

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): August 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 August 9, 2023, Bionano Genomics, Inc. (the “Company”) issued a press release reporting its financial results for the second quarter ended June 30, 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 August 9, 2023, reporting financial results for the second quarter ended June 30, 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: August 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 Second Quarter 2023 Results and Highlights Recent Business Progress

- Q2 2023 revenue was \$8.7 million, which represents a 30% increase over Q2 2022
- Installed base of Saphyr® systems totaled 281 as of June 30, 2023, which represents a 43% increase over Q2 2022
- Sold 7,062 nanochannel array flowcells as of June 30, 2023, which represents a 108% increase over the number of flowcells sold in Q2 2022
- Conference call today, August 9th, 2023, at 4:30 PM ET

SAN DIEGO, August 9, 2023 (GLOBE NEWSWIRE) — Bionano Genomics, Inc. (Nasdaq: BNGO) today reported financial results for the second quarter ended June 30, 2023.

Q2 2023 Highlights

- **Installed base of Saphyr® systems totaled 281 at the end of the second quarter 2023**, which was an increase of 22 systems over the first quarter of 2023 and represents a 43% increase over the 196 installed systems reported at the end of the second quarter of 2022.
- **7,062 nanochannel array flowcells sold during the second quarter**, which represents a 35% increase over the 5,226 flowcells sold during the first quarter of 2023 and represents an increase of 108% over the 3,394 flowcells sold during the second quarter of 2022.
- **Announced the commercial release of new kits for the 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.
- **Announced the Stratys™ system for high throughput optical genome mapping (OGM), which will enable a four-fold increase in raw data generation rate compared to the Saphyr® instrument.** The Stratys instrument is compatible with the Company's latest G2 chemistry 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.
- **Announced VIA™ software, which replaces NxClinical™ software** with a simple and integrated workflow for visualization, interpretation and reporting for hematologic malignancies across 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 genetic disease is expected later in 2023.
- **Announced the 2023 winners of the Bionano Innovator Research Grant program**, which was established to fuel novel research using the Company's OGM products to detect relevant structural variants (SVs). There were over 190 grant applications submitted from 46 countries and 15 winners were selected, including researchers from grand prize winner Stanford University, and runner up prize winners The Hospital for Sick Children and Duke University. All three winners will receive use of a Saphyr system and OGM reagents to conduct their project.
- **Bionano participated at key cytogenetic conferences**, including the European Hematology Association (EHA) 2023 Congress, the European Human Genetics (ESHG) 2023 Conference, the European Association for Cancer Research (EACR) 2023 Congress and the International Society for Stem Cell Research (ISSCR) Annual Meeting 2023. OGM was featured in 37 scientific posters

and presentations covering a wide range of research applications across key areas including constitutional genetic disorders, rare undiagnosed genetic disease (RUGD), solid tumor analysis, hematological malignancies, stem cell research and regenerative medicine.

- **Key studies that were published during Q2 outline support for OGM's utility for cancer and genetic disease research:**
- Three peer-reviewed publications collectively illustrate the building support in Europe for OGM as a powerful alternative to traditional methods of cytogenetic analysis for hematological malignancies. Taken together, the publications, a review paper and two independent studies, illustrate that OGM is not only comparable to traditional methods of cytogenetic analysis for hematological malignancies but is potentially more sensitive in the detection of relevant aberrations 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.
- A peer-reviewed study from Augusta University assessed the utility of a combined OGM and 523-gene next-generation sequencing (NGS) panel workflow for the standard evaluation of samples from 30 myeloid cancer subjects and compared it to the common approach of KT and FISH combined with a 54-gene NGS panel. The authors found that the combined workflow of OGM plus the 523-gene NGS panel performed significantly better than KT and FISH, identifying previously undetected pathogenic SVs and resulting in revisions to risk classifications and disease stratifications.
- Researchers at Radboud University Medical Center published a study showing the use of OGM to identify gene disruptive SVs that might contribute to inherited retinal diseases (IRDs). The authors sought to determine whether OGM could improve SV detection in genetically unexplained IRD cases. Their results identified several pathogenic SVs that had been overlooked in their initial genome analyses by NGS, illustrating the potential impact of combining NGS and OGM for more comprehensive variant analysis.

"We are pleased with our Q2 2023 results, which include record revenues and consumable sales for any quarter in Bionano's history," commented Erik Holmlin, PhD, president and chief executive officer of Bionano. "We continue to see growing momentum in our business, and we believe our recent and upcoming major product releases should help us further penetrate new markets and achieve our business goals."

Q2 2023 Financial Highlights

- **Total revenue for the second quarter of 2023 was \$8.7 million**, an increase of 30% compared to the second quarter of 2022.
- **GAAP gross margin for the second quarter of 2023 was 27%**, compared to 22% from the second quarter of 2022. Second quarter 2023 non-GAAP¹ gross margin was 29%, compared to 22% from the second quarter of 2022. Second quarter 2023 non-GAAP gross margin excludes \$0.2 million in stock-based compensation.
- **Second quarter 2023 GAAP operating expense was \$41.5 million**, compared to \$33.6 million in the second quarter of 2022. Second quarter 2023 non-GAAP operating expense was \$34.6 million, compared to \$26.3 million in the second quarter of 2022. Second quarter 2023 non-GAAP operating expenses exclude \$3.7 million in stock-based compensation, \$1.8 million in amortization of intangibles, and a \$1.4 million increase in the estimated fair value of the contingent consideration liabilities primarily related to the acquisition of Purigen Biosystems.
- **Cash, cash equivalents, and available-for-sale securities were \$77.1 million as of June 30, 2023**, compared to cash, cash equivalents and available-for-sale securities of \$95.8 million as of March 31, 2023.

Chris Stewart, chief financial officer at Bionano added, "I am very pleased with the progress we demonstrated in Q2 2023. We saw growth in flow cell consumption, driven by both new installations and higher consumable purchases from existing customers. We implemented the previously announced cost savings actions, which we expect to see in second half operating expenses. In addition, we further advanced our long-term growth strategy and delivered quantifiable progress both sequentially as well as year over year."

Webcast Details

<u>Webcast Details</u>	
Date:	Wednesday, August 9, 2023
Time:	4:30 p.m. Eastern Time
Live Call:	https://register.vevent.com/register/BI39dd6092cc5144f3bbd50c5bafd22ff2
Webcast:	https://edge.media-server.com/mmc/p/kdtv69k5

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

Bionano is a provider of genomic analysis solutions that can help reveal answers to challenging genetic questions. Our mission is to transform the way the world sees the genome through optical genome mapping (OGM). Our OGM solutions allow scientists and clinical researchers the ability to see and discover structural variations in a way unmatched by traditional cytogenetic techniques. Our products additionally include an industry-leading, platform-agnostic software solution, which integrates OGM, next-generation sequencing and microarray data in one consolidated view, and nucleic acid extraction and purification solutions using proprietary isotachopheresis (ITP) technology. Our Lineagen, Inc., d/b/a Bionano Laboratories, business provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. To learn more, visit bionano.com and connect with us on Twitter, LinkedIn, Instagram, and YouTube.

Unless specifically noted otherwise, Bionano products are provided for Research Use Only. Not for use in diagnostic procedures

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: the potential for the new Ionic® Purification System to improve the quality and yield of samples, the commercial rollout of the Stratys™ system for high throughput OGM, the timing of a workflow focused on genetic diseases using VIA™ software, 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 recent and upcoming product releases helping us penetrate new markets and achieve our business goals; our commercial expectations, including the potential market opportunity for structural variation analysis and OGM; 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; the execution of our stated strategy, and previously announced cost savings actions reflecting in operating expense for the second half of 2023. 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, potential resurgences of COVID-19 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)	
	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,856,000	\$ 5,091,000
Investments	62,206,000	108,095,000
Accounts receivable, net	7,613,000	7,022,000
Inventory	32,453,000	29,761,000
Prepaid expenses and other current assets	5,447,000	7,329,000
Total current assets	122,575,000	157,298,000
Restricted cash	400,000	400,000
Property and equipment, net	20,263,000	18,029,000
Operating lease right-of-use asset	6,697,000	7,222,000
Financing lease right-of-use asset	3,606,000	3,707,000
Intangible assets, net	37,559,000	41,143,000
Goodwill	77,281,000	77,289,000
Other long-term assets	3,000,000	2,414,000
Total assets	\$ 271,381,000	\$ 307,502,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 11,912,000	\$ 12,534,000
Accrued expenses	8,316,000	10,552,000
Contract liabilities	978,000	871,000
Operating lease liability	2,014,000	2,260,000
Finance lease liability	279,000	285,000
Contingent consideration	10,000,000	9,382,000
Total current liabilities	33,499,000	35,884,000
Operating lease liability, net of current portion	4,766,000	5,504,000
Finance lease liability, net of current portion	3,604,000	3,619,000
Contingent consideration, net of current portion	14,570,000	12,970,000
Long-term contract liabilities	186,000	127,000
Total liabilities	56,625,000	58,104,000
Stockholders' equity:		
Common stock	3,000	3,000
Preferred Stock	—	—
Additional paid-in capital	639,814,000	599,234,000
Accumulated deficit	(424,751,000)	(348,715,000)
Accumulated other comprehensive loss	(310,000)	(1,124,000)
Total stockholders' equity	214,756,000	249,398,000
Total liabilities and stockholders' equity	\$ 271,381,000	\$ 307,502,000

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 6,609,000	\$ 4,795,000	\$ 12,056,000	\$ 9,001,000
Service and other revenue	2,053,000	1,875,000	4,021,000	3,365,000
Total revenue	8,662,000	6,670,000	16,077,000	12,366,000
Cost of revenue:				
Cost of product revenue	4,752,000	3,973,000	8,610,000	7,549,000
Cost of service and other revenue	1,602,000	1,226,000	3,090,000	2,485,000
Total cost of revenue	6,354,000	5,199,000	11,700,000	10,034,000
Operating expenses:				
Research and development	14,610,000	11,767,000	28,547,000	22,296,000
Selling, general and administrative	26,936,000	21,783,000	52,913,000	42,060,000
Total operating expenses	41,546,000	33,550,000	81,460,000	64,356,000
Loss from operations	(39,238,000)	(32,079,000)	(77,083,000)	(62,024,000)
Other income (expenses):				
Interest income	689,000	192,000	1,392,000	301,000
Interest expense	(74,000)	(74,000)	(149,000)	(151,000)
Other income (expense)	(256,000)	(156,000)	(139,000)	(188,000)
Total other income (expense)	359,000	(38,000)	1,104,000	(38,000)
Loss before income taxes	(38,879,000)	(32,117,000)	(75,979,000)	(62,062,000)
Provision for income taxes	(33,000)	(41,000)	(59,000)	(50,000)
Net loss	\$ (38,912,000)	\$ (32,158,000)	\$ (76,038,000)	\$ (62,112,000)

Bionano Genomics, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP gross margin:				
GAAP revenue	\$ 8,662,000	\$ 6,670,000	\$ 16,077,000	\$ 12,366,000
GAAP cost of revenue	6,354,000	5,199,000	11,700,000	10,034,000
GAAP gross profit	2,308,000	1,471,000	4,377,000	2,332,000
GAAP gross margin %	27 %	22 %	27 %	19 %
Adjusted non-GAAP gross margin:				
GAAP revenue	\$ 8,662,000	\$ 6,670,000	\$ 16,077,000	\$ 12,366,000
GAAP cost of revenue	6,354,000	5,199,000	11,700,000	10,034,000
Stock-based compensation expense	(198,000)	—	(344,000)	—
Adjusted non-GAAP cost of revenue	6,156,000	5,199,000	11,356,000	10,034,000
Adjusted non-GAAP gross profit	2,506,000	1,471,000	4,721,000	2,332,000
Adjusted non-GAAP gross margin %	29 %	22 %	29 %	19 %
GAAP operating expense				
GAAP selling, general and administrative expense	\$ 26,936,000	\$ 21,783,000	\$ 52,913,000	\$ 42,060,000
Stock-based compensation expense	(2,433,000)	(2,309,000)	(4,812,000)	(4,084,000)
Intangible asset amortization	(1,793,000)	(1,419,000)	(3,585,000)	(2,838,000)
Change in fair value of contingent consideration	(1,429,000)	(79,000)	(2,218,000)	(158,000)
Adjusted non-GAAP selling, general and administrative expense	21,281,000	17,976,000	42,298,000	34,980,000
GAAP research and development expense	\$ 14,610,000	\$ 11,767,000	\$ 28,547,000	\$ 22,296,000
Stock-based compensation expense	(1,301,000)	(3,468,000)	(2,658,000)	(6,795,000)
Adjusted non-GAAP research and development expense	13,309,000	8,299,000	25,889,000	15,501,000
Total adjusted non-GAAP operating expense	\$ 34,590,000	\$ 26,275,000	\$ 68,187,000	\$ 50,481,000