ILMN Q4 and Fiscal Year 2021 Earnings Call
Prepared Remarks – February 10, 2022

Salli Schwartz, *Investor Relations*

Good afternoon, everyone, and welcome to our earnings call for the fourth quarter and full year 2021.

During the call today, we will review the financial results released after the close of the market, and offer commentary on our commercial activity, after which we will host a question and answer session. If you have not had a chance to review the earnings release, it can be found in the Investor Relations section of our website at illumina.com.

Participating for Illumina today will be Francis deSouza, President and Chief Executive Officer, and Sam Samad, Chief Financial Officer. Francis will provide an update on the state of Illumina's business and Sam will review our financial results which include GRAIL.

As a reminder, pending the outcome of the European Commission's investigation into Illumina's acquisition of GRAIL, the Commission has adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities for an interim period. Compliance with the order is monitored by a Monitoring Trustee. During this period, Illumina and GRAIL are not permitted to share confidential business information unless legally required, and GRAIL must be run independently, exclusively in the best interests of GRAIL. Commercial interactions between the two companies must be undertaken at arm's length.

This call is being recorded and the audio portion will be archived in the Investor section of our website. It is our intent that all forward-looking statements regarding our financial results and commercial activity made during today's call will be protected under the Private Securities Litigation Reform Act of 1995.

Forward-looking statements are subject to risks and uncertainties. Actual events or results may differ materially from those projected or discussed. All forward-looking statements are based upon current available information, and Illumina assumes no obligation to update these statements.

To better understand the risks and uncertainties that could cause actual results to differ, we refer you to the documents that Illumina files with the Securities and Exchange Commission, including Illumina's most recent forms 10-Q and 10-K.

With that, I will now turn the call over to Francis.

Francis deSouza, *President & Chief Executive Officer*

Thank you, Salli. Good afternoon, everyone.

I'm excited to share with you how our commitment to innovation is driving growth and unlocking the power of the genome. My comments will cover a few key areas, starting with our strong finish and exceptional results for 2021, followed by how our platforms and markets drove those results. I'll then conclude by highlighting a few of the many trends that will support our momentum and continued growth in 2022 and beyond.

Let's start with our financial results for both the fourth quarter and full year 2021.

Fourth quarter revenue of approximately $1.2 billion increased 26% year-over-year, with strong growth across both instruments and consumables, and across all regions.

Full year 2021 revenue of more than $4.5 billion increased 40% year-over-year, reflecting 76% growth in sequencing instruments and 43% growth in sequencing consumables. We are seeing record demand for our instruments across the

throughput spectrum and across geographies. In 2021, we shipped more than 3,200 sequencing instruments and added more than 930 new instrument customers, over 50% more than in 2020 or 2019.

Delving now into each of our platforms, starting with high-throughput:

We shipped 384 NovaSeq units in 2021, with more than one-third of those instruments for oncology testing. Approximately 50% of NovaSeq orders in 2021 were to new to high throughput or new to Illumina customers.

2021 NovaSeq consumable pull-through of more than $1.3 million per instrument was the highest-ever average, even with over double the placements compared to last year.

Moving to mid-throughput, in 2021 we shipped more than 1,100 NextSeq systems, surpassing 1,000 for the first time and nearly doubling 2020 shipments. This volume was driven by growing NextSeq 550 demand in clinical applications like oncology testing and reproductive health, as well as NextSeq 1000 and 2000 demand as customers expand into multi-omic applications. More than 20% of NextSeq 1000 and 2000 units this year were placed with new to Illumina customers as we continue to see new customers using higher throughput applications.

For low-throughput, in 2021 we shipped more than 1,600 units, another record, driven in part by the addition of more than 700 new customers.

Looking at our continued strong growth through the lens of our markets:

Our Clinical markets currently include testing for oncology, reproductive health, and genetic disease. In 2021, our consumable shipments to Clinical markets grew 42% driven in particular by oncology testing, where many customers are building out comprehensive genomic profiling, or CGP, and expanding into liquid biopsy and monitoring.

We continue to see expanding opportunities for our oncology products globally, including new studies launching in Europe and Asia with our research use only TruSight Oncology 500 assay. For example, our recent joint research project with the National Cancer Center Japan will develop personalized cancer treatments for patients with nasopharyngeal carcinoma, a cancer that occurs more frequently in Asia. And, our partnership with the Jean Perrin Center at the Clermont-Ferrand University Hospital in France will assess the clinical value of CGP in patients with late stage disease compared to the current standard of care.

Also in oncology, GRAIL continues to see strong momentum. GRAIL launched the Galleri test last year as the first clinically-validated multi cancer early detection test to be available to patients and providers. Galleri can detect more than 50 types of cancer, most of which have no current screening.

It's great to see the initial market reception, with multiple large employers and payers adopting Galleri and more than 1,500 prescribing providers, including participation from leading health systems, like the NHS, the Mayo Clinic and the Cleveland Clinic. The team continues to collaborate with pharmaceutical partners like AstraZeneca, Amgen and Bristol Myers Squibb on potential new innovations in the post-diagnostic space.

Finally, the recent initiatives launched in the U.S. and EU to beat cancer are very encouraging. The U.S.'s Cancer Moonshot national initiative and Europe's Beating Cancer Plan highlight the increasing recognition of early detection as a critical component in the fight against cancer. Illumina is deeply committed to supporting all early detection, oncology testing and treatment initiatives to improve care and save lives.

Beyond oncology, reproductive health also had a strong year in 2021. This was driven in part by revised American College of Obstetricians and Gynecologists, or ACOG, guidelines enabling genetic testing coverage for all US pregnancies, as well as increasing adoption of our VeriSeq NIPT v2 product globally.

Our third Clinical market, genetic disease testing, saw tremendous growth and additional evidence generation in 2021, with significant publications in both the New England Journal of Medicine and JAMA Pediatrics affirming the clinical utility of whole genome sequencing, or WGS, for critically ill children. In 2022, we are already seeing an increase in coverage with California, Oregon and Maryland Medicaid initiating coverage for WGS in the NICU setting. Expansion of

programs for WGS in NICU settings are also occurring globally, including our recent project with Germany's Hannover Medical School to implement the use of WGS in NICU patients. This program contributes to a growing body of evidence from other countries – including the United Kingdom and Australia – as well as in states across the U.S., showing that WGS offers significant benefits for diagnosis of genetic disease in critically-ill infants, along with cost efficiencies for health systems.

Turning to our Research and Applied markets, consumables grew 43% in 2021 driven by projects like All of Us, along with ongoing COVID surveillance efforts that contributed approximately $220 million in total revenue.

I'd now like to spend a few minutes on three key trends that will drive long-term growth.

First is the continued deepening and expansion of Illumina's addressable markets. We are seeing further penetration of our existing markets through increased access and adoption. The use of sequencing is proliferating globally across applications, and new initiatives continue to integrate genomics into national healthcare systems. Our technologies and genomics expertise are enabling programs like Our Future Health, the UK's largest-ever health research program, that will deliver genetic analysis of DNA samples from up to five million volunteers. This data will be used for a variety of potential discoveries, including new signals to detect diseases earlier, new ways to better predict high risk populations for diseases, and new personalized therapies or tools to delay diseases or change the course of their progression. We are excited to play a role in this project as the genotyping partner for the program.

We also continue to support a growing global COVID surveillance network that will extend to broader pan pathogen and genomic epidemiology work. This infrastructure is already being used to study other infectious diseases. For example, in South Africa, Dr. Tulio de Olivera's team at CERI, the Centre for Epidemic Response and Innovation, is using their fleet of sequencers to study other communicable diseases like HIV and malaria. We expect additional opportunities for epidemiology applications in the future, as global funding for pathogen surveillance and research expands.

And, new sequencing applications and opportunities are growing and evolving rapidly, including in multiple nascent spaces like multi-omics and drug development. We are supporting the spectrum of multi-omic applications across our instruments, including proteomics, where our co-development partnership with Somalogic is off to a strong start. We are also catalyzing growth in drug discovery, where genomic-based methods can dramatically improve speed to market, success rates and cost. In addition to our partnership with Nashville Biosciences, we are collaborating with The Montreal Neurological Institute-Hospital, Takeda, and Roche to enable large-scale analysis of patient data and identify promising targets for drug development in neurological diseases.

Programs like Our Future Health, growing applications, and increasing global access will support long-term adoption of NGS. The new markets we're opening, like drug discovery, will further enable adoption while also improving data equity and the integration of genomics into healthcare. We are experiencing this increasing demand for genomics as we enter 2022, with our instrument backlog almost twice the size it was entering 2021.

A second trend is the multifaceted growth in our customer base. Our existing customers are growing their instrument fleets. We are also seeing increasing numbers of customers new to Illumina. As a result, our installed base has grown to more than 20,000 instruments at the end of 2021.

A third trend is the demand for even greater data generation. In 2021, an average Illumina high throughput customer generated approximately four times more data than in 2017. This will continue as customers need more complete genomic information, and as NGS becomes standard in clinical settings. These shifts will increase the number of projects, number of samples per project, and the depth of sequencing per sample, as multiple tests are run per patient and as samples are used for reads across high-intensity applications like multi-omics. This demand for higher throughput sequencing will, in turn, continue to drive further growth in our sequencing consumables revenue. For 2021, between our consumables and services, more than 80% of our revenue is recurring in nature. This more predictable and profitable revenue stream provides a tremendous base to invest into the business and drive further growth.

Illumina's 2021 performance and significant momentum entering 2022 demonstrate our strong position to support our customers and partners as these trends accelerate genomics in healthcare. I'll now turn the call over to Sam to highlight additional details on our results and operations, as well as discuss our guidance for 2022. Sam?

Sam Samad, *Chief Financial Officer*

Thanks, Francis.

As a reminder, our fourth quarter financial results include the consolidated financial results for GRAIL. I'll start by reviewing our consolidated financial results, followed by segment results for Core Illumina and GRAIL, then conclude with our outlook for 2022. I will be highlighting non-GAAP results which include stock-based compensation. I encourage you to review the GAAP reconciliation of these non-GAAP measures which can be found in today's release and in the supplementary data available on our website.

Our record fourth quarter revenue again exceeded our expectations due to continued strength in our core business, with consolidated revenue growing 26% year-over-year to $1.198 billion .

For the fourth quarter, GAAP net income was $112 million, or $0.71 per diluted share, and non-GAAP net income was $117 million, or $0.75 per diluted share, which included $0.66 of dilution from GRAIL operating losses and $0.09 of incremental dilution from the 9.8 million shares issued to fund the GRAIL acquisition . Our non-GAAP tax rate was 15.6%, which decreased 280 basis points year-over-year primarily due to a more favorable mix of earnings in jurisdictions with lower statutory tax rates. Our weighted average diluted share count for the quarter was approximately 157 million.

Moving to segment results, I will start by highlighting the financial results of Core Illumina:

Core Illumina revenue grew 25% year-over-year to $1.193 billion, driven by another quarter of record shipments for both clinical and research , with notable strength in oncology testing, genetic disease testing, and population genomics .

Core Illumina sequencing consumables revenue grew 32% year-over-year to $792 million, driven by record NovaSeq consumables shipments resulting from the significant growth in installed base and strong pull-through that again exceeded our guidance range . Sequencing instruments revenue for Core Illumina grew 35% year-over-year to $191 million, driven by record NovaSeq shipments due to continued new-to-high throughput customer adoption and accelerating demand in oncology testing . NextSeq 1000/2000 shipments also reached a new high in the quarter , and there was strong growth across all mid- and low-throughput systems year-over-year . We are entering 2022 with a strong sequencing instrument backlog that is almost double the backlog entering 2021 .

Revenue from COVID-19 surveillance again exceeded our expectations , driven by the sustained focus on variant tracking due to the emergence of the Omicron variant. During the fourth quarter, COVID-19 surveillance contributed approximately $42 million in sequencing consumables revenue and $8 million in incremental instrument revenue .

Core Illumina sequencing service and other revenue of $106 million was flat year-over-year, as revenue growth from instrument service contracts and lab services was offset by lower IVD partnership revenue .

Moving to regional results for Core Illumina:

Revenue for the Americas region was $619 million, growing 25% compared to the prior year period, driven by clinical demand in oncology testing, strength in genetic disease research for pharma and population genomics initiatives like All of Us, and Covid surveillance testing .

EMEA delivered revenue of $350 million, representing 23% growth year-over-year, driven by strength in emerging markets, population genomics initiatives, and Covid surveillance testing .

Greater China revenue was $121 million, representing growth of 26% year-over-year due to continued clinical strength in the region driven by the growing installed base in hospitals .

Finally, APJ revenue of $103 million grew 34% year-over-year, driven by record NovaSeq placements and continued momentum in clinical markets, including genetic disease testing and oncology testing .

Moving to the rest of the Core Illumina P&L:

Core Illumina non-GAAP gross margin of 71.6% increased 470 basis points year-over-year due primarily to increased fixed cost leverage on higher volumes .

Core Illumina non-GAAP operating expenses of $580 million were up $141 million year-over-year due primarily to headcount growth, increased performance-based compensation expenses, higher one-time partnership related expenses and increased project spend driven by investments we are making in R&D and operations to support the growth and scale of our business . Non-GAAP operating expenses for the quarter were higher than expected due to higher variable compensation expense and higher partnership expense compared to previous expectations .

Core Illumina non-GAAP other expense of $8 million was $28 million lower than other income in Q4 2020 due to lower interest income on short-term investments liquidated to fund the GRAIL acquisition, as well as interest expense on the Term Notes issued in Q1 2021.

Transitioning to the financial results for GRAIL:

GRAIL revenue of $10 million for the quarter consisted of Galleri test fees and MRD partnership revenue . GRAIL non-GAAP operating expenses totaled $131 million for the quarter, which consisted primarily of expenses related to headcount and clinical trials .

Moving to consolidated cash flow and balance sheet items:

- Cash flow from operations was $282 million;
- DSO was 49 days compared to 50 days last quarter driven by revenue linearity;
- Fourth quarter 2021 capital expenditures were $70 million and free cash flow was $212 million;
- We did not repurchase any common stock in the fourth quarter.

We ended the quarter with approximately $1.3 billion in cash, cash equivalents and short-term investments.

Moving now to 2022 guidance:

We expect full year 2022 consolidated revenue to grow 14 – 16% to approximately $5.16 - $5.25 billion. We expect full year 2022 Core Illumina revenue to grow 13 – 15% to approximately $5.11 - $5.20 billion. GRAIL expects its revenue to be in the range of $70 million to $90 million for 2022, consisting primarily of Galleri test fees.

For fiscal 2022, at the midpoint of our revenue guidance range:

- We expect Core Illumina sequencing revenue to grow approximately 15% year-over-year driven by accelerating demand in our base business. This includes intercompany sales to GRAIL of approximately $25 million, which are eliminated in consolidation
- We expect Core Illumina sequencing instrument growth of approximately 10% year-over-year driven by continued strength in NovaSeq and NextSeq placements
- We expect Core Illumina sequencing consumables growth of approximately 18% year-over-year driven by our growing instrument installed base and strong utilization by our customers. We expect this strength to span our platforms, and we are raising our pull-through guidance for NovaSeq to a range of $1.2 million to $1.3 million per system for 2022 . We expect pull through for NextSeq 1000/2000 in the range of $130,000 to $180,000 per

system in 2022 and pull through for NextSeq 550 in the range of $100,000 to $150,000 per system. For MiSeq, we expect pull through in the range of $35,000 to $45,000 per system and for MiniSeq, we expect pull through in the range of $20,000 to $25,000 per system

We also expect revenue from COVID surveillance in the range of $130 million to $150 million in 2022.

We expect consolidated non-GAAP operating margin in the range of 15.5% - 16% and Core Illumina non-GAAP operating margin of approximately 28% for 2022. We also expect a consolidated non-GAAP tax rate of approximately 19%.

We expect consolidated non-GAAP earnings per diluted share in the range of $4.00 to $4.20, which includes dilution from GRAIL of $3.75, including GRAIL operating loss dilution of approximately $3.25 and incremental dilution of approximately $0.50 from the 9.8 million shares issued to fund the GRAIL acquisition, in line with previous expectations.

And finally, we expect diluted shares outstanding for fiscal 2022 to be approximately 159 million shares.

For the first quarter of 2022:

<u>For consolidated Illumina:</u>

- We expect revenue to increase 10% - 12% year-over-year from the first quarter of 2021. This represents a sequential increase from the fourth quarter of 2021, reflecting a strong start to the year
- We expect non-GAAP operating margin to increase approximately 300 basis points sequentially primarily due to a decrease in operating expenses
- We expect non-GAAP tax rate to be in line with our full year 2022 guidance of approximately 19%
- We expect diluted shares outstanding to be in line with our full year 2022 guidance of approximately 159 million shares

<u>For Core Illumina:</u>

- We expect non-GAAP operating margin in Q1 to be in line with our full year 2022 guidance of approximately 28%

I'll now hand the call back over to Francis for his final remarks.

Francis deSouza, *President & Chief Executive Officer*

Thanks, Sam. To close, I'd like to thank our teams, our network of partners and the extraordinary scientists and clinicians we serve. I am incredibly excited for the many opportunities ahead. Today, more than 1 billion people are covered for genomic testing globally, and we expect this number to double within 5 years as genomics accelerates the adoption and potential of personalized medicine. Illumina will continue to support the growing number of patients around the world accessing the life-saving benefits of genomics – from oncology therapy selection, to reproductive health, genetic disease testing, and pathogen surveillance. We will also continue to push genomics to new frontiers like drug development and proteomics.

Additionally, we will enable discovery across these existing and new markets with a pipeline of innovative products and solutions developed in collaboration with our customers. It has been fantastic to see the strong interest and excitement across our customer base for our latest developments, including our breakthrough Chemistry X and our Infinity long-read technology. We expect to not only directly address unmet market needs, but also revolutionize what scientists and clinicians can expect from sequencing. Together, we are enabling genomic-based discoveries that can transform healthcare, and ultimately provide a brighter future for human health.

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for diluted net income per share, net income, gross margins, operating expenses, including research and development expenses and selling general and administrative expenses, operating income (loss), operating margins, gross profit, other income (expense), and free cash flow (on a consolidated and, as applicable, segment basis for our Core Illumina and GRAIL segments) in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The company's financial measures under GAAP include substantial charges such as amortization of acquired intangible assets, non-cash interest expense associated with the company's convertible debt instruments that may be settled in cash, and others that are listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release. Management has excluded the effects of these items in non-GAAP measures to assist investors in analyzing and assessing past and future operating performance, including in the non-GAAP measures relating to our Core Illumina and GRAIL segments. Additionally, non-GAAP net income and diluted earnings per share are key components of the financial metrics utilized by the company's board of directors to measure, in part, management's performance and determine significant elements of management's compensation.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

Use of forward-looking statements

This document 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 impact to our business and operating results of the COVID-19 pandemic; (ii) changes in the rate of growth in the markets we serve; (iii) the volume, timing and mix of customer orders among our products and services; (iv) our ability to adjust our operating expenses to align with our revenue expectations; (v) our ability to manufacture robust instrumentation and consumables; (vi) the success of products and services competitive with our own; (vii) 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; (viii) the impact of recently launched or pre-announced products and services on existing products and services; (ix) 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; (x) the risks and costs associated with the integration of, and our ability to integrate, GRAIL's business successfully to achieve anticipated synergies, including the restrictions on integration during any hold separate period or any delay in integration following any hold separate period; (xi) the risk that disruptions from the consummation of our recent acquisition of GRAIL or any associated legal or regulatory proceedings or obligations will harm our business, including current plans and operations; (xii) potential adverse reactions or changes to business relationships resulting from the consummation of our recent acquisition of 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) our ability to successfully identify and integrate acquired technologies, products, or businesses; (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 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.