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

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934

Filed by the Registrant ☒

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

☐ Definitive Proxy Statement

☒ Definitive Additional Materials

☐ Soliciting Material under Rule 14a-12

Illumina, Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

☐ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

☐ Fee paid previously with preliminary materials.

☐ Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

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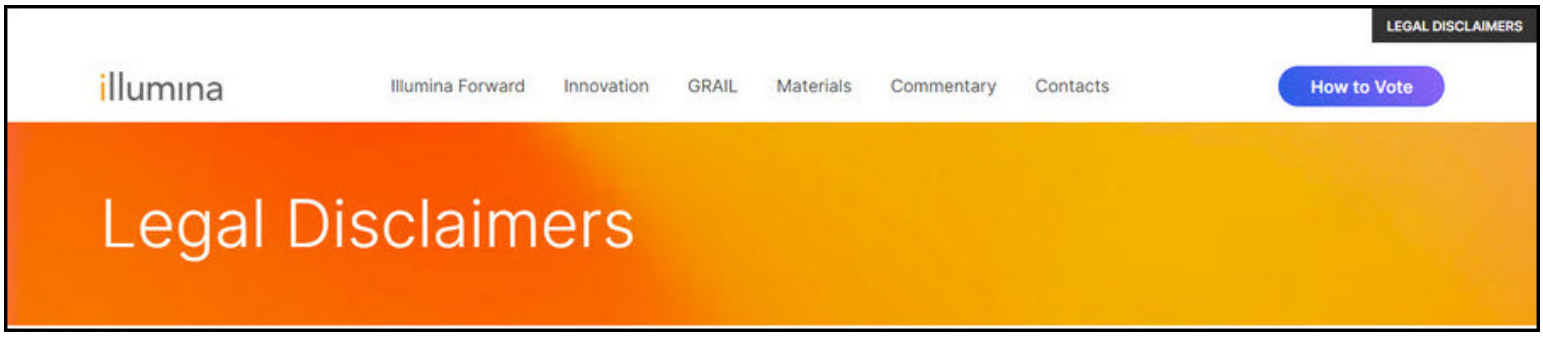
(4) Date Filed:

On April 20, 2023, Illumina, Inc. ("Illumina") launched a website in connection with Illumina's 2023 Annual Meeting of Stockholders. A copy of the materials (other than those previously filed) can be found below.



Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding mandates, the future, business plans and other statements that are not historical in nature. These statements are made on the basis of Illumina's views and assumptions regarding future events and business performance and plans as of the time the statements are made. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. Illumina does not undertake any obligation to update these statements unless required by applicable laws or regulations, and you should not place undue reliance on forward-looking statements. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) changes in the rate of growth in the markets we serve; (ii) the volume, timing and mix of customer orders among our products and services; (iii) our ability to adjust our operating expenses to align with our revenue expectations; (iv) our ability to manufacture robust instrumentation and consumables; (v) the success of products and services competitive with our own; (vi) challenges inherent in developing, manufacturing, and launching new products and services, including expanding or modifying manufacturing operations and reliance on third-party suppliers for critical components; (vii) the impact of recently launched or pre-announced products and services on existing products and services; (viii) our ability to further develop and commercialize our instruments, consumables, and products, including Galleri™, the cancer screening test developed by GRAIL, to deploy new products, services, and applications, and to expand the markets for our technology platforms; (ix) the risks and costs associated with our ongoing inability to integrate GRAIL due to the interim measures imposed on us by the European Commission as a result of their prohibition of our acquisition of GRAIL; (x) the risks and costs associated with the integration of GRAIL's business if we are ultimately able to integrate GRAIL; (xi) the risk that disruptions from the consummation of our acquisition of GRAIL and associated legal or regulatory proceedings, including related appeals, or obligations will harm our business, including current plans and operations; (xii) the risk of incurring fines associated with the consummation of our acquisition of GRAIL and the possibility that we may be required to divest all or a portion of the assets or equity interests of GRAIL on terms that could be materially worse than the terms on which we acquired GRAIL; (xiii) our ability to obtain approval by third-party payors to reimburse patients for our products; (xiv) our ability to obtain regulatory clearance for our products from government agencies; (xv) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business; (xvi) uncertainty, or adverse economic and business conditions, including as a result of slowing or uncertain economic growth, COVID-19 pandemic mitigation measures, or armed conflict; (xvii) the application of generally accepted accounting principles, which are highly complex and involve many subjective assumptions, estimates, and judgments and (xviii) legislative, regulatory and economic developments, together with the factors set forth in Illumina's Annual Report on Form 10-K for the year ended January 1, 2023 under the caption "Risk Factors", in information disclosed in public conference calls, the date and time of which are released beforehand, and in filings with the Securities and Exchange Commission (the "SEC") including, among others, quarterly reports on Form 10-Q.

Additional Information and Where to Find It

Illumina has filed with the SEC a definitive proxy statement on Schedule 14A, containing a form of WHITE proxy card, with respect to its solicitation of proxies for Illumina's 2023 Annual Meeting of Stockholders. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) FILED BY ILLUMINA AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT ANY SOLICITATION. Investors and security holders may obtain copies of these documents and other documents filed with the SEC by Illumina free of charge through the website maintained by the SEC at www.sec.gov. Copies of the documents filed by Illumina are also available free of charge by accessing Illumina's website at www.illumina.com.

Participants

Illumina, its directors and executive officers and other members of management and employees will be participants in the solicitation of proxies with respect to a solicitation by Illumina. Information about Illumina's executive officers and directors, including information regarding the direct or indirect interests, by security holdings or otherwise, is available in Illumina's definitive proxy statement for its 2023 Annual Meeting, which was filed with the SEC on April 20, 2023. To the extent holdings by our directors and executive officers of Illumina securities reported in the proxy statement for the 2023 Annual Meeting have changed, such changes have been or will be reflected on Statements of Change in Ownership on Forms 3, 4 or 5 filed with the SEC. These documents are or will be available free of charge at the SEC's website at www.sec.gov.

illumina

At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina innovative sequencing and array technologies are fueling groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

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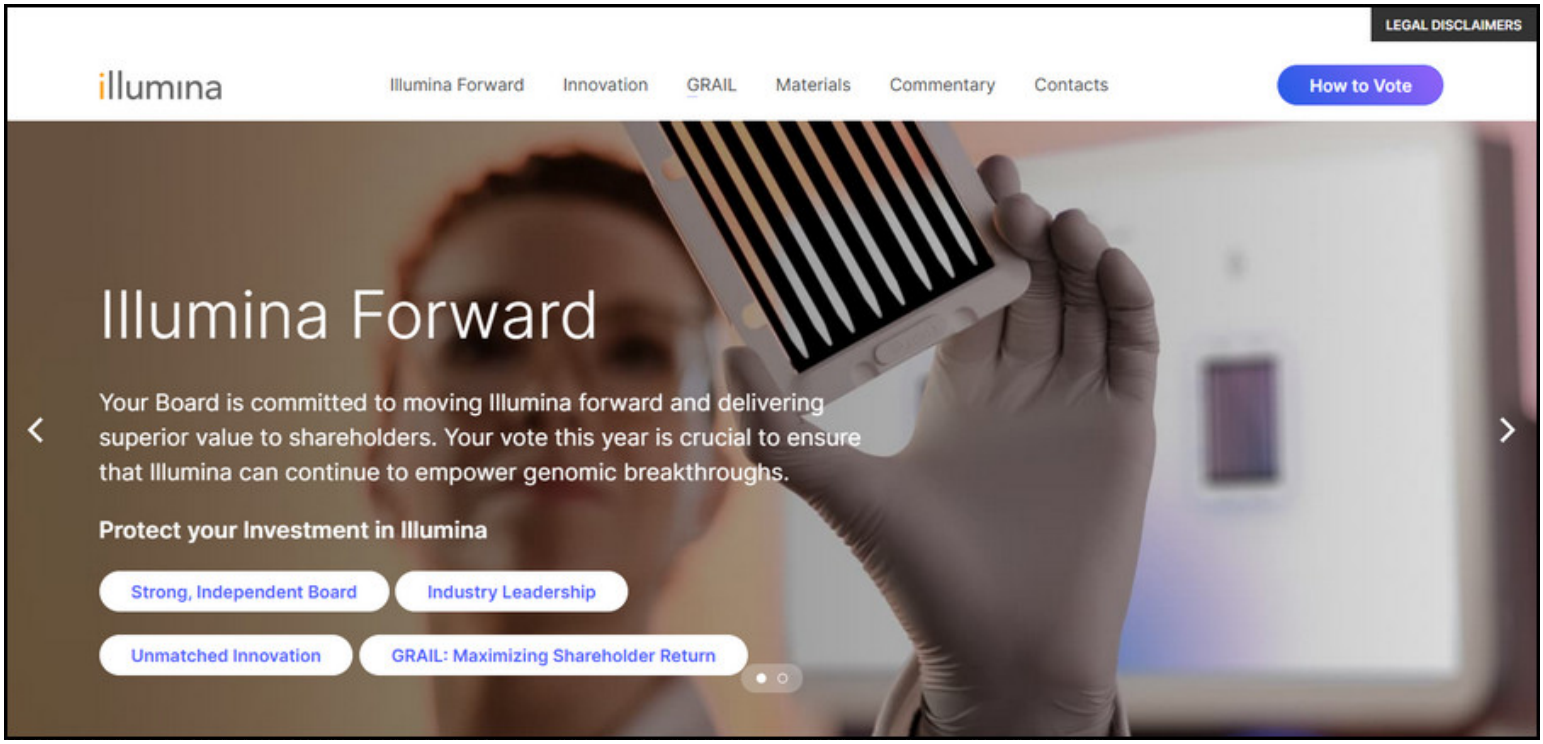
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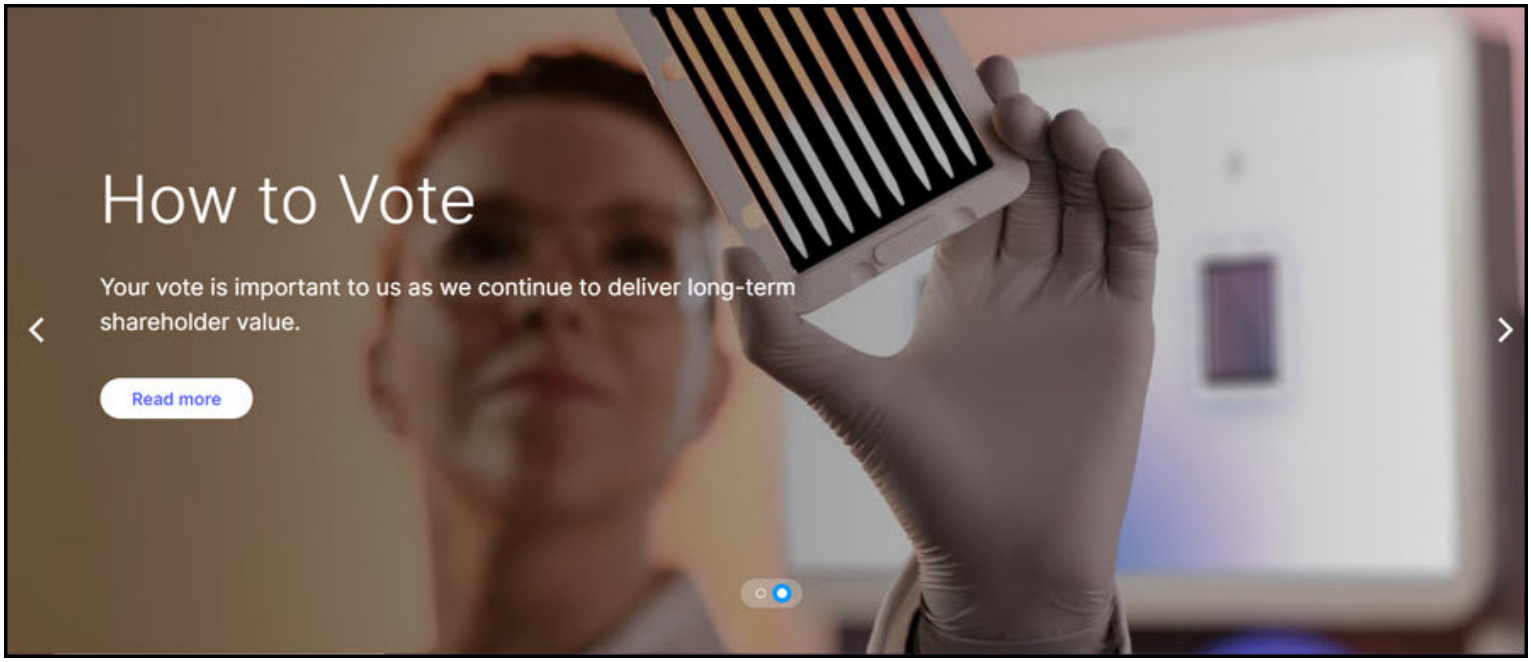
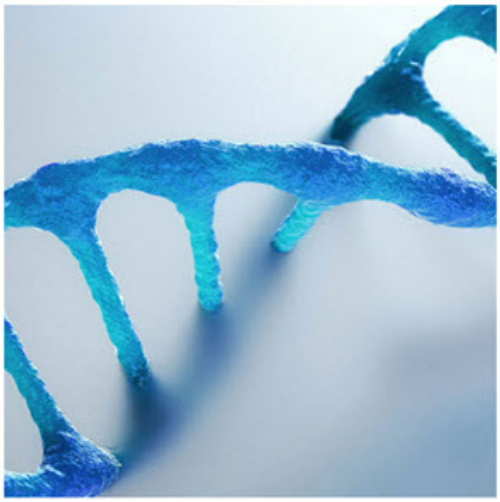
How to Vote
Illumina Forward
Your Board is committed to moving Illumina forward and delivering superior value to shareholders. Your vote this year is crucial to ensure that Illumina can continue to empower genomic breakthroughs.
Protect your Investment in Illumina
Strong, Independent Board
Industry Leadership
Unmatched Innovation
GRAIL: Maximizing Shareholder Return


How to Vote
Your vote is important to us as we continue to deliver long-term shareholder value.
Read more



Meet Your Board

Illumina's Board of Directors is committed to steering Illumina forward and maximizing value for all shareholders. Your Board is led by an independent chair and all nine members of the Board are independent with the exception of the CEO. Members of the Board have extensive business, financial, operating, and regulatory experience as well as scientific backgrounds in the life sciences and technology sectors.

Read more

Illumina Leads Research and Clinical Genomics with Unmatched Scale, Differentiation and Diversification

Scale[1]

$4.6B Revenue > 80% (consumables and services)[2]

> 9,500
Customers

> 155
Countries

~23,000
Instrument installed base

~10,000
Employees

Differentiation[1]

Clinical Expertise

62 Countries with regulatory approvals

FDA NMPA CE IVD

Innovation Track Record

> 8,800 Patents

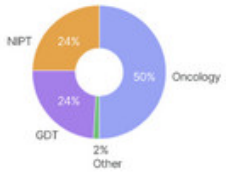
5 New sequencers launched since 2020

Diversification[1]

End Markets[3]



Clinical Markets[3]



1. Fiscal 2022 results for Core Illumina
2. Based on Core Illumina consumables and service and other revenue
3. Core Illumina % sequencing consumables shipments

Long-term targets of **revenue growth** in the mid-teens % and **operating profit growth** in the high-teens %

Company News



April 12th, 2023

Illumina's cloud-based informatics programs recognized for robust, international data privacy protections

Illumina announced it has received the international privacy certification of six of its cloud-based informatics programs.

Read more



April 11th, 2023

Illumina and Henry Ford Health team up to study impact of comprehensive genomic testing for cardiovascular patients

Series of studies will focus on genetic drivers of cardiovascular disease, and how data can improve care, especially in underserved communities

Read more



April 06th, 2023

Illumina celebrates 25 years of innovation

From genomics pioneer to global leader, the company ushers in the Genome Era of personalized health for all

Read more

View all Company News

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At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina innovative sequencing and array technologies are fueling groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

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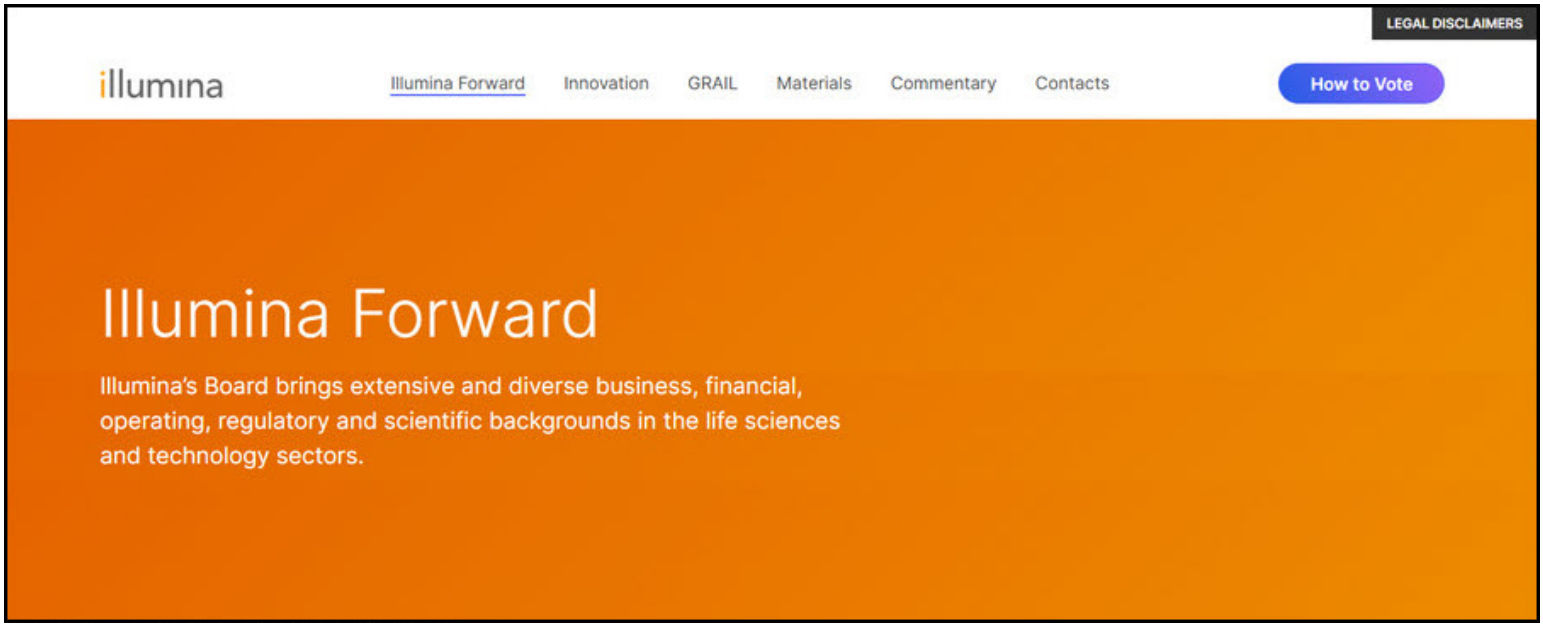
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Illumina Forward
Illumina's Board brings extensive and diverse business, financial, operating, regulatory and scientific backgrounds in the life sciences and technology sectors.

Illumina's Board and management team continue to move the business forward and fulfill the Company's important mission to improve human health with the goal of driving long-term shareholder value. Illumina's Board brings extensive and diverse business, financial, operating, regulatory and scientific backgrounds in the life sciences and technology sectors, and have presided over the growth of biotech companies, run public life sciences and technology companies, and brought world-class products to market.

Carl Icahn is attempting to install three associate nominees – two current employees and one former employee – to our Board of Directors. Mr. Icahn is not a long-term Illumina shareholder and made no attempt to engage constructively with the Company before presenting his demand that his three employees, each of whom are beholden to Mr. Icahn, are appointed.

The Board believes that Mr. Icahn's nominees lack relevant skills and their single-issue governance style would threaten the forward progress of Illumina's core business.

Your vote FOR all nine of Illumina's current director nominees on the WHITE proxy card will be critical at our upcoming Annual Meeting of Shareholders. We strongly urge you to simply discard and NOT vote using any GOLD proxy card sent to you by Carl Icahn or his affiliate entities.

At this year's Annual Meeting, we are asking shareholders to vote to maintain Illumina's industry-leading market positioning, growth prospects, portfolio strength and new breakthroughs, and long history of innovative execution.

Cast your vote for all of Illumina's highly qualified and experienced directors at our Annual Meeting on May 25, 2023.

Meet the Board

Illumina's Board of Directors is committed to steering the Company forward and maximizing value for all shareholders. Your Board is led by an independent chair and all nine members of the Board are independent with the exception of the CEO. Illumina's Board represents extensive business, financial, operating, and regulatory experience as well as scientific backgrounds in the life sciences and technology sectors.

Illumina firmly believes that it has the right team and strategy in place to deliver long-term shareholder value.

Illumina recommends shareholders vote in favor of the Company's Board of Directors and withhold votes for the three Icahn Group director nominees. Carl Icahn's involvement with Illumina risks the long-term success of the Company, and his director nominees bring no relevant skills to the Board of Directors.

Board



Frances Arnold, PhD

Director



Francis deSouza

CEO



Caroline Dorsa

Director



Robert S. Epstein, MD

Director



Scott Gottlieb, MD

Director



Gary S. Guthart, PhD

Director



Philip Schiller

Director



Sue Siegel

Director



John W. Thompson

Chair of the Board



Frances Arnold, PhD

Director

Dr. Arnold has been a director since 2016. She is the Linus Pauling Professor of Chemical Engineering, Bioengineering and Biochemistry at the California Institute of Technology, where she has been on the faculty since 1986. Dr. Arnold received the Nobel Prize in Chemistry in 2018 for pioneering directed enzyme evolution; she has used those methods to create enzymes for alternative energy, chemicals, and medicine. She co-chairs the Presidential Council of Advisors on Science and Technology. She received the Charles Stark Draper Prize of the US National Academy of Engineering in 2011, the US National Medal of Technology and Innovation from President Obama in 2013, and the Millennium Technology Prize in 2016. She has been elected to all three US National Academies of Science, Medicine, and Engineering, and was appointed by Pope Francis to the Pontifical Academy of Sciences in 2019. Dr. Arnold is a co-inventor on 62 issued US patents.

Dr. Arnold currently serves as a director of Alphabet Inc. and the following privately held companies: Provivi, an agriculture and pest management company, Aralez Bio, a bioengineering company, Resilience, a biopharmaceutical manufacturing company, Generate Biomedicines, a drug generation company, and Altos Labs, a biotechnology company. Dr. Arnold received her B.S. in Mechanical and Aerospace Engineering from Princeton University and her Ph.D. in Chemical Engineering from the University of California, Berkeley. She chairs the Advisory Panel of the David and Lucile Packard Foundation Fellowships in Science and Engineering and is a Trustee of the Gordon Research Conferences.



Francis deSouza

CEO

Francis deSouza was appointed CEO of Illumina in 2016 and is responsible for directing all aspects of company strategy, planning, and operations. He initially joined the company as President in 2013, and led Illumina's business units and core functions responsible for envisioning, developing and producing the company's products.

Previously, deSouza served as President of Products and Services at Symantec Corporation, where he was responsible for driving the vision for the company's market-leading portfolio and served in a variety of executive roles. He joined Symantec through the acquisition of IMlogic, where he was co-founder and CEO.

Prior to joining IMlogic, deSouza was co-founder and CEO of Flash Communications, a provider of corporate instant messaging that was acquired by Microsoft. Following the acquisition, he joined Microsoft and led the team responsible for the development of the company's enterprise real-time collaboration offerings. Currently, he is a member of the board of directors for The Walt Disney Company.

Francis deSouza received a B.S. and M.S. in Electrical Engineering and Computer Science from the Massachusetts Institute of Technology.



Caroline Dorsa

Director

Ms. Dorsa has been a director since January 2017. Ms. Dorsa served as Executive Vice President and Chief Financial Officer of Public Service Enterprise Group Incorporated, a diversified energy company, from April 2009 until her retirement in October 2015, and served on its Board of Directors from 2003 to April 2009. From February 2008 to April 2009, she served as Senior Vice President, Global Human Health, Strategy and Integration at Merck & Co., Inc., a pharmaceutical company. From November 2007 to January 2008, Ms. Dorsa served as Senior Vice President and Chief Financial Officer of Gilead Sciences, Inc., a life sciences company. From February 2007 to November 2007, she served as Senior Vice President and Chief Financial Officer of Avaya, Inc., a NYSE-listed telecommunications company. From 1987 to January 2007, Ms. Dorsa held various financial and operational positions at Merck & Co., Inc., including Vice President and Treasurer, Executive Director of U.S. Customer Marketing, and Executive Director of U.S. Pricing and Strategic Planning.

Ms. Dorsa also serves as Chair of the Board of Directors of Biogen Inc., and on the Boards of Intellia Therapeutics, Inc. and Duke Energy. From 2016 to 2021, she also served on the Board of Trustees of the Goldman Sachs ETF Trust, the Goldman Sachs MLP and Energy Renaissance Fund and the Goldman Sachs MLP Income Opportunities Fund, investment funds within the Goldman Sachs fund complex.

Ms. Dorsa received her M.B.A. from Columbia University and a B.A. from Colgate University.



Robert S. Epstein, MD

Director

Dr. Epstein has been a director since November 2012. Dr. Epstein is an epidemiologist who worked in public health and academia before joining the private sector. From 2010 to 2012, Dr. Epstein was Chief R&D Officer and President of Medco-UBC, a 2,400 person global research organization focused on conducting personalized medicine, health economics, drug safety, outcomes, and comparative effectiveness research on behalf of the biopharmaceutical, medical device, and diagnostics industries. Prior to this role, Dr. Epstein was Medco's Chief Medical Officer for 13 years, where he led formulary development, clinical guideline development, drug information services, personalized medicine program development, and client analytics and reporting. Dr. Epstein is also the former President of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and has served on the boards of directors of the Drug Information Association (DIA) and the International Society of Quality of Life. Dr. Epstein serves on the Board of Directors of Fate Therapeutics, Inc. and Veracyte, Inc. Dr. Epstein has published more than 100 peer-reviewed medical articles and book chapters and serves as a reviewer for several influential medical journals, including the New England Journal of Medicine and JAMA (The Journal of the American Medical Association).

Dr. Epstein received his M.D. and B.S. in biomedical science from the University of Michigan and an M.S. in preventative medicine from the University of Maryland.



Scott Gottlieb, MD

Director

Dr. Gottlieb has been a director since February 2020. Dr. Gottlieb is a physician and served as the 23rd Commissioner of the U.S. Food and Drug Administration from 2017 to 2019. His work focuses on advancing public health through developing and implementing innovative approaches to improving medical outcomes, reshaping healthcare delivery, and expanding consumer choice and safety. He is currently a Special Partner at the venture capital firm New Enterprise Associates and a Resident Fellow at the American Enterprise Institute for Public Policy Research, and he serves as a director of Pfizer, Aetion, Tempus Labs, National Resilience and the Mount Sinai Medical System. Dr. Gottlieb held several roles in the public and private sectors prior to serving as FDA Commissioner, including serving as a venture partner at New Enterprise Associates from 2007 to 2017. Dr. Gottlieb was previously the FDA's Deputy Commissioner for Medical and Scientific Affairs from 2005 to 2007, as well as a senior advisor to the FDA Commissioner from 2003 to 2004. He was also a senior advisor to the Administrator of the Centers for Medicare and Medicaid Services in 2004. Dr. Gottlieb has advised the states of Massachusetts, Maryland, and Montana on the Covid response as a member of state advisory boards. He is a contributor to CNBC and CBS Face the Nation.

Dr. Gottlieb received a B.A. in economics from Wesleyan University and his M.D. from Mount Sinai School of Medicine of New York University.



Gary S. Guthart, PhD

Director

Gary S. Guthart, Ph.D. has a been director since December 2017. Dr. Guthart is currently President and Chief Executive Officer of Intuitive Surgical, a global leader in the field of robotic-assisted minimally invasive surgery. He joined Intuitive Surgical in April 1996 and has served as the Chief Executive Officer since January 2010. In July 2007, he was promoted to President, having assumed the role of Chief Operating Officer in February 2006. Prior to joining Intuitive Surgical, Dr. Guthart was part of the core team developing foundation technology for computer enhanced-surgery at SRI International (formerly Stanford Research Institute). Dr. Guthart served as a member of the Board of Directors of Affymetrix, Inc. from May 2009 until its acquisition by Thermo Fisher Scientific Inc. in March 2016.

Dr. Guthart received a B.S. in Engineering from the University of California, Berkeley and an M.S. and a Ph.D. in Engineering Science from the California Institute of Technology.



Philip Schiller

Director

Mr. Schiller has been a director since July 2016. Mr. Schiller is currently an Apple Fellow at Apple Inc. He rejoined Apple Inc. in April 1997 and began serving as Senior Vice President, Worldwide Marketing in February 2002 as a member of Apple's executive team responsible for the company's product marketing, developer relations, business marketing, education marketing, international marketing, and App Store programs. He has helped Apple create and market some of the best-selling products in the world including the Mac, iPod, iTunes, iPhone, the App Store, Apple TV, and the Apple Watch. Prior to rejoining Apple, Mr. Schiller was Vice President of Product Marketing at Macromedia, Inc. from 1995 to 1997 and Director of Product Marketing at FirePower Systems, Inc. from 1993 to 1995. Prior to that, Mr. Schiller spent six years at Apple in various marketing positions.

Mr. Schiller received a B.S. in biology from Boston College.



Sue Siegel

Director

Sue Siegel has been a director since February 2019. She has driven game-changing ideas and powered companies that advance industries and improve lives for more than three decades. With vast experience across industries, she is on the forefront of the Fourth Industrial Revolution and is helping companies identify and seize transformative digital opportunities.

Most recently, as GE's Chief Innovation Officer and CEO of GE Ventures, Sue oversaw investments in startups, created and scaled new companies, and commercialized GE's intellectual property. She also led strategy planning and oversaw the global marketing function.

Before joining GE, Sue was a Silicon Valley-based healthcare and life sciences VC, leading investments in precision medicine, digital health, and life science tools. Prior to becoming a venture capitalist, Sue led Affymetrix as President and board member, where she led the company's transformation from a pre-revenue startup to a global, multi-billion-dollar market cap genomics leader. Sue also held executive leadership roles at Amersham, DuPont, and Bio-Rad after transitioning to a corporate career from early academic work in molecular biology and biochemistry.

Sue also serves on the boards of Align Technology (ALGN), Nevro (NVRO), the Kaiser Family Foundation, and is the Chair of MIT's The Engine. Additionally, she serves on the advisory boards for Mass General Brigham's Innovation Growth Board, University of California Innovation Council, RAND Health Care and the U.K. National Health Services Digital Academy. She co-chairs Stanford Medicine Board of Fellows.

Sue was a founding representative board member of NIH's National Center for Advancing Translational Sciences and served on President Obama's Precision Medicine Initiative Working Group.

A leader in technology and business, Sue has been recognized in Fortune's "34 Leaders Who Are Changing Health Care" and as one of "The 100 Most Influential Women in Silicon Valley" by Silicon Valley Business Journal. She is an Aspen Institute Henry Crown Fellow and is a featured "Multiplier" in the bestselling book: "Multipliers: How the Best Leaders Make Everyone Smarter."

Ms. Siegel holds a B.S. in Biology from the University of Puerto Rico and a M.S. in Biochemistry and Molecular Biology from Boston University Medical School.



John W. Thompson

Chair of the Board

John W. Thompson has been a director since 2017. He brings executive leadership experience having served in chief executive officer roles at Virtual Instruments and Symantec as well as 28 years of prior leadership experience at IBM where he held senior roles in sales, marketing, software development and as general manager of IBM Americas. He is currently a director at Microsoft and previously held roles as lead independent director and chair of its board. He has served on the corporate boards of Symantec , NIPSCO (Northern Indiana Public Service Company), Fortune Brands, Seagate Technologies, and United Parcel Service (UPS). Mr. Thompson is a member of the board of trustees for the Wetlands America Trust and formerly a member of the national board of Teach for America.

In addition, he has served on several government commissions including the Financial Crisis Inquiry Commission, the National Infrastructure Advisory Council, and the Silicon Valley Blue Ribbon Task Force on Aviation Security and Technology.

He received his B.A. in business administration from Florida A&M University and an M.S. in management science from MIT's Sloan School of Management.

Board Reflects Purpose-Built Mix of Skills and Diversity

Director Skillsets

Risk Oversight / Management
7 Directors
Skill critical for understanding Illumina's risks and opportunities

Life Science
7 Directors
Skill critical for understanding Illumina's core business and market

Public Company Executive
7 Directors
Skill critical for providing valuable perspectives in strategic and business development

Technology & Innovation
7 Directors
Skill critical for shaping long-term strategy and technology roadmap

Regulatory Expertise
6 Directors
Skill critical for understanding risks and opportunities associated with Illumina products

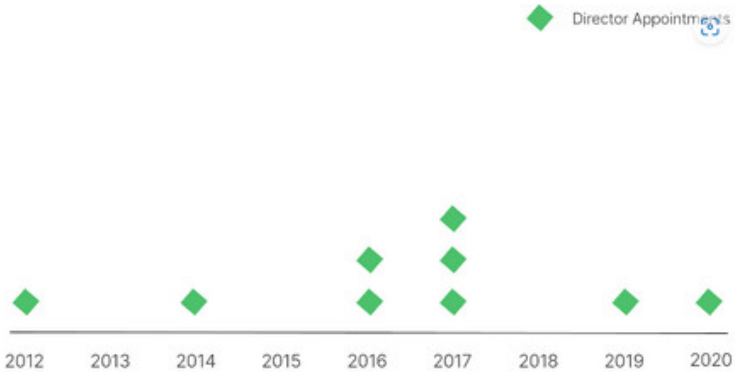
Financial Experience
5 Directors
Skill critical for fulfilling the Board's fiduciary duty

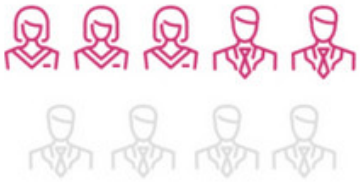
International Experience
5 Directors
Skill critical for expanding Illumina's global presence

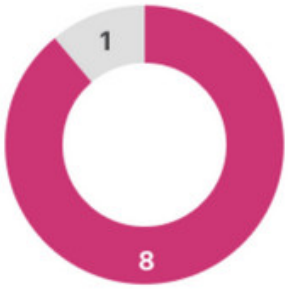
MD / PhD
4 Directors
Skill critical for providing strategic and technical subject matter expertise

Key Board Statistics

Number of Director Appointments by Year







56% Gender / Racial Diversity

89% Board Independence

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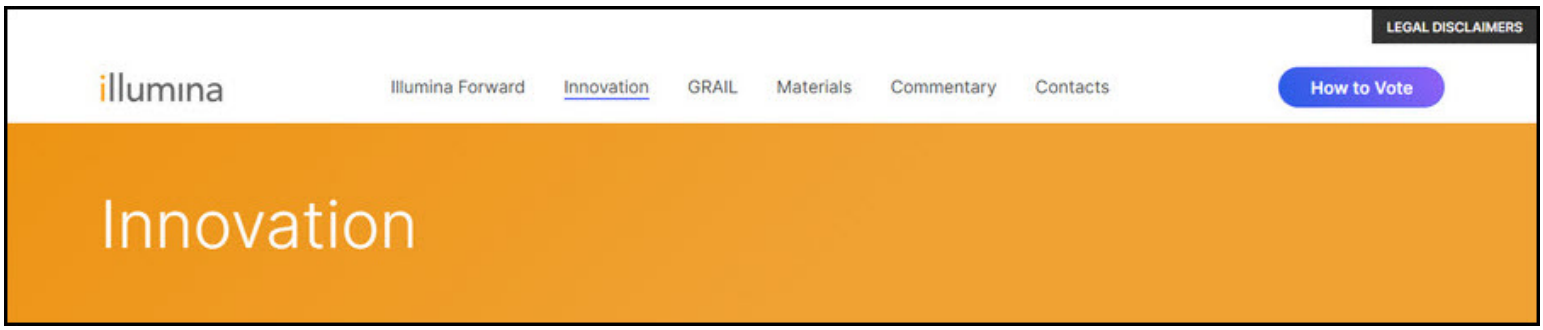
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Illumina's mission is to improve human health by unlocking the power of the genome



Our vision:

Genomics will transform lifetime health management, improving outcomes and lowering costs

Illumina Leads Research and Clinical Genomics

With a relentless focus on innovation, Illumina has gone from a genomics pioneer to a global leader. We have a successful long-term track record of innovating to fundamentally advance the understanding of biology and improve human health.

Illumina's sequencers and products enable researchers and clinicians to accurately read genomes, decode how they translate into health and disease, and leverage those insights in patient care.

More than 20,000 Sequencing Systems Installed Around the World

Our Sequencing Instruments

Low-throughput


MiSeq™


MiniSeq™


iSeq™100

Mid-throughput


NextSeq500 ™500


NextSeq550


NextSeq1000
NextSeq2000

IVD instruments


MiSeq Dx*


NextSeq 500Dx*


NovaSeq 6000Dx*

High-throughput


NovaSeq™ 6000


HiSeq™ 2000


HiSeq 2500


HiSeq X Ten


HiSeq 3000
HiSeq 4000


NovaSeq X
NovaSeq X Plus

For Research Use Only. Not for use in diagnostic procedures.
*For In Vitro Diagnostic Use. Not available in all countries or regions.

Illumina's Innovation Engine Continues to Generate Breakthrough Products

Launched Five New Sequencers Since 2020

2020



NextSeq 1000 & NextSeq 2000

75 breakthrough innovations offering higher output at lower sequencing cost

2021



NovaSeq 6000 Dx

First FDA-registered and CE-marked IVD high-throughput sequencer

2022



NovaSeq X & NovaSeq X Plus

Breakthrough high throughput sequencer with 2x speed and 2.5x throughput improvement

2023

Platform Extensions

- NovaSeq v1.5 reagents (2020)
- NextSeq 1K/2K P3 flow cell(2020)
- NextSeq 1K/2K P1 flow cell (2021)
- NextSeq 1K/2K extended shelf life(2021)
- NextSeq 1K/2K 600 cycle kits (2022)

Software Advancements

- Illumina Connected Analytics (2021)
- DRAGEN 4.0 (2022)
- Illumina Connected Insights (2023)

Issued Patents (Global)

2,663 (2017-2019) → 4,948 (2020-2022)

+86% increase

New Clinical Solutions and Assays

- TruSightOncology (TSO) 500 (2019)
- Respiratory Virus Oligo Panel (2020)
- Respiratory Pathogen Infectious Disease / Antimicrobial Resistance Kit (ID/AMR) (2020)
- COVIDSeqTest EUA (2020)
- COVIDSeqAssay RUO (2021)
- TSO 500 HRD (2022)
- Viral Surveillance Panel and Pan-Coronavirus Panel (2022)
- Urinary Pathogen ID/AMR Kit (2022)
- DNA Prep with Exome 2.0 Plus Enrichment (2022)
- TSO Comprehensive (EU) (2023)

2023 Upcoming Launches

- NovaSeq X Plus Roadmap with 25B and 1.5B flow cells
- Complete Long Reads, Whole Genome (2Q 2023)
- Complete Long Reads, Enrichment (2H 2023)

NovaSeq™ X

Illumina continues to lead the genomics industry with the latest and most innovative sequencing technology on-market.

First announced at the Illumina Genomics Forum last September, Illumina launched the revolutionary NovaSeq™ X Series – the most powerful, most sustainable, and most cost-effective sequencer ever developed. It offers high-throughput sequencing that is twice as fast and three times as accurate as previous Illumina products. It can generate more than 20,000 whole genomes per year at a cost of $200 per genome. The NovaSeq™ X has already exceeded more than 200 orders in the first quarter of 2023, representing a diverse customer base spanning research and clinical customer segments in nearly 30 countries and across five continents.

In February 2023, scientists at the Broad Institute of MIT and Harvard, the first recipient of a NovaSeq™ X, presented data confirming NovaSeq X Plus' performance meets or exceeds that of the NovaSeq 6000. This step-change in performance, coupled with the launch of Illumina Complete Long Reads in March 2023, enables customers to run long- and short-read sequencing on the same device, offering flexibility in a simplified and efficient workflow.

The NovaSeq™ X has enjoyed the strongest pre-launch demand Illumina has ever seen for any instrument, and customer enthusiasm continues to grow.



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At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina innovative sequencing and array technologies are fueling groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

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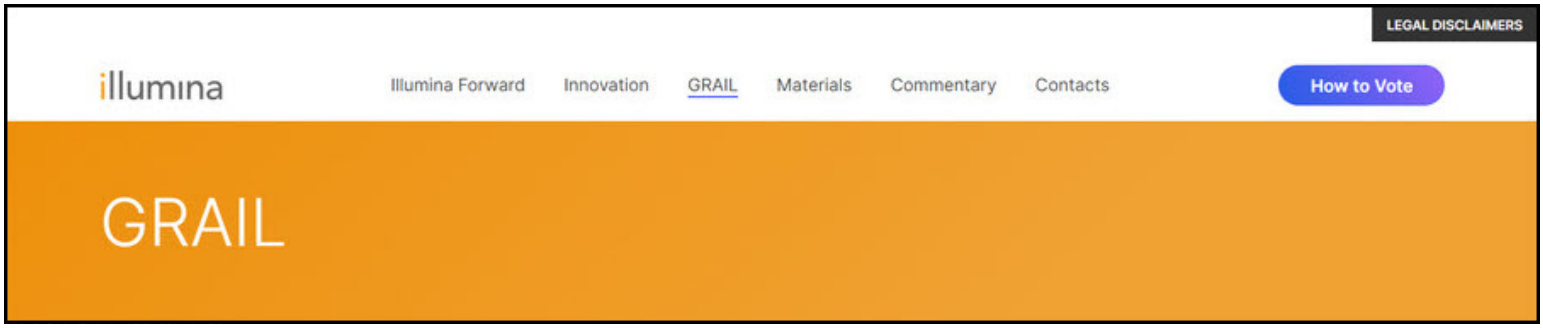
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Galleri™ Test

GRAIL's Galleri™ is among the most promising new tools in the fight against cancer and has enjoyed the fastest first-year revenue ramp of any cancer screening test. To date, more than 60,000 Galleri™ tests have been ordered and have impacted the lives of patients who have had the opportunity to take this groundbreaking test.

GRAIL Galleri™ is the Only Commercially Available Multi-Cancer Early Detection Test in the $44B Early Screening Market

>50

Stage I-IV Cancer types

45 of which have no other screens[1]



Galleri™ blood tests help save lives

Predicted to avert

1 in 3
Cancer deaths within 5-year timeframe[2]

67%
Stage I-III sensitivity in deadliest cancers

0.5%
False positive rate

89%
Cancer signal origin accuracy

Minimal Residual Disease (MRD)

2023
PLANNED LAUNCH

~2-3x
Reduction in turn-around time vs. tissue-based technology

[1] 45 of 50 cancers with no other recommended screens in the U.S.
[2] Hubbell E, Clarke CA, Aravanis AM, Berg Cd, Modeled Reductions in Late-stage Cancer with a Multi-Cancer Early Detection Test, Cancer Epidemiol Biomarkers Prev. 2023 Mar;30(3):460-468. doi: 10.1158/1055-9965.EPI-20-1134. As defined by the AJCC Staging Manual.

GRAIL, a healthcare company focused on life-saving early detection of multiple cancers, has tremendous long-term value creation potential and is a great example of Illumina's innovation strategy.

GRAIL offers the only commercially available multi-cancer early detection test, Galleri™, which is capable of screening for more than 50 different types of cancer, 45 of which do not have a recommended screening test.



Galleri™ has Strong Demand from Consumers, Physicians, Health Systems and Payors

Fastest first-year revenue ramp in cancer screening test history

>60,000 Galleri™ tests

>60 Partnerships with health systems, employers, etc.

>4,500 Physicians

97.1% Satisfaction rate

Progress toward reimbursement

FDA

2019 Breakthrough designation

2024/25 Final submission

>300,000 Collective participants across studies

The largest linked datasets of methylation and clinical data in the cancer field

Progress toward first national rollout with NHS

140,000

Participants enrolled in 10.5 months, an "unprecedented number of volunteers" [1]

1 million

Person rollout in 2024-2025 if trial is successful

MAYO CLINIC · Cleveland Clinic · HENRY FORD HEALTH · Sutter Health · NHS · OHSU · John Hancock

[1] Quote from Charles Swanton, MD, PhD, co-chief investigator of study, GRAIL and National Health Service (NHS) England Complete Enrollment of 140,000 Participants in Largest Study of Multi-Cancer Early Detection Test, (2022, July 18).

GRAIL expects a revenue CAGR of 60-90% over the next five years

Regulatory status

Illumina reacquired GRAIL in 2021. In light of the Federal Trade Commission (FTC) decision on April 3, 2023, overturning its own administrative law judge, and considering the expected timing and decision on its jurisdictional appeal in the European Court of Justice (ECJ), the Company has stated:

"Illumina intends to file a petition for review promptly with a US Court of Appeals and will seek expedited treatment of the appeal. The FTC's order to unwind the acquisition will be automatically stayed pending appeal.

Following the FTC Chief Administrative Law Judge's (ALJ) decision in favor of Illumina in September 2022, Illumina believes that it has a strong case on appeal. Illumina will move as quickly as possible and seeks to arrive at a resolution in the US Court of Appeals by late 2023 or early 2024, at approximately the same time as the decision in the European Court of Justice (ECJ) jurisdictional appeal.

Winning both appeals would maximize value for shareholders. It enables Illumina to expand the availability, affordability and profitability of the groundbreaking Galleri™ test in the $44-plus billion multi-cancer screening market. It also protects Illumina's ability to optimize a future divesture should that be in the best interest of shareholders.

If Illumina does not prevail in this appeal or the ECJ jurisdictional appeal, the company expects to move expeditiously to divest GRAIL in a manner that serves the best interests of Illumina's shareholders."

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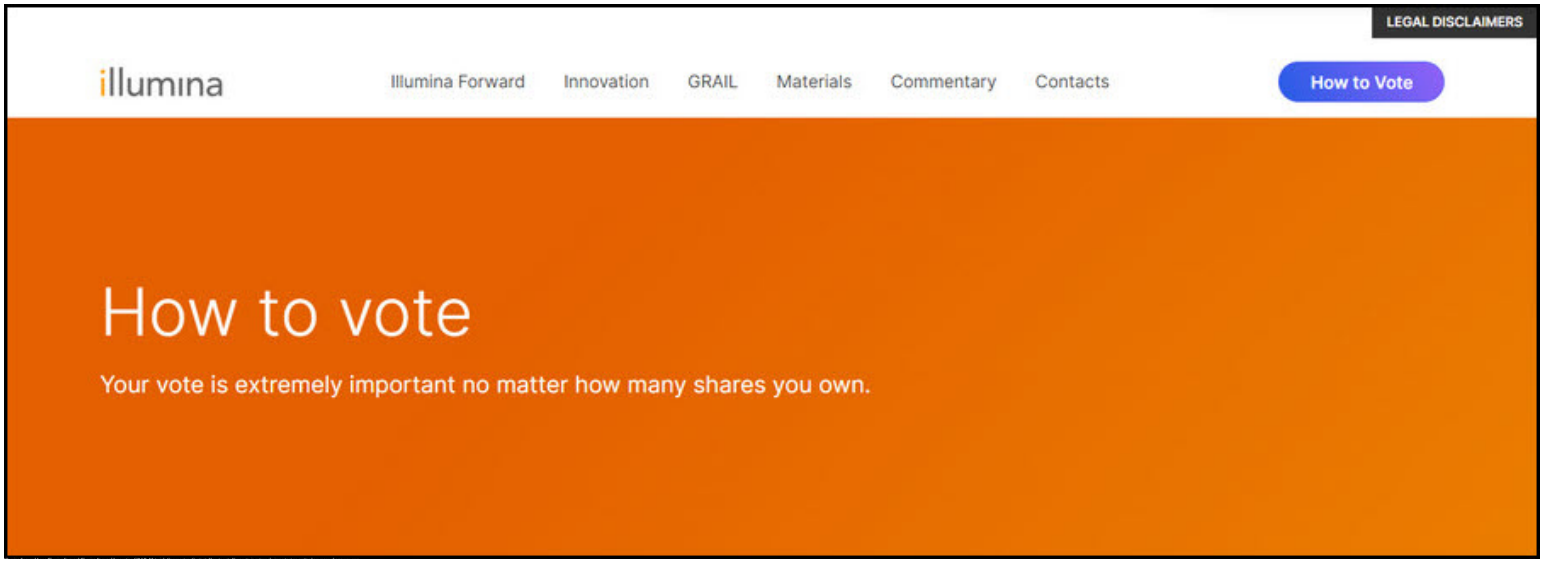
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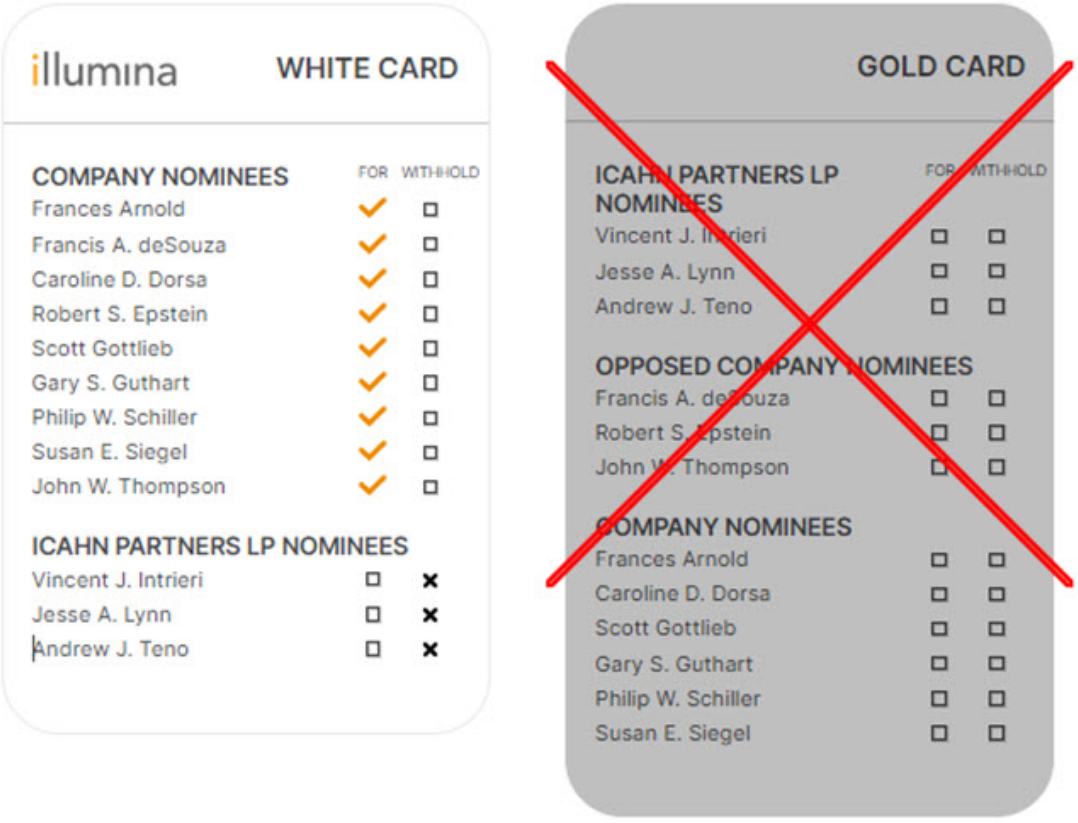
Your vote is extremely important no matter how many shares you own.

Illumina's Board of Directors urges shareholders to protect their investment and the future of the company – use the WHITE proxy card to vote "FOR" the nominees proposed by the Board and not Carl Icahn's three nominees.

If you have any questions or require any assistance with voting your shares, please contact Illumina's proxy solicitor, Innisfree M&A Incorporated, at 1 (800) 422-8620 (toll-free from the U.S. and Canada) or +1 (412) 232-3651 from other countries.

Remember: It's important you VOTE FOR only Illumina nominees on the WHITE proxy card.



Voting this year is critical
no matter how many shares you may own.

If you have any questions or require any assistance with voting your shares, please call Illumina's proxy solicitor Innisfree M&A Incorporated, at 1 (800) 422-8620 (toll-free from the U.S. and Canada) or +1 (412) 232-3651 from other countries.

Annual Meeting of Shareholders at 10:00 a.m. PT / 1:00 p.m. ET on May 25, 2023

Where to vote

Your vote is important. Voting is easy – you can use any of the methods below by following the instructions on your WHITE proxy card or voting instruction form:



INTERNET

Locate the control number included on your WHITE proxy card or voting instruction form and access the website indicated.



MAIL

Mark, sign and date your WHITE proxy card or WHITE voting instruction form and return it in the postage-paid envelope provided.



E-MAIL

If you received your proxy materials via e-mail, you can click the "VOTE NOW" button in the body of the e-mail. Please double check that the e-mail relates to the WHITE proxy card.

If you vote via the internet or by telephone, your electronic vote authorizes the named proxies in the same manner as if you signed, dated, and returned your physical proxy card. **If you vote electronically, you do not need to return your proxy card.**

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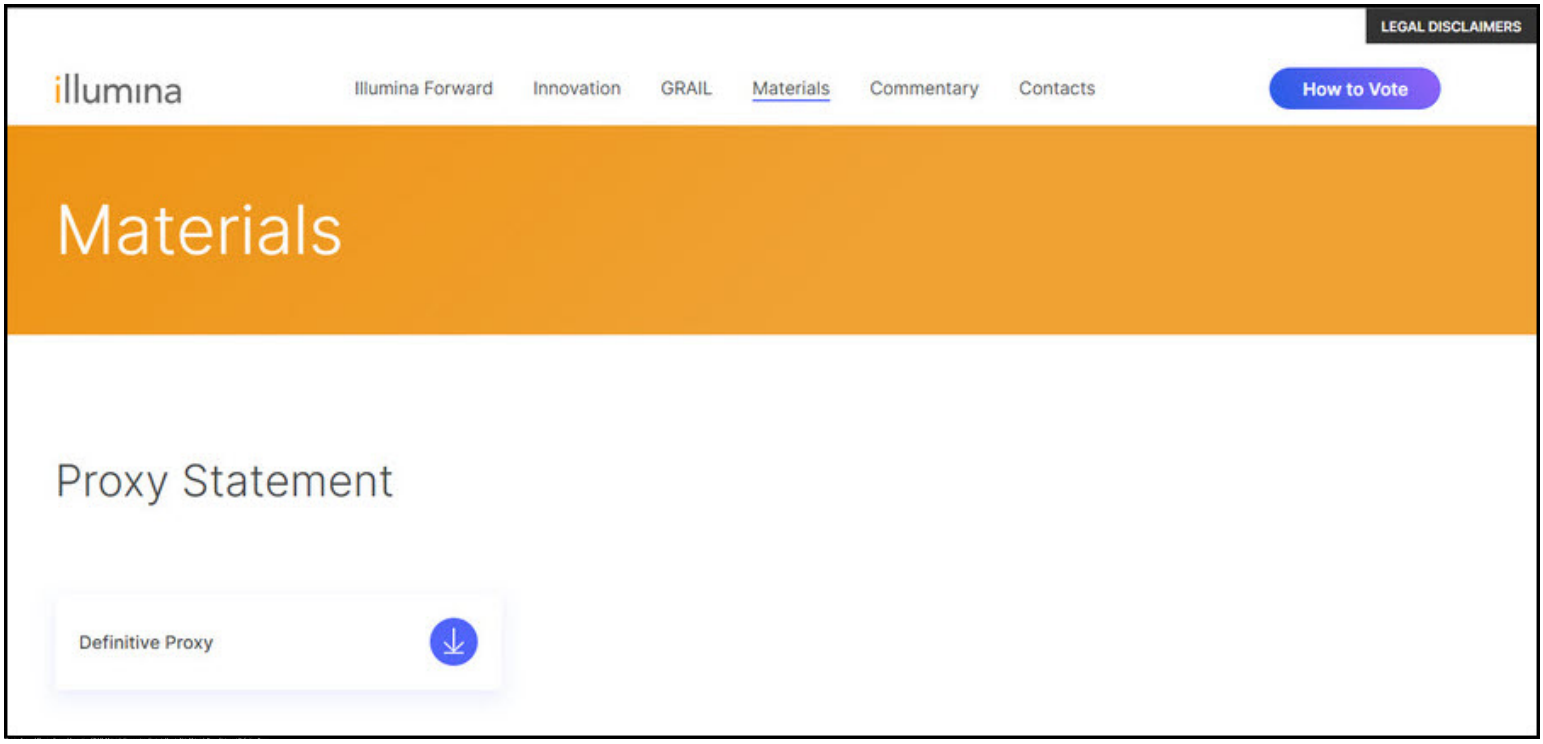
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Investor Presentation April 13, 2023

Shareholder Letters & Statements

Illumina Responds to Icahn Partners' Nomination of Directors

Illumina Underscores Commitment to Shareholder Value and Responds to Carl Icahn's Statements

Illumina Issues Statement in Response to Carl Icahn's Letter

Illumina Files Preliminary Proxy, Urging Shareholders to Vote for Its Director Nominees and Withhold for Each Icahn Group Nominee

Company News



April 12th, 2023

Illumina's cloud-based informatics programs recognized for robust, international data privacy protections

Illumina announced it has received the international privacy certification of six of its cloud-based informatics programs.

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April 11th, 2023

Illumina and Henry Ford Health team up to study impact of comprehensive genomic testing for cardiovascular patients

Series of studies will focus on genetic drivers of cardiovascular disease, and how data can improve care, especially in underserved communities

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April 06th, 2023

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April 04th, 2023

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April 03rd, 2023

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March 27th, 2023

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March 14th, 2023

Illumina launches its first product enabling long- and short-read sequencing on one instrument

Early customer data reinforces accuracy and flexibility of novel long-read technology, unlocking access to challenging, low DNA input samples

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February 17th, 2023

Form 10K

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Illumina's cloud-based informatics programs recognized for robust, international data privacy protections

SAN DIEGO, April 12, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, today announced it has received the international privacy certification of six of its cloud-based informatics programs. The certification, ISO/IEC 27701, recognizes that Illumina implements, and complies with, robust, international data privacy requirements.



Illumina has received the international privacy certification of six of its cloud-based informatics programs.

Illumina received an ISO/IEC 27701 certification for the following programs:

- BaseSpace Sequence Hub
- Clarity LIMS
- Correlation Engine
- Illumina Connected Analytics

The following products were also certified to support customers on historical software:

- TruSight Software
- BaseSpace Variant Interpreter

The certification was developed in 2019 by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) to provide a global standard for privacy protection. Obtaining an ISO/IEC 27701 certification requires the documentation of policies, procedures, and protocols demonstrating that a company applies high standards of data protection to personally identifiable information, such as names, Social Security numbers, and biometrics.

"Our newest privacy certification helps our customers comply with national and international data privacy standards, and better protects sensitive NGS data from potential cyberattacks," said Alex Aravanis, chief technology officer of Illumina. "Data breaches in the health care and pharmaceutical spaces are some of the costliest in the world, and Illumina prides itself on maintaining best-in-class privacy protections and processes."

ISO/IEC 27701 builds on Illumina's ISO/IEC 27001 certification, first earned in 2017. ISO/IEC 27001 is the international standard for information security management systems (ISMS), and it ensures that certified businesses have organized, implemented, and consistently maintain their ISMS. Both certifications were performed by Schellman, a US-based certification body accredited by the American National Standards Institute's National Accreditations Board and the United Kingdom Accreditation Service.

For more information on Illumina's cloud-based and on-premise software, visit illumina.com/products/by-type/informatics-products.html.

About Illumina

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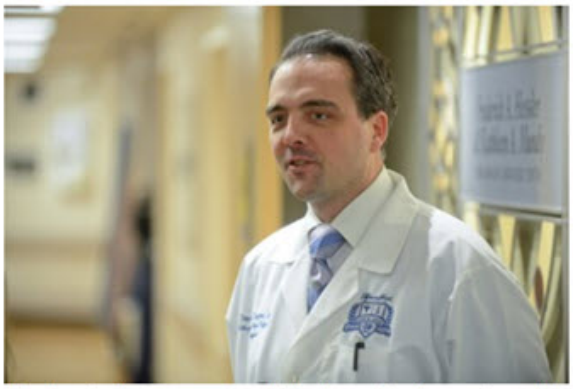
SOURCE Illumina, Inc.

Illumina and Henry Ford Health team up to study impact of comprehensive genomic testing for cardiovascular patients

Series of studies will focus on genetic drivers of cardiovascular disease, and how data can improve care, especially in underserved communities

SAN DIEGO, April 11, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, and Henry Ford Health, a not-for-profit health care organization in the Detroit metro area, today announced the launch of a partnership to assess the impact of comprehensive genomic testing in cardiovascular disease. The first study under this new partnership, CardioSeq, launches today and will include 1500 patients receiving care from the Division of Cardiovascular Medicine at Henry Ford.



Illumina today announced the launch of a partnership with Henry Ford Health, to assess the impact of comprehensive genomic testing in cardiovascular disease care. The first study under this new partnership, CardioSeq, launches today and will include 1500 patients at Henry Ford Health. Shown here, Dr. David Lanfear, vice president of clinical and translational research at Henry Ford and the study's lead clinician. Image credit: Ray Manning for Henry Ford Health

The Lisa and Christopher Jeffries Center for Precision Medicine and the Center for Individualized and Genomic Medicine Research at Henry Ford Health will conduct a series of implementation and clinical studies that will investigate the use of next-generation sequencing tests, including whole-genome sequencing (WGS), to assess their impact on clinical care. The studies will focus on cardiovascular disease, an area that imposes a substantial clinical and economic burden on the health care ecosystem, with a particular interest in diverse and underserved populations.

"This study is the first of several that will measure the impact of whole-genome sequencing in patients with cardiovascular disease," said Dr. David Lanfear, vice president of clinical and translational research at Henry Ford Health and the study's lead clinician. "What we're initially most interested in is the rate of the change in medical management due to the genetic information, but eventually we will be looking at differences in cost and clinical outcomes as well."

Dr. Phil Febbo, chief medical officer of Illumina, added: "We are honored to partner with Henry Ford Health to assess the potential benefits of integrating genomic testing within specialized care centers in the health care system. We share the belief that genomics should be integrated into standard of care across clinical indications as one of the key determinants of health. We intend for our partnership to demonstrate the benefits of such an approach for individual patients and the broader health care system, especially in underserved communities."

Cardiovascular disease is the leading cause of death globally, including in the United States, according to the World Health Organization. A patient's genetic make-up plays an important role in determining their risk of developing cardiovascular disease and how they respond to commonly prescribed medications. The CardioSeq study will use an accredited clinical test developed by Illumina that employs WGS to create a comprehensive cardiovascular genomic profile. Genomic profiling can provide clinicians and patients a more complete picture to base risk management and care planning decisions. This information could help facilitate early diagnosis and reduce unanticipated side effects, tests, and medical visits.

The WGS test used in CardioSeq will screen each patient for more than 200 genetic causes of cardiovascular disease as well as the American College of Medical Geneticists and Genomics' recommended secondary findings genes, which are associated with known inherited conditions for which interventions are available to mitigate the onset or severity of the clinical outcome. The test also returns pharmacogenetic results, based on Food and Drug Administration and Clinical Pharmacogenetics Implementation Consortium guidelines, yielding valuable insights into how an individual will respond to a particular drug, based on their DNA.

Genetic counselors will report any inherited disease findings to participating patients and offer them additional education. Pharmacists will review all pharmacogenetic findings and make indicated recommendations. The findings will also be shared with the patients' physicians. Henry Ford researchers aim to complete testing for all 1500 CardioSeq participants in 2024. With the patients' consent, their samples and clinical data will also be used by the partners for discovery efforts in genomic medicine to further the field of cardiovascular wellness and treatment.

About Illumina

Illumina is improving human health by unlocking the power of the genome. In 2023 we celebrate 25 years of innovation, which has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on Twitter, Facebook, LinkedIn, Instagram, TikTok, and YouTube.

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SOURCE Illumina, Inc.

Illumina celebrates 25 years of innovation

From genomics pioneer to global leader, the company ushers in the Genome Era of personalized health for all

SAN DIEGO, April 5, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, today begins a monthlong celebration of its 25th anniversary.



To kickoff its 25th anniversary celebration, Illumina employees, leaders and customers gathered in New York's Times Square on March 30 to ring the Nasdaq Stock Market Closing Bell. (Photography courtesy of Nasdaq, Inc.)

A quarter-century after its founding in San Diego in April 1998, the company is commemorating its anniversary by celebrating its employees, customers, and entire stakeholder ecosystem, and reflecting on its progress and impact over the last 25 years. With a diverse global workforce of nearly 10,000 in 34 locations worldwide, Illumina continues to deliver on its enduring mission to unlock the power of the genome to improve human health.

"As we celebrate our 25th anniversary, it is inspiring to reflect on the impact genomics—and our employees, customers, and partners—have had on human health," said Francis deSouza, CEO of Illumina. "Through our world-changing innovations, we've helped save patient lives, fight climate change, lift the world out of a pandemic, and so much more. We are incredibly grateful for our global community that is relentless in its pursuit of a world where personalized medicine is accessible to all."

Illumina's focus on innovating next-generation sequencing (NGS) technologies and democratizing access to genomics has played a critical role in enabling the global scientific community to advance the field through discoveries that have had profound impact on human health. Supported by an ever-expanding body of published research, NGS applications are now proven, powerful research and clinical health care tools in areas including rare disease, oncology, reproductive health, and infectious disease. As the need for NGS continues to grow, Illumina is focused on broadening access, awareness, and adoption of the technology.

One of Illumina's five founders, David Walt, noted that at the company's inception, before the Human Genome Project was completed, it really wasn't clear how the benefits of sequencing the human genome would scale. Since then, he says, Illumina's work has made a permanent impact on our understanding of science.

"Illumina has transformed genetic analysis through its arrays and then sequencing platforms, thereby democratizing genetic analysis by making it available to the research community and then for clinical use," he said. "We are only at the beginning of the genomics revolution. I'm so proud of what we've accomplished together but I'm more excited to see where it will take us in the next 25 years."

Since its founding, Illumina has earned several awards recognizing the company as a leader in workplace culture and innovation, including being named to TIME's 100 Most Influential Companies, Fast Company's Most Innovative Companies, and Forbes' World's Best Employers lists. The company also celebrated 25 years of innovation in New York's Times Square last week, when a group of Illumina's customers, employees, and leaders gathered with Chief Commercial Officer Susan Tousi to ring the Nasdaq Stock Market Closing Bell.

"We still have so much more to discover. And so many more lives to reach. To enable the discoveries of the next 25 years, we're developing the next leading sequencing innovations," she said. "And, we're making them even more accessible, affordable, and sustainable, to reach as many researchers, clinicians, and patients as possible."

A number of Illumina milestones and achievements are highlighted in the company's recently published feature article "25 greatest impacts in 25 years: A look back at Illumina and the evolution of genomics."

As part of its celebration, Illumina will launch a philanthropic grant program awarding $25,000 to 25 nonprofit organizations located in the communities where the company operates around the world.

Illumina's 25th anniversary month also coincides with National DNA Day on April 25, 2023. This year marks both the 20th anniversary of the completion of the Human Genome Project and the 70th anniversary of the discovery of the DNA double helix.

DeSouza said that while the field has come a long way and the science and technology continue to evolve, the company must do more to ensure these benefits are available to all.

"We've made tremendous progress over the last 25 years, with every discovery bringing us closer to unlocking the power of the genome to improve health—of humans and of the planet," he said. "Billions of people worldwide are counting on us to deliver on the promise of healthier lives, powered by genomics, for all. As we celebrate our 25th anniversary, the Illumina family is inspired, energized, and ready to help create the next 25 years of innovation."

About Illumina
Illumina is improving human health by unlocking the power of the genome. In 2023 we celebrate 25 years of innovation, which has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on Twitter, Facebook, LinkedIn, Instagram, TikTok, and YouTube.

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SOURCE Illumina, Inc.

Illumina's revolutionary NovaSeq X exceeds 200th order milestone in first quarter 2023

Strong demand drives record orders

SAN DIEGO, April 4, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, today announced it has already exceeded more than 200 orders for its revolutionary NovaSeq X sequencing system in the first quarter of 2023. The orders represent a diverse customer base spanning research and clinical customer segments in nearly 30 countries, across five continents, all seeking to add NovaSeq X – our fastest, most powerful, most sustainable high-throughput sequencer available.



Illumina CEO Francis deSouza visits employees at Illumina's manufacturing facility in Hayward, Calif. earlier this year, to celebrate the first shipment of the NovaSeq X.

"The NovaSeq X has enjoyed the strongest pre-launch demand we've ever seen for any instrument, and customer enthusiasm continues to grow," said Susan Tousi, chief commercial officer at Illumina. "Customers are thrilled about NovaSeq X's ability to enable and accelerate new projects that require more samples, more multiomic analyses, and depth of sequencing. In addition, NovaSeq X is proving to be an entry point for customers seeking more power and faster results – about 15 percent of pre-orders came from customers who are new to high-throughput sequencing."

First announced at the Illumina Genomics Forum last September, NovaSeq X offers high-throughput sequencing that is twice as fast and three times as accurate as previous Illumina products. It can generate more than 20,000 whole genomes per year at a cost of $200 per genome. In February, scientists at the Broad Institute of MIT and Harvard, the first recipient of a NovaSeq X, presented data confirming NovaSeq X Plus' performance meets or exceeds that of the NovaSeq 6000. This step-change in performance coupled with the launch of Illumina Complete Long Reads last month, enables customers to run long- and short-read sequencing on the same device, offering flexibility in a simplified and efficient workflow.

Illumina continues to lead the genomics industry with the latest and most innovative sequencing technology on-market and is committed to supporting its customers while driving additional orders and growing further adoption of whole-genome sequencing globally.

About Illumina

Illumina is improving human health by unlocking the power of the genome. In 2023 we celebrate 25 years of innovation, which has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on Twitter, Facebook, LinkedIn, Instagram, TikTok, and YouTube.

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SOURCE Illumina, Inc.

Illumina Will Appeal FTC Decision in Federal Court, Will Seek US Resolution by Late 2023 or Early 2024

SAN DIEGO, April 3, 2023 /PRNewswire/ — Illumina, Inc. (NASDAQ: ILMN) today announced that it will appeal the Federal Trade Commission's ("FTC") decision ordering the unwinding of Illumina's acquisition of GRAIL.

Illumina intends to file a petition for review promptly with a US Court of Appeals and will seek expedited treatment of the appeal. The FTC's order to unwind the acquisition will be automatically stayed pending appeal.

Following the FTC Chief Administrative Law Judge's (ALJ) decision in favor of Illumina in September 2022, Illumina believes that it has a strong case on appeal. Illumina will move as quickly as possible and seeks to arrive at a resolution in the US Court of Appeals by late 2023 or early 2024, at approximately the same time as the decision in the European Court of Justice (ECJ) jurisdictional appeal.

Winning both appeals would maximize value for shareholders. It enables Illumina to expand the availability, affordability and profitability of the groundbreaking Galleri test in the $44-plus billion multi-cancer screening market. It also protects Illumina's ability to optimize a future divesture should that be in the best interest of shareholders.

If Illumina does not prevail in this appeal or the ECJ jurisdictional appeal, the company expects to move expeditiously to divest GRAIL in a manner that serves the best interests of Illumina's shareholders.

Cautionary Note on Forward-Looking Statements

This release may contain forward-looking statements that involve risks and uncertainties. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) the commercial success of the Galleri test; (ii) the risks and costs associated with the integration of, and our ability to integrate, GRAIL's business successfully to achieve anticipated synergies, (iii) the risks and costs associated with the ongoing prohibition of integrating GRAIL with us; (iv) the outcome of any regulatory or legal proceeding; and (v) other legislative, regulatory and economic developments, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current quarter.

Cautionary Note on Statements of Opinion

In addition to forward-looking statements, this release contains statements of opinion with which all may not agree.

About Illumina

Illumina is improving human health by unlocking the power of the genome. Our focus on innovation has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on Twitter, Facebook, LinkedIn, Instagram, TikTok and YouTube.

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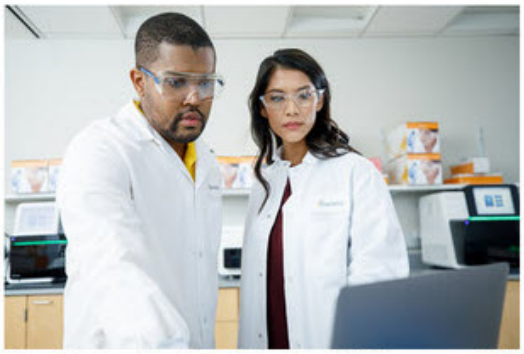
SOURCE Illumina, Inc.

Illumina launches new software to enable tertiary analysis for oncology applications, and soon rare disease

As demand for clinical next-generation sequencing grows, Illumina Connected Insights enables user to streamline data interpretation and report generation to inform precision care

SAN DIEGO, March 27, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, today announced the release of Connected Insights, a new cloud-based software enabling tertiary analysis for clinical next-generation sequencing (NGS) data.



Expanding on Illumina's Connected Software portfolio, Connected Insights is designed to streamline interpretation and reporting from a range of assay types, enabling labs to scale use of NGS and reduce turnaround time of clinical reporting via integration of third-party knowledge bases. The initial release will support somatic oncology applications, coinciding with the increasing use of comprehensive genomic profiling (CGP) for advanced tumors. Ultimately it is designed to support a diverse range of applications, soon including whole-genome sequencing (WGS) for rare disease. Connected Insights is commercially available in a limited number of countries. The product is undergoing beta testing in the US.

"We're seeing growing demand for NGS testing in health care systems, and with that comes the need for interpretation of large genomic data sets with complex health implications in a landscape of frequently changing guidelines and drug approvals," said Rami Mehio, head of global software and informatics at Illumina. "Connected Insights complements our suite of NGS solutions to generate, analyze, annotate, and interpret data consistently—today and into the future."

Growing use of NGS leads to greater need for data solutions

Albrecht Stenzinger, whose lab was an early-access customer of Connected Insights, says there has been a growing push in recent years for more CGP for cancer therapy response prediction at the time of diagnosis, and for the use of whole-exome sequencing (WES) and WGS for rare and pediatric cancers. Along with that, advances in earlier cancer detection and target drug approvals for early-stage disease will fuel the need for further comprehensive testing.

"If you are generating this massive amount of data, you need to interpret this in a meaningful way," Stenzinger, director of the Center for Molecular Pathology at the University of Heidelberg, said. "It's very hard nowadays to reliably interpret these thousands or even millions of different variants—even in intergenic regions—in a way that is clinically, directly applicable."

Mehio noted that Illumina and its peers across the industry are working to reduce the barriers to access and adoption of NGS testing—including cost, workflow, and reimbursement. He added, "As those barriers diminish, and clinical adoption of NGS matures, the need to bridge great volumes of data with manageable and clinically meaningful reporting becomes more critical for our customers."

Connected Insights enables labs to connect to a network of more than 45 third-party knowledge sources, including The Clinical Knowledgebase by The Jackson Laboratory. These sources provide digital directories for precision oncology, illustrating connections between cancer variants and therapies, citing evidence, and aiding analysis of complex cancer genomic profiles. Connected Insights can also link users to regional guidelines, clinical trial databases, drug labels, and a private, bespoke collection of data from previous cases within the customer's lab—all of which informs the generation of clinical reports for providers.

A connected software ecosystem

An existing challenge for labs generating genomic data is that analysis pipelines vary across NGS test types, making both standardization and data comparison more difficult. Connected Insights is designed to allow users to manage their data, which can enable standardized interpretation and reporting across NGS test types.

Eric Duncavage, professor of pathology and immunology and head of molecular oncology at Washington University, and an early-access customer of Connected Insights, said: "I used to always tell our trainees, 'There's not a Microsoft Office for genome analysis. You have to run all these different tools, and it's complicated.' I think what Illumina has done [with DRAGEN and its other software] is make genome analysis a step closer to an Office-like suite where it'll do everything."

"Connected Insights is the next step in creating a fully-integrated software ecosystem that scales with the pace of discovery, across NGS applications," said Jing Gao, vice president of software engineering at Illumina. "Building on our platforms of proven SBS technology with DRAGEN secondary analysis, Illumina Connected Analytics—and now Connected Insights—enables our users to bring a variety of knowledgebases and data together to discover clinical relevance. The ability to share and compare omic data within Illumina Connected Software facilitates collaboration that will advance medical science and patient care."

Connected Insights is assay-agnostic and compatible with variant calling files (VCF) from any secondary analysis solution, including Illumina's DRAGEN secondary analysis. Connected Insights supports a wide range of DNA and RNA assays with VCF output, including targeted and CGP panels, WES, WGS, and transcriptomic data from both tissue and liquid samples. As the use of clinical NGS testing grows, Illumina will expand the software's capabilities across other disease areas.

About Illumina Connected Software

Illumina Connected Software is an end-to-end software ecosystem that standardizes analysis tools and connects data across the genomics workflow. Integrating with Illumina sequencers and access to DRAGEN secondary analysis, Illumina Connected Software delivers an efficient, accurate, flexible analysis environment, ready to scale for each customer's workflow.

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SOURCE Illumina, Inc.

Illumina launches its first product enabling long- and short-read sequencing on one instrument

Early customer data reinforces accuracy and flexibility of novel long-read technology, unlocking access to challenging, low DNA input samples

SAN DIEGO, March 14, 2023 /PRNewswire/ — Illumina Inc. (NASDAQ: ILMN), a global leader in DNA sequencing and array-based technologies, today announced that its first product based on its novel Illumina Complete Long Read technology is now available to order. The high-performance, long-read, human whole-genome sequencing (WGS) assay – **Illumina Complete Long Read Prep, Human** – is compatible with Illumina NovaSeq X Plus, NovaSeq X, and NovaSeq 6000 Sequencing Systems. For the first time ever, it offers users access to both long- and short-read data on the same Illumina instrument. Illumina Complete Long Reads enables a simpler workflow with drastically reduced DNA input requirements compared to other long-read offerings.



"Illumina Complete Long Reads is more convenient than other long-read technologies. We can prepare long-read libraries with low DNA input and without many of the required materials and equipment needed for other technologies," said HyungIl Lee, head of NGS Department at Macrogen.

Seeing more of the most challenging genic regions

A small fraction of genic regions benefit from longer read lengths to enable improved resolution and mapping. By enabling access into these hard-to-map areas, Illumina's long-read data provides an additional tool in the advancement of genetic disease testing. This allows the scientific community to advance research by assaying the full breadth of genomic variation at scale to better facilitate discovery in areas of genetic disease research and pharmacogenomics.

Illumina Complete Long Read Prep combines Illumina sequencing by synthesis (SBS) chemistry with DRAGEN secondary analysis to deliver WGS with outstanding accuracy. The price of the Illumina Complete Long Read Prep, Human sequencing assay is inclusive of short- and long-read library prep, sequencing, and cloud analysis. The promotional price for customers is $1,350 USD per whole genome when using NovaSeq X Plus and a 25B flow cell, which will be commercially available later this year.

"Many long-read solutions have been stunted by high DNA input requirements, complex workflows with low throughput, and highly variable results on dedicated long-read instruments," said Alex Aravanis, chief technology officer and head of research and product development at Illumina. "Illumina Complete Long Reads overcomes those pain points and associated costs to make long-read sequencing accessible and streamlined for genomic labs."

Early customer data reinforces accuracy and flexibility

At the Illumina Genomics Forum in September 2022, Aravanis presented preliminary Illumina Complete Long Read performance data against the benchmarking data sets from the PrecisionFDA Truth Challenge v2. Illumina Complete Long Reads with DRAGEN analysis generated an F1 score—a compound statistic of precision and recall—of 99.87%.

Last month at the Advances in Genome Biology and Technology (AGBT) conference, early-access customers shared data reinforcing Illumina Complete Long Reads' high accuracy and flexible DNA input, as well as the capabilities that help to reduce cost and operational complexity.

Michael Quail, PhD, principal scientific manager, Sequencing R&D at Wellcome Sanger Institute, said, "The library prep was straightforward, with flexible input requirements. We are impressed with the accuracy of the data, along with the read lengths and phase blocks that can be generated on Illumina sequencers."

Illumina plans to use this technology as a platform for long-read application development. In the second half of 2023, Illumina will launch an enrichment assay, an even more affordable, higher throughput, targeted solution focused on regions known to benefit from additional insight with longer reads. Illumina will explore additional applications beyond WGS and nonhuman samples in the future.

To learn more, visit illumina.com/products/by-brand/complete-long-reads-portfolio.html.

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SOURCE Illumina, Inc.

illumina

At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina innovative sequencing and array technologies are fueling groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

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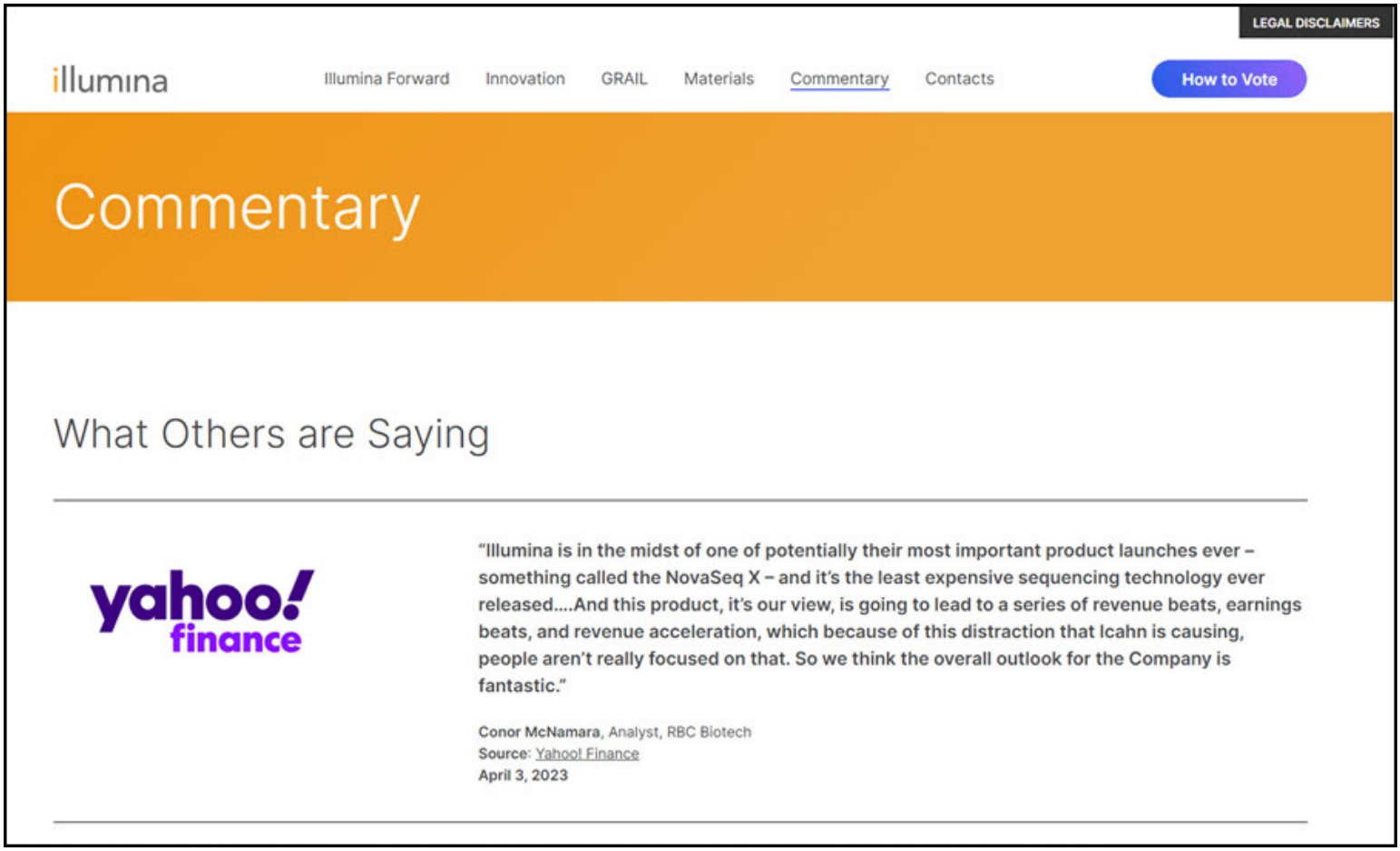
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"Illumina is in the midst of one of potentially their most important product launches ever – something called the NovaSeq X – and it's the least expensive sequencing technology ever released....And this product, it's our view, is going to lead to a series of revenue beats, earnings beats, and revenue acceleration, which because of this distraction that Icahn is causing, people aren't really focused on that. So we think the overall outlook for the Company is fantastic."
Conor McNamara, Analyst, RBC Biotech
Source: Yahoo! Finance
April 3, 2023

"It's apparent that Icahn doesn't fully understand the growth projections for the company...this is a long-term growth company in a market that they dominate and that isn't fully understood by all investors....to give up a third of your board to folks that don't necessarily understand the business or the market, or necessarily even what the company fully does, I think that would be a mistake."

Conor McNamara, Analyst, RBC Biotech
Source: Yahoo! Finance
April 3, 2023

"Illumina is at the very beginning stages of your latest high throughput product cycle, possibly the most impressive one technologically in your history."

Dan Brennan, Analyst, Cowen
Source: Seeking Alpha
March 7, 2023

FT FINANCIAL TIMES

"Illumina has over the past decade been an attractive, high-growth investment because it sells its sequencers at high prices (up to $1.25mn each) and has recurring revenues from the reagents and other products required to operate them."

Dan Brennan, Analyst, Cowen
Source: Financial Times
January 29, 2023

WSJ

"The Federal Trade Commission on Monday overruled its own in-house judge and ordered gene-sequencing giant Illumina to divest cancer blood-test startup Grail. FTC Chair Lina Khan is showing that the agency's administrative trials are a sham. Heads the agency wins, tails businesses lose. A FTC judge in September issued a 203-page opinion rejecting the agency's complaint that alleged the Grail acquisition would harm potential competitors in the embryonic market for multi-cancer early detection tests. Grail currently has no competitors, and the FTC complaint relies on speculative theories."

The Wall Street Journal Editorial Board
Source: The Wall Street Journal
April 3, 2023

SEMAFOR

"To bring its blood test to market more quickly, in higher quantities, and at lower cost to patients, Grail needs manufacturing, operations, and supply chain efficiencies, as well as experience working with regulators like the FDA — all things Illumina can and will provide if the companies are allowed to merge."

Joshua Wright, Professor, Antonin Scalia Law School at George Mason University; Executive Director, Global Antitrust Institute at Scalia Law School; former Republican FTC commissioner
Source: Semafor
April 4, 2023

FT FINANCIAL TIMES

"There is real cost with the delay from the regulatory scrutiny and over-reach. Grail isn't broadly accessible now because of it, and we are missing many opportunities now to detect people's cancers early. The very real cost is lives lost with every day of delay."

Jeff Huber, Co-Founder & General Partner, Triatomic Capital; Founding CEO, GRAIL
Source: Financial Times
April 4, 2023

SEMAFOR

"Illumina already beat the government once, and there's reason to believe it might do so again, avoiding a costly and embarrassing unwind of an acquisition on which it had pinned its future. It can choose its appeals court, and could find sympathetic ears in the Fifth Circuit, which has become the preferred venue for critics of the Biden administration."

Liz Hoffman, Business & Finance Editor, Semafor
Source: Semafor
April 4, 2023



"Board members are supposed to act as stewards of a company, not agents for a single investor. If any disputes along these lines arise for public companies where Icahn has nominees on the board, shareholders are going to use this as exhibit A for allegations that the directors followed Icahn rather than their own judgment."

Ann Lipton, Michael M. Fleishman Associate Professor in Business Law and Entrepreneurship, Tulane University
Source: The New York Times
March 31, 2023

GRAIL

"However, our work with GRAIL runs much deeper than just making Galleri accessible to our customers. We believe there is a critical need to expand awareness of and access to this type of groundbreaking technology. As a life insurer, we are deeply committed to helping our customers live longer, healthier, better lives and we know that preventative care and early detection are key components of that mission."

Brooks Tingle, President and CEO of John Hancock Insurance
Source: GRAIL
February 23, 2023

Awards & Recognition























illumina

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Yahoo! Finance: Icahn proxy fight is 'distraction' for Illumina outlook: RBC analyst
Anjalee Khemlani
April 3, 2023

Carl Icahn's proxy fight with Illumina (ILMN) escalated Monday with a new open letter as well as from a decision from the Federal Trade Commission (FTC).

The FTC is now ordering the biotech to unwind its $8 billion deal with cancer testing company Grail, saying that its ownership would restrict competition in developing cancer tests.

Icahn, who has a 1.4% stake in Illumina, wants to appoint three members to the company's board as well as bring back a former CEO to help with this task, to right-size what he sees as a failing trajectory.

"After speaking with numerous shareholders, we believe it is unconscionable that the board of directors still entrusts [current CEO, Francis] deSouza with running our potentially great company. During his tenure, not only has the company lost $50 billion of shareholder value but many of his talented executives have left or are in the process of leaving," Icahn wrote in a letter Monday.

The letter is the fifth Icahn has published since launching the proxy fight for control of the board last month, after months of private negotiations fell apart.

The FTC decision to bar the acquisition of Grail, which Illumina completed last year, follows a similar ruling late last year from the European Commission. Both regulators have warned the company could face fines that would result in billions in losses if it doesn't comply.

Illumina is already appealing the decision in Europe, and said Monday it would seek the same for the FTC. The company believes it has strong case since an FTC judge already sided with the company in September.

But in its statement Monday, Illumina added that if it does not prevail in the EU or with the FTC, "the company expects to move expeditiously to divest Grail."

Ultimately, that's what Icahn wants the company to do, according to RBC Biotech Analyst Conor McNamara.

"Some of his concerns are shared by shareholders, that GRAIL has been a distraction," McNamara said of the $8 billion deal.

He said that the proxy fight is taking attention away from Illumina's product launch of a new testing system NovaSeq X.

“This product, its our view, its going to lead to a series of revenue beats, earnings beats and revenue acceleration. Because of this distraction that Icahn is causing, people aren’t really focusing on that,” McNamara said.

The product is part of a growing space in biotech estimated to be a $40-plus billion market by 2030, according to the company.

McNamara says he believes Icahn is missing the growth projections for the company. In his original letter in March, Icahn has focused on the regulatory battles and $50 billion loss of shareholder value.

“If Illumina continues on its current path, the cost of fighting powerful regulators, especially when they obviously believe strongly in their position, will become extremely expensive no matter what happens,” Icahn said.

Illumina, Inc. (ILMN)

“Illumina’s share price performance, and the $50 billion of value destruction that has occurred since the GRAIL deal was closed, clearly shows that shareholders have lost faith in Illumina’s management team and board of directors,” he added.

Icahn instead wants to appoint three members of his firm to the board and unwind the GRAIL deal ahead of any appeal decision by regulators. He also wants to bring back former CEO Jay Flatley, Icahn recently told the Wall Street Journal.

Illumina countered with one board seat before negotiations broke down last month.

McNamara said the timing, right as a product is launching, bodes poorly for the company, but could also indicate a lack of knowledge about the industry on Icahn’s part.

“I think that’s the primary reason that Illumina can’t give up three board seats. This is a long term growth company in a market that they dominate and that isn’t fully understood by all investors,” McNamara said.

So to give up the board would “be a mistake,” he added.

This is the second time Illumina has struggled with an acquisition. The company first tried to acquire PacBio (Pacific Biosciences of California), which the FTC challenged in 2019. Illumina terminated that $1.2 billion merger agreement in early 2020.

Illumina, Inc. (ILMN) Presents at 43rd Annual TD Cowen Health Care Conference (Transcript)

March 7, 2023 9:50 AM ET

Company Participants

Joydeep Goswami - Chief Financial Officer & Chief Executive Officer

Salli Schwartz - Investor Relations

Conference Call Participants

Dan Brennan - Cowen and Company

Dan Brennan

Greetings, Day two of TD Cowen Healthcare Conference. I'm Dan Brennan. One of the tools analysts here. Really pleased to be joined with me on stage senior management team of Illumina. So to my left, we have Joydeep Goswami, who is the newly appointed permanent CFO, so congrats -- and COO. And we also have to his left, we have Salli Schwartz, who's lead IR at Illumina.

So first off, I'll welcome Joydeep and Salli.

Joydeep Goswami

Thank you, Dan.

Salli Schwartz

Thank you.

Question-and-Answer Session

Q - Dan Brennan

Awesome. So maybe a high-level way to kind of kick this off here. On the one hand, Illumina is at the very beginning stages of your latest high throughput product cycle, possibly the most impressive one technologically in your history. You have new markets for NGS are opening up, stock has lagged, hence the upside opportunity is significant. At the same time, competition has arguably never been more material, there's been notable pressure on your clinical customers and it's not clear when that lifts, and you're dealing with material uncertainty of the GRAIL deal.

So given you just took the CFO role, I would be interested to hear how you think of the current and future setup for Illumina, should investors be worried about some of these headwinds or rather more excited for the opportunity?

Joydeep Goswami

It's a long question, but let me try to parse that down. Look, when I look out and stepping into the role as part of Illumina's leadership team, we're incredibly excited, and I'm personally incredibly excited of the opportunities, right? So the reality is we are in a large TAM $120 billion by 2027. That's very underpenetrated, give or take about 7% penetration. NGS uniquely offers the opportunity to enhance the understanding of biology at a scale and at a speed that no other technology in the history of this field allows, right? And it isn't just about DNA anymore.

It's about DNA and RNA and increasingly proteomics, coupled with things like single cell and spatial that really allow you to understand biology at scale and in context. So incredibly excited about that market, incredibly excited about -- you talked about the new innovations that we are introducing that make -- that improved the utility of sequencing, but also drive down total cost of ownership, drive down -- drive of the simplicity, drive down complexity of workflows of post sequencing analysis, pre- sequencing prep time, et cetera.

So -- and coupled with things like Ambient shipped. So there's a lot of things that are opening up the market and further catalyzed a lot of what you're already seeing was happening in the field, right? So single cell spatial liquid biopsy, multiomics are not new things, but what NGS and our innovations do is they accelerate the adoption of that both from a cost standpoint, but also from a workflow and analytics, bio formatics point of view. So really excited about that and the opportunities that it opens up both research and clinical fields.

Dan Brennan

Thing you talk about competition. Look, the reality is that we've always had competition, right? At every point in our existence, whether it's arrays or sequencing, and a lot of the players like BGI or Thermo Fisher have existed. We have competed with them especially outside the United States as for BGI. So, we know how to do that. We have the playbooks. And even after the announcements of all the players from last year, we continue to have record interest in our platforms, record sales of our mid-throughput portfolio into the second half of the year. In fact, we had record sales of NextSeq 1000/2000 even in Q4, right?

So that does indicate that customers believe in the value that Illumina brings to them, again, beyond just the one thing that people highlighted is around cost per GB, but that's only very small part of the equation. There's many others in terms of reliability, service support, ability to move towards clinical diagnostics, ability to have that level of continued and collaborative innovation. So we feel good about that. We continue to invest in those dimensions and will continue going forward as well.

Dan Brennan

Great. Maybe thinking about the guidance, I love some insight into the seven to nine top line guidance. Core Illumina, I think it's six to nine, you called out a COVID headwind of about two points, right? So, I guess, if you normalize it 9x to 11x COVID. So I guess, 8 to 11 core. Do you have easy comps. You have the X launch, which I think most of us most of us expected something maybe stronger on the guide, given your LRP was 15% and you have the benefit of, again, this big one. So maybe give us a little color why we deviated and then I can follow up on something there.

Joydeep Goswami

Sure. So, the guide was 7 to 10 consolidated and 6 to 9, as you pointed out on the core. Yes, that was somewhat lower than initially what we were expecting around 10, but there are a few reasons, and we go through that. A lot of that is things that we had pointed out earlier. So first, 2023 is a transition year for us and the transition year really comes from the introduction of the X, right?

So we do -- we will see, at least in the first half of the year, a reduction in the number of 6,000 -- NovaSeq 6,000 sold as people transition towards the X. You see that both in terms of the instrument sales, but also in terms of some of the consumable sales, right, ex-consumer don't really ramp up until the second half of the year once people have brought on the instruments and done there initial validation.

So that's one part of it. And also we have said and is normal with any large instrument introduction. The first year, we will be somewhat supply constrained, right? So we had -- already had as of the Q1 earnings call. We had about 155 orders, right?

And then about 250 late-stage pipeline opportunities, which really means that customers have definitive interest and have funding lined up to buy the instrument in 2023. And we expect that number to end the year way ahead of the 300-plus instruments that we expect to be able to supply this year. So that's one part of the transition.

The other part of the transition is a little bit of a story that you're hearing from a lot of players in the life sciences field, right? But this is a somewhat back loaded year as you come into it. And for us, there are a few reasons for that.

In some of the macroeconomic headwinds will persist, we feel, at least through the first half of the year. We -- that includes some of the FX headwinds, which are more severe in the first half of the year, the COVID surveillance impact, which is about $100 million or two percentage points. That is also more front-loaded than not.

And then China COVID is another one, right, where we do expect that, that is more prevalent in the first part of the year as they move away from zero COVID tolerance to something that is more sustainable and they open up the market.

So that essentially says along with the transition of the X, our second half of the year is going to be meaningfully stepped up from the first part of the year. And you do see a step-up in each quarter both in terms of revenue and in terms of overall profitability, both from a gross margin standpoint and of course, from an operating margin standpoint.

Dan Brennan

All right. So typically, you go back with the NovaSeq and year two was a lot stronger than year one to your point. So presumably, we should be looking at the exit rate this year when we think about '24. But fair to say, clearly, at this point, '24 should be, we would assume a much stronger year than '23 absent anything uncertain changing in the market.

Joydeep Goswami

Yes, that's, I think, a good way to think about '24 having completed the initial transition and placement of the Xs. You start to see pull-through in the X consumables. And -- and this is something we're working on in particular. It is a lot about demand elasticity and catalyzing some of the newer applications, the increased pull-through on some of the newer applications that people are talking about, both in terms of the research and the clinical side of things.

Dan Brennan

So, how do we think about the plus? Your guidance is 300-plus placements for '23. What are the key factors here dictating how many you place? Is it actual demand? Is your ability to manufacture and install? Or is your interest to smooth out the launch or other?

Joydeep Goswami

It's definitely about the last one. It's really more in terms of scaling up manufacturing, right? So we have said, we -- we're going to start off the year with in Q1, about 40 to 50 instruments and then we'll continue to step up manufacturing from there. So, at the -- in fourth quarter, we expect at this point to roughly be at steady state, right? So as many orders come in, we should be able to get out the door. But it will take us into next year to clear all of the backlog of the orders that we get in 2023.

Dan Brennan

And manufacturing wise, you guys feel pretty good kind of where things were guided to and the ability to scale and kind of be on that ramp pace?

Joydeep Goswami

Yes. We don't tend to announce new instrument launch, we are confident that we can supply the instrument. There's a lot that goes into that in terms of both the instrument capabilities, the software capabilities and the consumables capabilities. So, we are -- where we need to be on that path at this point. We have shipped out as we announced at HVTN on our earnings call that we shipped the first instrument -- and we've -- we continue to make shipments as the quarter goes on.

Dan Brennan

Yes, the broad said this morning, just -- we host them. They said they have one, and they're waiting for the next four. So they're waiting. They're ready to roll. So given grants take a while to move, what early kinds of new projects you're hearing from customers that are being enabled by XLEAP chemistry? And what confidence does that give you in your outlook for '24?

Joydeep Goswami

Yes. So, let me break that down into research and clinical. And just to step back, right? I mean, the initial order book surprised us, of course, in the strength of it, right, but also in the makeup of it. So what we've said previously about 35% of the orders have come from clinical customers, which is a little bit higher than where we had expected it from a percentage basis at this point.

About -- we've seen about a 4x jump in the number of countries that have already placed orders with a similar time frame from where NovaSeq 6000 was. And we've seen about 15% of the orders that have come from new to sequencing or new to high- throughput customers. So again, that's a little bit of a surprise and a larger percentage. They are all reasons that they have given us, and they're consistent with the innovations that have gone into the X.

But let me come to the kinds of things that we are seeing, right? So first, from the research side, from some of the pop gen customers, we are hearing a lot more into, hey, we want to go from -- we've done whole genome sequencing. We want to go to whole transcriptome sequencing and the samples that are already there and increasingly look at proteomics on a much bigger scale than we have done before, right?

So, the good news about some of these is, yes, they'll need to secure funding, but the funding becomes more cost effective, if were to look at larger cohorts. But you don't need to collect samples, right? I mean you have samples insist in they're biobanks already. So, it's a little bit of a faster time scale there.

We are hearing also on the research side, especially around single cell and spatial a lot more interest in doing more, right? So, more cells going from thousands to tens of thousands to some talk even of millions of cells per run. So that's exciting and that -- although it's the same sample, it's actually more samples because you're looking at individual sales at that point.

And we have had very strong interest in pharma taking a much bigger look at genomics and multiomics and drug discovery, right? So part of it is things like Nash Bio, where the cohort exists and they're using this opportunity to move more towards sequencing these and combining that information. And as you can imagine, right, the first step is doing DNA sequencing on a whole genome basis. But very quickly after that, it will move as they get answers to diving deeper into proteomics or transcriptomics as it were.

So that's on the research side of things. On the clinical side, again, as I mentioned, this was surprising to see this level of interest And the dynamics in clinical are -- with the existing assays that have been validated, they will continue on the 6,000, right? We don't see an immediate switch over on that.

In fact, there will be some fleet additions on the 6,000 on those. What we are seeing is the next generation of assays that require either bigger panels or deeper analysis or both, right? Moving to the X directly. And they'll start with the XMDs. Obviously, the economics for them are better, but they can also move faster on clinical studies and more broadly from that angle.

So, that's encouraging, right? And we are seeing also so that there's, of course, a huge amount of interest on the oncology side. But we are also seeing some early kind of interest in having more holistic and deeper panels, larger panels, maybe all the way towards whole genome sequencing on things like cardiovascular and very early on the neuro side, right?

So encouraged by that, encouraged by the conversations getting accelerated, but some of these -- especially on the non-oncology thing, they will take time, but I think it's interesting to see some of the clinical activity and the average generation we had started.

Salli Schwartz

On oncology, this totals really nicely with the whole discussion you're probably hearing around the conference on MRD and liquid biopsy. So, there's a multitude of pieces that we're hearing.

Dan Brennan

Just kind of related to clinical since it kind of dovetails what the question on the -- kind of on the guide for '23. So like have you guys seen like this clinical destock and kind of it's -- we heard it from some other players as well, but that's been a headwind for you guys in the back half of '22, and presumably, that was one of the factors that you baked in to 23, I would think. But just kind of how do we think about that clinical destock and maybe some of it's due to belt tightening, some of it's due to the X coming out? Just kind of where do we stand there?

Joydeep Goswami

Yes. So it's a good question. So there were two things that happened on the clinical side last year, right? So there was one which was related to capital push out and just conservatives in the market, conservatism in the market that delayed some projects at our customers' ends, right? And part of it, again, if you remember early in the year, it was that plus there were some issues with supply chain, not related to NGS, but other things.

So that I think we've been a little bit more cautious this year and not factoring in everything that customers are have told us about we'll scale up to a certain extent. And you're right. Some of that actually, as I mentioned earlier, has moved from the 6,000 of the excess. And I think that's a good thing. It's more sustainable. They actually ramp up the amount of sequencing they're doing.

What we did see towards the -- as we progress towards through the second half of 2022 is the amount of inventory destocking that happened with both research and clinical customers, was slowing down towards the end of the year, right? So, the amount of destocking went down. And I think that was a trend we had expected to see. Our best guess at this point is some bit of it continues into Q1.

And as we get into Q2, especially latter part of Q2, that starts reflecting more of the underlying demand, which we get a good insight to that because we have connected instruments that represent lease North America and Europe, more than 60% of the instruments out there, especially in high throughput and the throughput. So, we're a pretty good idea of what the underlying utilization is, and that has continued very strong on clinical -- and we saw a little bit of a pick up again towards the end of the year.

Dan Brennan

Great. Maybe just one on competition. There's a lot of attention on the high throughput part of the market. But from a commercial perspective, the throughput is where there's more viable competition today with singular Element, BGI, MGI. What does your guide assume for the mid-throughput part of the market in terms of market growth and share loss? And what's been your experience so far?

Joydeep Goswami

So the experience so far has been very encouraging, actually. We -- as I mentioned earlier, we continued very strong sales of our mid-throughput portfolio, especially on the NovaSeq 1000, 2000, which were the newer instruments we introduced, I guess, but we continue to have record sales overall in the mid-throughput category in 2022. And more specifically, we exited 2022 in Q4 with record sales again in the quarter for our NexSeq 1000, 2000 instruments.

So despite all the noise about competition coming in, the reality is that customers are assessing this more holistically, right? So what value does Illumina bring in terms of total cost of ownership in fact, that 1000, 2000 continue to be the only instruments with DRAGEN on board, so the analytics gets a lot easier and a lot more cost effective again. The workflows are easier and with the introduction of the longer cycles and the actual chemistry on the NextSeq 1000, 2000, which is just a transition of flow cells. It doesn't require any changes to the instruments.

There's a lot of interest and continued interest in pent-up demand on the mid- throughput side. I think people always overlook the fact that reliability of supply, reliability to support our instruments over the long run regardless of which continent you're on is a big deal for customers, right? They're not getting into the technology for one of experiments and getting out, that reliability and the fact that we are by far, the only company that has the kind of infrastructure, both from a supply chain and the service and support capability, whether you're in research or in clinical is an important part of why people continue to choose Illumina over other instruments that are out there.

Dan Brennan

Great. Okay. Maybe switching over to GRAIL. So from our conversations at least, most of the investors we speak with would prefer to have GRAIL separated. They'd love to get access to the core Illumina and as ratably, this product cycle without kind of the uncertainty in the near term significant dilution and burn, although ultimately grow could be a home run opportunity. It just kind of really makes it difficult to get access to that core Illumina business.

So net-net, I'm just wondering, the management team, Francis has been significantly very positive, enthusiastic about the deal. But given the ongoing regulatory pleasure plus the margin cash solution, like where does management stand today on GRAIL?

Joydeep Goswami

Yes. So you're right, right, GRAIL, I want to continue expressing. It's a good asset. It's proven and sell-out. So, a little thing, and I'll go to where do we go from here. And GRAIL is still the only multi-cancer early detection test on the market and the only one with any line of sight to introduction on a multi-cancer basis, right?

More than 50 cancers detected of which 45 plus have no other screening tests available at this point, right? So it's a huge, huge impact on patient lives and the potential of the save lives. It's the only test where real-world data with this point, more than 40,000 patients absolutely corroborate the clinical trial data, which was already extensive to begin with.

The only one which actually pinpoints where in your body to cancer is which is absolutely essential for any liquid biopsy test to be able to be actionable. So all those are positives, right? But at the same time, I think we have been fairly clear that look, we did not anticipate the regulatory challenges that this vertical merger is facing. We will be pragmatic in terms of our next steps going forward, right, regardless of how good the asset is and how much we believe in it.

So how does that play out? We expect the divestment order to come from the EU in and when we get that that provides the guardrails for how a divestiture is to be affected. And we will immediately begin the -- we'll immediately move towards divestiture at that point, right? So that starts the clock on that.

Now we expect that to do this right, whatever the guidelines are takes us towards the end of 2023 or early into 2024. So, that's one piece, right, where we are committing to begin -- to immediately move on the divestiture order.

Now at the end of this year or early next year, we also expect to have the jurisdictional trial that really looks at the ability for the European Union or European Commission to really stop a merger of a company that did not have any revenues in Europe never plan to have any revenues in Europe and application of Article 22, which was retroactively applied despite them clearly saying that they wouldn't do so, right?

The reason I'm bringing it up is this trial plays out in a time frame where we would continue to work on the divestiture. So, we're not waiting for the trial. It just happens that the timing of the trial happens to be in that.

Now the trial is important because it's a binary result, right? There is no appeals to it, either for us nor for the European Commission. If we win the trial, then we immediately get to integrate well. There is no -- as you know, the FTC removed its injunction. So, there's no hurdles from the FTC in closing the deal or integrating the deal. We've already closed it.

So that then allows us to begin realizing the revenue and cost synergies that we knew we had in GRAIL and it reverses any fines that are paid to the European Commission as a result of closing open. So that's one potential outcome. Again, in that time frame of end of the year or early next year.

The other outcome is we lose the case, and we lose the trial. Let me just proceed with finishing off the divestiture as we have been planning anyways, right? So that's a -- again, there are obviously stays that give us more flexibility and when exactly and to make sure we get the best value for our shareholders. But there's no further elongation of release divestiture process beyond that time frame that I just don't mind.

Dan Brennan

And is there an expectation, I was thinking 1Q, but it's more Q2 now. That's what you're hearing on the director divestiture.

Joydeep Goswami

Yes, that's what they have. And again, this is out of our control. They need to process, what they need to do process at their right? But that's what we are hearing.

Dan Brennan

And is it a six-month time table they're going to give you to do this for 12 months?

Joydeep Goswami

We don't know. It's -- that will depend on the order that comes out. And I think what they are trying to do is be reasonable in terms of whatever time frame they give us.

Dan Brennan

So, Francis mentioned on the 3Q call that you would seek strategic partners to invest in GRAIL on a multistep process to a potential IPO. So, just maybe one comment on that like just any elaboration on kind of what that is?

Joydeep Goswami

No. That is one of the options as we have done some pre-work on this, that's one set of options. Again, I want to make sure you understand, right? It depends a lot on what the EU comes back with. And as we outlined in our Q1 earnings call, right, we will come back to you right after the order with more clarity on what's in the order, what we expect to do moving forward, right? So give us the time to get you information rather than me speaking and hypotheticals about that.

Dan Brennan

Got it. Okay. So switching gears here to your margin guidance. Looking at your '23 guidance, we were 22% core Illumina EBIT, right, even with high 60s gross margin. Just kind of I think that surprised some people, just the degradation in that margin, you kind of explained some of the factors there. But maybe can you just elaborate a bit on the step down in margins and kind of what supports that margin degradation and kind of as we think through, in fact, '24 season nice step-up in growth kind of where the margins go as we cycle past '23.

Joydeep Goswami

Yes. So look, let me start with that last part, right? So we're absolutely committed. I mean, at Investor Day, we said, hey, we do expect margin expansion and actually operating profit growth to exceed revenue growth. So we're absolutely committed to that. And you will see that happening as early as 2024, right? So you're absolutely right about that, and we remain committed to that.

So 2023, why are margins at 22%, right? So there are a few factors which are transitionary and are very specific. And so first, we had expected a lot more growth in 2022 when we started the year and even looking at the first quarter and most of the second quarter, right? We had been tooling up and investing to -- in our key innovations to support that. So part of the '23 margin you see is an overhang on some of that investment that we have provided. We had taken action again in the second half of the year. We reduced our hiring. We actually had a reduction in force of about 5%.

So all of that is already in there, and we had taken action to slow down some of that OpEx increase when it didn't match our growth expectations weren't met. Now '23, a few things happen, right? First of all, the revenue growth because of the transition or the factors that I talked about earlier, there -- there is a little bit of -- the margins will improve in the second half of the year, but not in the first half because of some of the headwinds.

Gross margin, while it's still within our range is towards the lower end of the range. And again, all of that is dictated by X, right? When you launch a new instrument and new consumables, the margins in that first year tend to be lower because you're investing and you're not fully at scale.

As you move through the year, first scale just improves those margins again you should expect margins in the second half of the year to be better than much better actually than the first half of the year. And then the second part of it is, as you move on into '24 and beyond, you'll see the normal productivity on COGS product that you would expect from us on any instrument, right, but you'll see a lot of that come through.

And then for '23, the one thing on the operating margin side. And in fact, all of the -- the increase in operating expense is really from a normalization of our variable comp, right? So last year, because we didn't hit our numbers, we didn't pay much where it will come to our employees. This year, we expect to meet our targets. So we are accruing at 100% of the same kind of pay policies.

And so that puts in a one-year kind of comp that accounts for any of the OpEx increase that we have seen in 2023. So again, going next year, we won't see that kind of a normalization. So, we're very confident that our operating margin will turn back into -- in the long term, getting into that 25% to 30% range.

Dan Brennan

Particularly if you beat numbers this year and your comp goes up a lot and the base will be -- then you'll have no, okay. So with that -- thank you. Joydeep, Salli for being here.

Thank you for one in the room, and have to give rest at the conference.

Joydeep Goswami

Thank you. Appreciate it.

Financial Times: Has DNA sequencing expert Illumina taken the wrong path in search of holy grail?
Jamie Smyth and Javier Espinoza
January 29, 2023

In September, the world's biggest genome sequencing company hosted Barack Obama, Bill Gates and other luminaries at its annual forum in San Diego, predicting its latest generation of machines would help "change the world".

Illumina could make the case that it had already done so with its existing technology. It provided the machines that in 2020 decoded the genetic sequence of the virus that causes Covid-19, enabling researchers to develop vaccines and drugs in record time.

Surging demand for its technology and a pandemic-era biotech investment boom caused the market capitalisation of the company — which has an 80 per cent share of the sequencing market — to peak at about $75bn in August 2021.

But as chief executive Francis deSouza took the stage in San Diego to introduce his guests and Illumina's new NovaSeq X Series there were signs the outlook was darkening.

In August it reported a quarterly loss, weighed down by the legal costs of an unsuccessful patent battle with Chinese rival BGI group, which is now free to enter the US market. A month later the EU blocked Illumina's $8bn acquisition of Grail, a cancer test developer that was initially founded by Illumina but spun off in 2017.

Since then, the company has downgraded its profit forecasts and announced it is cutting 5 per cent of its 10,000 workers. And within the next few weeks Brussels is expected to hit it with a fine of up to 10 per cent of revenues or about $450mn, for closing the Grail deal despite opposition from regulators.



Analysts say the bad news is prompting investors to question the company's strategy of buying Grail, which Illumina forecasts will generate an operating loss of $670mn in 2023 on revenues of $90-110mn. Illumina shares are hovering near five-year lows and it is now worth $33bn.

Dan Brennan, analyst at Cowen, an investment bank, said many investors are not "fans of the deal" and it came up in almost every conversation he had with them.

He said Illumina has over the past decade been an attractive, high-growth investment because it sells its sequencers at high prices (up to $1.25mn each) and has recurring revenues from the reagents and other products required to operate them. Grail is a riskier business because it is burning lots of cash and there is uncertainty about whether its technology will be a commercial success, said Brennan.

Grail, which counted Jeff Bezos and Gates among its early backers, has developed one of the world's first early detection blood tests. The test, which it named Galleri, aims to detect up to 50 different types of cancer, including many that are not part of national screening programmes. It is currently being tested in trials, including a UK National Health Service study involving 140,000 people.

In an interview with the Financial Times, deSouza said Illumina was right to buy Grail and press ahead with completion of the deal, adding it was "in the interests" of shareholders because of its high growth potential.

“The stakes are really high here in terms of human lives. This isn’t just another deal: if Illumina prevails it can bring Grail’s life-saving test to countries beyond just the US and the UK, which is what Grail is planning to do,” he said.

DeSouza said Illumina has a “huge amount of respect” for regulators but insists it will fight the EU’s order blocking the merger in court, arguing Brussels has no jurisdiction as Grail has no revenues in the bloc. Any EU fine for “gun jumping” — closing the deal despite opposition from regulators — would likely be similar to the $300mn break fee in the merger contract it signed with Grail, he said.

But Illumina’s course of action angered senior EU officials, including competition commissioner Margrethe Vestager, who said at the time: “Companies have to respect our competition rules and procedures.”

The EU’s prohibition of the merger is a test case for regulators, which are seeking to expand their powers against “killer acquisitions” — where big companies buy small innovative rivals before they become serious contenders, thereby undermining competition.

Grail’s competitors argue the deal would leave them unable to compete on fair terms with a combined Illumina/Grail, because they are reliant on its DNA sequencing technology. Illumina has said the deal is not a killer acquisition because Illumina and Grail are not rivals. It also said it has no plans to cut off rivals from its sequencing technologies.

Critics say Illumina’s dogged pursuit of Grail is misguided because it is soaking up management attention at a time when competition in its core business is rising and the high cost of funding the cancer test company is having an effect on earnings. This month, the company forecast profits will be between $1.25 and $1.50 a share this year, well below Wall Street forecasts of $2.53.

Illumina’s former CEO Jay Flatley also questioned the economics of the $8bn takeover, which was negotiated in 2020 near the top of the market.

“If they had waited a year then it would have been a $2bn acquisition,” said Flatley, who was chief executive for 17 years until 2016 and then chair until 2021.

“In retrospect, it would have been better to wait and realise that the market was sizzling hot at the time and therefore it was overpriced.”

Flatley, who persuaded deSouza to join Illumina in 2013, told the Financial Times he did not think the deal was a “strategic mistake” but operationally it had not gone the way management had hoped. It is a “huge disappointment” and investors want it spun back out, he said.

“Some investors frankly don’t care how much Illumina is going to get for it. In some ways it’s kind of a sunk cost. If they can spit it back out, then the earnings numbers get back to where they should be,” he said.

“If nothing happens on this in the next year, I think the grumbling will probably get louder . . . Francis is at the point of that spear.”

DeSouza said Illumina would be pragmatic. “I think Grail continues to represent a unique opportunity and delivers an important product in arguably the largest genomics market we’ll see over the next decade. But we still have to work through the regulatory process.”

It is not the first time Illumina has been tripped up by its M&A strategy. In January 2020, it was forced to abandon its $1.2bn takeover of rival Pacific Biosciences following opposition from regulators.

The departure of Sam Samad, Illumina’s former chief financial officer, has also unnerved some investors, analysts said. Joydeep Goswami, Illumina’s chief strategy and corporate development officer, has done the job in the interim since July, while the company seeks a replacement.

Four of Illumina’s largest investors — Baillie Clifford, Vanguard, BlackRock and Edgewood — all declined a request for comment.

One investor, who spoke on condition of anonymity, said Grail was a “natural extension” of Illumina’s technology and worth pursuing. Another said the company was “blindsided” by the EU and would likely be forced to spin off Grail.

A final EU court ruling on the Grail takeover could take years. In the meantime, abandoning it would be challenging for Grail in particular. It scrapped a planned initial public offering at a time when markets were booming following Illumina’s approach in 2020.

Raising money in the current environment to fund research is far tougher for firms without strong revenue streams. But there is also pressure on Illumina to diversify. It is launching the NovaSeq X into a market that is attracting new entrants at a good rate.

At a JPMorgan healthcare conference this month Element Biosciences, a company founded by several former Illumina executives, announced its sequencers can read a whole human genome for as little as $200.



Twelve years ago, the process cost around $10,000. Illumina's benchmark in 2020 was around $600 but it plans to reduce this to $200 with its new machine.

Another early-stage company Ultima Genomics has said it can cut sequencing costs to $100. MGI, which was spun out from BGI last year through an IPO, has begun selling its sequencers in the US market following the expiration of key Illumina patents last year.

"Illumina has really been dominating the market for more than a decade and customers need competition," said Molly He, a former Illumina executive who is chief executive and founder of Element Biosciences.

She said Illumina started offering Element customers big discounts when the company entered the market last year. But Element has also benefited from increased interest in its products from Grail competitors that use DNA sequencing, she added.

"They [customers] are obviously worried about what is going to happen after Illumina acquires Grail: would they still have access to high quality, low cost sequencing?"

Illumina said discounting was a standard business practice and rejected any suggestion that its ownership of Grail would influence its relationship with customers of its DNA sequencing business. But this was a key concern highlighted by European authorities when they blocked the Illumina/Grail merger.

Vijay Kumar, analyst at Evercore ISI, an investment bank, said it was a “big, bold and aggressive” move by Illumina to acquire Grail because Illumina was paying $8bn for a company with very little revenues at the time. But the decision to close the Grail acquisition despite opposition from Brussels was a gamble, he said.

“Francis bet big on this,” Kumar said. “Ultimately the buck has to stop with the CEO.”

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Opinion | Review & Outlook

The FTC's Unholy Antitrust Grail

The agency overrules its own law judge to block Illumina's acquisition.

By The Editorial Board

The Federal Trade Commission on Monday overruled its own in-house judge and ordered gene-sequencing giant Illumina to divest cancer blood-test startup Grail. FTC Chair Lina Khan is showing that the agency's administrative trials are a sham. Heads the agency wins, tails businesses lose.

A FTC judge in September issued a 203-page opinion rejecting the agency's complaint that alleged the Grail acquisition would harm potential competitors in the embryonic market for multi-cancer early detection tests. Grail currently has no competitors, and the FTC complaint.

Illumina makes the platforms that are used to run Grail and other genetic screening tests. Its scientists developed Grail's technology before the company spun off the startup in 2016. As the Grail test improved and became commercially viable, Illumina sought to reacquire Grail and closed its acquisition in August 2021.

Grail claims its test can detect the 12 most deadly cancers with 76% accuracy and has a false positive rate of less than 1%. Earlier detection of aggressive cancers could save thousand of lives a year. Illumina says it can bring the test to market faster owing to its relationships with insurers and reduce the price, now about $949 out of pocket.

But some companies that were interested in buying Grail or that were developing their own cancer tests complained to the FTC that Illumina would thwart rivals. This was the gist of the FTC complaint, which the agency's in-house judge dismissed after a detailed analysis of the facts. Administrative law judges are rarely so scathing.

"The Clayton Act protects competition, not competitors", FTC chief administrative law judge D. Michael Chappel wrote, emphasizing that antitrust theory and speculation cannot trump facts. He concluded that the FTC had failed to prove its case that Illumina had the ability and incentive to help Grail to the disadvantage of alleged rivals.

For Illumina to divert sales from multi-cancer early detection rivals to Grail, other test developers would have to have sales in the first place, he explained. But none do. He also noted that Illumina had offered a contractual commitment to provide access to its products to all of its future oncology testing customers equivalent to that it provides to Grail.

The FTC commissioners disagreed with the judge 4-0 and ordered Illumina to unwind its Grail acquisition. Republican Commissioner Christine Wilson wrote in a concurrence that she disagreed with some of her colleagues' legal analysis, but she didn't believe Illumina had met its burden of proof to show the government's competition theory was improbable.

Ms. Khan seems to be trying to make an example out of Illumina by ordering the company to pay "transition assistance to Grail's next acquirer plus expenses of a government-appointed special monitor to ensure that it complies with the divestiture order. The tacit message to other businesses is don't dare consummate a merger that the agency challenges.

The FTC could have gone to federal court to try to stop the acquisition. Instead, it challenged the deal in its administrative tribunal where it no doubt believed it was more likely to win because it almost always does. Yet after losing, it has now overruled its own judge. What was the purpose of the administrative trial if the FTC could ignore the judge's findings and do whatever it wants anyway?

That's a good question for the independent federal courts. Illumina plans to appeal the divestiture order in federal court where it will have the opportunity to raise several constitutional challenges to the FTC's authority and administrative proceeding that it had earlier raised before the commission. This could get interesting, and the FTC may come to regret its hell-bent effort to stop mergers by whatever means possible.

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Semafor: The FTC is wrong about Illumina

April 4, 2023

Joshua Wright is a professor at Antonin Scalia Law School at George Mason University, executive director of the Global Antitrust Institute at Scalia Law School, and a former Republican FTC commissioner.

As the FTC's own administrative courts ruled last year, the Illumina/Grail deal is a classic example of a vertical merger with obvious economic and consumer benefits — the kind of deal that ordinarily would have been approved by prior administrations from both parties.

Grail and Illumina do not compete. Grail has developed a novel cancer detection blood test. Illumina is a much larger company that provides inputs into Grail's tests. To bring its blood test to market more quickly, in higher quantities, and at lower cost to patients, Grail needs manufacturing, operations, and supply chain efficiencies, as well as experience working with regulators like the FDA — all things Illumina can and will provide if the companies are allowed to merge.

The FTC's theory of harm is that, sometime in the future, Illumina will be able to disadvantage potential rivals who are developing tests that compete with Grail because these rivals might also need Illumina's devices to perform their tests, and Illumina is the only provider of the devices.

The Commission's theory is totally speculative: there are no such rivals, and there won't be for years. Second, even if these rivals did exist now (or in the reasonably foreseeable future), Illumina has already offered a long-term agreement to allow other oncology companies access to Illumina's technology on the same terms as Grail.

There is now no hope that the FTC itself will come to its senses and understand that bringing life-saving cancer screenings to market faster and in higher quantities is more important than this administration's overly simplistic belief that most mergers are bad. All hope now lies with the Court of Appeals.

Financial Times: Illumina battle with regulators threatens cancer breakthrough, warn Grail alumni
Jamie Smyth and Javier Espinoza
April 4, 2023

Founding directors say political wrangling causing delays to potentially life-saving blood test

Two of Grail's founding directors have warned Illumina's battles with antitrust regulators and activist investor Carl Icahn over its ownership of the cancer screening company threaten to hamper access to potentially life-saving oncology tests.

Jeff Huber, former founding chief executive of Grail, and Meredith Halks-Miller, an Illumina scientist whose discovery led to development of its blood test that detects 50 types of cancer, said political wrangling was causing delays and funding concerns.

"One of the disappointing aspects of the European Union and Federal Trade Commission regulatory issues and now the Icahn proxy battle is that Grail is moving more slowly than it should," Huber told the Financial Times.

"There is real cost with the delay from the regulatory scrutiny and over-reach. Grail isn't broadly accessible now because of it, and we are missing many opportunities now to detect people's cancers early. The very real cost is lives lost with every day of delay."

Illumina spun off Grail in 2016 to raise funding to develop Galleri, which the company has billed as the world's first blood test capable of detecting multiple cancers at an early stage. The test works by using genetic sequencing and artificial intelligence to scan a certain type of DNA (cell- free DNA) found in people's blood for changes caused by cancer cells.

Grail raised $2bn from investors including billionaires Bill Gates and Jeff Bezos and was about to undertake an initial public offering in September 2020 when Illumina offered $8bn to buy it back. The subsequent takeover sparked a battle with regulators, which argued Illumina would have an incentive to cut off Grail's rivals from using its sequencing technology and so stifle innovation in the cancer testing market.

Illumina rejects this claim.

Last year Brussels blocked the deal and is expected to fine Illumina 10 per cent of annual turnover for closing it without approval. On Monday the FTC ordered the San Diego-based company to divest Grail, reversing an earlier ruling by a US administrative judge in favour of the acquisition.

Illumina has said it will appeal against the order.

The controversy has prompted activist investor Icahn to wage a proxy battle at Illumina , which he alleges squandered $50bn by closing the deal without regulatory approval. Illumina's market capitalisation has dropped from $75bn in August 2021 when it acquired Grail to just over $30bn last month.

Icahn wants to appoint three new directors to the board and remove Illumina chief executive Francis deSouza and chair John Thompson. On Monday he doubled down on his criticism, asking how the board could justify paying deSouza $27mn last year, an 87 per cent increase on 2021.

Illumina continues to run Grail separately while it battles an EU divestment order. If it had full control, Illumina claims it could roll out Grail's tests much faster and to more countries than planned.

Huber, who lost his wife to cancer shortly before joining Grail in 2016, said the company was "stuck" because Illumina was restricted from moving forward and "scaling the product and reducing cost" of Galleri tests until the EU issues were resolved.

Halks-Miller, who left Illumina to join Grail as its founding laboratory director, said her big concern was that the "political wrangling" with the EU and Icahn could cause Grail to struggle for funding following any forced divestment by Illumina .

"The current economic climate with banks failing and a poor IPO situation could raise questions about how Grail sustains itself if Illumina is forced to divest. Raising money is difficult now," she said. "I would hate to see Grail just sort of get passed around like a hot potato to people who don't know how to manage or take care of it."

Halks-Miller, who retired in 2020, said the Galleri test had huge potential but needed a lot of money to fund the clinical trials and development required to improve and roll out tests at prices everyone can afford.

Grail is forecast to lose $670mn in 2023 as it funds the largest ever clinical study of a multicancer detection test in the UK. It has partnered with the NHS, which has enrolled 140,000 people aged 50-77 to determine whether Galleri can detect cancers early, when they are usually easier to treat.

The NHS has said it may buy 1mn Galleri tests if the results are positive.

But the success of Galleri and several other early detection tests for cancer under development is far from guaranteed. Some health experts warn there is scant data to demonstrate their effectiveness and the NHS trial is not set up to measure improvement in mortality rates.

Paul Pharoah, professor of cancer epidemiology at Cedars-Sinai, a non-profit healthcare organisation in Los Angeles, said early detection tests had been "overhyped", as there was still no proof they could detect most early-stage cancers or that their use could improve survival rates.

He said the tests raised other potential problems, including overdiagnosis and overtreatment for cancers that for some people may never have become life-threatening. Chasing up false positives could also cost health systems money and cause stress for patients, said Pharoah, adding much more comprehensive studies were required before roll out.

Grail rejects these criticisms.

A trial measuring Galleri's impact on mortality would require a much larger study that would take a decade or more to complete, the company said. It said a smaller-scale study had already validated its tests and it felt a great sense of responsibility and urgency to address a "Covid-size pandemic" in cancer every year.

Last year Grail published data showing Galleri flagged 92 potential cancers from blood tests drawn from 6,662 people. Some 35 participants in the study were diagnosed with cancer. All but 10 of these diagnoses were for cancers that did not have routine cancer screening programmes in place. Fifty-seven were false positives, almost a third of which prompted an invasive procedure to rule out a cancer diagnosis.

Grail is selling Galleri to US consumers for about $950 as a “laboratory developed test” — a category that does not require approval from the US Food and Drug Administration and is not widely reimbursed by insurers. The company expects to generate between $90mn-$110mn in sales this year but must win approval before it will be adopted widely.

“We need commercial payers to be able to pay for [Galleri]. Many of them are going to wait for FDA approval to do that,” said Josh Ofman, Grail president. “We also need to get Medicare to have the authority to be able to pay for a test like this, which they do not have.”

Ofman said he was confident the tests could provide a big public health benefit by identifying cancers — pancreatic, bowel, head, neck and many others — earlier than at present. Grail’s existing work programme had not been delayed by the legal battle with Brussels or Icahn, Ofman said, adding that management remained confident in its business model.

Some analysts say it is Illumina rather than Grail that faces the biggest near-term risks given the terms of a holding agreement imposed by EU regulators on the company before they issue a final divestment order.

Under this agreement Illumina cannot immediately sell Grail, even if it decides to reverse course because of pressure from Icahn. The agreement also imposes funding obligations on Illumina for Grail.

“ Illumina is being forced to fund Grail at $700mn a year but has no control over the asset and may be forced to divest,” said Vijay Kumar, analyst at Evercore ISI.

This high cash burn rate is out of step with the market environment following the biotech crash and could pose unintended consequences for Grail following a divestment, he said.

“Can Grail right size its cost structure when capital markets have tempered? We hope the Grail saga comes to a conclusion sooner rather than later.”

Semafor: A big test for Biden's antitrust cops
Liz Hoffman
April 4, 2023

THE NEWS

Genetic-sequencing company Illumina plans to appeal a U.S. regulatory order to unwind its 2021 takeover of a cancer-test developer, setting up a high-stakes court fight with implications for antitrust cops, patients, and corporate dealmaking.

Reversing an administrative law judge ruling, the Federal Trade Commission said yesterday that Illumina's $7.1 billion purchase of Grail, which screens snippets of genetic code for early warnings of cancer, would stifle innovation. Regulators worry that Illumina might make its machines exclusive to Grail, whose tests run on them, strangling any potential upstart competitors.

Illumina has made a binding promise that any startups could use its machines at the same prices and the same time as Grail. That failed to satisfy the FTC, which under Chair Lina Khan has been aggressively swatting down corporate mergers.

The uncertainty has weighed on Illumina's stock price, which is down by 37% over the past year, trailing peers like Bio-Rad and Thermo Fisher. And it has given activist investor Carl Icahn, who is waging a fight for board seats, more ammunition in his campaign.

LIZ'S VIEW

There's a reason most corporate mergers wait until the government signs off.

When Illumina closed the deal, it knew that regulators didn't like it. The FTC had *already sued* in federal court to block the transaction. European antitrust officials had signaled they would block it (and later did).

For technical reasons, delaying would have restarted a separate FTC clock and added time and costs. But fair or not, the legal deck in merger challenges is stacked in favor of regulators, and Illumina's decision to plow ahead has proven to be a costly miscalculation. If ordered to unwind the deal, Illumina would be a forced seller in a tough market, and could face up to $458 million in fines in Europe for getting ahead of competition approvals there.

The whole affair has handed fresh ammunition to Icahn, who has accused Illumina of "brazenly thumb[ing] their noses" at regulators and throwing good money after bad to defend the deal. He also seized on a nearly 90% pay bump for Illumina's CEO, which was disclosed last week in an almost comical bout of bad timing.

While not known for his deep technical analysis, the octogenarian investor is good at reading a room. The albatross of the Grail deal has been a sore spot for Illumina shareholders for a while now.

“The Commission’s theory is totally speculative: there are no such rivals, and there won’t be for years,” Joshua Wright, a former Republican FTC commissioner who now teaches at George Mason University, wrote in an op-ed for Semafor. (You can read the full piece below.)

Antitrust law assumes that companies are economic animals, driven more or less solely by a desire to make money. The argument here assumes that Illumina wouldn’t have an incentive to cut off Grail rivals because it would ignore a huge source of potential revenue — namely, licensing its technology to others willing to pay for it.

It’s similar to the argument the FTC is making against the sale of video-game maker Activision to Microsoft, which regulators worry would take Activision’s most popular games off of a competing console, Sony’s PlayStation. But PlayStation accounted for 15% of Activision’s sales over the past three years, more than $1 billion a year, according to securities filings. It’s hard to imagine a company turning its back on that kind of money.

NOTABLE

Carl Icahn’s blistering critique of Illumina’s executives and board. FTC ex-Commissioner Christine Wilson, an outspoken critic of Chair Lina Khan’s merger crackdown whose resignation in protest was effective last week, supported the decision to block the Grail deal. She explains her reasons here.

The New York Times: Carl Icahn and Jesus
Andrew Ross Sorkin, Ravi Mattu, Bernhard Warner, Sarah Kessler, Michael J. de la Merced, Lauren Hirsch and Ephrat Livni
March 31, 2023

Illumina, the DNA sequencing company, stepped up its fight with the activist investor Carl Icahn on Thursday, pushing back against his efforts to secure three board seats and force it to spin off Grail, a maker of cancer-detection tests that it bought for $8 billion. But it is a reference to Jesus that the company says he made that is garnering much attention.

The company said that it had nearly reached a settlement with Mr. Icahn before their fight went public, in a preliminary proxy statement. It added that he had no plan for the company beyond putting his nominees on the board.

But Illumina also said Mr. Icahn told its executives that he "would not even support Jesus Christ" as an independent candidate over one of his own nominees because "my guys answer to me."

Experts say Mr. Icahn's comments could be used against him in future fights. Board members are supposed to act as stewards of a company, not agents for a single investor. "If any disputes along these lines arise for public companies where Icahn has nominees on the board, shareholders are going to use this as exhibit A for allegations that the directors followed Icahn rather than their own judgment," said Ann Lipton, a professor of law at Tulane University.

Mr. Icahn doesn't seem to care. He said the comments were "taken out of context" and the company broke an agreement to keep negotiations private.

"It was a very poor choice of words and he is usually much smarter than that," said John Coffee, a corporate governance professor at Columbia Law School. "But he can always say that he was misinterpreted and recognizes that directors owe their duties to all the shareholders."

John Hancock expands access to Galleri®, GRAIL's breakthrough cancer screening technology

February 23, 2023

Carrier previously became the first life insurer to offer access to the Galleri test through a pilot in 2022

BOSTON (February 23, 2023) – Today, John Hancock, a unit of Manulife (NYSE: MFC), announced it will expand access to GRAIL's Galleri® multi-cancer early detection test to eligible life insurance customers participating in the John Hancock Vitality PLUS program, a significant milestone in John Hancock's ongoing efforts to help customers live longer, healthier, better lives. The expanded access comes after John Hancock became the first life insurance carrier to make the breakthrough screening technology available to a pilot group of customers in September 2022.

Galleri is the first-of-a-kind test available for detection of a shared cancer signal across more than 50 cancer types that can be localized to specific tissues or organs to help clinicians focus their diagnostic evaluation. For the majority of these cancer types, there are no alternative screening options available. According to the American Cancer Society (ACS), cancer is the second leading cause of death in the United States with 610,000 deaths estimated to occur in 2023. The ACS cites better early detection, among other advances, as a driving factor in reducing the death rate by a third since 19911.

"The initial pilot exceeded our expectations in terms of the number of tests requested, validating our hypothesis that our customers want access to this level of insight into their health. It was always our intention to expand beyond the pilot phase and we are thrilled to see this vision come to life," said Brooks Tingle, President and CEO of John Hancock Insurance. "However, our work with GRAIL runs much deeper than just making Galleri accessible to our customers. We believe there is a critical need to expand awareness of and access to this type of groundbreaking technology. As a life insurer, we are deeply committed to helping our customers live longer, healthier, better lives and we know that preventative care and early detection are key components of that mission."

The John Hancock Vitality Program combines life insurance with a technology-enabled program that offers education, support, incentives, and rewards designed to help and encourage customers to live healthier lives. The program covers a broad spectrum of activities — including exercise, nutrition, sleep and mindfulness — and rewards customers for the steps they take to stay healthy.

Based on the successful customer uptake during the pilot, John Hancock decided to expand access to the Galleri test, following a similar model, to all eligible John Hancock Vitality PLUS customers, while exploring other potential expansions for the future.

"Every day counts for cancer patients and their families," said Lindsay Hanson, Vice President, Head of Behavioral Insurance, Global Strategy and Delivery. "Early detection, through tests like Galleri, is a way to write a different story to a cancer diagnosis. We're proud to bring this technology to our customers."

“The expansion of this first-of-its-kind program shows the benefits of bringing together two industries that share a common goal of improving health outcomes,” said Bob Ragusa, Chief Executive Officer at GRAIL. “We are thrilled to see the success of the pilot program and look forward to continuing to work with the leadership at John Hancock as it expands its multi-cancer early detection offering, with the goal of ultimately reducing the burden of cancer and keeping cancer from claiming even more lives.”

Offering access to the Galleri test builds on existing Vitality program features that encourage customers to take part in recommended preventative care, including mammograms and other cancer screenings, annual physical exams, dental visits, and more. The John Hancock Vitality Program is constantly growing and evolving with advances in science to make cutting-edge technology and information available to customers to help them live longer, healthier, better lives.

Abbott, B. (2023, January 12). U.S. Cancer Death Rate Has Dropped by a Third Since 1991. The Wall Street Journal. https://www.wsj.com/articles/u-s-cancer-death-rate-has-dropped-by-a-third-since-1991-11673535327

Disclaimer

Galleri is a registered trademark of GRAIL, LLC (“GRAIL”). The test is manufactured and distributed by GRAIL. John Hancock is not an affiliate of GRAIL. John Hancock does not provide medical advice, is not involved in the design or manufacture of the Galleri test and is not responsible for the accuracy or performance of the Galleri test. There is no coordination between John Hancock and any other health plan you may be enrolled in. You may incur additional costs for diagnostic screenings recommended by your healthcare provider.

John Hancock does not receive any individual test results from GRAIL. It will only receive aggregate, anonymized data to understand the success of the offering.

Galleri is not a test to confirm or rule out genetic or other conditions that may indicate a predisposition to cancer. It is important to underscore that Galleri does not detect all cancers and is not a means of diagnosis, but rather a tool to help individuals screen for cancer earlier.

The Galleri test does not replace recommended routine cancer screenings. The Galleri test has not been cleared or approved by the Food and Drug Administration but has received a breakthrough device designation by the FDA. GRAIL’s clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). As GRAIL pursues FDA approval, they have launched Galleri as a Laboratory Developed Test in compliance with applicable regulatory requirements, backed by evidence.

The Galleri test is only available to registered John Hancock Vitality PLUS members who are 50 years of age or older, have completed the Vitality Health Review (VHR) for the current program year. For eligible policies with coverage amounts of $500,000 or greater, 100% of the cost of the test will be subsidized. For policies with less than $500,000 in coverage, 50% of the cost of the test will be subsidized.

The Galleri test through The John Hancock Vitality Program is not currently available in New York, Idaho or Guam. The offer of discounted access to the Galleri test is subject to change.

Insurance products are issued by: John Hancock Life Insurance Company (U.S.A.), Boston, MA 02116 (not licensed in New York) and John Hancock Life Insurance Company of New York, Valhalla, NY 10595

Vitality is the provider of the John Hancock Vitality Program in connection with policies issued by John Hancock. John Hancock Vitality Program rewards and discounts are available only to the person insured under the eligible life insurance policy, may vary based on the type of insurance policy purchased and the state where the policy was issued, are subject to change and are not guaranteed to remain the same for the life of the policy. Life insurance policies and/or associated riders and features may not be available in all states.

Important Safety Information

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of "Cancer Signal Not Detected" does not rule out cancer. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g., imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

About John Hancock and Manulife

John Hancock is a unit of Manulife Financial Corporation, a leading international financial services provider that helps people make their decisions easier and lives better by providing financial advice, insurance, and wealth and asset management solutions. Manulife Financial Corporation trades as MFC on the TSX, NYSE, and PSE, and under 945 on the SEHK. Manulife can be found at manulife.com.

One of the largest life insurers in the United States, John Hancock supports more than ten million Americans with a broad range of financial products, including life insurance and annuities. John Hancock also supports US investors by bringing leading investment capabilities and retirement planning and administration expertise to individuals and institutions. Additional information about John Hancock may be found at johnhancock.com.

About Vitality

Guided by a core purpose of making people healthier, Vitality is the leader in improving health to unlock outcomes that matter. By blending industry-leading smart tech, data, incentives, and behavioral science, we inspire healthy changes in individuals and their organizations. As one of the largest wellness companies in the world, Vitality brings a dynamic and diverse perspective through successful partnerships with the most forward-thinking insurers and employers. More than 30 million people in 40 markets engage in the Vitality program. For more information, visit vitalitygroup.com or follow us on Twitter and LinkedIn.

About GRAIL

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate from Illumina Inc. under the terms of the Interim Measures Order of the European Commission.

For more information, visit grail.com.

About Galleri®

The earlier that cancer is detected, the higher the chance of successful outcomes. The Galleri multi-cancer early detection test can detect a shared cancer signal across more than 50 types of cancer, as defined by the American Joint Committee on Cancer Staging Manual, through a routine blood draw. When a cancer signal is detected, the Galleri test predicts the cancer signal origin, or where the cancer is located in the body, with high accuracy to help guide the next steps to diagnosis. The Galleri test requires a prescription from a licensed health care provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. It is intended for use in people with an elevated risk of cancer, such as those aged 50 or older.

For more information about Galleri, visit galleri.com.
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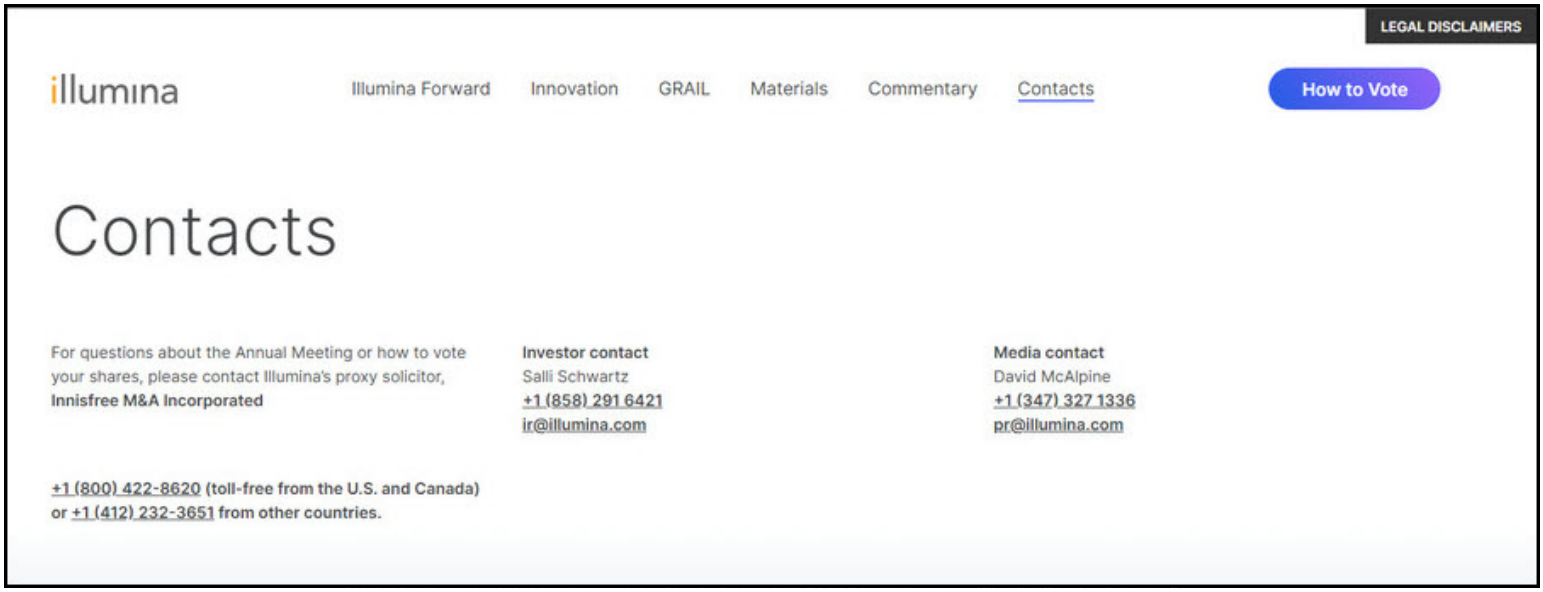
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At Illumina, our goal is to apply innovative technologies to the analysis of genetic variation and function, making studies possible that were not even imaginable just a few years ago. It is mission critical for us to deliver innovative, flexible, and scalable solutions to meet the needs of our customers. As a global company that places high value on collaborative interactions, rapid delivery of solutions, and providing the highest level of quality, we strive to meet this challenge. Illumina innovative sequencing and array technologies are fueling groundbreaking advancements in life science research, translational and consumer genomics, and molecular diagnostics.

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On April 20, 2023, Illumina issued the following press release in connection with Illumina's 2023 Annual Meeting of Stockholders:

Illumina Urges Shareholders to Vote the WHITE Proxy Card FOR all Nine of Illumina's Nominees

SAN DIEGO, April 20, 2023 /PRNewswire/ -- Illumina, Inc. (NASDAQ), a global leader in DNA sequencing and array-based technologies, urged shareholders to vote in favor of Illumina's slate of highly qualified director nominees. It also announced that its Annual Meeting will be held virtually on May 25, 2023, at 10:00 am Pacific Time (1:00 pm Eastern Time).

Illumina's Board of Directors urges shareholders to protect their investment and reject all three of Carl Icahn's nominees by voting the **WHITE** proxy card today "**FOR**" all nine of the Company's Board of Directors. Shareholders of record as of close of business on April 3, 2023, are entitled to vote at the meeting.

Illumina's Board is led by an independent chair, John W. Thompson, a highly distinguished executive with a long history of shareholder value creation, and all nine members are independent with the exception of Chief Executive Officer Francis A. deSouza. Members of the Board bring an extensive range of professional backgrounds and skills relevant to Illumina's business.

Carl Icahn seeks to replace Mr. deSouza, Robert S. Epstein, MD, and Mr. Thompson, with his nominees. Icahn's nominees cannot replace the unique collection of strengths and experience that these three directors bring to the Board.

The Board does not endorse Carl Icahn or his unqualified nominees and believes the election of any such nominees would detract from Illumina's long-term strategy.

Carl Icahn, whose firm owns less than 1.5% of Illumina's outstanding common shares, has made it clear that his three director nominees – Vincent J. Intrieri, Jesse A. Lynn, and Andrew J. Teno, all current or former Icahn employees – would represent Mr. Icahn's interests on the Board of Illumina and answer to Carl Icahn, not the shareholders of Illumina. Unlike Icahn's director nominees, Illumina's Board of Directors acts in the best interests of all of its shareholders and exercises considered and deliberate independent judgement.

Mr. Thompson brings over four decades of experience leading high-growth companies. He is currently a director at Microsoft and previously held roles as lead independent director and chair of its board, where he led the appointment of Satya Nadella as CEO. Since his appointment to the board in 2012, as of fiscal year 2022, revenue more than doubled to $198.3 billion, net income more than tripled to $72.7 billion, and diluted earnings per share almost quadrupled to $9.65. During his tenure as director, chair and lead independent director from February 2012 to present, Microsoft's total shareholder return (TSR) of 885% outperformed the S&P 500's return of 202%, a difference of 683 percentage points.

At Symantec, where he was CEO for 10 years, he grew revenue from $600 million to $6 billion and delivered a TSR of 819%, outperforming the S&P 500's TSR of (37%) by 856 percentage points. He is one of the most distinguished executives and board members in Corporate America, ranked as one of The Best-Performing CEOs in the World, according to Harvard Business Review in 2010. His unparalleled experience guiding a number of the world's most respected companies through periods of transformative growth and value creation greatly contributes to the Board's strategic leadership of the Company.

Mr. deSouza has ten years of experience in the genomics industry and has a history of successfully developing and commercializing new technologies from incubation stage. As CEO of Illumina, he has led the Company further into the clinical setting and overseen technology advances in mid- and high-throughput capabilities, unlocking new markets, with the launches of TruSight Oncology 500, the DRAGEN Bio-IT Platform, Illumina Complete Long Reads, NovaSeq 5000/6000, NextSeq 1000/2000, and the revolutionary NovaSeq X Series. He has significantly expanded Illumina's commercial footprint, achieving an approximate 11% revenue CAGR over the last five years. Under Mr. deSouza's leadership, Illumina has earned several awards recognizing the Company as a leader in workplace culture and innovation, including being named to TIME's 100 Most Influential Companies, Fast Company's Most Innovative Companies, and Forbes' World's Best Employers lists. With his extensive experience developing and commercializing technologies, establishing industry partnerships and opening new markets, Mr. deSouza is uniquely capable of leading Illumina as it innovates for the future.

Dr. Epstein brings in-depth scientific experience and a strong background in managing and growing healthcare organizations to Illumina's Board. His understanding of the clinical setting and the risks and opportunities associated with operating in markets regulated by the FDA and other global regulatory bodies, is invaluable to Illumina. Specifically, Dr. Epstein brings 35 years of experience in diagnostic and biopharmaceutical reimbursement both as a developer of evidence and payer in the U.S. and European Union. Dr. Epstein has distinctive knowledge of global market access, and development and commercialization of clinical diagnostic products, which is key to Illumina's growth trajectory. He is currently a director at Veracyte and Fate Therapeutics and is the CEO of Epstein Health LLC, a strategic advisory firm in the healthcare technology space. Previously, he served as Chief Medical Officer of Medco and then as President of Medco-UBC, where he led the Medical Affairs, Statistics and Research Analytics Divisions, started and grew the Medco Research Institute and oversaw several acquisitions in the healthcare services and life sciences services spaces.

The Company's definitive proxy statement has been filed with the Securities and Exchange Commission and is being mailed to shareholders. That and other important information related to the Annual Meeting can be found at IlluminaForward.com.

The full text of the letter follows:

VOTE USING THE WHITE PROXY CARD TODAY IN SUPPORT OF ILLUMINA'S NINE HIGHLY QUALIFIED DIRECTORS

April 20, 2023

Dear Shareholder,

We are grateful for your long-held support of Illumina.

It is crucial to vote this year to ensure that Illumina can continue to empower genomic breakthroughs as well as deliver long-term sustainable value for shareholders.

Carl Icahn has launched a campaign to replace three of our deeply experienced Board nominees – Francis A. deSouza, Robert S. Epstein, MD, and John W. Thompson – with his unqualified nominees – Vincent J. Intrieri, Jesse A. Lynn, and Andrew J. Teno – as directors at the 2023 Annual Meeting. All three of his nominees are either current or former Icahn employees.

Illumina's Board is led by an independent chair, John W. Thompson, and all nine members are independent with the exception of the Chief Executive Officer. Members of the Board bring the highest personal character, integrity, and ethical standards, and reflect a range of professional backgrounds and skills relevant to Illumina's business.

Illumina's Board of Directors urges shareholders to protect their investment and reject all three of Carl Icahn's nominees by voting the **WHITE** proxy card today "**FOR**" all nine of the Company's highly qualified director nominees. The Annual Meeting will be held virtually on May 25, 2023, at 10:00 am Pacific Time (1:00 pm Eastern Time). Shareholders of record as of close of business on April 3, 2023, are entitled to vote at the meeting.

The Board does not endorse Carl Icahn or his unqualified nominees and believes the election of any such nominees would detract from Illumina's long-term strategy.

Illumina firmly believes that it has the right team and strategy in place to deliver long-term sustainable value for shareholders.

PLEASE VOTE THE WHITE PROXY CARD TODAY

Your Board recommends that you vote the **WHITE** proxy card FOR all **NINE** of Illumina's nominees. We urge you NOT to vote using any gold proxy card from Carl Icahn or Icahn Partners LP and certain of its affiliates. Please disregard and discard any gold proxy card. Please note that if you inadvertently voted using Icahn's gold proxy card, you may cancel that vote simply by voting again TODAY using the Company's WHITE proxy card. Only your latest-dated vote counts. Additional information related to the Annual Meeting can be found at IlluminaForward.com.

On behalf of Illumina's Board of Directors, thank you again for your continued support of Illumina.

Sincerely,

Board of Directors
Illumina, Inc.

YOUR VOTE IS IMPORTANT!

Please follow the easy instructions on the enclosed **WHITE** proxy card or in the accompanying email.

If you have any questions, or need assistance in voting your shares
please call our proxy solicitor:

INNISFREE M&A INCORPORATED

1 (800) 422-8620
(toll-free from the U.S. and Canada)
or
+1 (412) 232-3651
(from other countries)

Remember, if you hold your shares in more than one account,
you will receive separate notifications for each account.
Please be sure to vote ALL your accounts
using the **WHITE** proxy card relating to each account.

Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding mandates, the future, business plans and other statements that are not historical in nature. These statements are made on the basis of Illumina’s views and assumptions regarding future events and business performance and plans as of the time the statements are made. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Illumina does not undertake any obligation to update these statements unless required by applicable laws or regulations, and you should not place undue reliance on forward-looking statements. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) changes in the rate of growth in the markets we serve; (ii) the volume, timing and mix of customer orders among our products and services; (iii) our ability to adjust our operating expenses to align with our revenue expectations; (iv) our ability to manufacture robust instrumentation and consumables; (v) the success of products and services competitive with our own; (vi) challenges inherent in developing, manufacturing, and launching new products and services, including expanding or modifying manufacturing operations and reliance on third-party suppliers for critical components; (vii) the impact of recently launched or pre-announced products and services on existing products and services; (viii) our ability to further develop and commercialize our instruments, consumables, and products, including Galleri™, the cancer screening test developed by GRAIL, to deploy new products, services, and applications, and to expand the markets for our technology platforms; (ix) the risks and costs associated with our ongoing inability to integrate GRAIL due to the interim measures imposed on us by the European Commission as a result of their prohibition of our acquisition of GRAIL; (x) the risks and costs associated with the integration of GRAIL’s business if we are ultimately able to integrate GRAIL; (xi) the risk that disruptions from the consummation of our acquisition of GRAIL and associated legal or regulatory proceedings, including related appeals, or obligations will harm our business, including current plans and operations; (xii) the risk of incurring fines associated with the consummation of our acquisition of GRAIL and the possibility that we may be required to divest all or a portion of the assets or equity interests of GRAIL on terms that could be materially worse than the terms on which we acquired GRAIL; (xiii) our ability to obtain approval by third-party payors to reimburse patients for our products; (xiv) our ability to obtain regulatory clearance for our products from government agencies; (xv) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business; (xvi) uncertainty, or adverse economic and business conditions, including as a result of slowing or uncertain economic growth, COVID-19 pandemic mitigation measures, or armed conflict; (xvii) the application of generally accepted accounting principles, which are highly complex and involve many subjective assumptions, estimates, and judgments and (xviii) legislative, regulatory and economic developments, together with the factors set forth in Illumina’s Annual Report on Form 10-K for the year ended January 1, 2023 under the caption “Risk Factors”, in information disclosed in public conference calls, the date and time of which are released beforehand, and in filings with the Securities and Exchange Commission (the “SEC”) including, among others, quarterly reports on Form 10-Q.

Additional Information and Where to Find It

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Participants

Illumina, its directors and executive officers and other members of management and employees will be participants in the solicitation of proxies with respect to a solicitation by Illumina. Information about Illumina's executive officers and directors, including information regarding the direct or indirect interests, by security holdings or otherwise, is available in Illumina's definitive proxy statement for its 2023 Annual Meeting, which was filed with the SEC on April 20, 2023. To the extent holdings by our directors and executive officers of Illumina securities reported in the proxy statement for the 2023 Annual Meeting have changed, such changes have been or will be reflected on Statements of Change in Ownership on Forms 3, 4 or 5 filed with the SEC. These documents are or will be available free of charge at the SEC's website at www.sec.gov.

Investors:
Salli Schwartz
858-291-6421
IR@illumina.com

Media:
David McAlpine
347-327-1336
PR@illumina.com

On April 20, 2023, the following letter was shared with Illumina's shareholders in connection with Illumina's 2023 Annual Meeting of Stockholders:

illumina®

VOTE USING THE WHITE PROXY CARD TODAY IN SUPPORT OF ILLUMINA'S NINE HIGHLY QUALIFIED DIRECTORS

April 20, 2023

Dear Shareholder,

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Carl Icahn has launched a campaign to replace three of our deeply experienced Board nominees – Francis A. deSouza, Robert S. Epstein, MD, and John W. Thompson – with his unqualified nominees – Vincent J. Intrieri, Jesse A. Lynn, and Andrew J. Teno – as directors at the 2023 Annual Meeting. All three of his nominees are either current or former Icahn employees.

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The Board does not endorse Carl Icahn or his unqualified nominees and believes the election of any such nominees would detract from Illumina's long-term strategy.

Illumina firmly believes that it has the right team and strategy in place to deliver long-term sustainable value for shareholders.

PLEASE VOTE THE WHITE PROXY CARD TODAY

Your Board recommends that you vote the **WHITE** proxy card FOR all **NINE** of Illumina's nominees. We urge you NOT to vote using any gold proxy card from Carl Icahn or Icahn Partners LP and certain of its affiliates. Please disregard and discard any gold proxy card. Please note that if you inadvertently voted using Icahn's gold proxy card, you may cancel that vote simply by voting again TODAY using the Company's WHITE proxy card. Only your latest-dated vote counts. Additional information related to the Annual Meeting can be found at IlluminaForward.com.

On behalf of Illumina's Board of Directors, thank you again for your continued support of Illumina.

Sincerely,

Board of Directors
Illumina, Inc.

illumina®

YOUR VOTE IS IMPORTANT!

Please follow the easy instructions on the enclosed WHITE proxy card or in the accompanying email.

If you have any questions, or need assistance in voting your shares please call our proxy solicitor:

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(toll-free from the U.S. and Canada)
or
+1 (412) 232-3651
(from other countries)

Remember, if you hold your shares in more than one account, you will receive separate notifications for each account. Please be sure to vote ALL your accounts using the **WHITE** proxy card relating to each account.

Forward-Looking Statements

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On April 20, 2023, the following message was electronically shared with employees of Illumina in connection with Illumina's 2023 Annual Meeting of Stockholders:

April 20, 2023

Dear Team,

I want to provide an update on the ongoing proxy contest between Illumina and activist investor Carl Icahn. Since our all-employee meetings a few weeks ago, you have likely seen Illumina responding to Icahn's public criticisms of our Company and leadership. As expected, he has pursued a deliberately misleading campaign with the clear goal of electing all three of his director nominees to our Board of Directors. We believe his nominees are unqualified, lacking both relevant skills and experience, and if elected, would do harm and damage to our core business.

To contest Carl's nominees, we are urging our shareholders to vote in favor of Illumina's Board at our upcoming 2023 Annual Shareholder Meeting. Our Board members have extensive business, financial, operating, and regulatory experience as well as scientific backgrounds in the life sciences and technology sectors. They are committed to driving Illumina's business forward and to maximizing value for all shareholders while fulfilling our critical mission.

All Illumina shareholders will receive materials in the mail, including a WHITE proxy card, where you can vote "FOR" all nine of Illumina's nominees proposed by the Board. The Board does not endorse Carl Icahn or his unqualified nominees and believes the election of any such nominees would detract from Illumina's long-term strategy, which is why we recommend shareholders withhold votes for the three Carl Icahn, or Icahn Group, director nominees.

Our virtual 2023 Annual Shareholder Meeting has been scheduled for May 25, 2023, at 10:00 am Pacific Time. Related to the Annual Meeting, today we filed our definitive proxy, which includes information and materials about important Company matters as well as voting instructions. You can find this information in our press release or visit IlluminaForward.com for more information on our Board nominees and our proxy. I encourage each of you who own Company shares as of the record date April 3, 2023, to exercise your right to vote – no matter how many shares you own.

Together, with all of your hard work, we've made tremendous progress delivering faster, more affordable, more accurate and more sustainable sequencing capabilities that are empowering genomic breakthroughs around the world – but the continuation of that progress is in jeopardy. Leading up to the Annual Meeting, we will continue to send communications to shareholders, urging them to protect their investment and the future of this Company. We firmly believe that we have the right team and strategy to execute on our innovation roadmap and deliver long-term sustainable value to shareholders.

If you receive any questions about this matter, please refer them to Investor Relations at IR@illumina.com and/or Public Relations at PR@illumina.com, as appropriate. Also, I ask that you please refrain from commenting on this matter on social media.

Thank you for your continued focus and commitment to our Company.

Francis

Forward-Looking Statements

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Investors:
Salli Schwartz
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212-230-5930