

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): March 23, 2021

**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 March 23, 2021, Bionano Genomics, Inc. (the “Company”) issued a press release reporting its financial results for its fourth quarter and fiscal year ended December 31, 2020. 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 8.01 Other Events.**

As previously announced, the Company is hosting a conference call on March 23, 2021 at 4:30 PM Eastern Time to review its financial results for its fourth quarter and fiscal year ended December 31, 2020 and to provide a business update (the “Earnings Call”). A presentation to accompany the Earnings Call (the “Corporate Presentation”) is attached hereto as Exhibit 99.2. The Company may use information contained in the Corporate Presentation at investor and other meetings.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued March 23, 2021, reporting financial results for the fourth quarter and fiscal year ended December 31, 2020.</a>
99.2	<a href="#">Corporate Presentation, March 23, 2021</a>

**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 23, 2021

By:           /s/ R. Erik Holmlin, Ph.D.            
R. Erik Holmlin, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

## Bionano Genomics Announces Financial Results for the Three and Twelve Months Ended December 31, 2020 and Highlights Recent Corporate Updates

*-Solidified Financial Position Raising Approximately \$335 Million in Q1 2021*

*-Executed on Commercial Offerings for Saphyr®, Driving Towards Global Adoption*

*-Conference Call Today, March 23, 2021, at 4:30 pm EST*

SAN DIEGO, March 23, 2021 -- Bionano Genomics, Inc. (Nasdaq: BNGO) today reported financial results and business achievements for the fourth quarter and year ended December 31, 2020 and highlighted recent corporate updates.

"2020 was an important momentum-building year for Bionano and one that allowed us to showcase many of our strengths. Despite 2020's challenges, we executed well on our commercial offerings for Saphyr® by expanding the number of systems in the field and the number of samples analyzed in our data services lab. We believe this progress helped create the awareness needed to develop the market for structural variation analysis and optical genome mapping, or OGM, furthering our goal of disrupting the genomics industry," said Erik Holmlin, PhD, CEO of Bionano. "2021 is shaping up to be a transformational year for the company. With a strong balance sheet, we are focused on driving the global development of Saphyr-based assays for use in clinical testing of patients with genetic disease and hematological malignancies, and on adoption of Saphyr for use in larger clinical studies aimed at obtaining a critical mass of data on Saphyr application across key areas of structural variation analysis including prenatal and post-natal genetics, hematologic malignancies and solid tumors. These data are expected to expand the number of publications, including peer-reviewed ones, grow significantly the number of laboratory developed tests, or LDTs, on the market and support reimbursement of Saphyr-based LDTs by third party payers in the US and around the world."

Chris Stewart, Chief Financial Officer of Bionano added, "As we begin 2021, Bionano's balance sheet is in its strongest position ever. Since the start of 2021, we have raised approximately \$335 million, which we believe significantly de-risks the company, solidifies our financial future, and allows us to focus on the achievement of our long-term vision to disrupt genomics through the global adoption of Saphyr."

### Saphyr® System Highlights

#### *Executed on Commercialization Offerings for Saphyr*

The Company executed on its commercialization strategy, expanded the utilization of its Saphyr system and increased the amount of Bionano data generated across the globe, driving scientific momentum. The installed base of Saphyr systems was 97 at the end of the year, an increase of 24 from year-end 2019.

***Validated System Utility with Benchmarking, Scientific Publication and Clinical Adoption***

Rigorous and extensive benchmarking of Saphyr was conducted against traditional cytogenetic methods and long read sequencing and these results were published and validated in several key publications, presentations and announcements including:

- OGM concordant with traditional cytogenetics in landmark leukemia study;
- International consortium demonstrates that Bionano's Saphyr detects all 100 chromosomal aberrations in 85 genetic disease patients;
- Large multi-center study on 100 AML samples shows that Saphyr outperforms standard-of-care and leads to the recommendation of Saphyr being a first line test;
- Publication reveals in side-by-side comparison that method using PacBio sequencing detects only 72% of the large structural variants detected by optical genome mapping with Saphyr; and
- University of Iowa Hospitals and Clinics (UIHC) switched their method of clinical molecular testing for patients with presumed Facioscapulohumeral Muscular Dystrophy (FSHD) to optical mapping using Bionano's Saphyr.

***Expanded System Beyond Cytogenetics and Improved Diagnostics***

The Saphyr system demonstrated its expanded capabilities beyond standard cytogenetics and traditional diagnostics as evidenced in several key publications including:

- UCSF & Children's Hospital Oakland study finds that Saphyr can diagnose an additional 18% of children with genetic disease who were undiagnosed after standard of care testing.

***Revealed Genetic Drivers of Severe Covid-19 Susceptibility***

OGM with Saphyr identified SVs that affect genes in pathways that control immune and inflammatory response, viral reproduction and mucosal function. These results became the foundation of multiple research efforts, including one international consortium and publication:

- COVID-19 Host Genome SV Consortium identifies structural variants with possible roles in pathogenesis and outcomes in severely ill COVID-19 patients using Bionano's Saphyr® system.

***Expanded Applications of OGM in Human and Non-Human Research***

Several other published studies illustrated key applications of OGM to areas of human and non-human research, including:

- Bionano Genomics data is essential part of the first ever complete assembly of a human X-Chromosome;

- Vertebrate Genome Project rules Bionano optical genome mapping technology as essential part of assembling reference quality genomes; and
- Bionano's Saphyr plays essential role in identifying three previously unknown genetic mutation types in cancer in study from Weill Cornell.

***Advanced and Optimized the Performance of the Saphyr System for Adoption in Labs that will Develop Clinical Assays and LDTs***

The Company effected several enhancements to the Saphyr System and made significant advancements in the system's capabilities, including utility in identifying SVs in solid tumor oncology indications and DNA isolation:

- Bionano Genomics released Saphyr updates for industry-leading data yields that enable analysis of complex cancer samples at unprecedented depths;
- Bionano Genomics solidifies its entry into solid tumor analysis with launch of a new kit and protocol that significantly simplify tissue and solid tumor analysis; and
- Bionano Genomics achieved a key milestone with software update for its Saphyr system that increases throughput to 96 human genomes per week and adds Saphyr Assure for monitoring system health.

**Recent Corporate Highlights**

- Since the start of 2021, the Company raised approximately \$335 million, from two underwritten public offerings of shares of its common stock, the full utilization of its \$40 million ATM facility, and the exercise of outstanding warrants;
- The Company completed the acquisition of diagnostics services provider, Lineagen, an important step toward accelerating the clinical adoption of Saphyr for digital cytogenetics, and expanded Lineagen's diagnostic testing menu with the launch of Lineagen's EpiPanelDx PLUS Gene Panel Test that identifies genetic conditions related to epilepsy; and
- The Company enhanced its senior management team with the appointments of Christopher Stewart as Chief Financial Officer and Dr. Alka Chaubey as Chief Medical Officer.

**Financial Highlights**

**Revenue**

- Revenues for the fourth quarter of 2020 were \$4.0 million, an increase of \$1.2 million, or 43% when compared to \$2.8 million for the same period in 2019. The increase was primarily due to a \$1.1 million increase in service revenue contributed primarily by our Lineagen subsidiary.
- Revenues for the year ended December 31, 2020 were \$8.5 million, down \$1.6 million from \$10.1 million in 2019. The decrease was driven by primarily by customers limiting their lab operations in response to COVID-19 restrictions and the introduction of our reagent rental program, partially offset by \$1.6 million increase in services revenue.

## Gross Margin

- Gross margin for the fourth quarter of 2020 was 30%, down 9% from 39% in the same period in 2019. The decrease was primarily due to approximately \$400 thousand in one time charges related to year end accounting.
- Gross margins for the year ended December 31, 2020 were 33%, consistent with 2019.

## Operating Expenses

- Operating expense for the fourth quarter of 2020 was \$12.3 million, an increase of approximately \$3.4 million compared to \$8.9 million for the same period in 2019. The increase is primarily due to an increase in salary expense. During 2020, headcount increased by 49, including 33 that joined as a result of the Lineagen acquisition.
- Operating expense for year ended December 31, 2020 was \$41.3 million, an increase of approximately \$11.4 million from \$29.9 million for the same period in 2019. The increase was comprised of \$4.5 million of salary expense, \$3.4 million of legal and other outside services related to the Lineagen acquisition and other corporate activities, \$2.6 million of Lineagen expenses, and \$0.9 million of other increases.

## Upcoming Milestones in 2021 – Driving Global Adoption of Saphyr

2Q21: Accreditation of Saphyr based LDTs for ALL & FSHD in certain EU markets

3Q21: Commercial release of prenatal assays and expansion of the menu of pediatric assays

4Q21: Interim publication of results from pediatric clinical study

4Q21: Validation of 3 LDTs total with billing codes (PLA and/or z-codes) by sites in both our prenatal clinical study and validation of 3 LDTs total with billing codes (PLA and/or z-codes) by sites in our pediatric clinical study

4Q21: Prototype of next gen high throughput Saphyr

4Q21: Reach installed base of 150 systems, a 50% increase over year end 2020

## Conference call & Webcast Details

<u>Conference Call &amp; Webcast Details</u>	
Date:	Tuesday, March 23, 2021
Time:	4:30 p.m. Eastern Time
Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13717068
Webcast:	<a href="http://public.viaavid.com/index.php?id=143782">http://public.viaavid.com/index.php?id=143782</a>

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

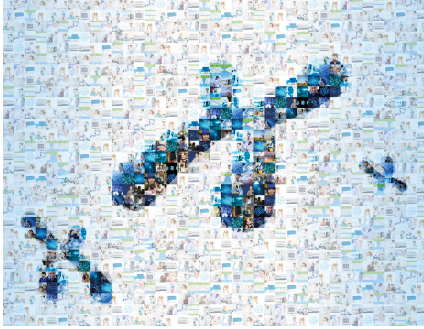
Bionano is a genome analysis company providing tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and providing diagnostic testing for those with autism spectrum disorder (ASD) and other neurodevelopmental disabilities through its Lineagen business. Bionano's Saphyr system is a research use only 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 to streamline the study of changes in chromosomes, which is known as cytogenetics. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools. Bionano provides genome analysis services to provide access to data generated by the Saphyr system for researchers who prefer not to adopt the Saphyr system in their labs. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns. For more information, visit [www.bionanogenomics.com](http://www.bionanogenomics.com) or [www.lineagen.com](http://www.lineagen.com).

### 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 anticipated benefits of the Lineagen acquisition, including with respect to driving potential reimbursement for Saphyr-based LDTs; potential market opportunity for structural variation analysis and OGM, and our ability to disrupt the genomics industry;



the opportunities presented by demonstrating the expanded capabilities of the Saphyr System; continued research involving our technology and its ability to drive adoption of our technology as well as LDTs based on our technology; and the execution of Bionano's 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 impact of the COVID-19 pandemic on our business and the global economy; 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 ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; our recent rapid expansion of our employee headcount; 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, 2019 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

### Company Contact:

Erik Holmlin, CEO  
Bionano Genomics, Inc.  
+1 (858) 888-7610  
[eholmlin@bionanogenomics.com](mailto:eholmlin@bionanogenomics.com)

**Investor Relations and**

**Media Contact:**

Amy Conrad  
Juniper Point  
+1 (858) 366-3243  
[amy@juniper-point.com](mailto:amy@juniper-point.com)

**Financial Tables to Follow**

**Bionano Genomics, Inc.**

**Condensed Consolidated Statement of Operations**

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
<b>Revenue:</b>				
Product revenue	\$ 2,726,354	\$ 2,604,187	\$ 6,229,611	\$ 9,474,444
Service and other revenue	1,263,272	184,943	2,273,373	655,064
<b>Total revenue</b>	<b>3,989,626</b>	<b>2,789,130</b>	<b>8,502,984</b>	<b>10,129,508</b>
<b>Cost of revenue:</b>				
Cost of product revenue	2,383,631	1,612,922	4,810,408	6,495,693
Cost of service and other revenue	427,721	77,837	919,729	272,454
<b>Total cost of revenue</b>	<b>2,811,352</b>	<b>1,690,759</b>	<b>5,730,137</b>	<b>6,768,147</b>
<b>Operating expenses:</b>				
Research and development	2,876,985	2,399,183	10,256,109	9,080,891
Selling, general and administrative	9,428,862	5,859,681	31,068,060	20,155,376
<b>Total operating expenses</b>	<b>12,305,847</b>	<b>8,258,864</b>	<b>41,324,169</b>	<b>29,236,267</b>
<b>Loss from operations</b>	<b>(11,127,573)</b>	<b>(7,160,493)</b>	<b>(38,551,322)</b>	<b>(25,874,906)</b>
Total other expenses	(602,988)	(740,102)	(2,555,029)	(3,940,164)
<b>Net loss</b>	<b>\$ (11,730,561)</b>	<b>\$ (7,900,595)</b>	<b>\$ (41,106,351)</b>	<b>\$ (29,815,070)</b>

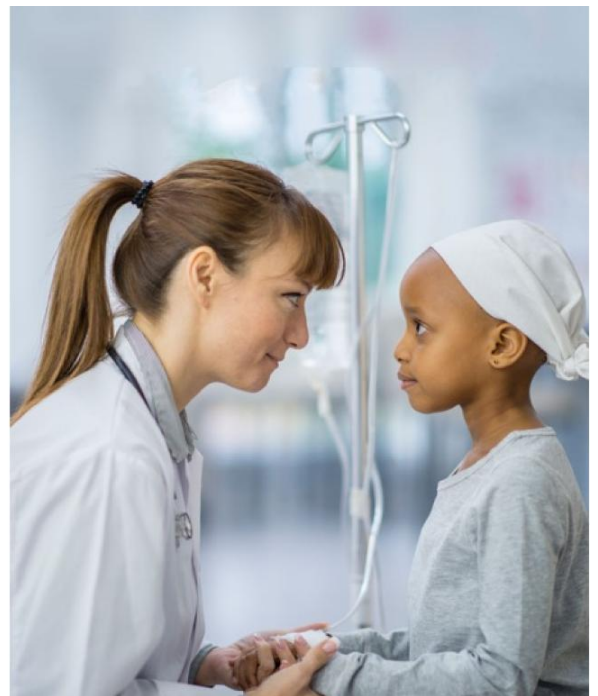
**Bionano Genomics, Inc.**  
**Condensed Consolidated Balance Sheet**

	December 31,	
	2020	2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,448,710	\$ 17,311,373
Accounts receivable, net	2,775,042	6,333,963
Inventory	3,315,708	3,443,559
Prepaid expenses and other current assets	2,249,696	1,169,346
<b>Total current assets</b>	<b>46,789,156</b>	<b>28,258,241</b>
Property and equipment, net	4,910,414	1,949,625
Intangible assets	1,474,667	—
Goodwill	7,172,649	—
Other Long Term Assets	102,640	—
<b>Total assets</b>	<b>\$ 60,449,526</b>	<b>\$ 30,207,866</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,929,662	\$ 2,699,153
Accrued expenses	5,598,810	3,225,431
Deferred revenue	415,504	357,492
Current portion of long-term debt	—	20,084,945
<b>Total current liabilities</b>	<b>8,943,976</b>	<b>26,367,021</b>
Long-term debt, net of current portion	16,325,501	—
Long-term deferred revenue	97,875	182,648
Other non-current liabilities	—	44,479
<b>Total liabilities</b>	<b>25,367,352</b>	<b>26,594,148</b>
Total stockholders' equity	35,082,174	3,613,718
<b>Total liabilities and stockholders' equity</b>	<b>\$ 60,449,526</b>	<b>\$ 30,207,866</b>



## Q4 YE 2020 Webcast & Call

March 23, 2021



## Legal Disclaimer

This presentation contains forward-looking statements. Forward-looking statements describe future expectations, plans, results or strategies and are generally preceded by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof). Forward-looking statements in this presentation include, but are not limited to, statements regarding: (i) growth drivers and expected levels of our organic growth; (ii) improvements to our manufacturing cost efficiency; (iii) the impact of our investment in R&D and commercial initiatives; (iv) our ability to stay in front of competitors' improvements in technologies; and (v) other statements that are not historical facts.

Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Forward-looking statements are based only on current information, assumptions and expectations, and involve a number of risks and uncertainties relating to (i) challenges inherent in developing, manufacturing and commercializing products; (ii) the timing and mix of customer orders among our products; (iii) our ability to further deploy new products and applications and expand the markets for our technology platforms; (iv) third parties' abilities to manufacture our instruments and consumables; (v) the success of products competitive with our own; (vi) our expectations and beliefs regarding future growth of the business and the markets in which we operate; (vii) the accuracy of our estimates, (viii) our ability to fund our operations and (ix) the application of generally accepted accounting principles which are highly complex and involve many subjective assumptions. We are under no duty to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this presentation.

More information about these and other statements, risks and uncertainties is contained in our filings with the U.S. Securities and Exchange Commission. All forward-looking statements contained in this presentation speak only as of the date on which they were made. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, occurrence of future events or otherwise except as required by applicable law.

# 2020: A Momentum-Building Year for Bionano



# Validated System Utility with Benchmarking, Scientific Publication and Clinical Adoption

**Next-generation cytogenetics: Comprehensive assessment of 48 leukemia genomes by genome imaging**  
Marian Stevens-Kroef<sup>1</sup>, Tuomo Mantere, Kornelia Neveling, Marc Pauper, Guillaume van de Zande, Susan Vermeulen, Ellen Kater-Baats,  
Michel Oomsprong, Ronald van Beek, Daniel Oude-Vrielink, Dominique Smeets, Alexander Heischen  
Radboud University Medical Center, Nijmegen, The Netherlands

Radboudumc

EHA Library. Stevens-Kroef M. 06/12/20; 294288; EP369

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES



BMJ Yale

HOME | ABC

Search

## A National Multicenter Evaluation of the Clinical Utility of Optical Genome Mapping for Assessment of Genomic Aberrations in Acute Myeloid Leukemia

[Comment on this paper](#)

Brynn Levy, Linda B. Baughn, Scott Chartrand, Brandon LaBarge, David Claxton, Alan Lennon, Yasmine Akkari, Claudia Cujar, Ravindra Kolhe, Kate Kroeger, Beth Pitel, Nikhil Sahajpal, Malini Sathanoori, George Vlad, Lijun Zhang, Min Fang, Rashmi Kanagal-Shamanna, James Broach

doi: <https://doi.org/10.1101/2020.11.07.20227728>

bioRxiv

THE PREPRINT SERVER FOR BIOLOGY

New Results

### De novo assembly of 64 haplotype-resolved human genomes of diverse ancestry and integrated analysis of structural variation

Peter Ebert, Peter A. Audano, Qihui Zhu, Bernardo Rodriguez-Martin, David Purkayast, Marc Jan Bender, Arvis Salomon, Jina Elnor, Vishchen Zhou, Rebecca Serra, Mari Feysa Yilmaz, Xiaofang Zhao, Pengshan Hsieh, Joyce Lee, Sushant Kumar, Jialong Lin, Tobias Rausch, Ye Chen, Jingwen Ren, Martin Samadpour, Václav Hájek, Huihui Ashraf, Nelson T. Chuang, Xiaofu Yang, Katherine H. Munson, Alexander P. Lewis, Susan Farley Luke, J. Talbot, Wayne E. Clarke, Anna O. Baitik, Maria Byrnka Bishop, André Corvellec, Mark J.P. Chausson, Janice Chen, Cheng Li, Harrison Broad, Aaron M. Wenger, Marjan Ghahanghar, William T. Harvey, Benjamin Raeder, Patrick Hasenfeld, Allison Ragge, Haley Abul, Ira Hall, Paul Flicek, Oliver Stegle, Mark B. Gerstein, Jose M.C. Tobias, Zeyang Ma, Hong Li, Jinghui Shi, Alex R. House, Kai Ye, Zechen Cheng, Ashley D. Sanders, Michael C. Zody, Michael E. Tilson, Ryan E. Mills, Scott E. Devine, Charles Lee, Jun O. Karbet, Tobias Marschall, Evan E. Eichler

doi: <https://doi.org/10.1101/2020.12.16.423102>

bioRxiv

THE PREPRINT SERVER FOR BIOLOGY

New Results

### Next generation cytogenetics: genome-imaging enables comprehensive structural variant detection for 100 constitutional chromosomal aberrations in 85 samples

Tuomo Mantere, Kornelia Neveling, Céline Pebré-Richard, Marion Benoit, Guillaume van der Zande, Ellen Kater-Baats, Inane Bastou, Ronald van Beek, Tony Yasmine, Michel Oomsprong, Daniel Oude-Vrielink, Ned Meglani, Susan Vermeulen, Marc Pauper, Anna Lebbat, Marian Stevens-Kroef, Damien Santalisse, Dominique Smeets, Jean Michel Dupont, Alexander Heischen, Caroline Schluth-Balard, Laila El Khattabi

doi: <https://doi.org/10.1101/2020.07.15.305245>

## Bionano Data are Proving to be Essential in Advancing Discovery Research



**ALS**  
Resolved mosaic repeat expansions



**Leukemia**  
In 12 patients, found dozens of novel genes with recurring structural variants



**Alzheimer's Disease**  
Identified deletions in CR1



**Epilepsy and Developmental Delay**  
Detected 90 kbp mosaic deletion in CDKL5



**Hepatocellular Carcinoma**  
Identified Hep B Virus insertion that caused tumor and replication stress



**Congenital Diaphragmatic Hernia**  
Revealed complex genome structures and new candidate genes



**Disorder of Sex Development**  
Identified 6 kbp insertion in WDR11

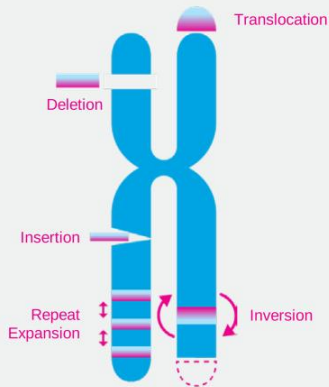


**3q29 Microdeletion Syndrome**  
Characterized large, complex repeats and rearrangements in parents of 3q29 patients



## Structural Variation Matters!

SV refers to changes in location, orientation and the amount of functional elements in the genome ...



... and not to changes in sequence.



Essentially every patient who undergoes evaluation for cancer or genetic disease will be tested for Structural Variation



SV analysis is first line patient management according to Medical Guidelines




FSHD, Rare Genetic Disease: Univ. of Iowa Switched to Saphyr


FSHD is the third most common form of muscular dystrophy and a significant market with few available therapies. Bionano can help unlock other rare disease opportunities by providing access to new therapeutic targets.



UCSF & Children's Hospital of Oakland Study – Largest study of Dx Yield - Shows Saphyr can Diagnose Additional 18% of Undiagnosed Patients

**medRxiv**  **BMJ** Yale  
THE PREPRINT SERVER FOR HEALTH SCIENCES

**Application of Full Genome Analysis to Diagnose Rare Monogenic Disorders**


Joseph T. Shieh,  Monica Penon-Portmann, Karen H.Y. Wong, Michal Levy-Sakin, Michelle Verghese, Anne Slavotinek, Renata C. Gallagher, Bryce A. Mendelsohn, Jessica Tenney, Daniah Belefond, Hazel Perry, Stephen K. Chow, Andrew G. Sharo, Steven E. Brenner, Zhongxia Qi, Jingwei Yu, Ophir D. Klein, David Martin, Pui-Yan Kwok, Dario Boffelli

**doi:** <https://doi.org/10.1101/2020.10.22.20216531>

Advanced and Optimized the Performance of the Saphyr System for Adoption in Labs to Support Development of Clinical Assays and LDTs

**SAPHYR<sup>®</sup> SPEED UPDATE**

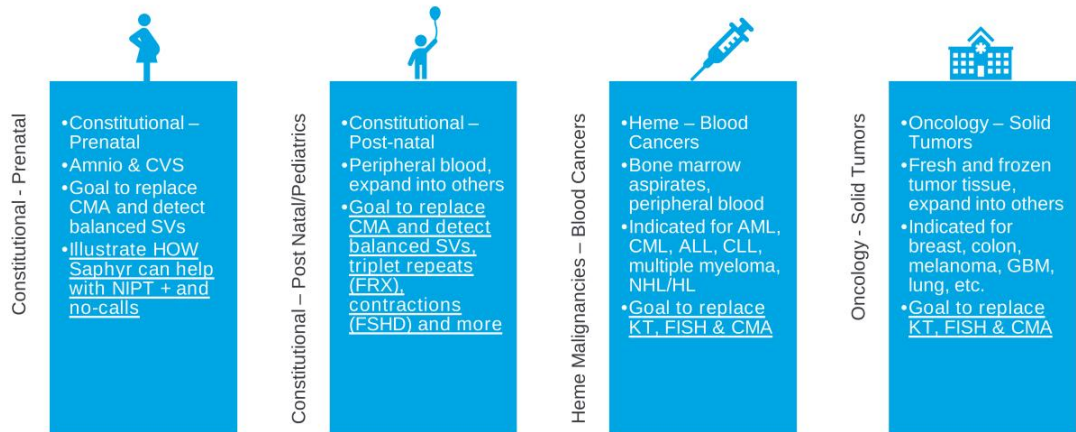
**NOW UP TO 96  
HUMAN GENOMES  
PER WEEK**



**bionano**  
GENOMICS

THE  
STRUCTURAL  
VARIATION  
COMPANY

## Four Large Clinical Studies Getting Underway to Support Penetration of our Target Markets & Support 3<sup>rd</sup> Party Reimbursement



# Lineagen Adds Revenue & Accelerates Clinical Adoption of Saphyr

## REVENUE: IMMEDIATE IMPACT



Lineagen adds new revenue streams to help support growth of the combined business

## COMBINING PRODUCT- AND SERVICE-BASED BUSINESSES



Provides centralized and decentralized offerings to support the broader market



## ESSENTIAL COMPONENTS FOR BUILDING REIMBURSED DX MENU ON SAPHYR

Accelerates Saphyr entry into the clinic by adding content, skills, expertise and sample archives



CLIA Certification

- Development of proprietary LDTs helps drive Saphyr adoption
- Enhances Bionano offering to pharma customers seeking new therapeutic targets



Proprietary Content in Pediatric Neuro Developmental Disorders

Proprietary database from Toronto Sick Kids Hospital provides basis for differentiated tests, current and future



Patient Samples & Database

+60,000 tests performed on +30,000 patients, and counting



Clinical Cytogeneticists & Custom Interpretation Software

Provide expertise for improved Saphyr Dx and workflow integration



Genetic Counseling

Differentiated service and critical link between physicians, patients and families



Certified Coders

Trained billing specialists lay groundwork for reimbursement of Saphyr LDTs



3rd Party Payor Contracts

Leverage existing relationships and contracts with payors

# Financial Overview

Chris Stewart  
CFO  
cstewart@bionanogenomics.com



## Q4 and YE 2020 – Financial Results

### Q4 2020 Key Financial Highlights

- Grew installed base to 97 at YE 2020
- Grew Q4 2020 revenues by 43% to \$4.0M
- YE 2020 cash balance of \$38.4M

	Year Ended December 31,	
	2020	2019
<b>Revenue:</b>		
Product revenue	\$ 6,229,811	\$ 9,474,444
Service and other revenue	2,273,373	655,064
<b>Total revenue</b>	<b>8,502,984</b>	<b>10,129,508</b>
<b>Cost of revenue:</b>		
Cost of product revenue	4,810,408	6,495,693
Cost of service and other revenue	919,729	272,454
<b>Total cost of revenue</b>	<b>5,730,137</b>	<b>6,768,147</b>
<b>Operating expenses:</b>		
Research and development	10,256,109	9,080,891
Selling, general and administrative	31,068,060	20,155,376
<b>Total operating expenses</b>	<b>41,324,169</b>	<b>29,236,267</b>
<b>Loss from operations</b>	<b>(38,551,322)</b>	<b>(25,874,906)</b>
<b>Other expenses</b>		
Interest expense	(2,518,893)	(2,286,196)
Loss on debt extinguishment	—	(1,333,496)
<b>Other expenses</b>	<b>(6,943)</b>	<b>(299,424)</b>
<b>Total other expenses</b>	<b>(2,525,836)</b>	<b>(3,919,116)</b>
<b>Loss before income taxes</b>	<b>(41,077,158)</b>	<b>(29,794,022)</b>
Provision for income taxes	(29,193)	(21,048)
<b>Net loss</b>	<b>\$ (41,106,351)</b>	<b>\$ (29,815,070)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.39)</b>	<b>\$ (1.99)</b>
<b>Weighted-average common shares outstanding, basic and diluted</b>	<b>104,251,327</b>	<b>14,977,901</b>

Strong cash position to begin 2021 with \$335M raised in Q1

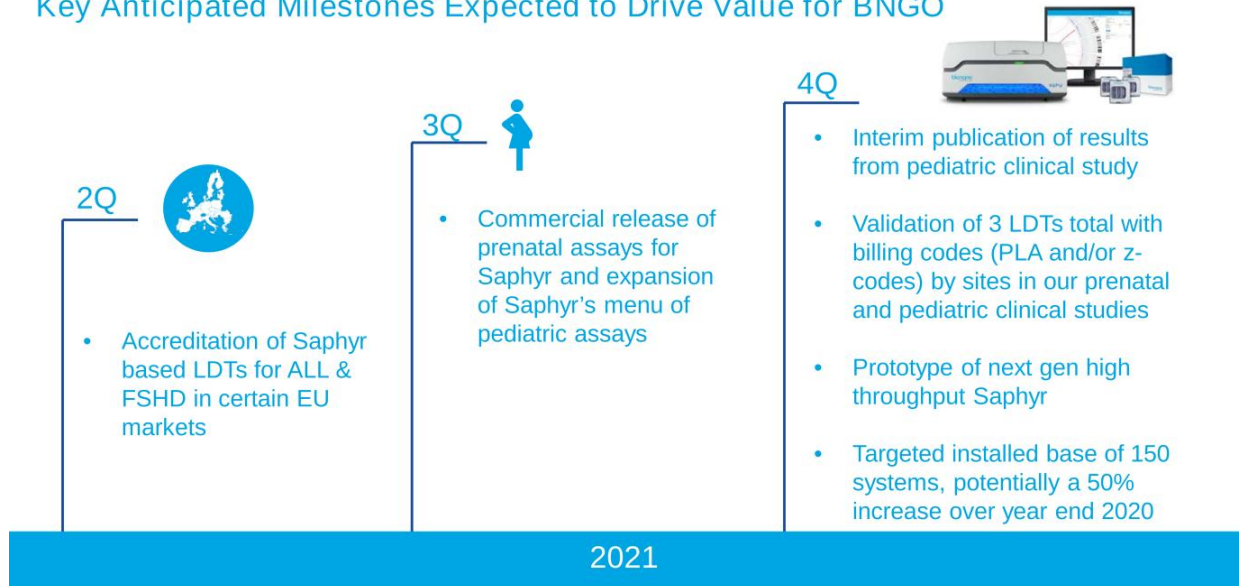
# Summary

R. Erik Holmlin  
CEO  
[eholmlin@bionanogenomics.com](mailto:eholmlin@bionanogenomics.com)





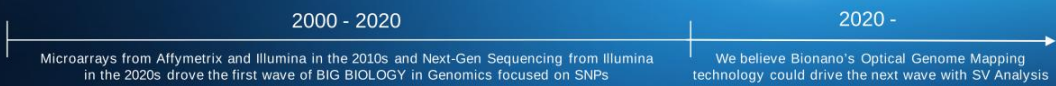
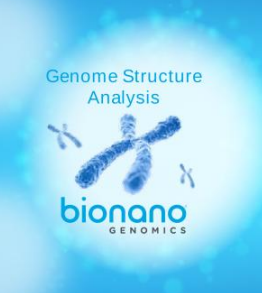
## Key Anticipated Milestones Expected to Drive Value for BNGO



# Genomics has been Disrupting Healthcare and Creating Substantial Value over the Last 20 Years. We Believe SV Analysis is Next Disruption



-  Molecular Diagnostics & Personalized Medicine
-  Targeted Therapies
-  Immuno Oncology
-  CRISPR Gene Editing
-  Consumer Genomics



# Questions & Answers

Contact:

R. Erik Holmlin  
CEO

[eholmlin@bionanogenomics.com](mailto:eholmlin@bionanogenomics.com)

Chris Stewart  
CFO

[cstewart@bionanogenomics.com](mailto:cstewart@bionanogenomics.com)



