendous year for Bionano," added Gülsen Kama, chief financial officer of Bionano.

Bionano has not completed preparation of its financial statements for the fourth quarter or full year of 2023. The financial performance measures presented in this press release for the fourth quarter of 2023 and for the year ended December 31, 2023 are preliminary and unaudited, based on management's initial review of the information presented, and are thus inherently uncertain and subject to change as Bionano completes its end-of-period reporting process and related activities for the fourth quarter of and full year 2023. Bionano is in the process of completing its customary year-end close and review procedures as of and for the year ended December 31, 2023, and the final results for this period could differ from the preliminary estimated results disclosed in this press release. During the course of the preparation of Bionano's unaudited consolidated financial statements and related notes as of and for the year ended December 31, 2023, Bionano's independent registered public accountants may identify items that could cause final reported results to be materially different from the preliminary estimates presented herein. Additional information and disclosures would be required for a more complete understanding of Bionano's financial position and results of operations as of and for the fourth quarter and year ended December 31, 2023. Accordingly, undue reliance should not be placed on this preliminary information.

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 technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Unless specifically noted otherwise, Bionano's OGM products are for research use only and not for use in diagnostic procedures.

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 "anticipate," "believe," "could," "estimate," "expect," "may," "plan," "will," "should" "intend" 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: certain financial measures, such as our preliminary revenue, installed base and flowcell sales expected for the fourth quarter 2023 and fiscal year 2023; our ability to execute on our strategy and achieve our objectives; the impact and utility of our cost savings initiative and our recent financing to position us for success in 2024; our ability to continue to drive OGM adoption by potential customers for routine use in genomic analysis to expand our OGM installed base and planned product launches and regulatory developments; the timing of the full commercial release of the Stratys system and Ionic Purification System and their potential impact; continued research, presentations and publications involving OGM and its utility compared to traditional cytogenetics and our technologies; and our ability to drive adoption of OGM and our technology solutions; and our prospects for 2024. 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: adjustments to our preliminary measures of financial performance resulting from, among other things, the completion of our end-of-period review and reporting processes; the timing and amount of revenue we are able to recognize in a given fiscal period; the impact of adverse geopolitical and macroeconomic events, such as recent and future bank failures, global pandemics, inflation, supply chain disruptions and the ongoing conflict between Ukraine and Russia and Israel and Hamas, on our business and the global economy; general market conditions; our ability to meet the funding conditions to gain access to the minimum cash amount held as restricted cash in an account control agreement under the financing; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; our need and ability to obtain sufficient additional financing to fund our strategic plans and commercialization efforts, our ability to effectively manage our uses of cash, and our ability to continue as a "going concern"; the ability or potential 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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