Bionano Genomics Reports Fourth Quarter and Full-Year 2022 Results and Provides Revenue Outlook for 2023

March 9, 2023

- Q4 revenue was $8.2 million, which represents a 30% increase over Q4 2021
- 2022 revenue was $27.8 million, which represents a 55% increase over year end 2021
- Reached installed base of 240 Saphyr® systems as of YE 2022, which represents a 46% increase over YE 2021
- Conference call today, March 9th, 2023 at 4:30 PM ET

SAN DIEGO, March 09, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today reported financial results for the fourth quarter and full year ended December 31, 2022 and revenue outlook for 2023.

“We started the year against a challenging external backdrop, and over the course of the year achieved or exceeded all of the stated 2022 ELEVATE! milestones we outlined at the beginning of 2022,” commented Erik Holmlin, PhD, president and chief executive officer of Bionano. “Bionano issued revenue guidance for the first time in 2022, and we exceeded our total 2022 guidance range. We were also pleased to see an uptick in overall awareness and adoption of optical genome mapping (OGM) across the globe.”

Recent Highlights

- **Published peer-reviewed publication for prenatal validation study**, which evaluated 114 samples for prenatal genetic disease using OGM; results showed OGM to have 100% concordance with traditional cytogenetic methods and 100% interrun, intrarun, and interinstrument technical and analytical reproducibility.
- **Published peer-reviewed publication for postnatal validation study,** which compared OGM to standard of care (SOC) methods across 7 clinical sites, using 404 constitutional postnatal samples; results showed that 99.5% of samples were fully concordant with SOC methods, with 100% inter- and intrasite repeatability.

Q4 2022 and YE 2022 Highlights

- **Installed base of Saphyr® systems totaled 240 at year-end**, which was an increase of 23 systems over third quarter 2022 and represented a 46% increase over the 164 installed systems reported at the end of 2021.
- **Sold 4,781 flowcells in Q4 2022,** which was an increase of 49% percent over fourth quarter 2021; 15,375 flowcells were sold in 2022, which represented a 23% increase over the total number of flowcells sold in 2021.
- **Acquired Purigen Biosystems**, which we expect to accelerate the adoption of OGM due to anticipated improvements in Bionano’s ultra-high molecular weight (UHMW) DNA sample preparation workflow.
- **Key publications validated OGM’s utility for research applications including cancer and genetic disease:**
    - Researchers from The University of Texas MD Anderson Cancer Center published the first study to evaluate the utility of OGM for myelodysplastic syndrome (MDS) prognostication. The publication reported that when OGM was used instead of karyotyping, 17 to 21% of study subjects had different prognostic risk scores depending on the scoring system used, and in 13% of study subjects additional pathogenic variants were revealed.
    - In a study published in *Blood Cancer Journal*, researchers found that in 33% of MDS samples and 54% of acute myeloid leukemia (AML) samples, more clinically relevant variants were detected using OGM than were found by traditional cytogenetic methods and these variants were reported to be highly relevant to the understanding of pathogenesis of these disorders.
    - Researchers from eight research institutes analyzed OGM’s utility for detection of cytogenetic abnormalities in AML samples, finding that OGM identified pathogenic variants in 12% of cases that altered European LeukemiaNet risk-level or identified eligibility for clinical trials.
    - The first published validation study to evaluate the performance of OGM versus traditional cytogenetic techniques for the analysis of hematological neoplasms showed that OGM’s technical performance resulted in a 100% first-pass rate, with concordance to traditional methods showing a sensitivity of 98.7%, a specificity of 100%, and an accuracy of 99.2%.
    - A study demonstrated the utility of OGM as part of a workflow to evaluate the quality of hypoimmunogenic induced pluripotent stem cells (iPSCs) which could be used in regenerative medicine. This research provides scientific and practical support for OGM’s ability to detect cryptic and balanced SVs in CRISPR-edited cells, some of which were not detected by karyotyping, and which may impact the genomic integrity of iPSCs.

Achieved All Full-Year 2022 ELEVATE! Milestones

- **Launched OGM laboratory developed tests (LDTs)** for hematological malignancy and genetic disorder applications through Bionano Laboratories.
- **Pre-commercial version of next generation OGM system running in the field** with a planned commercial launch in first half of 2023.
- **Developed and released enhanced Bionano Prep SP-G2 (SP-G2) labeling kit and Bionano Prep Direct Label and Stain-G2 (DLS-G2) DNA isolation kit** which enable sample to results in as little as 3 days for cancer samples.
    - In partnership with Hamilton, released an automated version of Bionano's DNA isolation chemistry.
- **NxClinical™ software version 7.0, which is the version of NxClinical software enabled for OGM data analysis, is being used in the field** and full commercial release for applications in hematological malignancies is planned for the first half of 2023.
- **Met all previously stated 2022 milestones** for prenatal, postnatal and hematological clinical trials, including: study enrollment targets; completion of postnatal study, which has been submitted for publication as a pre-print; interim publication of the prenatal study, which was published in December 2022 as a pre-print; and initiation of the solid tumor trial.

Q4 2022 and Full Year 2022 Financial Highlights

- **Total revenue for the fourth quarter of 2022 was $8.2 million**, an increase of 14% compared to $7.2 million in the third quarter of 2022 and an increase of 30% compared to the fourth quarter of 2021. Full year 2022 revenue was $27.8 million, an increase of 55% compared to 2021.
- **Gross margin for the fourth quarter of 2022 was 22%**, compared to 4% from the fourth quarter of 2021. The increase was primarily due to major improvements in chip yield year-over-year. Full year 2022 total gross margin was 21%, slightly down from 22% in 2021.
- **Fourth quarter 2022 GAAP operating expense was $39.3 million**, compared to $29.0 million in the prior year. Fourth quarter 2022 non-GAAP operating expense was $30.6 million, compared to $21.8 million in the fourth quarter of 2021. Fourth quarter 2022 non-GAAP operating expenses exclude $5.5 million in stock-based compensation, $1.5 million in amortization of intangibles, and $1.7 million in acquisition-related expenses. The year-over-year increase was primarily due to increased headcount-related spending, increased R&D expenses, and expenses associated with our acquisition of Purigen Biosystems. Full year 2022 GAAP operating expense was $137.6 million and non-GAAP operating expense was $107.7 million. Full year 2022 non-GAAP operating expense excludes $22.4 million in stock-based compensation, $5.8 million in amortization of intangibles, and $1.8 million in acquisition-related transaction costs associated with our acquisition of Purigen Biosystems.[1]
- **Cash, cash equivalents, and available-for-sale securities were $113.2 million as of December 31, 2022** compared to cash, cash equivalents and available-for-sale securities of $250.6 million as of December 31, 2021.

2023 Financial Guidance

- Bionano expects full year 2023 revenue to be in the range of $35 million to $38 million, which would represent a range of 26% to 37% growth over full year 2022 revenue. We anticipate the installed base of OGM systems will total 325 by the end of 2023.

Chris Stewart, chief financial officer at Bionano added, "Q4 2022 was an outstanding quarter, capping off a tremendous year where we achieved impressive year-over-year revenue growth of 30%. We leveraged our strong balance sheet to acquire Purigen Biosystems and their industry leading isotachophoresis (ITP) solution for DNA isolation and analysis on the Ionic® Purification System in Q4 2022. We begin 2023 well-positioned, and look forward to executing on our goal to drive value for our stakeholders."

Webcast Details

Webcast Details	
Date:	Thursday, March 9, 2023
Time:	4:30 p.m. Eastern Time
Participant Registration:	**https://register.vevent.com/register/BI1a2ac25870e84ed0aeee268edd291fca**
Webcast:	**https://edge.media-server.com/mmc/p/wi7rgr4x**

Participants should register at the link above in advance of the call, and then click the webcast link before the call begins. An archived version of the webcast will be available for replay in the Investors section of the Bionano website.

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 and for other applications including bioprocessing. Through its 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. Through its Purigen Biosystems business, the Company offers nucleic acid extraction and purification solutions using proprietary ITP technology. For more information,visit www.bionano.com, www.bionanolaboratories.com or www.biodiscovery.com

Non-GAAP Financial Measures

To supplement Bionano's financial results reported in accordance with U.S. generally accepted accounting principles (GAAP), the Company has provided non-GAAP operating expense in this press release, which is a non-GAAP financial measure. Non-GAAP operating expense excludes from GAAP reported operating expense the following components as detailed in the reconciliation table accompanying this press release: stock-based compensation, amortization of intangibles and acquisition-related expenses.

Bionano believes that non-GAAP operating expense is useful to investors and analysts as a supplement to its financial information prepared in accordance with GAAP for analyzing operating performance and identifying operating trends in its business. Bionano uses non-GAAP operating expense internally to facilitate period-to-period comparisons and analysis of its operating performance in order to understand, manage and evaluate its business and to make operating decisions. Accordingly, Bionano believes this measure allows for greater transparency with respect to key financial metrics it uses in assessing its own operating performance and making operating decisions.

This non-GAAP financial measure is not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with the Company's consolidated financial statements prepared in accordance with GAAP; has no standardized meaning prescribed by GAAP; and is not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future, there may be other items that the Company may exclude for purposes of its non-GAAP financial measures; and the Company may in the future cease to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. Likewise, the Company may determine to modify the nature of its adjustments to arrive at its non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measure as used by Bionano in this press release and the accompanying reconciliation table has limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

For a reconciliation of non-GAAP operating expense to operating expense reported in accordance with GAAP, please refer to the financial tables accompanying this release.

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," "estimate," "expect," "may," "plan," "will," "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: our expectations regarding product uptake, revenue growth, market development and increased OGM adoption, including through publications highlighting the utility and applications of OGM; our growth prospects and future financial and operating results, including our 2023 revenue guidance; the growth of our installed Saphyr system base; the sales of our flowcell consumables and the other expectations related thereto; our ability to meet our stated goals, including to drive value and penetrate into our target markets; our commercial expectations, including the potential market opportunity for structural variation analysis and OGM; the anticipated benefits and success of our collaboration efforts, including the opportunities offered by our anticipated collaborations with Hamilton and NVIDIA; the expected benefits from our acquisition of Purigen Biosystems and its ITP technology to help accelerate the adoption of OGM; the expected launch of our next-generation OGM system; the ability and utility of the DLS G2 and SP Next reagents to decrease processing time; continued research, presentations and publications involving OGM, its utility compared to traditional cytogenetics and our technologies; our ability to drive adoption of OGM and our technology solutions; and expected timing and results from our clinical studies; and the execution of our strategy. 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 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 the COVID-19 pandemic and the ongoing conflict between Ukraine and Russia, 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; 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; study results that differ or contradict the results mentioned in this press release; 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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BIONANO GENOMICS, INC
Consolidated Statement of Operations (Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 6,178,000	$ 4,841,000	$ 20,425,000	$ 12,686,000
Service and other revenue	2,037,000	1,461,000	7,377,000	5,295,000
Total revenue	8,215,000	6,302,000	27,802,000	17,981,000
Cost of revenue:				
Cost of product revenue	4,709,000	4,801,000	15,966,000	10,524,000
Cost of service and other revenue	1,701,000	1,262,000	5,891,000	3,583,000
Total cost of revenue	6,410,000	6,063,000	21,857,000	14,107,000
Operating expenses:				
Research and development	14,011,000	9,215,000	49,047,000	22,485,000
Selling, general and administrative	25,321,000	19,807,000	88,596,000	58,490,000
Total operating expenses	39,332,000	29,022,000	137,643,000	80,975,000
Loss from operations	(37,527,000)	(28,783,000)	(131,698,000)	(77,101,000)
Other income (expenses)				
Interest income	770,000	236,000	1,507,000	236,000
Interest expense	(75,000)	(206,000)	(298,000)	(927,000)
Gain on forgiveness of Paycheck Protection Program Loan	—	—	—	1,775,000
Loss on debt extinguishment	—	—	—	(2,076,000)
Other income (expenses)	(40,000)	37,000	(223,000)	(59,000)
Total other income (expenses)	655,000	67,000	986,000	(1,051,000)
Loss before income taxes	(36,872,000)	(28,716,000)	(130,712,000)	(78,152,000)
Benefit (provision) for income taxes	(1,805,000)	5,767,000	(1,884,000)	5,717,000
Net loss	$ (38,677,000)	$ (22,949,000)	$ (132,596,000)	$ (72,435,000)

BIONANO GENOMICS, INC
Consolidated Balance Sheet (Unaudited)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 5,091,000	$ 24,571,000
Investments	108,095,000	226,041,000
Accounts receivable, net	7,022,000	4,934,000
Inventory	29,761,000	12,387,000
Prepaid expenses and other current assets	7,329,000	4,481,000
Total current assets	157,298,000	272,414,000
Restricted cash	400,000	—
Property and equipment, net	18,029,000	10,318,000
Operating lease right-of-use assets	7,222,000	6,691,000
Financing lease right-of-use assets, related party	3,707,000	3,926,000
Intangible assets, net	41,143,000	26,842,000
Goodwill	77,289,000	56,160,000
Other long-term assets	2,414,000	749,000
Total assets	$ 307,502,000	$ 377,100,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 12,534,000	$ 10,769,000

Accrued expenses	10,552,000	8,621,000
Contract liabilities	871,000	684,000
Operating lease liability	2,260,000	1,467,000
Finance lease liability	285,000	299,000
Contingent consideration	9,382,000	—
Total current liabilities	35,884,000	21,840,000
Operating lease liability, net of current portion	5,504,000	5,288,000
Finance lease liability, net of current portion	3,619,000	3,642,000
Contingent consideration	12,970,000	9,066,000
Long-term contract liabilities	127,000	146,000
Total liabilities	$ 58,104,000	$ 39,982,000
Stockholders' equity:		
Common Stock	30,000	29,000
Additional paid-in capital	599,207,000	553,747,000
Accumulated deficit	(348,715,000)	(216,119,000)
Accumulated other comprehensive loss	(1,124,000)	(539,000)
Total stockholders' equity	249,398,000	337,118,000
Total liabilities and stockholders' equity	$ 307,502,000	$ 377,100,000

BIONANO GENOMICS, INC

Reconciliation of GAAP Operating Expense to Non-GAAP Operating Expense (Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	**2021**	**2022**	**2021**
Total GAAP operating expense	$ 39,332,000	$ 29,022,000	$ 137,643,000	$ 80,975,000
GAAP selling, general and administrative expense	25,321,000	19,807,000	88,596,000	58,490,000
Stock-based compensation expense	(2,478,000)	(2,480,000)	(9,015,000)	(6,188,000)
Intangible asset amortization	(1,543,000)	(1,196,000)	(5,800,000)	(1,400,000)
Transaction related expenses	(1,673,000)	(1,218,000)		(1,458,000)
Adjusted non-GAAP selling, general and administrative expense	19,627,000	14,913,000	72,021,000	49,444,000
GAAP Research and development expense	14,011,000	9,215,000	49,047,000	22,485,000
Stock-based compensation expense	(3,001,000)	(2,322,000)	(13,402,000)	(3,531,000)
Adjusted non-GAAP research and development expense	11,010,000	6,893,000	35,645,000	18,954,000
Total adjusted non-GAAP operating expense	$ 30,637,000	$ 21,806,000	$ 107,666,000	$ 68,398,000

[1]GAAP operating expense is a non-GAAP financial measure. For a description of this non-GAAP financial measure, please refer to "Non-GAAP Financial Measures", and for a reconciliation of non-GAAP operating expense to operating expense reported in accordance with GAAP, please refer to the financial tables accompanying this release

Source: Bionano Genomics