# bionano

# **Strategy Day**

February 02, 2023

#### Disclaimers:

#### Preliminary Financial Results

This presentation includes preliminary financial information of Bionano for the fourth quarter and full year of 2022. Bionano has not completed preparation of its financial statements for these periods and the information presented (including preliminary revenue and the corresponding breakdowns of revenue by product/service and geography) in this presentation for such periods is preliminary and unaudited, based on management's initial review of the information presented, and are thus inherently uncertain and subject to change as Bionano completes its end-of-period reporting process and related activities for the fourth quarter of and full year 2022. Bionano is in the process of completing its customary year-end close and review procedures for these periods, and the final results for these periods may differ from these estimates. During the course of the preparation of Bionano's consolidated financial statements and related notes as of and for the quarter and year ended December 31, 2022, Bionano's independent registered public accountants may identify items that could cause final reported results to be materially different from the preliminary financial estimates presented herein. Additional information and disclosures would be required for a more complete understanding of Bionano's financial position and results of operations as of and for the fourth quarter and year-ended December 31, 2022. Accordingly, undue reliance should not be placed on this preliminary information.



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This presentation (and accompany oral commentary) also includes statements made by third party presenters related to their research and experiences with OGM and Bionano products. Such statements are not statements by Bionano, and Bionano disclaims any such statements.



## Welcome

Erik Holmlin, PhD
President and Chief Executive Officer

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# Agenda

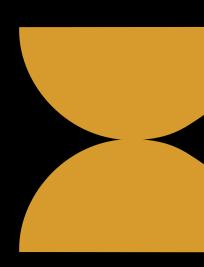
1:30 PM	CEO Welcome and Introduction to Event – Erik Holmlin, CEO	
1:45 PM	Financial Growth Plan - Christopher Stewart, CFO	
2:10 PM	The OGM Difference – Alex Hastie, VP Scientific and Clinical Affairs	
2:25 PM	Product Portfolio & Development Roadmap – Mark Oldakowski, COO	
2:45 PM	Clinical Development for Transforming Medical Practice – Alka Chaubey, CMO	
3:05 PM	BREAK (15 min.)	
3:20 PM	Meet Bionano Customers in Fireside Chats with Dan Brennan, Cowen & Co	
3:20 PM	Clinical Research Panel featuring Drs. Adam Smith, Ravindra (Ravi) Kolhe and Gordana Raca	
3:45 PM	Q&A with Clinical Research Panel	
3:55 PM	Translational Research Panel featuring Drs. Ben Finlay, Rashmi Kanagal-Shamanna & Catherine Brownstein	
4:25 PM	Q&A with Translational Research Panel	
4:35 PM	Fireside Chat with Erik Holmlin	
4:55 PM	Q&A with Bionano Management	
5:15 PM	Reception	

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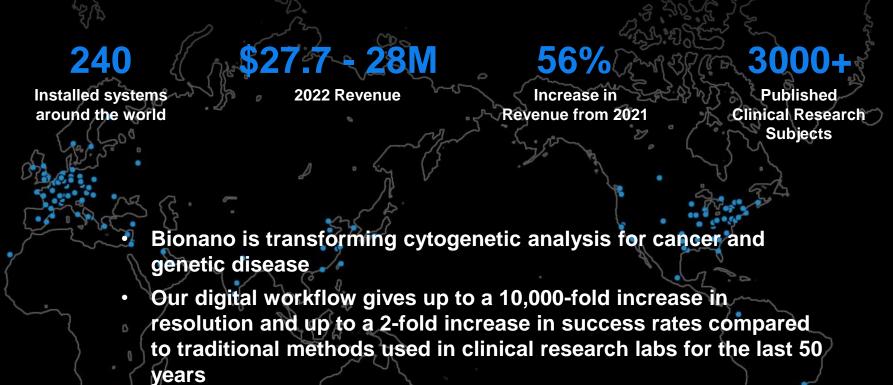
#### What We Hope You Take Away from Strategy Day

#### A clear understanding of:

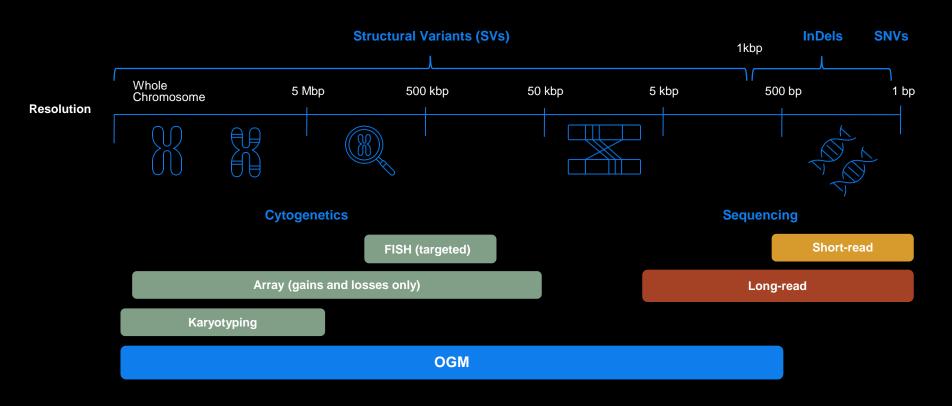
- Where Bionano fits in the genome analysis landscape
- Who's using Bionano solutions today and why
- What our target markets are and who our customers are
- What our financial growth plan is
- How OGM compares to sequencing and why sequencing will not obsolete OGM
- How we are overcoming remaining hurdles to transform medical practice
- What our product development plan is to continue innovating and achieve our financial goals



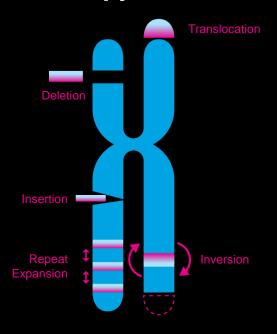
#### Bionano's Purpose is to Elevate the Health and Wellness of All People



#### We Believe Optical Genome Mapping will Transform Cytogenetics



#### Large Structural Variants (SVs) are Vital to Patient Stratification and Therapy Selection



# Cytogenetic Analysis is the **Recommended First-Line Test for Patients Diagnosed with Genetic Disease and Cancer According to Global Medical Guidelines**



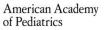












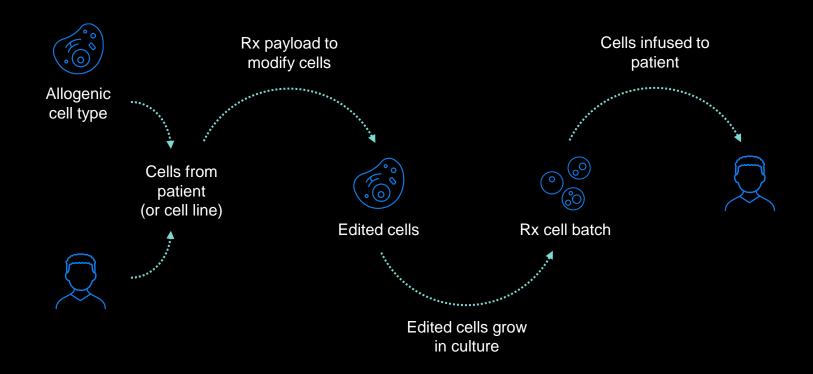








#### **Emerging Cell Therapies are Dependent on Cytogenetics for QC**



## We Believe the Opportunity in **Cytogenetics is Large**

10K

Labs Worldwide 10M

**Patient Samples** 

1.4K

**Rx Cos in** Cell Rx

**\$10B** 

**Estimated** TAM



### We Believe our Products **Enable a Cytogenetics** Revolution



### Saphyr® System

- G1 Saphyr (released in 2017)
  - 384 human genomes per year
  - \$1500 per genome
  - \$350k per system
- G2 Saphyr (released in 2020)
  - 13-fold increase in throughput
  - \$450 per genome
  - \$150k per system
- New mapping system under development
  - Anticipate up to 13-fold increase in throughput

## **Acquisitions Added Powerful Solutions** to Help Create the End-to-End Workflow



#### Bionano Ionic® Purification System Automated extraction, purification and concentration of DNA& RNA

- Acquired Purigen in Nov 2022
- \$32M in cash upfront + up to \$32M in cash based on development & commercial milestones
- Adds strategic business & we believe will accelerate OGM adoption



#### $N_{\mathbf{v}}Clinical^{\mathsf{TM}} \rightarrow VIA^{\mathsf{TM}}$

Comprehensive analysis, interpretation & reporting tool for data including microarray, NGS & OGM

- Acquired BioDiscovery in Oct 2021
- \$90M in cash & stock upfront + potential \$10M in cash based on achievement of development & commercial milestone
- Adds strategic business & we believe will accelerate OGM adoption

# bionano **laboratories**

CLIA-certified and CAP-accredited\* lab in San Diego

> CLIA-certified service in Salt Lake City

6 ABMGG-certified lab directors

15 certified genetic counselors

Clinical test menu of 10 LDTs

Nearly 10,000 clinical tests reported annually

#### bionano

#### Bionano Laboratories is a Platform for **LDT Development that Addresses the Needs of New OGM Users**



#### **RUO Testing Services**

- Supports proof-of-concept studies
- Enables potential users to experience the power of OGM across a number of applications



#### **OGM-Based Clinical Testing Services**

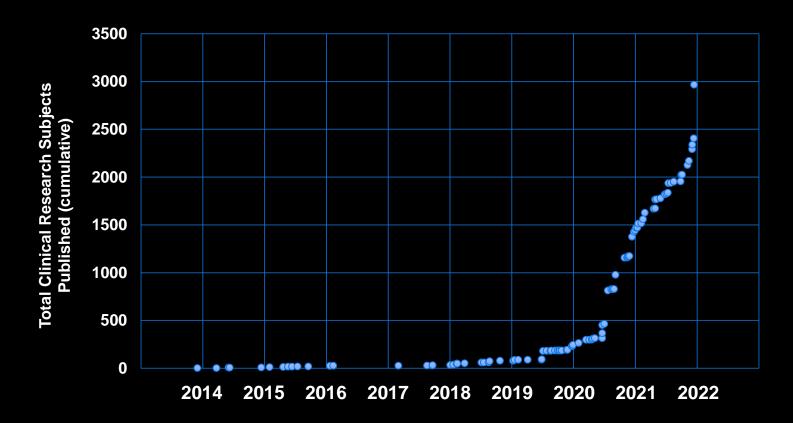
- OGM-Dx<sup>™</sup> HemeOne<sup>™</sup> and OGM-Dx<sup>™</sup> FSHD1
- Allow health care providers to explore the clinical utility of OGM-based assays
- Supports coding and reimbursement efforts through payor engagement
- Developing best practices for OGM while supporting the global OGM community



#### Traditional Clinical Testing Services for Genetic Disease

- Whole Exome Sequencing, Chromosomal Microarray, Fragile X, Pharmacogenomics for pediatric neurodevelopmental disorders
- Direct avenue to engage with health care providers, including pediatric genetics and neurodevelopment delay specialists
- Potential source of patient samples for clinical trials

#### **Are We Making Progress? YES! We Believe We Are!**



#### **Hear it From Our Leaders**



**Chris Stewart** Chief Financial Officer



Alex Hastie, PhD VP Scientific & Clinical Affairs



Mark Oldakowski **Chief Operating Officer** 



Alka Chaubey, PhD **Chief Medical Officer** 

#### **& Meet Bionano Customers** in Fireside Chats



Dan Brennan, Moderator Managing Director- Research, Healthcare Cowen & Co.



Adam C. Smith, PhD, FCCMG, FACMG, erCLG University Health Network, University of Toronto



Darren "Ben" Finlay, PhD Sanford Burnham Prebys Medical Discovery Institute



Ravindra Kolhe, MD, PhD, FCAP Georgia Cancer Center, Medical College of Georgia



Rashmi Kanagal-Shamanna, MD The University of Texas MD **Anderson Cancer Center** 



Gordana Raca, MD, PhD, **FACMG** Children's Hospital Los Angeles



Catherine Brownstein, MPH, PhD Boston Children's Hospital

# Financial Growth Plan

Christopher Stewart
Chief Financial Officer

bionano



#### **Bionano Overview**



\$27.7 - \$28.0M

Preliminary FY 2022 revenue

240

Installed systems around the world

165

Software customers

48k

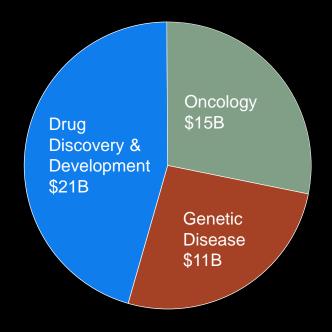
Flowcells sold

406

**Employees** 

Sites

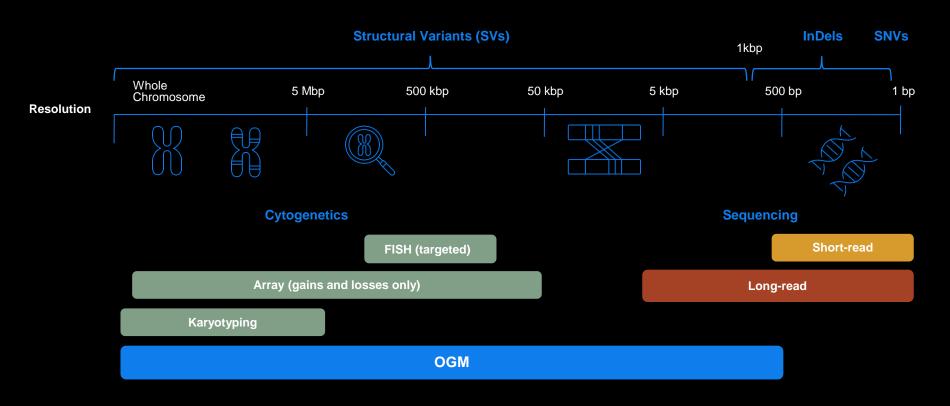
#### We are Focused on Three Segments of the Genomics Market



\$47B Segments of the Genomics TAM

- We believe millions of people could benefit from genome analysis
- Access to genomic technology and knowledge of the genome is increasing every year
- Optical Genome Mapping plays a unique and critical role in genome analysis by reliably revealing relevant structural variants
- How Bionano will participate in this market:
  - Conversion of existing testing volume to OGM
  - Addition of OGM to NGS testing

#### We Believe Optical Genome Mapping will Transform Cytogenetics



## We Estimate Our Target Markets Include 10,000 labs and 1,400 **Therapeutics Companies**

	W	orldwide Marke	ts*	China Cyto	China Cytogenetics	
	(P)	HHH				
	Large AMC's & Hospitals	Regional reference labs	Ultra-large reference labs	Tier 3 Hospitals	ICL	Pharma & Biotech
# of Labs	1,000	4,000	40	3,275	2,000	1,400
Avg Samples Per Year	3,000	1,000	24,000	3,000	1,000	TBD

Source: L.E.K interviews, research and analysis; Statistical Bulletin on Health Development in China 2021; Department of Woman and Child Health Services of the NHC; management estimates

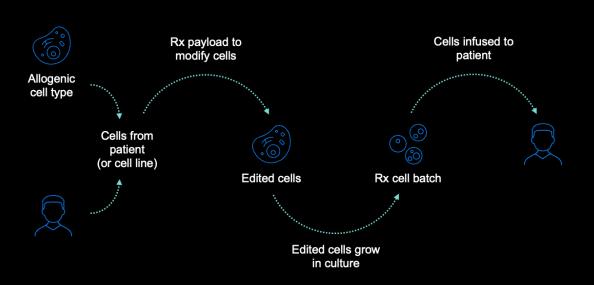
<sup>\*</sup>Excludes China, India, and developing countries

#### The Indications We are Targeting Generate ~10M Samples Per Year

Application		Specific use case	Target indications	Estimated annual samples	
	Prenatal	Invasive prenatal testing	NIPT positive or no result, abnormal ultrasound, advanced maternal age	300k	
Constitutional genetic testing	Postnatal	Reproductive testing	Infertility, pregnancy loss & POC	600k	
		Developmental disabilities	Developmental & intellectual disabilities, autism spectrum disorder	300k	
		Other genetic disorders	Birth defects, RUGD	120k	
		China market	NIPT positive or no result, FSHD	370k	
Constitutional genetic testing total					
		Diagnosis		400k	
Heme malignancy		Tx response	Lymphomas, myelomas, AML, CLL, CML, ALL, myelodysplastic syndromes	100k	
		Surveillance		2.4M	
		Clinical trials	OGM testing on enrolled patients in heme cancer trials		
		China market	Leukemias and lymphomas	2M	
Heme malignancy total					
Solid tumor		Tx guidance	Breast cancer, lung cancer, colon cancer, prostate cancer		
		Clinical trials	OGM testing on enrolled patients in solid tumor trials		
		1	Solid tumor total	3.3M	



#### Cell Bioprocessing QC Can be a \$3B Opportunity



- In 2020, there were 176 clinical assets for cancer therapy in development
- By 2025, the FDA is expected to approve 10 to 20 cell and gene therapy products per year
- QC is required in development and post approval to evaluate target effects and to assess genome integrity throughout the production process
- Each approved asset is estimated to generate 50k to 120k samples per year
- Companies are currently using karyotyping for Cell QC; lacks the required performance and will not scale

### What Our Customers are Using OGM for Today

Customer Type	Customer	What are they using OGM for?	Why are they using OGM?	Potential future use
Ultra large reference lab	Large US based central reference lab	Heme testing	Replacing CLL FISH panels for heme	Replace all FISH panels for heme 40,000 samples per year
Academic Medical Center	Memorial Sloan Kettering	Heme testing	Replacing myeloma FISH panels for heme	Replace all FISH panels for heme 5,000 to 10,000 samples per year
Regional Reference Lab	Perkin Elmer	Muscular dystrophy / FSHD	Adjunct to NGS for neuromuscular disorders	Repeat expansion disorders 1,000 samples per year
Cell therapy	Global pharmaceutical company	Cell QC for IPSC and CAR-T production	For measuring target effects in genome editing and genome integrity in production for drug development	Replacement of karyotyping for routine QC for cell therapy



# Product and Market Development Initiatives are Driving Penetration of Our Target Markets

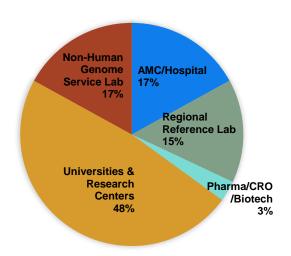
- Increased throughput 13x
- Reduced ASP per genome from \$1500 to \$450
- Upgrades to analysis & reporting tools
- Initiated clinical studies, interim readouts
- Built a strong commercial team
- Published results on > 1000 human samples

2020 to 2022

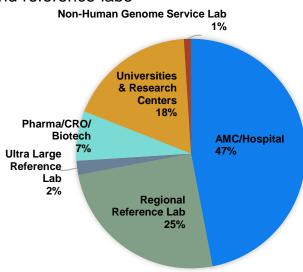
2023 to 2025

#### Our Customer Mix is Shifting Toward Routine Use in Cytogenetics Laboratories and Away from Non-Human and Basic Research

- Through 2019: 32% of systems installed were at academic medical centers (AMCs) and reference labs
- **2020 through 2022: 74%** of systems installed were at AMCs and reference labs



Through 2019



2020 through 2022

240 Saphyr Systems Installed

#### Routine Use Customers Drive Higher Utilization

- Academic medical centers, reference labs, pharma, and biotech customers generate more pull-through
- We believe utilization will increase as our customer base matures

### **2022 Estimated Average Annual** Consumable Revenue Per System<sup>1</sup>

Pharma & Biotech

**\$60k Academic Medical Centers** 

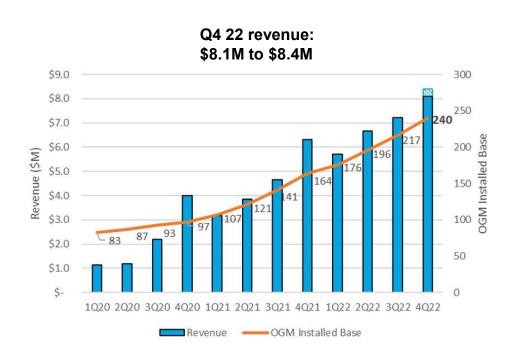
\$38k Reference Labs

Non-Human Genome Labs

**\$10k** Universities & Research Centers

<sup>1</sup> Using average ASP per flowcell including reagents of \$470 and the average number of systems installed by customer type in 2022

#### **Delivering Consistent Growth of Revenue and Installed Base**

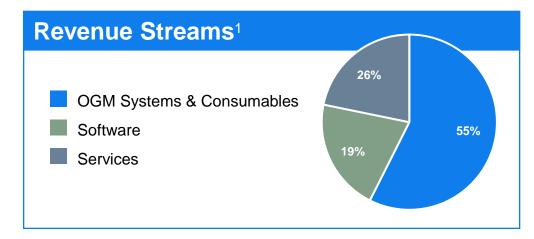


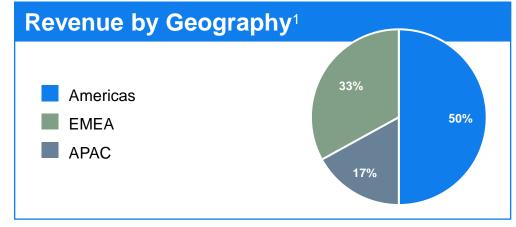
- Q4 2022 installed base of 240
   systems, up 46% from 164 in Q4 2021
- Q4 2022 revenues expected to be \$8.1 to \$8.4 million, a 27% to 33% year-over-year increase and above prior expectations
- 2022 revenue expected to be \$27.7 to \$28.0 million exceeding prior guidance of \$24M to \$27M
- Q3 2022 ending cash and cash equivalents balance of \$180.2M
- Closed Purigen acquisition in Q4 2022

#### **Recent Revenue Metrics**

#### 2022E Revenue: \$27.7 to \$28M

- Diversified revenue base across product lines and geography
- Expected to beat
   2022 revenue guidance







135 Commercial Employees

Countries with Employees

Commissioned Sales Professionals

Field Support Professionals

23 Authorized Distributors

#### Our Strategy for Key Catalysts as We Drive Toward an Inflection Point

- Increased throughput 13x
- Reduced ASP per genome from \$1000 to \$500
- Upgrades to analysis & reporting tools
- Initiated clinical studies, interim readouts
- Built a strong commercial team
- Published results on > 1000 human samples

- Increase throughput 13x: launch HT Saphyr
- Expand menu of OGM sample types & automate sample prep with ITP: launch lonic for OGM
- Deliver analysis & reporting toolset: full commercial release of VIA
- Expand publication of clinical genomes & clinical study results
- Obtain key regulatory approvals including FDA
- Address the needs for reimbursement through coding & coverage

2020 to 2022

2023 to 2025

# **Financial Targets**



## Target P&L at Scale<sup>1</sup>

50% to 70% Gross Margin

40% to 60%
Operating Expense

10% to 20%
Operating Income

## **The OGM Difference**

Alex Hastie, PhD
Vice President of Clinical and Scientific Affairs

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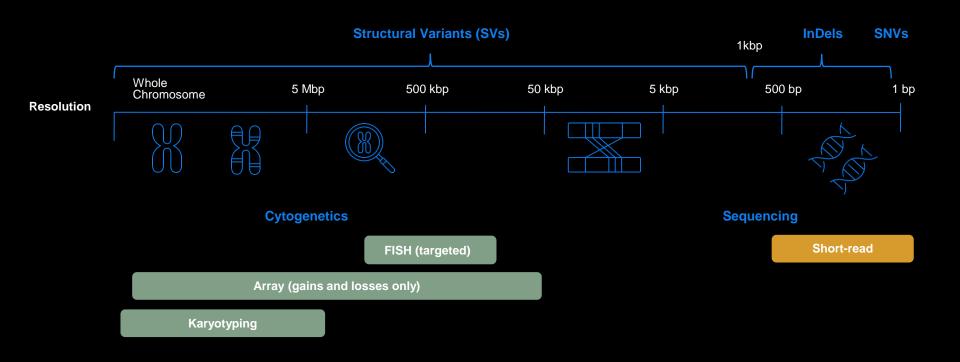


#### Genes Control Biology and Variants Cause Disease



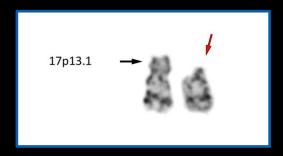
- TP53 is a well-known character in oncology. As the guardian of the genome, when its function is disrupted, we get cancer.
- Disruption of *TP53* function (and that of any gene) can be caused by many different classes or types of genome variation.
- Many of these variants can be detected with NGS, BUT most of them cannot.
- Medical guidelines are now being updated to require detection of bi-allelic events, meaning seq. should be used but other technologies should also be used.

#### The Standard of Care has Evolved to Address These Challenges



#### The Gap Between Karyotyping and NGS is Huge

## **Karyotyping (KT)**



- First line test for blood cancers and solid tumors
- Hasn't changed in 50 years

#### **NGS**

AGGTCCTTTAGCATCTA

TCCTGTAGCATCTACGA

GGTCCTTTAGCAGCTACGATT

CCTTTAGCATCTCCG

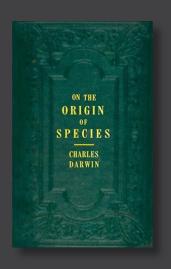
TCCTTTACCATCTACGATT

- First line test with KT for SNVs in blood cancers
- Best for SNVs and small in/dels

## Two Decades of NGS Have Not Closed the Gap



## NGS is Unable to Reliably Tackle SVs for Fundamental Reasons



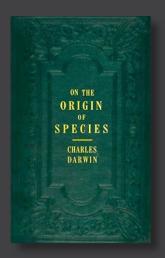


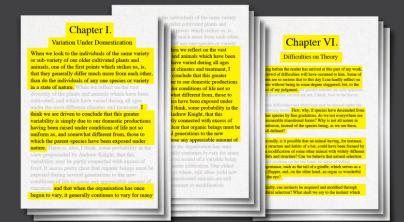
FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.





## The OGM Difference is Context from Ultra Long Reads



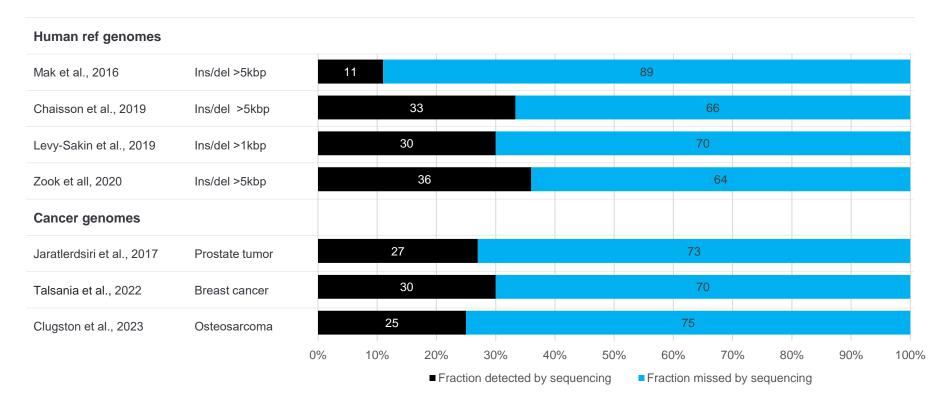


### Chapter I. Variation Under Domestication

When we look to the individuals of the same variety or sub-variety of our older cultivated plants and animals, one of the first points which strikes us, is, that they generally differ much more from each other, than do the individuals of any one species or variety in a state of nature. When we reflect on the vast diversity of the plants and animals which have been cultivated, and which have varied during all ages under the most different climates and treatment, I think we are driven to conclude that this greater variability is simply due to our domestic productions having been raised under conditions of life not so uniform as, and somewhat different from those to which the parent-species have been exposed under nature. There is, also, I think, some probability in the view propounded by Andrew Knight, that this variability may be partly connected with excess of food. It seems pretty clear that organic beings must be exposed during several generations to the new conditions of life to cause any appreciable amount of variation; and that when the organisation has once begun to vary, it generally continues to vary for many generations. No case is on record of a variable being ceasing to be variable under cultivation. Our oldest cultivated plants, such as wheat, still often yield new varieties: our oldest domesticated animals are still capable of rapid improvement or modification.

It has been disputed at what period of life the causes of variability, whatever they may be, generally act; whether during the early or late period of development of the embryo, or at the instant of conception. Geoffroy St. Hilaire's experiments show that unnatural treatment of the embryo causes monstrosities; and monstrosities cannot be separated by any clear line of distinction from mere variations. But I am strongly inclined to suspect that the most frequent cause of variability may be attributed to the male and female reproductive elements having been affected prior to the act of conception. Several reasons make me believe in this; but the chief one is the remarkable effect which confinement or cultivation has on the functions of the reproductive system; this system appearing to be far more susceptible than any other part of the organisation, to the action of any change in the conditions of life. Nothing is more easy than to tame an animal, and few things more difficult than to get it to breed freely under confinement, even in the many cases when the male and female unite. How many animals there are which will not breed, though living long under not very close confinement in their native country! This is generally attributed to vitiated instincts; but how many cultivated plants display the utmost vigour, and yet rarely or never seed! In some few such cases it

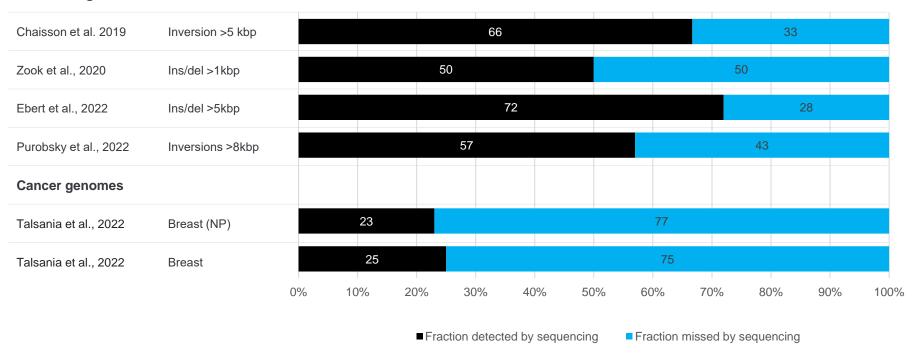
### Benchmark Studies Show How Much SVs Short-Read Misses



Mak, et al. Genetics. 2016;202(1):351-362., Chaisson, et al. Nat Commun. 2019;10(1):1784., Levy-Sakin, et al. Nat Biotechnol. 2020;38(11):1347-1355. Jaratlerdsiri, et al. Oncotarget. 2017;8(14):23588-23602. Talsania, et al. Genome Biol. 2022;23(1):255. Clugston, et al., unpublished poster presentation

## Long-Read Sequencing Performs Better but Still Misses Many SVs

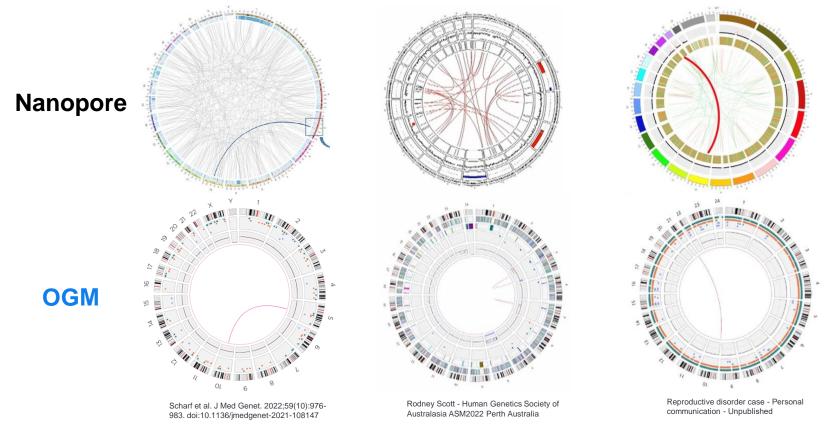
### **Human ref genomes**



Chaisson, et al. Nat Commun. 2019;10(1):1784. Zook, et al. Nat Biotechnol. 2020;38(11):1347-1355. Ebert, et al. Science. 2021;372(6537). Porubsky, et al. Cell. 2022;185(11):1986-2005.e26. Talsania, et al. Genome Biol. 2022;23(1):255.



## Studies Show Nanopore Detects SVs but with High False Positives



## KOL Opinions of LR and SR Sequencing

Recent comments in publications from leading US sequencing consortiums





### Utility of long-read sequencing for All of Us

M. Mahmoud<sup>1,2</sup>, Y. Huang<sup>3</sup>, K. Garimella<sup>3</sup>, P. A. Audano<sup>4</sup>, W. Wan <sup>3</sup>, N. Prasad<sup>5</sup>, R. E. Handsaker<sup>6</sup>, S. Hall<sup>5</sup>, A. Pionzio<sup>5</sup>, M. C. Schatz<sup>7</sup>, M. E. Talkowski<sup>8,9</sup>, E. E. Eichler<sup>10,11</sup>, S. E. Levy<sup>12</sup>, F. J. Sedlazeck1,2,13

- "The percentage of SVs agreed upon by all three technologies is approximately 22.00%; ONT and HiFi agreed on 53.86% of all SVs"
- "For long reads to advance, several major considerations must be addressed including costs, throughput, robustness of software cycles, and predictable/variable yields from sequence components or DNA quality fluctuations."



### Beyond the exome: what's next in diagnostic testing for Mendelian conditions

Monica H. Wojcik<sup>1,2,3</sup>, Chloe M. Reuter<sup>4</sup>, Shruti Marwaha<sup>4</sup>, Medhat Mahmoud<sup>5</sup>, Michael H. Duyzend<sup>1,2,6</sup>, Hayk Barseghyan<sup>7,8</sup>, Bo Yuan<sup>9</sup>, Philip M. Boone<sup>1,2,6</sup>, Emily E. Groopman<sup>1,2,6</sup>, Emmanuèle C. Délot<sup>8,10,11</sup>. Deepti Jain<sup>12</sup>. Alba Sanchis-Juan<sup>1,6</sup>. Genomics Research to Elucidate the Genetics of Rare Diseases (GREGoR) Consortium, Lea M. Starita<sup>13,14</sup>, Michael Talkowski<sup>1,6,15,16</sup>, Stephen B. Montgomery<sup>17,18,19</sup>, Michael J. Bamshad<sup>13,14,20</sup>, Jessica X. Chong<sup>13,20</sup>, Matthew T, Wheeler<sup>4</sup>, Seth I, Berger<sup>21</sup>, Anne O'Donnell-Luria<sup>1,2,22</sup>, Fritz J. Sedlazeck<sup>5,23</sup>, Danny E. Miller<sup>13,20,24,\*</sup>

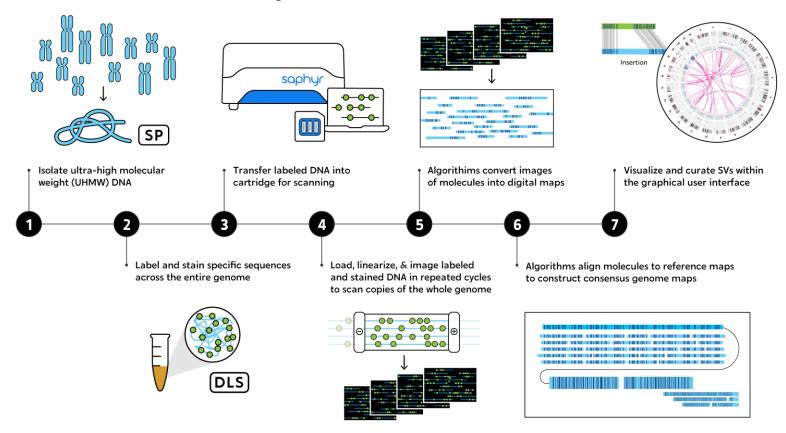
"A direct comparison of IrGS, srGS, and OGM on the same sample showed that 1 in 3 deletions and 3 in 4 insertions larger than 10 kb were detectable only by OGM."

**Bionano is Focused** on Providing a **Robust Solution for** Clinical **Translational** Research

### **Key Success Criteria in Clinical** Research Environment<sup>1</sup>

- High Specificity >95% Low false positivity
- High Sensitivity >95% High true positivity
- High complexity 3 cancer genomes
- 4 Detect low VAF <5%
- Cost Effective
- Simple workflow 6 Fast TAT and easy analysis

## The OGM Workflow is Sample to Answer for SV Detection



## Multiple Studies Show that OGM Matches SOC and Adds Yield

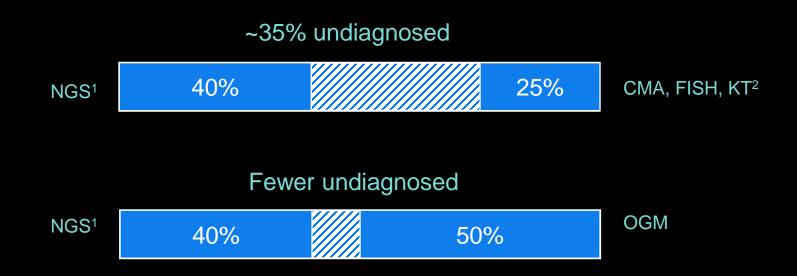
Study	Application	Concordance	Yield Increase
Broeckel et al, 2022	Dev disorders	98.7%	15%*
Yang et al, 2022	Heme	99%	28%
Levy et al, 2022	Heme	100%	18%
Hsieh et al, 2021	Dev disorders	NA	12%
Pang et al, 2022	Heme	100%	37%
Sahajpal et al, 2022	Heme	98.7%	22%
Sahajpal et al, 2022	Prenatal	100%	51%*

99%

25%

Broeckel et al. (2022) medRxiv. 2022.12.26.22283900., Yang et al. (2022). Leukemia. 2022;36(9):2306-2316., Levy et al. (2022). Blood Adv. 2022; Blood advances.2022007583., Shieh et al. (2021). NPJ Genom Med. Sep 23;6(1):77., Pang et al. (2022) medRxiv. 2022.12.27.22283973., Sahajpal et al. (2023). J Mol Diagn. 25(3) in press., Sahajpal et al. (2022). J Mol Diagn. 24(12):1279-1291.

## Cytogenetics and Molecular Genetics are Standard of Care

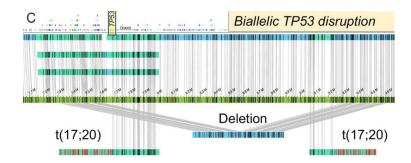


<sup>100,000</sup> Genomes Project Pilot Investigators, Smedley D, Smith KR, et al. 100,000 Genomes Pilot on Rare-Disease Diagnosis in Health Care - Preliminary Report. N Engl J Med. 2021;385(20):1868-1880. <sup>2</sup>Taylor A, Alloub Z, Tayoun AA. A Simple Practical Guide to Genomic Diagnostics in a Pediatric Setting. Genes (Basel). 2021;12(6):818. Published 2021 May 27. doi:10.3390/genes12060818

## NGS AGGTCCTTTAGCATCTA TCCTGTAGCATCTACGA $\mathsf{GGTCCTTTAGCA}$ CTACGATT CCTTTAGCATCTCCG TCCTTTACCATCTACGATT

## We Need to Detect All Variant Classes!

### **OGM**



Courtesy of Rashmi Kanagal Shamanna

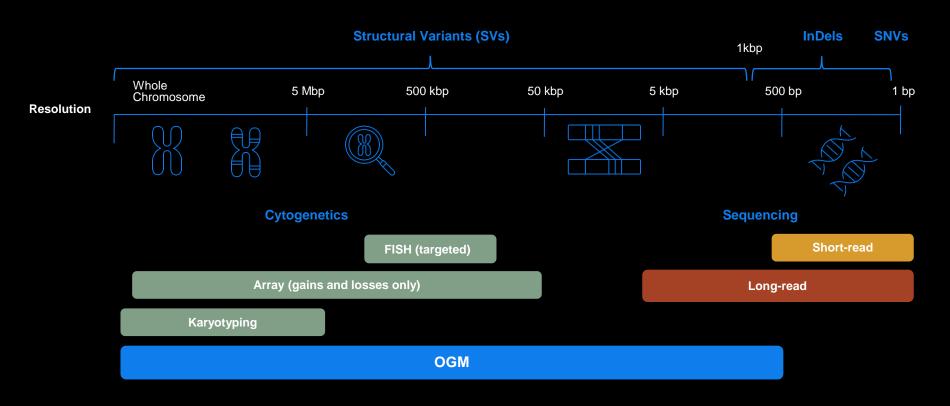
# Product Portfolio & Development Roadmap

Mark Oldakowski Chief Operating Officer

bionano

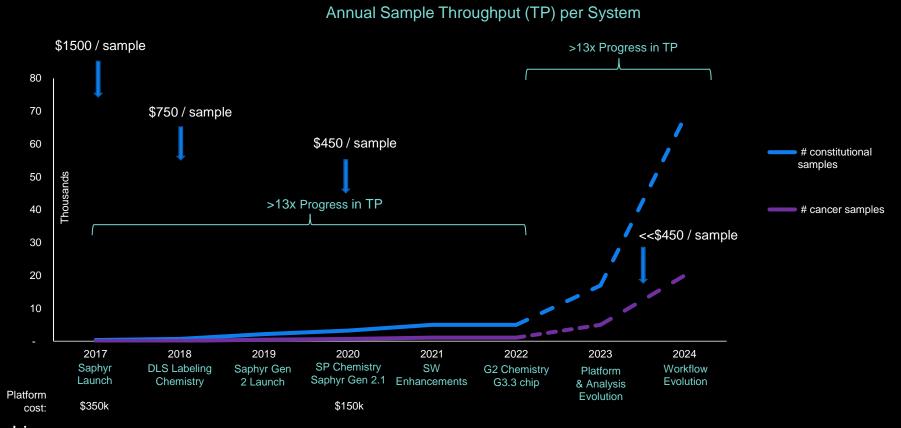


## We Believe Optical Genome Mapping will Transform Cytogenetics



### **Evolution of OGM Workflow**

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.



## **End To End Solutions for OGM**



### Saphyr ® System

Optical Genome Mapping in a User-Friendly Workflow

- Instrument, Consumables, Reagents
- Software, Compute
- Up to 4,500Gbp of data per day
- Up to max. 15,000Gbp per Saphyr Chip
- As low as \$0.09 per Gbp
- Up to 1,100 deep coverage cancer whole genomes per year
- Low bioinformatics burden

# **Enhancing and Integrating Workflows Across Genomics Applications**



Bionano Ionic Purification System Automated ITP extraction, purification and concentration of genomic DNA/RNA for breath of genomic applications

- Ionic Purification System
- Ionic Purification Kits
- Tackles complex samples like FFPE

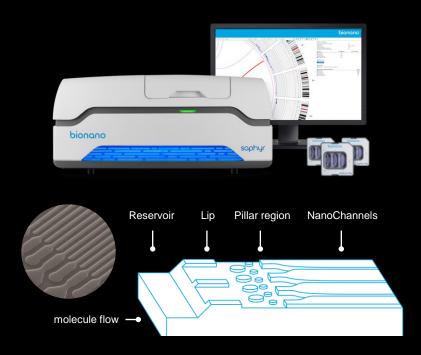


### N<sub>x</sub>Clinical

Comprehensive analysis in one system for analysis and interpretation of data from microarray and NGS

- Integrated analysis of CNVs, SNVs, and LOH in One View
- Automated interpretation
- HRD analysis

## **OGM** with Saphyr Uses Nanochannel Arrays to Linearize Ultra-High **Molecular Weight DNA**





## **Summary – Bionano IP Protection**

Patents and applications<sup>1</sup>

Broad protection on (i) nanochannel arrays and methods of manufacture and use; and (ii) ITP methods and systems



### **Bionano-owned IP (software)**

- NGS and Array: proprietary algorithms for analysis and presentation of NGS and microarray data in a consolidated view (soon to include OGM data as well)
- **OGM:** proprietary algorithms for processing and analysis of OGM data

### **Exclusively licensed from leading universities**

- Nanochannel: multiple patents and applications directed to nanochannel arrays, systems and labelling covering OGM technology
- ITP: multiple patents directed to extracting nucleic acid from a mixture, hybridizations, separations, and chemical reactions

### **Bionano-owned IP (patents)**

### PROTECTING BIONANO PRODUCTS

- Nanochannel: methods and improved devices covering OGM technology and alternate embodiments
- **ITP:** methods and devices for ITP implementation

### PROTECTING FUTURE OPPORTUNITIES

Nanonozzle: methods and devices for single molecule detection





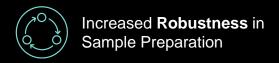
How is Bionano Scaling with Customers' Volume Needs

bionano

## Second Generation (G2) Reagents for Better Results in Less Time

Introducing New Product Offerings and Updates Across Your Entire OGM Workflow







Decreased **turnaround times** for DNA labeling and imaging



Improved **Throughput** and **N50** quality metrics

## **Hamilton's Long String Automation + Bionano** SP Generation 2 for **UHMW DNA Isolation**

Walk-away automation to run higher sample numbers and reduce hands-on time



## Sample Types (Fresh or Frozen)



### **Utilize optimized SP-G2.LS kits**

- Pre-packaged and configured kits for automation Isolate 24 DNA samples in a day
- Increase sample throughput routinely **Optimize with Generation 2 Chemistry**
- Improved DNA quality & throughput, length metrics



Where Do We Go From Here

bionano

### **Future Evolution in How the World Sees the Genome**

Enhancing usability, access, and results across genomics



Enhancing
Throughput &
Usability

Building toward an end to end high throughout future



Simplified Sample Prep

Enhancing sample prep across genomics application



Time to Result

The power of NVIDIA in OGM



Analysis Integration

SW that integrates OGM, NGS, and CMA and speeds interpretation

## **High Throughput Saphyr**

Addressing the needs of high-volume labs and low-cost regions



The next step in the evolution of the OGM workflow:

- Up to 96 cancer or 338 constitutional samples per week
- Ultimate menu flexibility
  - Random access / no batching
  - Application freedom: constitutional, cancer, cell bioprocessing
  - 15 samples on board / up to 3 STAT samples
- Designed to scale with multiple systems orchestrated for higher throughputs – "workcell"
- Compatible with current Bionano reagents and software
- Manufactured in FDA-registered facility
- To be submitted to FDA as part of a 510k filing

## We are accelerating the transformation in how we analyze the human genome!



## **Bionano & NVIDIA: Accelerating Analysis for Fast Time to Results**



Technological solution to **support higher throughput** 



New high-performance algorithms from Bionano



Powered by NVIDIA RTX™ 6000 Ada Generation GPUs



Analysis of highly complex cancer whole genomes in **less than 2 hours** 



Workflow tailored for a small lab and IT footprint



### **Bionano Ionic + OGM**

Next-gen sample prep: 2 hours for 8 samples with minimal hands-on time

The Ionic® Purification System in unlike any other on the market; next generation platform for DNA and RNA isolation and purification

- Overcomes limitations with all other binding approaches
- Highly effective with challenging sample types (i.e. FFPE)
- Capable of evolving to support very long DNA for OGM use, including
  - Minute samples (i.e. fine needle biopsies)
  - Dilute samples (i.e. buccal swabs)

## Future Evolution in Bionano Analysis SW!

Automation-assisted Interpretation of OGM Data Stand-alone or with Microarray and NGS Data Sets

In-Preview



## **Anticipated Product Milestones**

- High throughput Saphyr in first half 2023
- High throughput Saphyr Workcell in first half 2024
- High throughput Saphyr Compute in first half 2023
- Sample menu expansion via manual, Ionic and third-party workflows throughout 2023 and 2024
- VIA Automated variant Interpretation and reporting for OGM data fully commercial in second half 2023
  - Constitutional disorders and cancers
- High throughput Saphyr FDA 510k submission in 2024
  - Reagents received NMPA class I approval in China in 2022 for cancer indications

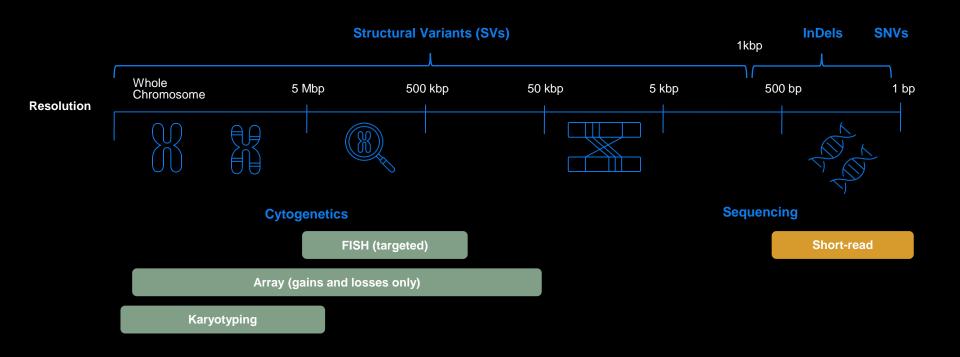
# **Clinical Development for Transforming Medical Practice**

Alka Chaubey, PhD, FACMG Chief Medical Officer

bionano



### **Standard of Care in Cancer and Genetic Disease**



## **Standard of Care is Defined by Medical Societies**

Disease Areas	Patients	First Line Test (Reflex)	OGM Replaces
GENETIC DISEASE	PRENATAL	Chromosomal Microarray (KT, FISH, WES)	CMA, KT, FISH
	POSTNATAL	Chromosomal Microarray, Southern Blot (KT, FISH, WES)	CMA, KT, FISH, Southern Blot
BLOOD CANCERS	LEUKEMIA	Karyotype, FISH, Seq panels (CMA)	KT, FISH, CMA
	LYMPHOMA	Karyotype, FISH, Seq panels (CMA)	KT, FISH, CMA





















## **Transforming Medical Practice Dependent on 2 Key Elements**

### **Drivers**

Medical Community on Board Abundant Data on OGM
Clinical Validity & Utility
Health Economic Data
Publications
Adoption & Utilization
Payor Specific Data
Inclusion in Guidelines
Coding & Reimbursement

Payors on Board

## Large Clinical Trials Program Underway To Address Key Drivers

We are following the paths already set by molecular methods for infiltrating the medical guidelines!

### **Study Description**

•	Multi-site, multi-operator,
	multi-instrument study

- Establish concordance with 1 of more SOC methods
- Retrospective arm
- Prospective arm
- Assess % increase in Dx Yield
- Assess cost effectiveness
- Assess TAT
- Assess Health Economics

	Pubs	
Prenatal Cultured amnios/CVS	<ul> <li>100% site-to-site reproducibility</li> <li>100% concordance with SOC*</li> <li>Replaces SOC (whether 1, 2 or 3 tests were required for diagnosis)</li> </ul>	3
Postnatal Blood, cell lines	<ul> <li>100% site-to-site reproducibility</li> <li>&gt;99% concordance with SOC</li> <li>Increase in Dx Yield (~10-15%)</li> </ul>	4
Blood Cancers Blood, Bone Marrow Aspirates, Lymph node suspensions	<ul> <li>100% concordance with SOC</li> <li>Increase in Dx Yield (~37%)</li> </ul>	5
Solid Tumors Tumor Tissue	<ul><li>100% concordance with SOC</li><li>Using OGM for HRD calculations</li></ul>	2

### Clinical Trial Sites and Pls Influence Guidelines and Reimbursement



### Brynn Levy, PhD Columbia

Board ISPD, Co-Editor Prenatal Diagnosis, CGC Founding Member



### Aaron Bossler, MD, PhD University of Iowa

AMA CPT Editorial Committee Member



#### Rashmi Kanagal-Shamanna MD Anderson

AMP BOD, CGC BOD, NCCN Liaison



### Ravindra Kolhe, MD, PhD Augusta University

US and Canadian CAP, AACR/ASCO visibility, NCI match PI, TSO500 driver for Illumina



### Adrian Dubuc, PhD Harvard

Former CGC president, and Harvard



#### Barb Dupont, PhD, Greenwood Genetics Center

Constitutional (Agilent validation, Affy validation, Illumina FDA sequencing validation consortium)



### Jim Broach, PhD Penn State Medical College

Track record of success with Bionano technology



### Gordana Raca, PhD CHLA

CGC President, NCCN Liaison ACMG Technical Standards



#### Saurabh Gupta, PhD Quest – Med Fusion

Quest, high volume



### Anwar Iqbal, PhD University of Rochester

CGC Founder, NY state



#### Yassmine Akkari, PhD Nationwide Childrens

AMCG lab QA, AMP training and ed chair. CGC President



### Ron Wapner, PhD CUMC

KOL for influencing Prenatal/postnatal auidelines



### Roger Stevenson, MD Founder of Greenwood Genetics Center

World renowned geneticist



### Aleksandar Rajkovic, PhD, MD UCSF Chief Genomics Officer

Stuart Lindsay Distinguished Professor in Experimental Pathology



#### Teresa Smolarek, PhD Cincinnati Children's Hospital

Director, Genetics and Genomics Diagnostic Laboratory



### Peter Bui, PhD, FACMG Quest Diagnostics

National Chief Director, Cytogenetics



## Consortia Advancing OGM Too: International Heme Working Group



Adam Smith, PhD, FCCMG



Brynn Levy, MSc, PhD, FACMG



Adrian Dubuc, PhD



Barbara Dewaele, PhD Katrina Rack, PhD



Blanca Espinet, PhD Anna Puiggros, PhD



Tuomo Mantere, PhD



Gordana Raca, MD, PhD, FACMG



Francesc Sole. Phd Mar Mallo, PhD



Nikhil Sahajpal, PhD



Rashmi Kanagal, MD



Alex Hoischen, PhD Kornelia Neveling, PhD Marian Stevens-Kroef, PhD Daniel Olde Weghuis



Alka Chaubey, PhD, FACMG Alex Hastie, PhD



Ravindra Kolhe, MD, PhD



James Broach, PhD David Claxton, MD

### OGM AML Consortium- Advancing Adoption in the US





RESEARCH ARTICLE | NOVEMBER 23, 2022

### Optical Genome Mapping in Acute Myeloid Leukemia: A Multicenter Evaluation

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



Track record of success with Bionano technology



Co-director of the Clinical Genomics Laboratory



Rashmi Kanagal-Shamanna, MD MD Anderson

AMP BOD, CGC BOD, NCCN Liaison. Current CGC president



Min Fang, M.D., Ph.D. Fred Hutchinson Cancer Center

CGC president, Chair of SWOG Leukemia Committee, AMP Board of Directors



Ravindra Kolhe, MD, PhD Augusta University

US and Canadian CAP, AACR/ASCO visibility, NCI match PI, TSO500 driver for Illumina



Yassmine Akkari, PhD Nationwide Childrens

AMCG lab QA, AMP training and ed chair, CGC President



Patrick Lennon, Ph.D. LabCorp

Past president of Cancer Genomics Consortium



COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Brynn Levy, PhD Columbia

Board ISPD, Co-Editor Prenatal Diagnosis, CGC Founding Member

### **Efforts of our Clinical Trials and Consortia Advancing OGM** are Providing Critical Publications and Data

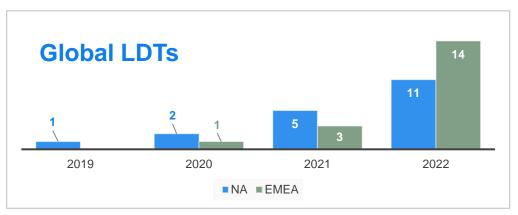
		Genetic Disease		Cancer					
REFERENCE	COHORT SIZE	FSHD	Prenatal	Postnatal	AML/CML//MP N/MDS	ALL/CLL	Lymphoma	MM/PCM	Solid Tumor
University of Iowa Stence, et al., 2021	351	•							
Multisite trial Stevenson, et al., 2022	123		•						
Multisite trial lqbal, et al.,in press	404			•					
Multisite trial Broeckel, et al., 2022	560			•					
Radboud University Neveling et al., 2020	48				•	•		•	
Multi-site Pang et al. 2022	68				•				
Augusta, Emory Sahajpal et al. 2022	69				•		•	•	
M.D. Anderson Yang et al., 2022	101				•				
Cancer Genomics Consortium Levy et al., 2022	100				•				
Penn State Med Goldrich et al., 2021	20				• Pre	-print			•
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# Adoption of OGM is Another Key Driver

- We are seeing validation of OGM as an LDT on a global basis – 25 LDTs as of 31-Dec 2022
- We leverage Bionano Labs for OGM-LDT development to engage with payors and support the global community



- CLIA-certified, CAP-accreditation pending
- Menu of OGM LDTs
  - OGM-Dx FSHD1
  - OGM-Dx HemeOne
  - OGM-Dx Constitutional (in progress)
- Lab supports the global community (clinical report)
- Engage with payors for pricing and reimbursement
- CLIA site for clinical trials
- Heme RUO study- 83% pathogenic abnormality detection rate!





#### Parallel Paths to OGM Adoption and Reimbursement

#### **PLA codes: Constitutional Genetic Disorders and Hematological Malignancies**

- Augusta University 0260U priced \$1263
- Praxis 0264U priced \$1263
- Augusta University 0331U; pending pricing
- Praxis 0299U, 0300U; pending pricing
- Other labs in the US are applying for PLA codes

#### **Category 1 CPT code:**

- Gathered AMA panel's feedback from application in 2022
- Reapplying in 2023 for 2 OGM codes

#### **Engagement with Payors:**

- Medicare Administrative Contractors (MACs) for local coverage determination (LCD) for OGM reimbursement
- Private Payors for positive medical policies

### **US Peer Reviewed Publications Showing Clinical Utility will Support CPT Code Application**

2022		2023				
Constitutional genetic disorde	ers	Constitutional genetic disorders				
Shieh et al., (2021). NPJ Genom Med. Sep 23;6(1):77.	50 postnatal cases	Shieh et al., (2021). NPJ Genom Med. Sep 23;6(1):77.	50 postnatal cases			
Stence et al. (2021). J Mol Diagn. Nov;23(11):1506-1514.	351 FSHD1 cases	Stence et al. (2021). J Mol Diagn. Nov;23(11):1506-1514.	351 FSHD1 cases			
		Iqbal et al. (2023). J Mol Diagn. Feb;25(3) in press.	404 postnatal cases			
		Sahajpal et al. (2023). J Mol Diagn. 25(3) in press.	91 prenatal cases			
		Hematologic malignancies				
		Sahajpal et al. (2022). J Mol Diagn. 24(12):1279-1291.	69 heme cases			
		Levy et al. (2022). Blood Adv. 2022; Blood advances.2022007583.	100 AML cases			
		Yang et al. (2022). Leukemia. 2022;36(9):2306-2316.	101 MDS cases			
		Jean et al. (2022). Blood Adv. 2022;6(11):3343-3346.	42 pediatric ALL cases			

#### Status Summary (2 yr period: 2020-2022)



**OGM** Data and Pubs

Human samples 600% increase

Pubs 275% increase



Clinical Utility and Validity

Prenatal Postnatal Heme



**OGM Health Economics** 

Global efforts: ongoing



**OGM** Adoption and Utilization

**LDTs** 1500% increase

#### **Transforming Medical Practice With OGM**

Drivers	2022	2023-2024		
Abundant Data on OGM	3000 genomes	6000 OGM genomes		
Clinical Validity & Utility	<10 publications	>20 pubs ~20% Increase in success rate		
Health Economic Data	-	Establish health economic benefits of OGM vs SOC		
Payor Specific Data	-	Meeting key evidence requirements for payor coverage		
Publications	30	>100 publications		
Adoption & Utilization	25	>100 LDTs globally		
Consensus Statement by KOLs	-	Constitutional and Heme		
Coding & Reimbursement	PLA codes	Cat 1 CPT codes for heme and constitutional; Medicare LCD on OGM		
Inclusion in Guidelines	First line test statements in pubs	Evidence based review - precursor to guidelines		

### **Clinical Research Panel**

Moderated by Dan Brennan, Cowen & Co

Featuring Drs. Adam Smith, Ravindra (Ravi) Kohle, and Gordana Raca











**Clinical Research Panel Audience Q & A** 

#### **Translational Research Panel**

Moderated by Dan Brennan, Cowen & Co

Featuring Drs. Ben Finlay, Rashmi Kanagal-Shamanna and Catherine Brownstein











Translational Research Panel Audience Q & A





### **Fireside Chat**

Erik Holmlin, PhD
Bionano President and Chief Executive Officer
with Moderator Dan Brennan
Cowen & Co

#### We Believe Bionano has Reached a Key **Inflection Point with Great Momentum**

- We are squarely focused on transforming cytogenetic analysis with our OGM, DNA isolation & software solutions
- We believe we have the only solution capable of comprehensive structural variation analysis for cytogenetics
- Publications from clinical research studies are ramping, and our trials and the work of multiple consortia around the world are advancing awareness of OGM
- We consistently deliver on our product development programs
- We believe our current product roadmap will enable us to penetrate our target markets
- We have global initiatives underway to pursue reimbursement for OGM applications
- We are seeing compelling interest from pharma and biotech for applications in cell Rx



**Bionano Management Q & A** 

#### Non-GAAP Financial Measures

To supplement Bionano's financial results reported in accordance with U.S. generally accepted accounting principles (GAAP), Bionano has provided non-GAAP (also referred to as adjusted or non-GAAP) financial measures in this presentation: adjusted operating expense and adjusted operating income (each as a percentage of revenue). Adjusted operating expense excludes from GAAP operating expense the following components: [stock-based compensations expense, intangible asset amortization and transaction related expenses]. [BNGO: Please confirm. Adjusted operating income is calculated GAAP revenue minus adjusted operating income (as determined in the prior sentence). Further, adjusted operating expense and adjusted operating income are expressed in this presentation as a percentage of revenue, which can be obtained by dividing each of these measures by GAAP reported revenue. Because this presentation includes forward-looking or projected non-GAAP operating expense and non-GAAP operating income for future periods, we have not reconciled our projections for non-GAAP operating expense and non-GAAP operating income to their most comparable GAAP reported financial measures (GAAP reported operating expense and GAAP reported operating income, respectively) due to the unavailability of information needed to calculate reconciling items and due to the variability, complexity and limited visibility of such reconciling items. For example, the reconciliation for stock-based compensation expense would require additional inputs such as the number and value of awards granted that are not currently ascertainable, uncertain and out of our control, and thus cannot be reasonably predicted. The actual amounts of reconciling items during the future periods presented will have a significant impact on GAAP operating expense or GAAP operating income. Accordingly, a reconciliation of these non-GAAP measures to their most directly comparable GAAP measure are not available without unreasonable efforts.

We believe that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts, and that each of these non-GAAP measures, when considered together with our financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to compare our results from period to period and to our forward-looking guidance, to identify operating trends in our business and to understand our objectives for financial and operating performance. We use these non-GAAP measures internally to understand, manage and evaluate our business and to make operating decisions. These non-GAAP financial measures are not meant to be considered in isolation or as substitutes for comparable GAAP measures; should be read in conjunction with our 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 we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of our adjustments to arrive at our non-GAAP financial measures. Because of the nonstandardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this presentation have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.



