ILMN Q1 Fiscal Year 2022 Earnings Call
Prepared Remarks – May 5, 2022

Salli Schwartz, *Investor Relations*

Good afternoon, everyone, and welcome to our earnings call for the first quarter of 2022.

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 an independent 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.

We maintained strong momentum across regions and markets in the first quarter. We saw particular strength in oncology, genetic disease testing, and infectious disease and achieved record quarterly performance in the Americas and APJ. I'll share an overview of our results, as well as our progress across our portfolio and markets, before turning it over to Sam for additional detail. Before I begin, I'd like to extend my thoughts to everyone dealing with the war in the Ukraine, and we will continue to support humanitarian efforts to help the affected communities.

Starting with our financial results... First quarter revenue of approximately $1.22 billion increased 12% year-over-year. We received record orders in the quarter, with sequencing consumables orders surpassing $1 billion for the first time. And, we exited the quarter with record total backlog, a great leading indicator for upcoming quarters.

Turning now to performance across our platforms:

Sequencing instrument shipments grew more than 20% year-over-year in the first quarter.

We shipped a record number of NovaSeqs and received record NovaSeq consumables orders, demonstrating both strong demand in the instrument's sixth year since launch and addition to our substantial installed base for future consumables revenue. More than half of NovaSeq shipments were to clinical customers, and we saw particular strength in oncology testing as high-throughput sequencing and comprehensive genomic profiling become increasingly critical to cancer patient care.

In mid-throughput, the installed base of NextSeq 1000/2000 instruments has now exceeded 1,000. Additionally, Q1 shipments for the P1 flow cell that we launched in the fourth quarter of 2021 were nearly double our expectations. We're seeing strong adoption of the P1 flow cell from both new customers and customers moving up the throughput spectrum, as well as broad kit utilization from existing NextSeq 1k/2k users due to the P1 flow cell's efficiency and cost-effectiveness.

Our low-throughput platforms also continue to perform well and provide a great entry point to sequencing. More than one-third of shipments in the first quarter were to new-to-Illumina customers, further increasing our installed base and enabling adoption of sequencing across a broad customer network.

Looking now at our markets:

Oncology testing sequencing consumables grew almost 20% year-over-year, as we continue to help democratize sequencing in this critical area of healthcare. In March, we received CE IVD approval for TruSight Oncology Comprehensive in Europe. This new, in vitro diagnostic comprehensive genomic profiling kit is the first distributed IVD for both DNA and RNA. TSO Comp IVD covers a range of mutations and biomarkers associated with the European Society for Medical Oncology guidelines, maximizing opportunities to find actionable information from each patient's biopsy. We are pleased with the early reception and excitement from customers across the EU, and we look forward to introducing TSO Comp IVD in other markets, including Japan, where we recently applied for regulatory approval.

The TSO Comp IVD offering will build upon the incredible expansion we're seeing globally for TSO 500, which grew nearly 120% year-over-year in Q1.

Also in oncology, customer and provider interest for Galleri, GRAIL's groundbreaking multi-cancer early detection blood test, is growing. To date, Galleri has been prescribed by more than 2,400 prescribing physicians, and GRAIL has entered into 34 partnerships with health systems, employers and insurers who are investing in multi-cancer early detection to improve outcomes. This includes GRAIL's recent partnership with Point32Health, the combined organization of Harvard Pilgrim Health Care and Tufts Health Plan. Point32's two-phased pilot of Galleri marks GRAIL's first collaboration with a commercial health plan in the U.S. Last week, GRAIL also announced a multi-year partnership with Munich Re Life US to provide Galleri as part of Munich Re's commitment to advancing cancer early detection and treatment. Munich Re and GRAIL will collaborate to enable carriers and distributors to offer Galleri to existing policyholders who are at high risk of cancer, such as those aged 50 and older. Also, the NHS Galleri trial continues to progress, with more than 90,000 of the planned 140,000 participants enrolled.

To support the increasing interest around Galleri, and to further their R&D efforts, the GRAIL team has almost doubled in the last 8 months to more than 850 employees, with another almost 250 job openings. Looking ahead, GRAIL plans to expand its existing salesforce for Galleri to reinforce launch traction and drive continued market adoption.

Turning to our other markets, genetic disease testing had another record quarter, as we enable expanding coverage and utilization of whole genome sequencing, or WGS, globally. In the US, critically ill infants are now eligible for WGS in California, Oregon and Maryland through Medicaid, providing coverage for an additional 17 million lives. And last week, we announced an agreement with Germany's Hannover Medical School to implement the use of WGS for critically ill children suspected of having a genetic or rare disease. This project, like our collaborations with other children's hospitals around the world, helps demonstrate how WGS can support earlier diagnoses and treatment for children in neonatal and pediatric intensive care.

In reproductive health, coverage, reimbursement, and evidence generation continue to increase, particularly in Europe. Both Spain and Italy have expanded coverage for non-invasive prenatal testing, or NIPT, with Germany likely doing so as well later this year.

In infectious disease and microbiology, we saw a record quarter with incremental global investments in pathogen identification, monitoring and resistance. While this was driven by COVID surveillance, we are also seeing traction for other pathogens, including tuberculosis. In March, the Milken Institute called for a network of multi-sector stakeholders to collaborate on data, insights and responses for early disease outbreaks. In the same month, the World Health Organization announced a 10-year strategy to use the power of genomics for global pan-pathogen surveillance, demonstrating the growing trend for broader pathogen monitoring. For example, FIND , a Geneva-based global alliance for diagnostics, established Seq&Treat, a global initiative using sequencing for drug resistant tuberculosis which affects nearly half a million people globally each year. We are providing instruments to help Seq&Treat accelerate discovery for the half of patients with drug resistant tuberculosis who are not currently successfully treated.

In our Research and Applied markets, we continue to see genomic research expanding across applications and disease states. Lab budgets specifically for NGS are increasing, including for both academic labs growing approximately 9.5% and pharmaceutical and industry labs growing at approximately 14% . As part of our efforts to support growth in genomic research, we recently partnered with Allelica to provide cutting-edge polygenic risk score digital tools to our customers. With Allelica's software, researchers can better identify individuals with high genetic susceptibility for developing life-threatening diseases. Also in research, increasing utilization and demand for multiomics, particularly proteomics, is driving sequencing growth and opportunities. Our partnership with Somalogic to co-develop a high plexity, high sensitivity and high specificity proteomics assay is progressing well. Together, we look forward to empowering the next generation of novel insights.

Another fast-developing area is the integration of multiomic and genomic data into drug development and clinical trials. Drug development R&D spend is more than $123 billion annually, yet more than 90% of drugs that enter Phase 1 clinical trials fail to reach clinical approval, with fewer than 70 entering the market each year. A main contributor to this high failure rate is target selection, where genomic-based methods can more than double success rates and dramatically improve cost and speed to market. Because more than 85% of the human proteome cannot currently be targeted pharmacologically, we are excited to support genetic-led discovery and emerging drug modalities that could significantly expand the total number of potential therapeutic targets. In addition to our partnership with Nashville Biosciences, today we announced a partnership with Deerfield Management. This first-of-its-kind collaboration will combine Illumina's genetic and AI-led approach to discovery with Deerfield's expertise in pre-clinical and clinical development. Together, we plan to translate genetic insights into new therapies across diseases with unmet medical needs and drive a step change in the pace and efficiency of drug development. This will ultimately help more patients access potentially life-changing therapies. We also recently announced a collaboration with Janssen (JAN-sen) to accelerate development of precision medicines. This includes developing companion diagnostics across our new TSO Comp IVD, and exploring discovery and research initiatives for drug and biomarker targets across disease states. These collaborations are a few of what we expect will be many pharmaceutical strategic partnerships leveraging the power of Illumina to create precision medicine at scale.

Overall, we were pleased with our first quarter performance, including 20% sequencing instruments growth and sequencing consumables orders surpassing $1 billion for the first time. The significant, ongoing growth in our installed base, as well as our record backlog exiting the quarter, lay the groundwork for continued acceleration of our business in the coming quarters. I'm also really excited about the work we're doing with our collaboration partners. These efforts underpin our ongoing progress in driving sequencing trends to improve human health. I'll now turn the call over to Sam to discuss additional details on our results and outlook. Sam?

Sam Samad, *Chief Financial Officer*

Thanks, Francis.

As a reminder, our first 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

current 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 first quarter revenue of $1.223 billion grew 12% year-over-year with Core Illumina sequencing instruments growing at 20% and sequencing consumables growing at 13%. Sequencing consumables growth was solid across both clinical and research, with both market segments growing in double digits .

For the first quarter, GAAP net income was $86 million, or $0.55 per diluted share, and non-GAAP net income was $169 million, or $1.07 per diluted share, which included dilution from GRAIL's non-GAAP operating loss of $134 million for the quarter. Our non-GAAP tax rate was 17.8%, which decreased 250 basis points year-over-year primarily due to tax expense recognized in Q1 2021 on certain foreign subsidiary earnings that are no longer indefinity reinvested . The increase in the non-GAAP tax rate from Q4 2021 was primarily due to the impact of R&D expense capitalization requirements implemented by the Tax Cuts and Jobs Act of 2017 . Our weighted average diluted share count for the quarter was approximately 159 million.

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

Core Illumina revenue grew 12% year-over-year to $1.221 billion . Core Illumina sequencing consumables revenue grew 13% year-over-year to $784 million, driven by the growing NovaSeq installed base across clinical and research markets . Sequencing instruments revenue for Core Illumina reached a new high, growing 20% year-over-year to $212 million. This was driven by another record quarter of NovaSeq system shipments resulting from accelerating demand in oncology testing, which accounted for almost 40% of the NovaSeq shipments for the quarter . We also continued to see strong demand for NextSeq 1000/2000 from new to Illumina customers, who represented more than a third of the shipments for the quarter .

During the first quarter, COVID-19 surveillance contributed approximately $53 million in sequencing consumables revenue and $7 million in incremental instruments revenue driven by the sustained focus on pathogen surveillance .

Core Illumina sequencing service and other revenue of $111 million was up slightly year-over-year driven by growth in instrument service contracts .

Moving to regional results for Core Illumina:

Revenue for the Americas region was $646 million, growing 15% compared to the prior year period. Growth in the region was primarily driven by strength in three key areas: First, continued sample growth in oncology therapy selection; second, emerging applications such as single cell and proteomics; and third, pathogen surveillance initiatives .

EMEA delivered revenue of $316 million, representing 4% growth year-over-year, driven by strength across both clinical end markets and emerging markets, partially offset by the conclusion of the UK BioBank program in the third quarter of 2021, as expected . EMEA growth was modestly impacted by lower shipments to Russia as a result of the war in Ukraine.

Greater China revenue of $127 million was flat year-over-year as the region's robust clinical demand in hospitals was offset by COVID-19 restrictions that began in March .

Finally, APJ revenue of $132 million grew 33% year-over-year, with stronger than expected growth from large-scale research projects, oncology and genetic disease testing, and pathogen surveillance initiatives .

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

Core Illumina non-GAAP gross margin of 70.2% decreased 30 basis points year-over-year due primarily to increased freight costs attributable to broader global supply chain pressures .

Core Illumina non-GAAP operating expenses of $505 million were up $85 million year-over-year due primarily to headcount growth and investments we are making in R&D and operations to support the growth and scale of our

business . Despite the year-over-year increase, non-GAAP Core Illumina operating expenses for the first quarter were roughly $15 million lower than we expected as a result of the slower hiring and timing of project spend shifting into the second quarter .

Transitioning to the financial results for GRAIL:

GRAIL revenue of $10 million for the quarter consisted primarily of Galleri test fees . GRAIL non-GAAP operating expenses totaled $139 million for the quarter, which consisted primarily of expenses related to headcount and clinical trials . GRAIL non-GAAP operating expenses were approximately $15 million lower than we expected due to timing of spend shifting to the second quarter .

Moving to consolidated cash flow and balance sheet items:

- Cash flow from operations was $172 million;
- DSO was 46 days compared to 49 days last quarter;
- First quarter 2022 capital expenditures were $61 million and free cash flow was $111 million; and
- We did not repurchase any common stock in the quarter.

We ended the quarter with approximately $1.4 billion in cash, cash equivalents and short-term investments.

Moving now to 2022 guidance:

- We continue to expect consolidated revenue growth of 14% - 16% for 2022, including Core Illumina revenue growth of 13% – 15%, and GRAIL revenue of $70 - $90 million.
- And we continue to expect non-GAAP earnings per diluted share in the range of $4.00 to $4.20, which includes dilution from GRAIL of $3.75, in line with previous expectations.

We are reaffirming all other financial guidance for full year 2022 we provided in February, with the exception of our consolidated non-GAAP tax rate, which we now expect to be approximately 18%. Our outlook for 2022 assumes the lockdowns in China ease by June, and our business in China recovers in the second half of 2022.

For the second quarter of 2022:

- We expect consolidated revenue to increase 7% - 9% year-over-year from the second quarter of 2021, including an approximately 300-basis point headwind on overall revenue growth related to current COVID-related shutdowns in China .
- We expect consolidated non-GAAP gross margin to be roughly flat sequentially from the first quarter of 2022.
- We expect consolidated non-GAAP operating margin to be approximately 10%, with the sequential decrease from Q1 2022 driven primarily by a $60 million increase in Core Illumina operating expenses and a $25 million increase in GRAIL operating expenses. The expected increase in operating expenses are driven primarily by our typical ramp in compensation-related expenses, including our merit increase cycle, the timing of hiring and project spend shifting into Q2 from Q1, and a ramp in Grail’s operating expenses.
- We expect Core Illumina non-GAAP operating margin to be approximately 23% in the second quarter.
- We expect the second quarter consolidated non-GAAP tax rate to be in line with our full year 2022 guidance of approximately 18%.

- And lastly, we expect diluted shares outstanding to be in line with our full year 2022 guidance of approximately 159 million shares.

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

Francis deSouza, *President & Chief Executive Officer*

Thanks, Sam. As we look ahead, our business fundamentals remain very strong. The continued growth in our installed base, our record backlog exiting Q1, and the increasing volumes we're seeing as customers pursue higher-intensity sequencing applications, all bode well for future growth, especially in the second half of this year.

We also continue to drive increased access and deliver breakthrough genomic innovations. We are making progress across our innovation pipeline, with data and excitement building around our breakthrough Chemistry X, our Infinity long-read technology, and our NovaSeq Dx platform. We will provide additional updates on these technologies in the coming months, and we look forward to welcoming thousands of customers from around the world to the Illumina Genomics Forum in late September.

Also, we are pleased to invite you to join us this Fall for our Investor Day, which will be held Monday, October 3rd in San Diego, following the Illumina Genomics Forum. We will be announcing additional details in the coming days.

Across our global business, we are at the forefront of genomics in healthcare. We are excited to deliver new technologies, collaborate with pioneering partners, champion patient access, and support incredible researchers and clinicians around the world as we collectively unleash the power of genomics for the betterment of human health.

I'll now invite the Operator to open for Q&A.

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for earnings per diluted share, net income, gross margin, operating expenses, including research and development expense and selling general and administrative expense, operating income (loss), operating margin, 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 among 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 related to our Core Illumina and GRAIL segments. Additionally, non-GAAP net income and earnings per diluted 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 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 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 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 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.