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

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): March 14, 2019

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.)

9640 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))

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 \boxtimes

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 March 14, 2019, Bionano Genomics, Inc. (the "Company") issued a press release reporting its financial results for its fourth quarter and fiscal year ended December 31, 2018. 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 March 14, 2019, reporting financial results for the fourth quarter and fiscal year ended December 31, 2018.

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.

Bionano Genomics, Inc.

Date: March 14, 2019

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

R. Erik Holmlin, Ph.D. President and Chief Executive Officer (Principal Executive Officer)

bionano

Bionano Genomics Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2018

<u>Highlights:</u>

- Record quarterly revenue of \$4.0 million; 41% increase over 4Q17
- Record annual revenue of \$12.0 million; 26% increase over 2017
- Substantial improvement to essentially many aspects of the Saphyr workflow; capability of processing 42 whole human genomes per week; clinical-grade sensitivity at as low as 5% allele fraction; prices below \$500 per genome
- Record number of publications; a 70% increase of human-centered publications over 2017; studies validating the use of Saphyr as an alternative to traditional cytogenetics technologies

SAN DIEGO, Mar. 14, 2019 (GLOBE NEWSWIRE) - **Bionano Genomics, Inc. (NASDAQ: BNGO)**, a life sciences instrumentation company that develops and markets Saphyr, a platform for ultra-sensitive and ultra-specific structural variation detection in genome analysis, today reported financial results for the fourth quarter and year ended December 31, 2018.

Accomplishments and Recent Business Highlights

• Bionano continued its focus on advancing the capabilities of its Saphyr system for whole genome mapping of structural variations. Throughout 2018 and culminating in a series of product launches in February 2019, Bionano has simplified the Saphyr workflow making it easier to run, return faster results, and cost less than \$500 per sample. Saphyr is now capable of processing 42 whole human genomes per week with a workflow that can be automated from sample to answer. We believe these improvements are driving Saphyr

adoptions among clinical and translational research centers as well as cytogenetics labs as a digital cytogenetics platform.

- Bionano expanded the capabilities of its data analysis solutions, improving their sensitivity to all types of structural variations, including those that are present at very low abundance. Access to tools for Bionano data analysis was enhanced through the development of a cloud-based implementation of the analysis pipeline. In addition, the suite now includes a novel routine that has been tested in different leukemias and shown to have high sensitivity for structural variation detection even when the variant of interest is present in as low as 5% allele fraction, which is a critical capability for analysis of cancer samples.
- Bionano collaborated with Genoox, a company that manages next-generation sequencing data analysis, to develop and launch a platform that combines raw sequencing reads with Bionano-based structural calls from a single patient. Children's National Health System in Washington D.C., which is ranked #1 in the U.S. for infant care, became the initial adopter of the Genoox integrated platform. The new technology offers Children's National a single platform for sensitive, accurate detection of structural variations and genetic mutations for rare disease, not previously practicable, helping to accelerate genetic diagnosis for children and their families.
- Bionano users published a record number of papers detailing the application of Bionano technology. In particular, 70% more human-centric publications were released in 2018 over 2017. One such publication detailed the largest study conducted on Bionano's platform, which was comprised of 154 humans across 26 distinct ethnic populations. This publication revealed never-before-seen human genomic variations and genome sequence not represented in the human genome reference, which demonstrated that the widely used method of aligning short sequencing reads to a static reference genome may be inadequate.
 - Another key paper showed Saphyr's ability to provide accurate molecular diagnoses of facioscapulohumeral muscular dystrophy (FSHD) patients. Saphyr was shown to be an alternative to the Southern blot method, a traditional cytogenetics technique, by offering a simplified workflow that yields highly accurate results with the potential to increase clinical

performance by readily adding new clinical markers without modifying the assay or workflow. The replacement of traditional cytogenetics workflows with Saphyr represents the transition to digital cytogenetics where Saphyr modernizes the entire cytogenetic workflow.

- Adoption of Saphyr in 2018 by top thought leaders in cytogenetics such as Dr. Brynn Levy at Columbia University and Dr. Alex Hoeschin at Radboud University Medical Center in the Netherlands, and others, has enabled Bionano to initiate a number of studies designed to show equivalency of Saphyr to traditional cytogenetic methods in hematologic oncology indications such as Acute lymphocytic leukemia (ALL) and Acute myelocytic leukemia (AML). We expect initial results from these studies to be presented at scientific meetings beginning in the third quarter of this year and throughout the second half of 2019. We believe these studies will lay the groundwork for Saphyr to penetrate labs that may develop assays for cytogenetic applications, making Saphyr the first digital cytogenetics platform.
- Bionano expanded its commercial team with the addition of key senior executives, including the addition of a head of commercial operations and a seasoned sales team in China as well as a new global head of marketing.
- In August 2018, Bionano completed its initial public offering, raising \$23.7 million in gross proceeds.

"We are very pleased with how Saphyr is becoming an essential tool for genome analysis and digital cytogenetics worldwide," said Erik Holmlin, Ph.D., CEO of Bionano. "We are seeing accelerated interest in our Saphyr system, as our differentiated capabilities, the unique detection of structural variations, and our new price point below \$500 per whole human genome sample continues to drive demand."

Dr. Holmlin added, "We continue to focus on expanding and executing on our commercial plan. We plan to continue building our commercial team, and look forward to executing on our strategies to make structural variation analysis as commonplace as next-generation sequencing and to lead the emergence of digital cytogenetics."

Fourth Quarter Financial Highlights

Total Revenue. Total revenue for the fourth quarter 2018 was \$4.0 million compared to \$2.8 million in the fourth quarter 2017, or an increase of 41%. Growth over the fourth quarter of 2017 was predominantly due to an increase in product sales.

Product Revenue. Product revenue for the fourth quarter 2018 was \$3.8 million compared to \$2.6 million in the fourth quarter 2017, or an increase of 50%.

Cost of Revenues. Cost of revenues for the fourth quarter 2018 was \$3.0 million compared to \$1.5 million in the fourth quarter 2017. The cost of revenue was higher in the fourth quarter of 2018 primarily due to increased sales.

Operating Expenses. Operating expenses for the fourth quarter 2018 were \$7.1 million compared to \$6.6 million in the fourth quarter 2017, or an increase of 8%. The increase was primarily due to an increase in SG&A resulting from the additional costs of being a public company.

Full-Year 2018 Financial Highlights

Total Revenue. Total revenue for 2018 was \$12.0 million compared to \$9.5 million in 2017, or an increase of 26%. The increase was predominantly due to significant increases in sales of instruments and consumables.

Product Revenue. Product revenue for 2018 was \$11.5 million compared to \$8.8 million in 2017, an increase of 31%. The majority of the increase in product revenue was due to a 29% increase in instrument unit sales and a 63% increase in consumable unit sales.

Cost of Revenues. Cost of revenues for 2018 was \$8.7 million compared to \$6.0 million for 2017. The increase in cost was primarily due to increased sales of instruments and consumables and predecessor instrument inventory write-offs of \$1.3 million in 2018 as compared to \$0.4 million in 2017.

Operating Expenses. Operating expenses for 2018 were \$23.7 million compared to \$26.7 million in 2017. This represents a decrease of 11% in operating expenses for 2018 compared to 2017. The decrease in operating expenses was primarily due a \$2.5 million decrease in spending for research & development.

Cash and Cash Equivalents Balance on December 31, 2018

At December 31, 2018, the Company had cash and cash equivalents of \$16.5 million, compared to cash and cash equivalents of \$1.0 million at December 31, 2017.

Conference Call & Webcast Details

The Company will host a conference call and live webcast to discuss its fourth quarter and full year 2018 financial results and provide an update on business activities. The event will be held today at 4:30pm Eastern Time. Dial-in details are as follows:

Thursday, March 14 @ 4:30pm Eastern Time

Domestic: 877-407-0789 International: 201-689-8562 Passcode: 13687797 Webcast: <u>http://public.viavid.com/index.php?id=133342</u>

To access the call, participants should dial the applicable telephone number above at least 5 minutes prior to the start of the call. An archived version of the webcast will be available for replay in the Investors section of the Bionano website.

About Bionano Genomics

Bionano is a life sciences instrumentation company in the genome analysis space. Bionano develops and markets the Saphyr system, a platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and is designed to drive the adoption of digital cytogenetics, which is a more

systematic, streamlined and industrialized form of traditional cytogenetics. The Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "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: the benefits of recent improvements to the Saphyr system, including with respect to increased demand, sales and adoption of the Saphyr system; the opportunities presented by increased adoption of the Saphyr system, including with respect to increased studies; the anticipated benefits of conducting additional studies using the Saphyr system; our efforts to execute on our commercial strategy, including plans to expand our commercial team. 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 that our sales, revenue, expense and other financial guidance may not be as expected, as well as risks and uncertainties associated with: general market conditions; changes in the competitive landscape and the introduction of competitive products; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; the loss of key members of management and our commercial team; 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, 2018 and in other filings subsequently made by us with the Securities and Exchange Commission. All forwardlooking 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 forwardlooking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

Contacts

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Financial tables follow

Bionano Genomics, Inc.

Consolidated Statements of Operations

		Three Months Ended December 31,			Year Ended December 31,			
	2018 2017		2017	2018			2017	
Revenue:								
Product revenue	\$	3,844,766	\$	2,556,208	\$	11,463,173	\$	8,769,704
Other revenue		168,771		288,915		537,562		735,339
Total revenue		4,013,537		2,845,123		12,000,735		9,505,043
Cost of revenue:								
Cost of product revenue		2,853,339		1,496,172		8,562,042		5,958,537
Cost of other revenue		134,777				149,284		71,975
Total cost of revenue		2,988,116		1,496,172		8,711,326		6,030,512
Operating expense:								
Research and development		2,521,467		2,457,483		9,484,163		12,009,170
Selling, general and administrative		4,602,518		3,526,310		14,220,331		14,079,658
Impairment of property and equipment		_		604,511		_		604,511
Total operating expenses		7,123,985		6,588,304		23,704,494		26,693,339
Loss from operations		(6,098,563)		(5,239,353)		(20,415,085)		(23,218,808)
Other income (expense)						i		<u>·</u>
Interest expense		(266,971)		(159,524)		(1,381,024)		(590,927)
Change in fair value of preferred stock warrants and expirations		_		(356,429)		3,991,081		751,933
Other expense		(36,716)		(163,686)		(675,853)		(289,010)
Total other income (expenses)		(303,687)		(679,639)		1,934,204		(128,004)
Loss before income taxes		(6,402,251)		(5,918,992)	·	(18,480,881)		(23,346,812)
Benefit (provision) for income taxes		(9,207)		(932)	·	(15,511)		(18,552)
Net loss	\$	(6,411,458)	\$	(5,919,924)	\$	(18,496,392)	\$	(23,365,364)
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Bionano Genomics, Inc.

Consolidated Balance Sheets

	December 31,					
	2018			2017		
Assets						
Current assets:						
Cash and cash equivalents	\$	16,522,729	\$	1,021,897		
Accounts receivable, net		4,514,333		3,352,214		
Inventory		1,068,557		1,693,742		
Prepaid expenses and other current assets		919,500		1,071,512		
Total current assets		23,025,119		7,139,365		
Property and equipment, net		1,777,302		3,005,788		
Total assets	\$	24,802,421	\$	10,145,153		
Liabilities, convertible preferred stock, and stockholders' equity (deficit)				<u> </u>		
Current liabilities:						
Accounts payable	\$	1,351,736	\$	2,302,964		
Accrued expenses	-	2,900,129	-	3,508,894		
Deferred revenue		270,998		211,697		
Preferred stock warrant liability				3,898,944		
Current portion of long-term debt		_		6,729,752		
Total current liabilities		4,522,863		16,652,251		
Long-term debt, net of current portion		9,029,374				
Long-term deferred revenue		304,467		142,929		
Other non-current liabilities		808,366		567,047		
Total liabilities		14,665,070		17,362,227		
Total stockholders' equity (deficit)		10,137,351		(50,227,211)		
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	\$	24,802,421	\$	10,145,153		