

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

FORM 8-K

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

Date of Report (Date of earliest event reported): January 7, 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))

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.

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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

In this report, “we,” “us” and “our” refer to Bionano Genomics, Inc.

## **Item 2.02 Results of Operations and Financial Condition.**

On January 7, 2021, we announced the commencement of a proposed underwritten public offering of our common stock. In connection with the proposed offering, we filed a preliminary prospectus supplement in which we disclosed that we expect to report that our total revenue for the three months ended December 31, 2020, was between \$3.8 and \$4.2 million and cash and cash equivalents as of December 31, 2020, was between \$38.0 and \$39.0 million. This amount of cash and cash equivalents excludes approximately \$15.0 million of additional cash received between January 1, 2021 and January 6, 2021 pursuant to the exercise of warrants to purchase our common stock. These amounts reflect our estimates based solely upon information available to us as of the date of this Current Report on Form 8-K, are not a comprehensive statement of our financial results or position as of or for the quarter ended December 31, 2020, and have not been audited, reviewed or compiled by our independent registered public accounting firm. Our financial closing procedures for the quarter ended December 31, 2020 are not yet complete and, as a result, our final results upon completion of our closing procedures may vary from this preliminary estimate, and any such differences may be material.

## **Item 8.01 Other Events.**

The information contained in Item 2.02 above is incorporated herein by reference.

On January 7, 2021, we made available on our website the slide presentation attached hereto as Exhibit 99.1. Information contained in this slide presentation may be used in meetings with institutional investors or analysts.

## **Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this report that are not historical facts may be considered “forward-looking statements,” including, but not limited to, statements regarding our preliminary estimates of revenue and cash and cash equivalents as of December 31, 2020. Forward-looking statements are typically, but not always, identified by the use of words such as “may,” “would,” “believe,” “intend,” “plan,” “anticipate,” “estimate,” “expect,” and other similar terminology. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to preliminary financial results, including the risks that the preliminary financial results reported herein reflect information available to us only at this time and may differ from actual results, including in connection with our completion of financial closing procedures, risks associated with market conditions, risks and uncertainties associated with our business and finances in general, risks associated with the COVID-19 global pandemic, as well as other risks detailed in our recent filings on Forms 10-K and 10-Q with SEC. We undertake no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, nor shall there be any sale of our securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

## **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	Slide Presentation.
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.

**Bionano Genomics, Inc.**

Date: January 7, 2021

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

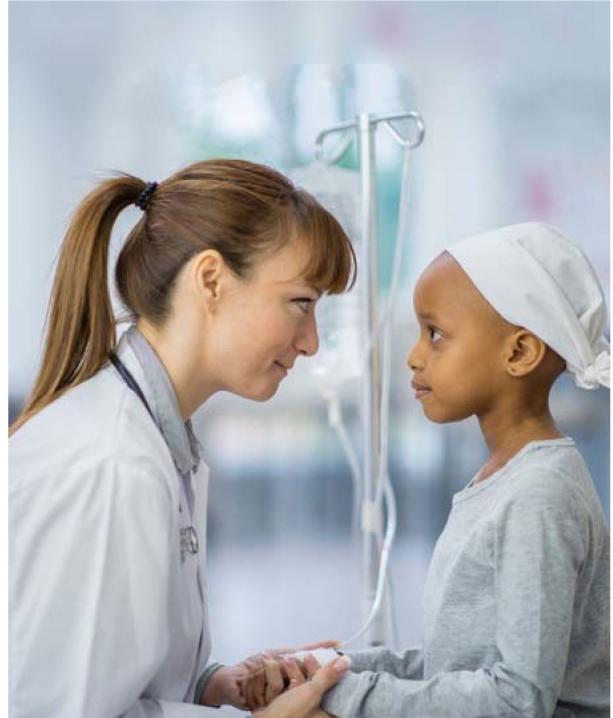
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## Corporate Overview

January 2021

R. Erik Holmlin, CEO  
Chris Stewart, CFO



## 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.

# bionano<sup>®</sup> GENOMICS

Creating a Market Leader in Cytogenomics

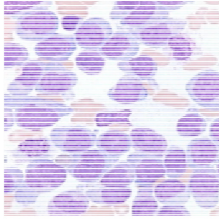


## The Diagnostic Journey Often Ends in Frustration, Disappointment and Premature Death Because the Current Tools are Insufficient



### Constitutional Genetic Diseases

- Neuro-developmental disorders (NDDs) occur at a rate of 1 in 6
- A substantial fraction (50 – 70%) of test results are negative
- Without a definitive molecular diagnosis, these patients may not get optimal treatment and their diagnostic odyssey continues



### Blood Cancers

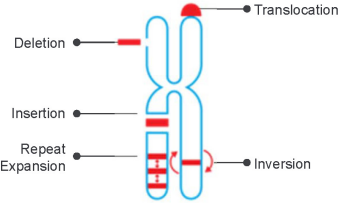
- 200,000 new cases diagnosed each year in US among approximately 1 million patients tested
- Again, most test results are negative
- Even with a definitive diagnosis and good prognosis, average survival in leukemia tends to be split between good outcomes (long survival) and poor outcomes (short survival) – current methods are insufficient

# Better Tools are Needed Because the Genome Variations that Cause Disease Are Not All the Same!

A-G-C-T-A-C-T  
| | | | | | |  
T-C-~~A~~-A-T-G-A

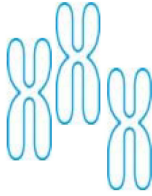
Single Nucleotide Polymorphisms (SNPs)

1 base pair (bp)



Structural Variations (SVs)

100s bp to Millions bp



Aneuploidy

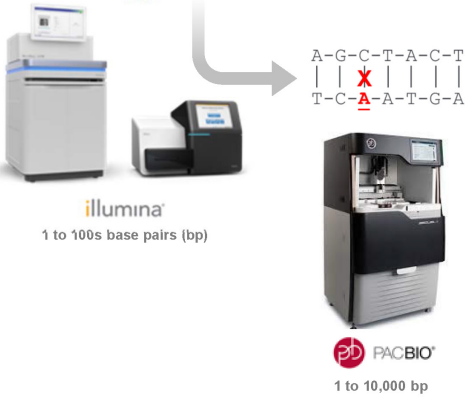
Full Chromosomes



# Sequencers Cannot Reliably Detect Structural Variations

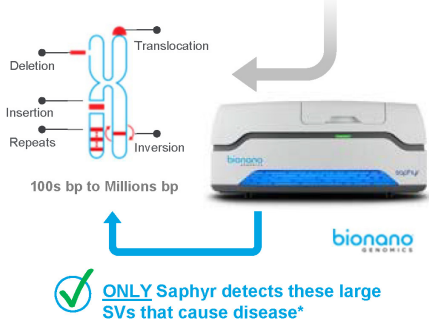
## SNPs to Small Structural Variants

✓ Sequencers can detect these



## Large Structural Variations (SVs)

✗ Sequencers are BLIND to these



We believe that Saphyr is the only genome analysis platform capable of comprehensive, cost effective & efficient detection of large SVs (500 bp and larger)

## Cytogenetics & Cytogenomics are the Current Paradigm in Testing for SVs

What is Cytogenetic Analysis?

Cytogenetics means the detection of chromosomal disorders in the laboratory by karyotyping (examining the chromosomes within a cell). Molecular cytogenetics involves testing of a specific disease locus by fluorescence-in-situ hybridization (FISH) assay.

What does it test for?

Diseases caused by large genomic aberrations also known as structural abnormalities (not sequence abnormalities). Structural abnormalities include translocations, insertions, deletions and other chromosomal rearrangement of genomic information.

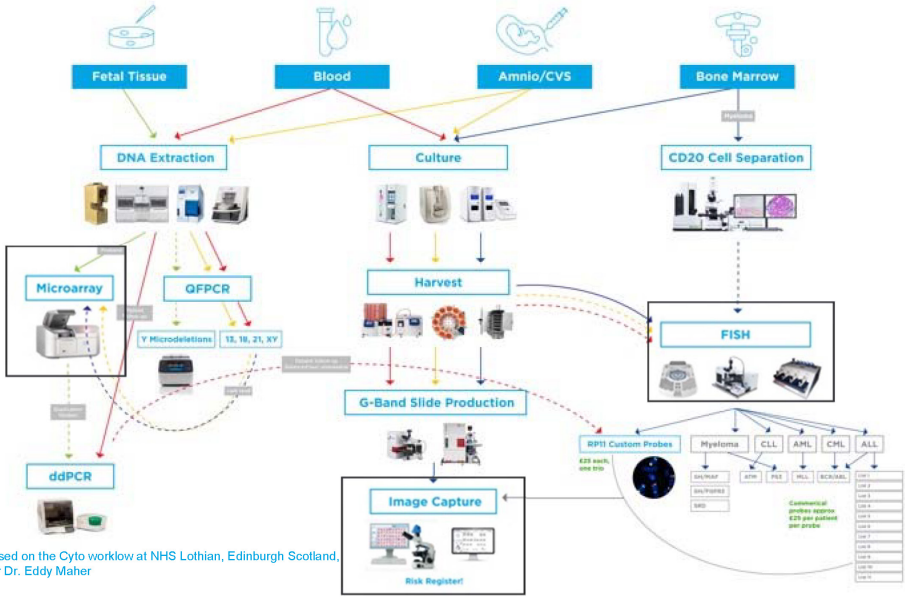
What do Medical Guidelines say?

ACMG, AMP, AAN, AAP recommend KT/FISH/CMA/Frag-X as the standard of care for constitutional disorders  
WHO/NCCN/NCI/NHS recommend KT/FISH/CMA as standard of care for hematologic malignancies.

Why sequencing cannot address Cytogenetics?

The human genome is highly repetitive and large structural abnormalities are often hidden among repeats. Reads from NGS and *even* long-read sequencing are too short to span the repetitive sections and thus are unable to capture the large structural abnormalities/genomic aberrations.

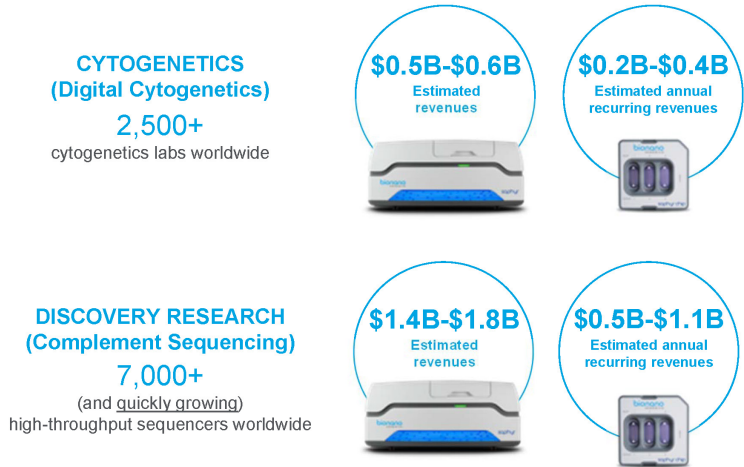
# The Cytogenetics Workflow is a Nightmare!



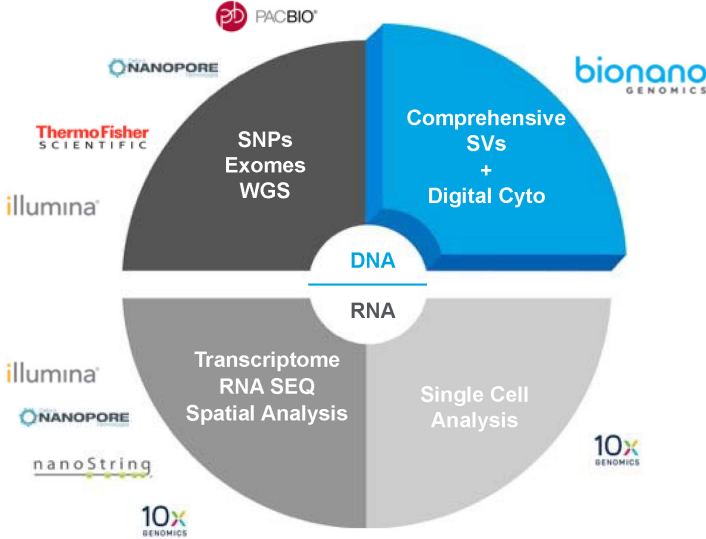
# Saphyr offers an Alternative to Traditional Cyto Methods by Offering a One-Stop-Shop for Detecting all SVs Recommended by Medical Guidelines



**We Estimate our Market Opportunity to be \$2.6B – \$3.8B Based on Selling As Many as 10,000 Saphyr Systems**



# We Believe Bionano is Alone in Addressing SVs and Digital Cytogenetics



## Studies Show 100% Concordance with the Standard of Care Methods



**Radboud  
University  
Nijmegen**



**Hôpital Cochin**

New Results

[2 comments](#)

### **Next generation cytogenetics: comprehensive assessment of 48 leukemia genomes by genome imaging**

Kornelia Neveling, Tuomo Mantere, Susan Vermeulen, Michiel Oorsprong, Ronald van Beek, Ellen Kater-Baats, Marc Pauper, Guillaume van der Zande, Dominique Smeets, Daniel Olde Weghuis, Marian J Stevens-Kroef, Alexander Hoischen

**doi:** <https://doi.org/10.1101/2020.02.06.935742>

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

Tuomo Mantere, Kornelia Neveling, Céline Pebrel-Richard, Marion Benoist, Guillaume van der Zande, Ellen Kater-Baats, Imane Baatout, Ronald van Beek, Tony Yammine, Michiel Oorsprong, Daniel Olde-Weghuis, Wed Majdali, Susan Vermeulen, Marc Pauper, Aziza Lebbar, Marian Stevens-Kroef, Damien Sanlaville, Dominique Smeets, Jean Michel Dupont, Alexander Hoischen, Caroline Schluth-Bolard, Laila El Khattabi

**doi:** <https://doi.org/10.1101/2020.07.15.205245>

### **BIONANO FOUND ALL**





clinically reported variants detected  
by Karyotype, FISH and  
Chromosomal Microarray

### **NO OTHER TECH**

has been shown, in a single  
assay, to deliver results of  
all 3 traditional technologies



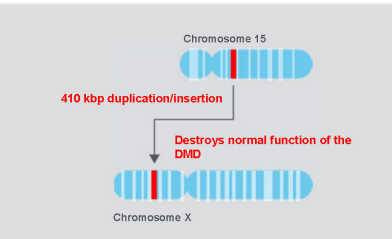
## Consortium of US Thought Leaders Recommend Saphyr as an Alternative to Karyotyping in AML

| ABC  
ch  
THE PREPRINT SERVER FOR HEALTH SCIENCES  
  
[Comment on this paper](#)  
  
**A National Multicenter Evaluation of the Clinical Utility of Optical Genome Mapping for Assessment of Genomic Aberrations in Acute Myeloid Leukemia**  
  
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>



## Case Study: Saphyr Found the SV that Was Responsible, Helping Solve This Case in Pediatric Genetic Disease


- ✓ Saphyr detected a 410kbp duplication & insertion in the DMD gene which provided a definitive molecular diagnosis of Duchenne's Muscular Dystrophy



- ✗ Juvenile male patient suffering from muscular weakness and developmental delay  
Patient tested negative by standard and advanced molecular methods

- ✗ Chromosomal Microarray      ✗ Multiplexed Ligation Polymorphism Assay (MLPA)  
✗ PCR and Sanger Sequencing      ✗ Whole Exon & Whole Genome Sequencing


## 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



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**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>

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

	 <p><b>ALS</b> Resolved mosaic repeat expansions</p>		 <p><b>Leukemia</b> In 12 patients, found dozens of novel genes with recurring structural variants</p>
	 <p><b>Alzheimer's Disease</b> Identified deletions in CR1</p>		 <p><b>Epilepsy and Developmental Delay</b> Detected 90 kbp mosaic deletion in CDKL5</p>
	 <p><b>Hepatocellular Carcinoma</b> Identified Hep B Virus insertion that caused tumor and replication stress</p>		 <p><b>Congenital Diaphragmatic Hernia</b> Revealed complex genome structures and new candidate genes</p>
	 <p><b>Disorder of Sex Development</b> Identified 6 kbp insertion in WDR11</p>		 <p><b>3q29 Microdeletion Syndrome</b> Characterized large, complex repeats and rearrangements in parents of 3q29 patients</p>

## Bionano Saphyr is Prominently Involved in the Search for Risk Markers that Stratify COVID-19 Patients by Risk and May Help Vaccine and Rx Development

- Saphyr will be used to identify variants in host genomes that influence COVID-19 response, severity, progression and drug response

### CHINA

 **GrandOmics 希望组**

First study in Wuhan with Bionano service provider GrandOmics is underway

### EUROPE



European study involving University of Hannover genomic epidemiologists launched March 2020

### US-BASED CONSORTIUM



COVID19HostGenomeSV.com

Consortium founded by Dr Ravi Kolhe at Augusta is enrolling 100s to 1000s of patients in a study that has shown preliminary promise

### COMPUTE PARTNERS



Rescale, together with Amazon, Google and Microsoft, are donating compute capacity

## In August 2020, We Acquired the Diagnostics Service Provider, Lineagen, a Leader in Diagnostic Services for Pediatric Neurodevelopmental Disorders



### FROM ONE BUCCAL SWAB . . .

- Multiple revenue streams
- CLIA-certified LDTs and services
- Personalized, easy-to-understand results
- Genetic counseling and clinical education
- End-to-end support with reimbursement
- Test menu that matters

#### FSDx



Chromosomal Microarray (CMA) designed to detect larger deletions and duplications in the genome

#### FRx

##### Fragile X Syndrome

Screening and diagnosis of Fragile X syndrome, the most common known genetic cause of ASD/ID that runs in families  
Ordered with 75% of FirstStep<sup>®</sup> PLUS CMA cases.

#### PGx

##### Pharmacogenetics Testing

Testing of genes that can impact dosage and choice of drug types, including Anti-Epilepsy and ADHD drugs

#### NSDx



Next generation whole exome gene sequencing (WES) to detect single genome letter changes undetectable by CMA

#### WGDx

##### Whole Genome Diagnostic

Most comprehensive genetic test that can detect majority of genome mutations (deletions/duplications/single base changes)

#### EPDx



A comprehensive and proprietary panel of over 220 curated genes associated with epilepsy-related conditions



# 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

# 2020 Corporate Highlights

Q1	Q2	Q3	Q4
<p><b>5</b> Saphyr Shipped 83 installed</p> <p><b>694</b> FCs Sold VS 468 in Q1 2019</p> <p>New Go to Market – Bionano Data Centric Services, Reagent Rentals &amp; Capital Purchase</p> <p><b>19</b> Presentations</p> <p>AGBT 2020 PRECISION HEALTH</p> <p>Landmark Publication: Concordance with Cyto in Leukemias</p> <p>Initiated COVID-19 Host Genome Studies</p> <p>Increased Throughput/output</p> <p>SAPHYR ADOPTION</p> <p><b>GeneDx</b></p>	<p><b>6</b> Saphyr Shipped 87 installed</p> <p><b>1424</b> FCs Sold VS 493 in Q2 2019</p> <p>ESHG Consortium Presentation: Saphyr Concordance with Cytogenomics Standard of Care in Constitutional Disorders</p> <p>SAPHYR ADOPTION</p> <p>NHS Hospital (UK) adopts Saphyr</p> <p>Largest US FSHD testing site</p> <p>BOARD OF DIRECTORS NEW ADDITIONS</p> <p>Yvonne Linney</p> <p>Hannah Mamuszka</p>	<p><b>11</b> Saphyr Shipped 93 installed</p> <p><b>1785</b> FCs Sold VS 1332 in Q3 2019</p> <p>Landmark Publication: Concordance with Cyto in Constitutional Disorders</p> <p>Consortium Formation: COVID-19 Host Genetics SV Consortium</p> <p>German accreditation for Saphyr LDTs</p> <p>Acquisition of CLIA business w Clinical Sales</p> <p><b>Lineagen</b></p> <p>Addition of Key New Executives</p> <p>Alka Chaubey, PhD, Chief Medical Officer</p> <p>Chris Stewart, Chief Financial Officer</p>	<p><b>12*</b> Saphyr Shipped 97 installed</p> <p><b>2362*</b> FCs Sold VS 1332 in Q3 2019</p> <p>Landmark Publication: in Acute Myeloid Leukemia; Authors recommend Saphyr as Karyotype replacement</p> <p>UCSF Publication: Saphyr Increases Diagnostic Yield</p> <p>ASHG MEETING 2020</p> <p><b>18</b> Presentations</p> <p>COVID Consortium Adds Studies in Comparative Genomics and MIS-C</p> <p>Improved and Simplified Clinical Analysis Tools</p> <p>Saphyr Throughput – 96 human genomes per week</p>
Revenue: \$0.9M	Revenue: \$1.2M	Revenue: \$2.2M	Revenue*: \$3.8M to \$4.2M

## Experienced Management Team and Board

### Executive Management Team



**Erik Holmlin, PhD**  
President, CEO & Board Member



**Mark Oldakowski**  
Chief Operating Officer



**Christopher Stewart**  
Chief Financial Officer



**Alka Chaubey, PhD**  
Chief Medical Officer



### Board of Directors (Non-Executive)

**David Barker, PhD**  
Chairman of Bionano,  
former CSO of Illumina



**Christopher Twomey**  
Former CFO of Biosite,  
Ernst & Young



**Albert Luderer, PhD**  
CEO – Integrated Dx



**Kristiina Vuori, MD, PhD**  
President – Sanford  
Burnham Prebys MDI



**Hannah Mamuszka**  
CEO – Alva10



**Yvonne Linney, PhD**  
Founder – Linney  
BioConsulting





# Thank You

**Contact:**

R. Erik Holmlin  
CEO

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CFO

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

