ILMN Q3 Fiscal Year 2022 Earnings Call
Prepared Remarks – November 3, 2022

Salli Schwartz, *Vice President, Investor Relations*

Hello everyone, and welcome to our earnings call for the third 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 Joydeep Goswami, Chief Strategy and Corporate Development Officer as well as Interim Chief Financial Officer. Francis will provide an update on the state of Illumina's business and Joydeep 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.

Illumina delivered revenue of $1.1 billion in the third quarter, up 1% year-over-year, and 3% on a constant currency basis, and in line with our expectations despite deepening macroeconomic challenges.

Looking at our Q3 performance across our platforms:

In high-throughput, we shipped 65 NovaSeq 6000s in Q3, down from the prior year, in line with our expectations. We had a fantastic customer response to the NovaSeq X Series launch at the Illumina Genomics Forum, where we reached more than 12,000 viewers in our Innovation Roadmap Session. Labs are excited by NovaSeq X's industry-leading power, efficiency and cost-effectiveness. And they love, in their words, its 'unexpected and revolutionary' sustainability breakthroughs including ambient shipping and a 90% reduction in packaging weight and waste. Customer traction for NovaSeq X is exceeding our expectations. We already have an advanced pipeline of more than 170 instruments in

addition to the 50 orders we have received. Our manufacturing scaling is proceeding well and we expect to ship 40-50 NovaSeq X units in Q1 2023 and over 300 units in the year.

At the Illumina Genomics Forum, we also launched the NovaSeq 6000 Dx, the first-ever FDA-registered and CE-marked IVD high-throughput sequencer. We are excited to now provide Dx offerings across the throughput spectrum.

In mid-throughput, we saw record NextSeq 1K/2K shipments, which were up 40% year-over-year. This increase was driven by accelerated adoption of multiomics, primarily in cancer research, and cellular and molecular biology, both by new and existing customers. And, as part of our ongoing innovation roadmap, our launch of X-LEAP SBS Chemistry on NextSeq 1k/2k remains on track for 2024.

Finally, low-throughput shipments were up 13% year-over-year. These instruments continue to provide a great entry point to sequencing.

This continued demand for our sequencing platforms across the throughput spectrum will contribute to a larger installed base and drive future consumables revenue.

We're also receiving extremely positive feedback from early access customers of Illumina Complete Long Reads, and Complete Long Reads with Enrichment, and we are expanding to additional customer sites. Customers appreciate Illumina's unique ability to deliver a high quality, cost effective, and complete view of the genome on a single platform, enhancing utility across our installed base.

Shifting to our market segments…

Clinical sequencing consumables shipments were up 5% year-over-year, driven by continued growth in oncology testing and in genetic disease testing. Sequencing run activity by our Clinical customers remained robust. As expected though, lab expansion delays and consumables inventory deleveraging have persisted due to broader macro dynamics.

Oncology testing consumables grew 9% year-over-year, as our larger customers continued to shift toward higher throughput applications, our decentralized clinical testing customers ramped up business, and new customers came online. Our market-leading True Sight Oncology assay, TSO 500, grew 17% year-over-year as large customers took advantage of the assay's utility, reimbursement, and proficiency. TSO 500 adoption continues to grow, with total accounts approaching 500.

Also in oncology, GRAIL continued to make good progress in Q3, delivering clinical results and signing up a broad range of customers across the healthcare ecosystem, including health systems and life insurance providers. GRAIL announced a first-of-its-kind partnership with Carrum Health, the first digital health company connecting employers and employees to centers of excellence through a value-based care platform. The partnership provides Galleri as part of Carrum's oncology offering to self-insured employers. Also, John Hancock, the US division of Manulife with over 1.5 million life insurance participants, recently became the first life insurance carrier to offer Galleri. The GRAIL team expanded its clinical sales force in Q3 and is seeing test orders increase.

Evidence for Galleri's efficacy also continues to grow. In September at ESMO, GRAIL presented compelling final results from its PATHFINDER study. The study demonstrated that when added to standard-of-care screening, Galleri multi-cancer early detection testing more than doubled the number of cancers detected compared to standard screening alone. In fact, Galleri detected more cancers than all US Preventive Services Task Force-recommended standard single cancer screenings combined. And, Galleri's positive predictive value of about 40% is significantly higher than commonly used screening tests, like the annual screen for colorectal cancer which has a PPV of 8.7% or the biennial mammography screen with a PPV of 4.4%.

Galleri is the only multi-cancer early detection test available on the market. An analysis of the first 38,154 Galleri commercial test results in a real-world setting shows high concordance with the PATHFINDER study results.

In addition, PATHFINDER study participants' experience with the Galleri test has also been positive, with 97.1% of participants reporting a high level of satisfaction with the test.

In Genetic Disease Testing, sequencing consumables shipments grew 11% year-over-year. National health system funding for rare diseases is increasing in multiple geographies, including EMEA and China. And, evidence generation continues to grow. For example, in September, Genetics in Medicine published a study from Karolinska Institute indicating that genome sequencing is a sensitive first-line test for neuro-developmental disorders. We are also seeing customer excitement around the potential for NovaSeq X to create efficiencies for both whole genome and whole exome sequencing.

Turning to our Research and Applied markets, sequencing consumables shipments were down 8% year-over-year as customers continued to manage inventory and capital spend, and due to expected headwinds from COVID surveillance and the completion of the UK Biobank project in Q3 2021. We continue to support our customers through these dynamics, and at the same time are making ongoing progress in facilitating genomic-based drug discovery. As this area continues to grow, we will partner with a range of pharmaceutical companies, like our recent collaboration with AstraZeneca, to help accelerate genomics and find promising drug targets based on omic insights.

In our infectious disease and microbiology markets, we are broadening genomic opportunities across disease states. For example, we recently announced a partnership with Genoscreen to help countries impacted by tuberculosis to more effectively detect and combat multi-drug resistant strains. TB claims more than 1.5 million lives each year, and for the first time in a decade, deaths are on the rise after the pandemic. We hope that with this work, we can help vulnerable populations and make progress toward eliminating TB worldwide.

Turning now toward the end of 2022 and entering 2023, we expect the macroeconomic challenges we have previously discussed to persist into 2023, and we feel that it is prudent to adjust our near-term guidance accordingly. Joydeep will address our revised FY 2022 guidance shortly.

Despite the near-term challenging macroeconomic environment, we remain confident in our long-term growth trajectory. Customers around the world continue to share their excitement for our latest innovations. We're staying focused on supporting them and advancing our innovation roadmap to accelerate the genome era.

I'll now turn the call over to Joydeep for more detail on the quarter and on our year-end outlook.

Joydeep Goswami, *Chief Strategy and Corporate Development Officer, Interim Chief Financial Officer*

Thanks, Francis.

As a reminder, our third 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, and then conclude with additional remarks on our current outlook for 2022. I will be discussing 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 earnings release and in supplementary data available on our website.

In the third quarter, consolidated revenue was $1.12 billion, up 1% year-over-year, or 3% on a constant currency basis, net of the effects of hedging. As expected, our core business growth was impacted by anticipated headwinds from customer supply chain issues that delayed lab expansions, as well as tighter customer inventory and capital management due to the challenging macroeconomic environment, including inflation and the negative impact of FX. These dynamics have persisted, and in some cases accelerated through the third quarter, leading to our guidance reduction for the full year 2022, which I will address later in my remarks.

For the third quarter, GAAP net loss was $3.82 billion, or a net loss of $24.26 per diluted share, which includes goodwill impairment of $3.91 billion related to the GRAIL segment, primarily due to the negative impact of current capital market conditions and higher discount rates, including a standalone risk premium, on the fair value calculation of the GRAIL segment.

Non-GAAP earnings were $54 million, or $0.34 per diluted share, including dilution from GRAIL's non-GAAP operating loss of $148 million for the quarter.

Our non-GAAP tax rate was 43.2%, which increased from 25.8% last quarter and 13.2% in Q3 2021, primarily due to the increased impact of R&D expense capitalization requirements implemented by the Tax Cuts and Jobs Act of 2017.

Our non-GAAP weighted average diluted share count for the quarter was approximately 159 million.

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

Core Illumina revenue of $1.11 billion was approximately flat year-over-year, or up 3% on a constant currency basis, net of the effects of hedging.

Core Illumina sequencing consumables revenue of $725 million was approximately flat year-over-year. As expected, growth driven by the increased installed base was muted by the year-over-year impact of customer inventory and cash management, headwinds from foreign exchange rates, the conclusion of the UK BioBank project in Q3 2021, and the anticipated decrease in COVID surveillance revenue. Sequencing activity on our connected instruments for Clinical customers remained strong, while the pace of Research sequencing activity was tempered by various macroeconomic challenges Francis mentioned.

Sequencing instruments revenue for Core Illumina declined 10% year-over-year to $162 million, driven by lower NovaSeq shipments due to expected customer lab expansion delays and capital management, as well as purchasing delays in advance of next year's availability of NovaSeq X. This decline was partially offset by record NextSeq 1K/2K shipments, which grew 40% year-over-year as we continue to see strong adoption by new-to-Illumina customers.

During the third quarter, COVID surveillance contributed approximately $28 million in total revenue, comprised of $23 million in sequencing consumables and $5 million in instruments. This was in line with our expectations and down nearly 50% year-over-year, driven by lower testing samples and a decline in instrument shipments as COVID surveillance capacity was largely established in 2021.

Core Illumina sequencing service and other revenue of $123 million was up 12% year-over-year, driven primarily by higher instrument service contract revenue on a growing installed base and an increase in core licensing revenue.

Moving to regional results for Core Illumina:

Revenue for the Americas was $592 million, up 2% year-over-year, primarily driven by NovaSeq consumables growth due to demand from genetic disease testing, oncology testing and cancer research customers. As expected, growth in the region was largely offset by customer lab expansion delays and inventory and capital management, as well as a decline in COVID surveillance revenue.

EMEA revenue of $290 million represented a 7% decrease year-over-year, or a 2% decrease on a constant currency basis, net of the effect of hedges. Strong growth in mid-throughput instrument shipments driven by clinical demand was more than offset by the conclusion of the UK BioBank program and a decline in COVID surveillance revenue.

Greater China revenue of $133 million represented a 9% increase year-over-year, or a 14% increase on a constant currency basis. Record quarterly revenue in the region was driven by growth in sequencing consumables for routine NGS-based research that resumed after the COVID restrictions that began in March this year were lifted, as well as strong sales of NovaSeq 6000 primarily to Clinical customers for oncology testing. We continue to expect base business growth to be impacted by headwinds from the zero-COVID-19 policy, exchange rates, and slowing GDP growth in the region.

Finally, APJ revenue of $95 million grew 6% year-over-year, or 10% on a constant currency basis, net of the effects of hedges. Growth in the region was driven by strong demand in emerging markets, notably in India, Indonesia and Thailand, and continued strength in NIPT and oncology testing.

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

Core Illumina non-GAAP gross margin of 68.9% decreased 240 basis points year-over-year primarily due to less fixed cost leverage on lower manufacturing volumes and higher freight costs, partially offset by favorable product mix.

Core Illumina non-GAAP operating expenses of $514 million were up $36 million year-over-year due primarily to headcount growth and investments we are making in R&D to support the continued advancements of our innovation roadmap. Despite the year-over-year increase, non-GAAP Core Illumina operating expenses were approximately $25 million lower than we had originally planned, as a result of lower performance-based compensation expense given our lower revenue outlook, as well as cost containment initiatives focused on prioritizing hiring and discretionary spend, including travel.

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 $149 million for the quarter and consisted primarily of expenses related to headcount and clinical trials.

Moving to consolidated cash flow and balance sheet items:

- Cash flow used in operations was negative $(52) million, a net outflow due to a one-time payment related to the litigation settlement with BGI that we mentioned to you last quarter;
- DSO was 51 days compared to 50 days last quarter due to revenue linearity;
- Third quarter 2022 capital expenditures were $67 million and free cash flow was negative $(119) million;
- We did not repurchase any common stock in the quarter.

We ended the quarter with approximately $1 billion in cash, cash equivalents and short-term investments.

Moving now to 2022 guidance:

We now expect full year 2022 consolidated revenue to be flat to up 1% year-over-year, including approximately flat Core Illumina revenue compared to 2021 and GRAIL revenue in the range of $55 million to $65 million. Our revised outlook for the full year reflects the more challenging expected macroeconomic headwinds we observed through October.

For Core Illumina, approximately one-third of the reduction in our 2022 guidance from our previous expectations is primarily driven by delayed recruitment for some large research projects in the Americas and Europe and the impact of inflation on Research customers in Europe. The remaining two-thirds of this reduction is split approximately 70/30 across two higher-than-expected factors:

(1) delays in instruments and consumables purchases primarily due to the excitement around NovaSeq X;

and

(2) negative FX impact and consumables inventory deleveraging.

For the full year we now expect Core Illumina sequencing revenue to be approximately flat year-over-year. This continues to include intercompany sales to GRAIL of approximately $25 million, which are eliminated in consolidation.

Within Core Illumina sequencing revenue, we now expect:

- Instrument revenue to be slightly down year-over-year and consumables revenue to be approximately flat, which reflects NovaSeq pull-through slightly below our guidance range of $1.1 to $1.2 million per system for 2022, primarily driven by the recruitment challenges at some large Research and popgen customers.

- The remainder of our pull-through ranges are in line with the historical guidance ranges that we have previously provided.

- For full year 2022, we now expect consolidated non-GAAP operating margin in the range of 9.5% - 10% and Core Illumina non-GAAP operating margin of approximately 23%, reflecting our lower revenue outlook.

We expect a consolidated non-GAAP tax rate of approximately 7%, which continues to assume that the R&D expense capitalization requirements implemented by the Tax Cuts and Jobs Act of 2017 will be repealed in Q4.

We now expect non-GAAP earnings per diluted share in the range of $2.35 to $2.50 which includes a lower than previously expected non-GAAP operating loss dilution from GRAIL of approximately $600 million.

Lastly, we continue to expect diluted shares outstanding of approximately 159 million shares for 2022.

We expect these macroeconomic headwinds to persist into 2023, and are proactively aligning our operating expenses accordingly while maintaining our focus on sustainable long-term revenue growth. We are well-positioned to seize opportunities to scale in key areas that align to customers' future needs and our innovation roadmap. At the same time, you will see us gain additional scale and efficiencies from other areas. We will continue to adapt our investments and expenses to support our customers, drive further progress in the genomics industry, and enable our long-term growth.

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

Francis deSouza, *President & Chief Executive Officer*

Thanks, Joydeep.

As Joydeep shared, we will continue to identify opportunities to mitigate the near-term effects of the global economic environment. At the same time, we are prioritizing our innovation roadmap, and we remain confident in our long-term growth trajectory. As I shared earlier, we are hearing high praise for the innovations we announced at the Illumina Genomics Forum, from Illumina Complete Long Reads to our most powerful and most sustainable sequencer yet, the NovaSeq X Series. These innovations will continue to evolve the genomics industry, and we look ahead with tremendous optimism over the long term. We will help our customers through the current challenges and seize the potential of the genome era – together.

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for diluted earnings per share, net income, gross margin, operating expenses, including research and development expense, selling general and administrative expense, legal contingencies and settlement, and goodwill impairment, operating income (loss), operating margin, gross profit, other income (expense), constant currency revenue growth, 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, as well as the effects of currency translation. 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 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 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, including any related appeals, 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) 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; (xiv) our ability to obtain approval by third-party payors to reimburse patients for our products; (xv) our ability to obtain regulatory clearance for our products from government agencies; (xvi) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business; (xvii) our ability to successfully identify and integrate acquired technologies, products, or businesses; (xviii) the application of generally accepted accounting principles, which are highly complex and involve many subjective assumptions, estimates, and judgments and (xix) 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.