

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2023

Bionano Genomics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38613
(Commission
File Number)

26-1756290
(IRS Employer
Identification No.)

9540 Towne Centre Drive, Suite 100
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's telephone number, including area code: **(858) 888-7600**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	BNGO	The Nasdaq Stock Market, LLC
Warrants to purchase Common Stock	BNGOW	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Bionano Genomics, Inc. (the “Company”) issued a press release reporting its financial results for the first quarter ended March 31, 2023. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information contained or incorporated herein, including the press release filed as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued May 9, 2023, reporting financial results for the first quarter ended March 31, 2023
104	Inline XBRL for the cover page of this Current Report on Form 8-K

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 9, 2023

Bionano Genomics, Inc.

By: /s/ R. Erik Holmlin, Ph.D.

R. Erik Holmlin, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

Bionano Reports First Quarter 2023 Results and Highlights Recent Business Progress

- Q1 2023 revenue was \$7.4 million, which represents a 30% increase over Q1 2022
- Installed base of 259 Saphyr® systems totaled as of Q1 2023, which represents a 47% increase over Q1 2022
- Sold 5,226 nanochannel array flowcells in Q1 2023, which represents a 62% increase over the number of flowcells sold in Q1 2022
- Conference call today, May 9th, 2023 at 4:30 PM ET

SAN DIEGO, May 9, 2023 (GLOBE NEWSWIRE) — Bionano Genomics, Inc. (Nasdaq: BNGO) today reported financial results for the first quarter ended March 31, 2023.

Q1 2023 Highlights

- **Installed base of Saphyr® systems totaled 259 at the end of the first quarter 2023**, which was an increase of 19 systems over the fourth quarter of 2022 and represents a 47% increase over the 176 installed systems reported at the end of the first quarter of 2022.
- **5,226 nanochannel array flowcells sold during the first quarter**, which represents a 9% increase over the 4,781 flowcells sold during the fourth quarter of 2022 and represents an increase of 62% over the 3,225 flowcells sold during the first quarter of 2022.
- **Announced a collaboration with NVIDIA to develop an acceleration platform for use in Bionano's optical genome mapping (OGM) workflow**; collaboration is expected to significantly improve data processing speed while reducing time and cost associated with secondary analysis of OGM data.
- **Announced that an original equipment manufacturing (OEM) partner in China, Beijing Genome Precision Technology (BGPT), a comprehensive molecular diagnostics company, obtained reagent class I registrations** from China's National Medical Products Administration (NMPA) for Bionano's DNA extraction kit and labeling products for use in *in vitro* diagnostics (IVD); which allows BGPT to market these products to independent clinical labs in China.
- **Significantly expanded 4-day 2023 Symposium year-over-year**: 31 oral presentations on OGM; 114 countries represented; 69 scientific posters; and an average of 750 daily attendees, a 32% increase over 2022 daily attendance.
- **Held first-ever Strategy Day at Nasdaq MarketSite in New York**, where Bionano's management team delivered an in-depth review of the Company's strategy and growth initiatives and outlined our three-year financial targets including 30-50% compound annual growth in revenues. Key opinion leaders from MD Anderson Cancer Center, Augusta University, Boston Children's Hospital, Children's Hospital Los Angeles, University of Toronto and Sanford Burnham Prebys Institute, spoke about their experience using OGM in translational and clinical research areas including cancer, genetic disease and cell bioprocessing and how it's different from other technologies, such as next-generation sequencing (NGS) and long read sequencing (LRS). All presentations from the event were recorded and are available to view in the Investors section of the Bionano website.
- **Key publications support OGM's utility for research applications including cancer and genetic disease:**

- Three publications from European institutions collectively illustrated the continued development of data supporting OGM as an alternative to traditional cytogenetic methods for the analysis of hematological malignancies. The studies confirmed OGM's high level of concordance and ability to identify relevant variants that are not detected by traditional methods but that could have an impact on clinical research, potentially leading to improved patient management, including therapy selection and overall risk assessment.
- Researchers from Augusta University published the first study to evaluate OGM as a method to identify rare structural variants (SVs) that might contribute to the development of Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome. OGM detected rare SVs with potential disease relevance in 19.5% of samples and identified mosaicism in 21.4% of confirmed variants. Study authors also used OGM to identify the first described female with MRKH to possess mosaicism for trisomy 12, which potentially confirms a genetic driver that researchers have thought to be linked to MRKH.
- A pre-print publication described the multi-site evaluation of OGM for postnatal genetic disorders in 560 unique samples, with a study total of 749 unique samples to-date from 1,037 datapoints, and showed 99.6% concordance with standard of care (SOC) methods and showed 42% more reportable findings in samples suspected of a genetic disorder, and 32% more reportable findings in samples suspected of autism spectrum disorders (ASD), when compared with traditional cytogenetic methods.
- A published interim report described the multi-site evaluation of OGM for prenatal genetic disorders in 200 samples across 9 sites, assessing performance and reproducibility of OGM versus SOC methods. The report showed OGM was comparable, in a single assay, to the results of two separate SOC tests in 56% of cases and to three separate SOC tests in 19% of cases, with 100% concordance for all calls and variant calls, and 100% reproducibility of analytical quality control and variant calls from site-to-site.
- A study from Institut Curie analyzed OGM as a method to identify homologous recombination deficiency (HRD) in breast cancer samples. The study reported that OGM successfully assessed levels of HRD in all samples, potentially improving genomic profiling of solid tumor samples and offering an efficient, lower-cost method of detecting HRD with greater sensitivity than whole genome sequencing (WGS).

"We are pleased with our Q1 2023 results, which include record revenues for any Bionano Q1 and mark the tenth consecutive quarter of year-over-year revenue growth, dating back to the fourth quarter of 2020. This quarter's expansion in the Saphyr system installed base, combined with the increasing number of publications on OGM that reported consistently high concordance with traditional cytogenetic methods across key applications within cytogenomics and genomics research, provide additional indications of the potential for further OGM adoption," commented Erik Holmlin, PhD, president and chief executive officer of Bionano. "We believe our achieved and planned product introductions, together with the growing evidence of OGM utility shown in recent publications, lay the foundation for potential further penetration of our target markets and revenue growth."

Q1 2023 Financial Highlights

- **Total revenue for the first quarter of 2023 was \$7.4 million**, an increase of 30% compared to the first quarter of 2022.
- **GAAP gross margin for the first quarter of 2023 was 28%**, compared to 15% from the first quarter of 2022. The increase was primarily due to year-over-year improvements in our flowcell chip production yield. First quarter 2023 non-GAAP¹ gross margin was 30%, compared to 15% from the first quarter of 2022. First quarter 2023 non-GAAP gross margin excludes \$146,000 in stock-based compensation.
- **First quarter 2023 GAAP operating expense was \$39.9 million**, compared to \$30.8 million in the first quarter of 2022. First quarter 2023 non-GAAP operating expense was \$33.6 million, compared to \$24.2 million in the first quarter of 2022. First quarter 2023 non-GAAP operating expense excludes \$3.7 million in stock-based compensation, \$1.8 million in amortization of intangibles, and a \$0.8 million increase in the estimated fair value of the contingent consideration liabilities primarily related to the acquisition of Purigen.
- **Cash, cash equivalents, and available-for-sale securities were \$95.8 million as of March 31, 2023**, compared to cash, cash equivalents and available-for-sale securities of \$113.2 million as of December 31, 2022.

Chris Stewart, chief financial officer at Bionano added, "Q1 2023 was an important quarter for the Company. Our gross margins improved, and we believe momentum for OGM continues to build. We are leveraging our investments in the commercial organization and evidence development to drive adoption of the Saphyr system. We continue to execute on our strategy as we seek to generate long-term shareholder value."

Plan to Reduce Future Cash Expenditures

Bionano recently undertook a strategic review of our operations, and today we announce our initiative to reduce cash expenditures by approximately \$20 million over this and the next four to five quarters. This cost-reduction initiative includes, among other things, a reduction in force that we effected May 8, 2023, plans to decrease anticipated new hires for the remainder of 2023, a reduction to our safety stock of inventory due to a reduced risk we are seeing with our supply chain, implementation of operational efficiencies, and other cost controls to reduce previously planned spending. We expect to continue to prioritize and invest in our high priority programs that support the ongoing adoption of OGM and new product launches, and we remain on track to meet our previously publicly announced 2023 ELEVATE! Anticipated Milestones, including the advancement of our clinical studies, expansion of our OGM installed base, and planned product and regulatory developments.

Webcast Details

<u>Webcast Details</u>	
Date:	Tuesday, May 9, 2023
Time:	4:30 p.m. Eastern Time
Live Call:	Toll-Free: (800) 715-9871, Conference ID: 4068548
Webcast:	https://edge.media-server.com/mmc/p/tw7qar43

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.

¹Non-GAAP gross margin and operating expense are non-GAAP financial measures. For a description of these non-GAAP financial measures, please refer to "Non-GAAP Financial Measures", and for a reconciliation of non-GAAP cost of revenue and operating expense to cost of revenue and operating expense reported in accordance with GAAP, please refer to the financial tables accompanying this release.

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 isotachopheresis (ITP) technology. For more information, visit www.bionano.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 gross margin and non-GAAP operating expense in this press release, which are non-GAAP financial measures. 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 change in fair value of contingent consideration. Non-GAAP gross margin excludes from GAAP reported gross margin stock-based compensation as detailed in the reconciliation table accompanying this press release.

Bionano believes that non-GAAP gross margin and non-GAAP operating expense are 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 gross margin and 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 these measures allow for greater transparency with respect to key financial metrics it uses in assessing its own operating performance and making operating decisions.

These non-GAAP financial measures are 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; have no standardized meaning prescribed by GAAP; and are 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 measures as used by Bionano in this press release and the accompanying reconciliation table have 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 gross margin and non-GAAP operating expense to gross margin and 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” 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 compound annual growth in revenues; 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 NVIDIA; the expected benefits of our partner’s IVD registrations in China; continued research, presentations and publications involving OGM and its utility compared to traditional cytogenetics and our technologies; our ability to drive adoption of OGM and our technology solutions; and the execution of our stated 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 recent and potential future bank failures, 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.

CONTACTS

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BIONANO GENOMICS, INC
Condensed Consolidated Balance Sheet (Unaudited)

	(Unaudited)	
	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,104,000	\$ 5,091,000
Investments	91,704,000	108,095,000
Accounts receivable, net	6,780,000	7,022,000
Inventory	33,113,000	29,761,000
Prepaid expenses and other current assets	6,856,000	7,329,000
Total current assets	142,557,000	157,298,000
Restricted cash	400,000	400,000
Property and equipment, net	19,050,000	18,029,000
Operating lease right-of-use asset	7,062,000	7,222,000
Financing lease right-of-use asset	3,657,000	3,707,000
Intangible assets, net	39,351,000	41,143,000
Goodwill	77,289,000	77,289,000
Other long-term assets	2,785,000	2,414,000
Total assets	\$ 292,151,000	\$ 307,502,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 15,780,000	\$ 12,534,000
Accrued expenses	9,250,000	10,552,000
Contract liabilities	1,127,000	871,000
Operating lease liability	2,235,000	2,260,000
Finance lease liability	282,000	285,000
Contingent consideration	9,461,000	9,382,000
Total current liabilities	38,135,000	35,884,000
Operating lease liability, net of current portion	5,043,000	5,504,000
Finance lease liability, net of current portion	3,612,000	3,619,000
Contingent consideration	13,680,000	12,970,000
Long-term contract liabilities	194,000	127,000
Total liabilities	60,664,000	58,104,000
Stockholders' equity:		
Common stock	31,000	30,000
Additional paid-in capital	617,960,000	599,207,000
Accumulated deficit	(385,839,000)	(348,715,000)
Accumulated other comprehensive loss	(665,000)	(1,124,000)
Total stockholders' equity	231,487,000	249,398,000
Total liabilities and stockholders' equity	\$ 292,151,000	\$ 307,502,000

Bionano Genomics, Inc.
Condensed Consolidated Statement of Operations (Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Product revenue	\$ 5,447,000	\$ 4,206,000
Service and other revenue	1,968,000	1,490,000
Total revenue	7,415,000	5,696,000
Cost of revenue:		
Cost of product revenue	3,858,000	3,576,000
Cost of service and other revenue	1,487,000	1,259,000
Total cost of revenue	5,345,000	4,835,000
Operating expenses:		
Research and development	13,937,000	10,527,000
Selling, general and administrative	25,976,000	20,277,000
Total operating expenses	39,913,000	30,804,000
Loss from operations	(37,843,000)	(29,943,000)
Other income (expenses):		
Interest income	704,000	110,000
Interest expense	(76,000)	(77,000)
Other income (expense)	117,000	(33,000)
Total other income (expense)	745,000	—
Loss before income taxes	(37,098,000)	(29,943,000)
Provision for income taxes	(26,000)	(9,000)
Net loss	\$ (37,124,000)	\$ (29,952,000)

Bionano Genomics, Inc.

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

	Three Months Ended March 31,	
	2023	2022
GAAP gross margin:		
GAAP revenue	\$ 7,415,000	\$ 5,696,000
GAAP cost of revenue	5,345,000	4,835,000
GAAP gross profit	2,070,000	861,000
GAAP gross margin %	28 %	15 %
Adjusted non-GAAP gross margin:		
GAAP revenue	7,415,000	5,696,000
GAAP cost of revenue	5,345,000	4,835,000
Stock-based compensation expense	(146,000)	—
Adjusted non-GAAP cost of revenue	5,199,000	4,835,000
Adjusted non-GAAP gross profit	2,216,000	861,000
Adjusted non-GAAP gross margin %	30 %	15 %
GAAP operating expense		
GAAP operating expense	\$ 39,913,000	\$ 30,804,000
GAAP selling, general and administrative expense	25,976,000	20,277,000
Stock-based compensation expense	(2,379,000)	(1,774,000)
Intangible asset amortization	(1,792,000)	(1,419,000)
Change in fair value of contingent consideration	(789,000)	(79,000)
Adjusted non-GAAP selling, general and administrative expense	\$ 21,016,000	\$ 17,005,000
GAAP research and development expense	\$ 13,937,000	\$ 10,527,000
Stock-based compensation expense	(1,357,000)	(3,328,000)
Adjusted non-GAAP research and development expense	12,580,000	7,199,000
Total adjusted non-GAAP operating expense	\$ 33,596,000	\$ 24,204,000