ILMN Q3 2021 Earnings Call

Prepared Remarks – November 4, 2021

Brian Blanchett, *Investor Relations, Illumina*

Good afternoon everyone, and welcome to our earnings call for the third quarter of 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. Also joining us today is Bob Ragusa, Chief Executive Officer of GRAIL. Francis will provide an update on the state of Illumina's business, Bob will provide updates on GRAIL's business, and Sam will review both Core Illumina and GRAIL financial results.

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 now turn the call over to Francis.

Francis deSouza, *President & Chief Executive Officer, Illumina*

Thank you, Brian, and good afternoon everyone.

Illumina's third quarter was another exceptionally strong quarter, with $1.108 billion in revenue, up 40% year-over-year and, once again, significantly ahead of expectations. Our customer base continues to expand rapidly and in the first three quarters of 2021, we added 50% more new customers than in all of 2020, or 2019. Because of this strength across our business, we are raising our full year revenue growth outlook, for the third quarter in a row, to approximately 36%. This is approximately double the growth rate, and $567 million higher than the midpoint of the range we guided to the beginning of the year.

I will talk through the third quarter results for Core Illumina, as defined as Illumina other than GRAIL, and then I'll turn the call over to Bob Ragusa, the CEO of our GRAIL subsidiary, to cover the GRAIL business.

Core Illumina revenue was $1.106 billion. Sequencing instrument revenue was up 65% year-over-year, and we exited the quarter with a record instrument backlog, a positive leading indicator for future revenue. Sequencing activity in the quarter was also strong, with sequencing consumable revenue up 45% year-over-year, setting a new record.

Our high-throughput platform order volume is accelerating. Oncology testing, population sequencing and drug discovery initiatives drove record NovaSeq consumable and instrument shipments. Oncology testing customers represented the highest proportion of NovaSeq shipments for the quarter as large oncology testing labs added to their fleets to support

expanded reimbursement for therapy selection testing. Drug discovery is emerging as a new application for high-throughput sequencing, with opportunities across common diseases ranging from obesity to aging.

Our mid-throughput platforms also drove growth and expanded our installed base. In the third quarter, over 50% of NextSeq 1000 and 2000 placements were to new-to-Illumina customers or to customers upgrading from low-throughput instruments. These instruments continue to unlock new applications. Researchers at Tulane School of Medicine are using the NextSeq 2000 for single-cell experiments focused on infection and inflammation. The team is working to develop inhaled vaccines for pneumonia and used single-cell RNASeq on a NextSeq 2000 to study the immune cells elicited by this vaccine platform in a recent paper published in Science Immunology.

Benchtop platforms also saw significant growth year-over-year, with the highest number of MiSeq shipments since Q4 2015. MiSeq, coupled with our COVIDSeq 96-sample assay, is enabling labs around the world to engage in local pathogen surveillance. This quarter, MiSeq placements in both Argentina and Brazil brought COVID surveillance to local communities in conjunction with broader national programs.

Now turning to Clinical and Research & Applied segments.

Oncology testing, our largest market segment, had another record quarter. Sequencing is becoming the standard of cancer care in therapy selection, which is driving robust demand for Illumina sequencers, and our oncology testing customers are rapidly scaling their fleets in response. Reimbursement for genetic testing for therapy selection continues to expand, with over 70% of insured lives in the US now covered for these tests. Additionally, there are over 60 targeted and immunotherapy treatments currently on the market, highlighting the power of comprehensive genomic profiling in matching patients to treatments.

TruSight Oncology 500, our research-use only comprehensive genomic profiling assay, had another record quarter, with over 340 customers now using the assay in their labs. In September, we announced a CDx partnership with Merck to develop and commercialize tests leveraging TSO 500 content and an HRD status based on Myriad's MyChoice in patients with ovarian cancer. Approximately 300,000 women around the world will be diagnosed each year with ovarian cancer, the fifth deadliest cancer for women. This partnership will help these patients access additional treatment options with the goal of improving care.

In Reproductive Health, we saw another quarter of strong year-over-year growth. Almost 80% of pregnancies in the US are now covered for non-invasive prenatal testing, and we are seeing additional progress as states begin to incorporate the ACOG guideline revision from last year into their prenatal screening programs. In California, the prenatal screening program is being revised to include non-invasive prenatal testing, and the state has now issued a request for proposal. NIPT is increasingly being incorporated into guidelines outside the US as well. In September, the Italian Ministry of Health issued new guidelines supporting the use of NIPT in a contingent model. With the continued momentum in coverage and guidelines, our end-to-end VeriSeq V2 solution is gaining traction across global markets.

Genetic Disease testing also posted another strong quarter, as broad reimbursement and compelling clinical utility data drive a shift to whole genome sequencing. This quarter, the results of the groundbreaking NICUSeq trial, co-authored by Illumina scientists, were published in JAMA Pediatrics. The randomized time-delayed trial demonstrated that clinical whole genome sequencing drives a two-fold improvement in both diagnostic efficacy and change of clinical management for acutely ill newborns. We are working to ensure that families and NICU patients around the world can access these tests. In the US, Michigan recently became the first state to offer rapid Whole Genome Sequencing to acutely ill infants and children regardless of insurance, and other states like California and Florida are making progress in this direction as well. Outside the US, last week we announced a pilot program in Israel to implement whole-genome sequencing for critically ill infants suspected of having a genetic disorder in neonatal intensive care units. This program will accelerate time to diagnosis for these patients and support rapid clinical decision making.

Turning to our Research and Applied segments, we saw another strong quarter of sequential and year-over-year growth.

The 30-plus population genomics initiatives that we support around the world drove growth in the quarter. The accuracy and scalability of our sequencing platforms, combined with our end-to-end solutions like Illumina Connected Analytics,

make Illumina an ideal partner for large sequencing initiatives. The value of these population programs is expanding across clinical outcomes, research, and drug discovery. This traction is generating significant interest and investment for additional programs, like Our Future Health – the UK's largest-ever research program focused on developing new ways to detect, treat and prevent disease. Just yesterday, we announced that Illumina Connected Analytics solutions are being used by HostSeq, part of the Canadian COVID-19 Genomics Network. Our sequencing and bioinformatics solutions will be used to identify biomarkers that can help predict potential risk of serious disease and support the development of novel therapeutics to combat COVID-19. We anticipate these types of population programs will become increasingly critical to innovation as their findings translate into greater use of sequencing in clinical workflows and actionable data for drug discovery. We are already seeing this with the initial data from the UK BioBank as the program concludes. Regeneron is utilizing the UK BioBank data in multiple ways, including to find more than 500 genes with variant trait associations linked to higher risk of diseases like hypertension, asthma, and liver disease, and as part of their dataset to create new obesity medicines in partnership with AstraZeneca. And, companies like Relay Therapeutics are utilizing genomic data, along with AI and machine learning, to advance drug discovery.

COVID surveillance drove $55 million in sequencing shipments in the quarter, of which $15 million were instrument purchases, as concerns about variants continue to heighten the focus on surveillance efforts. We see the infrastructure for COVID surveillance as the foundation for broader pathogen surveillance to increase around the world. For example, CERI, a new genomics facility in South Africa, was launched this quarter with capabilities to bolster the pandemic and epidemic response across Africa. With resources like this in place, sequencing data from 51 of the 54 countries in Africa is now available in GISAID, and a total of 50,000 SARS CoV 2 genomes have been sequenced, two months ahead of Africa CDC's schedule.

Turning to GRAIL, in August we closed our acquisition, which we believe will help accelerate patient access and affordability for multi-cancer early detection screening. I am delighted to introduce Bob Ragusa on his first call as GRAIL's CEO. Bob most recently served as Illumina's Chief Operations Officer, and he has more than 30 years of experience in genomics. He played a critical role in providing the sequencing systems for the Human Genome Project, and was responsible for significantly scaling Illumina's business in more than 140 countries and enabled the first NovaSeq shipments. With his decades of deep expertise, Bob is uniquely positioned to lead GRAIL during a time of extraordinary growth and discovery. I will now turn the call over to Bob to discuss GRAIL's business updates.

Robert Ragusa, Chief Executive Officer, GRAIL

Thank you, Francis. I'm honored to lead the talented team at GRAIL as we advance the mission - to detect cancer early when it can be cured.

I am pleased to share a few thoughts on our recent progress.

First, I want to highlight Galleri commercial progress. We see significant pre-reimbursement opportunities for Galleri and are encouraged with the momentum across our three primary channels.

In the employer channel, we are gaining momentum and expect to announce notable new partnerships in the technology, industrial, professional services and transportation sectors. We are also successfully engaging with key high cancer risk area public sector employers such as firefighters.

For health systems, we are focused on establishing strategic agreements with influential systems in the medical community to increase awareness and experience with Galleri. Health systems are also strategic partners to generate real-world evidence in key patient communities and regions. To date we have signed agreements with several health partners who are planning to start providing access to Galleri in the fourth quarter. We are also in contract discussions with several additional influential health systems that we expect will begin offering Galleri to patients early next year.

In addition, we are excited to see interest from progressive and innovative payers, including Medicare Advantage, where we expect to communicate our first partnership soon.

Medical practices are an important driver of the Galleri launch. We have agreements with several of the largest primary-care private practice networks and expect to continue to expand in this area. We are focused on onboarding physicians in these networks and see positive prescriber trends.

We also recently partnered with Genome Medical, an independent healthcare provider, to serve individuals who prefer a telemedicine option. We launched this service several weeks ago on Galleri.com and believe this will be an important future pre-reimbursement growth driver. In addition, we partnered with PWN Health, a national telehealth network, to further extend our service capability for some employer programs.

Additionally, in September the state of New York granted approval for the Galleri test. The standard set by New York state represents one of the most rigorous levels of validation required for a Laboratory developed test.

Finally, there is tremendous excitement around the recent start of the NHS-Galleri study - a 140,000-participant, real-world randomized-controlled study that has generated widespread national and international media coverage. This is part of England's national priority to speed up earlier detection of cancer to improve survival. Enrollment has been robust and is on track with our expectations. Based on data generated from this initial study, access to Galleri could expand to around 1 million people in 2024 and 2025 and to a larger population after that time.

Lastly, I would like to note that the reported GRAIL revenue represents both revenue recognized from the sale of our Galleri tests and generated from our MRD collaboration agreements with biopharmaceutical companies.

We are encouraged by the initial test results generated with our partners and plan to expand the number of pilot studies to support development of MRD and PDx product opportunities.

We also expect MRD and PDx collaboration income will continue as an important component of GRAIL's revenue mix and is an attractive future growth driver of our business.

I look forward to sharing with you more about GRAIL's progress in the coming quarters.

Now, I'll turn it over to Sam.

Sam Samad, *Chief Financial Officer, Illumina*

Thanks, Bob

As a reminder, our third quarter financial results include the consolidated financial results for GRAIL for the period beginning after the acquisition closed on August 18, 2021. I'll start by reviewing our consolidated financial results, followed by segment results for Core Illumina and GRAIL, then conclude with our outlook. 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 the supplementary data available on our website.

Third quarter revenue once again significantly exceeded our expectations, growing 40% year-over-year to $1.108 billion, driven by Core Illumina revenue growth of 39% and $2 million of revenue from GRAIL.

For the third quarter, GAAP net income was $317 million, or $2.08 per diluted share, which included a $900 million gain from our previously held investment in GRAIL as a part of the acquisition and $654 million in day one compensation expense related to the GRAIL acquisition. Non-GAAP net income for the third quarter was $221 million, or $1.45 per diluted share, which included $0.19 of dilution from GRAIL operating losses and $0.06 of incremental dilution from the 9.8 million shares issued to fund the GRAIL acquisition. Our weighted average diluted share count for the quarter was approximately 153 million.

Moving to the rest of the consolidated P&L:

Non-GAAP operating expenses of $528 million increased $57 million sequentially, primarily due to the inclusion of GRAIL non-GAAP operating expenses of $50 million for the quarter and a $7 million increase in Core Illumina non-GAAP

operating expenses. Non-GAAP operating expenses increased $163 million year-over-year, driven by $50 million of GRAIL non-GAAP operating expenses, and a $113 million increase in Core Illumina non-GAAP operating expenses.

Non-GAAP other expense of $6 million increased $4 million sequentially and was $13 million lower than other income in Q3 of last year as expected. The year-over-year decline was primarily due to lower interest income on short-term investments as we repositioned our investment portfolio and subsequently liquidated our holdings to fund the GRAIL acquisition, as well as interest expense on the Term Notes issued in Q1 2021.

The non-GAAP tax rate of 13.2% decreased from last quarter and year-over-year due to the tax impact of including GRAIL in Illumina's consolidated results of operations. The decrease in the non-GAAP tax rate year-over-year was partially offset by discrete tax benefits recorded in the third quarter of 2020 related to prior year return adjustments and tax reserve releases.

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

Core Illumina revenue grew 39% year-over-year to $1.106 billion, driven by record shipments for both clinical and research. Core Illumina sequencing revenue of $1.013 billion grew 43% year-over-year and represented 92% of Core Illumina revenue.

Core Illumina sequencing consumables revenue grew 45% year-over-year to $723 million, led by record NovaSeq consumables shipments that grew over 50% year-over-year. Sequencing instruments revenue for Core Illumina grew 65% year-over-year to $180 million, driven by record NovaSeq shipments that again more than doubled year-over-year due to accelerating demand in oncology testing. NextSeq 1000 and 2000 orders reached a new high in the quarter, and there was solid growth across all mid and low-throughput systems year-over-year. We ended the quarter with record sequencing instrument backlog that is almost double the backlog entering the year.

Revenue from COVID-19 surveillance again exceeded our expectations due to the sustained focus on variant tracking and surveillance infrastructure scaling in the quarter, contributing approximately $40 million in sequencing consumables revenue and $15 million in incremental instrument revenue.

Core Illumina sequencing service and other revenue grew 11% year-over-year to $110 million, driven by higher instrument service contract revenue on a growing installed base as well as GEL sample growth.

Moving to regional results for Core Illumina:

Revenue for the Americas region was $581 million, growing 33% compared to the prior year period. Revenue growth in the region was driven by record oncology testing shipments and ongoing population genomics initiatives such as All of Us. The regional performance was also driven by COVID surveillance strength due to expanded public health network adoption of NGS in Latin America.

EMEA delivered revenue of $313 million, representing 47% growth year-over-year. EMEA's performance was driven by significant growth across all clinical markets and strength in emerging markets. Population genomics initiatives, partially driven by UKBB which concluded in Q3, and COVID surveillance testing also contributed to the strong third quarter performance in the region.

Greater China revenue was $122 million, representing growth of 47% year-over-year due to continued clinical strength in the region led by NextSeqDx demand in hospitals and oncology testing growth. Almost half of the NextSeqDx shipments were to new-to-ILMN hospital customers, and the expanding footprint in hospitals is helping drive growth in infectious disease testing, which more than doubled year-over-year.

Finally, APJ revenue of $90 million grew 45% year-over-year, driven by sequencing instrument growth from clinical demand for NextSeq2000 as well as consumables revenue growth across oncology testing and research.

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

Core Illumina non-GAAP gross margin of 71.3% declined sequentially by 50 basis points due primarily to one-time revenue from the NIPT patent litigation settlement recorded in the prior quarter. On a year-over-year basis, non-GAAP gross margin increased 390 basis points due to increased fixed cost leverage on higher volumes, partially offset by higher freight costs as a result of the pandemic.

Core Illumina non-GAAP operating expenses of $478 million were up $7 million sequentially, but overall were lower than expected due to the timing of hiring and project spend shifting into Q4. As expected, non-GAAP operating expenses were up $113 million year-over-year, due to increased performance-based compensation expenses and headcount growth, as well as additional investments to support the significant growth of our business.

Core Illumina non-GAAP operating margin was 28.0%, compared to 30.0% in the second quarter of 2021. Operating margins declined sequentially as expected, mostly due to $20 million of one-time patent litigation settlement revenue recognized in the prior quarter.

Transitioning to the financial results for GRAIL:

GRAIL revenue of $2 million for the quarter consisted primarily of Galleri test fees, the multi-cancer early detection test that commercially launched in June, as well as moderate MRD partnership revenue. GRAIL non-GAAP operating expenses totaled $50 million for the quarter, which consisted primarily of expenses related to headcount and clinical trials. As a reminder, GRAIL's third quarter financial results are for the period beginning after the acquisition closed on August 18.

Moving to cash flow and balance sheet items for Consolidated Illumina:

- Cash flow used in operations was $(272) million, which was a net outflow for the quarter due to expenses related to the GRAIL acquisition;
- DSO of 50 days compared to 44 days last quarter driven by revenue linearity;
- Third quarter 2021 capital expenditures were $52 million and free cash flow was negative $(324) million;
- We did not repurchase any common stock in the third quarter.

We ended the quarter with approximately $1.3 billion in cash, cash equivalents and short-term investments. During the third quarter, we used $2.9 billion to fund the GRAIL acquisition.

Before I discuss guidance, I wanted to acknowledge that I am especially proud of our teams' strong execution to fulfill surging demand and deliver another record quarter in a challenging global environment. While there were some small pockets of supply constraints for certain products in specific geographies this quarter, there was no material impact thanks to our team's incredible efforts. We will continue to source, produce, and operate with agility to enable further growth and support our customers.

Moving now to 2021 guidance:

We now expect full year 2021 consolidated and Core Illumina revenue to grow approximately 36%. This represents consolidated revenue of approximately $4.41 billion for 2021, or revenue growth of approximately $1.17 billion compared to 2020, and an increase of approximately $100 million compared to the midpoint of our prior guidance.

For fiscal 2021 we now expect:

- Core Illumina sequencing revenue to grow approximately 39% year-over-year driven by continued momentum in our base business
- We now expect Core Illumina non-GAAP operating margin to be between 27.5-28%, which reflects our higher revenue expectations. We expect Core Illumina operating expenses for Q4 2021 to increase by approximately

$50 million compared to Q3 2021 due to the timing of expenses shifting from Q3 into Q4, increased investments to support the robust growth of our business, as well as expected payments in Q4 2021 related to certain partnerships. Our focus continues to be on improving the Core Illumina operating margin leverage over time

- We now expect our non-GAAP tax rate to be approximately 17.5%
- We now expect consolidated non-GAAP earnings per diluted share in the range of $5.50 to $5.60, which includes dilution from GRAIL operating loss of approximately $1.00, and incremental dilution of $0.15 from the 9.8 million shares issued to fund the GRAIL acquisition
- We now expect GAAP earnings per diluted share in the range of $4.41 - $4.51
- We now expect diluted shares outstanding in fiscal 2021 to be approximately 151 million

For the fourth quarter of 2021:

- We expect non-GAAP earnings per diluted share in the range of $0.35 to $0.45, and GAAP earnings per diluted share in the range of $0.10 to $0.20.
- We expect diluted shared outstanding for the fourth quarter of 2021 of approximately 158 million.
- Now, I'll hand the call back over to Francis for his final remarks.

Francis deSouza, *President & Chief Executive Officer*

Thank you, Sam.

Our third quarter performance reflects the strength of our business, the talent and dedication of our people, and the enduring value of our mission.

Before I close, I would like to highlight how we are furthering this mission through our ESG work. Human health and the health of the environment are intertwined, as are our company mission and our commitment to operating responsibly and sustainably. In the third quarter, we announced aggressive environmental goals, including our Net Zero commitment, to advance the climate component of our ESG strategy. Sam and I will discuss this strategy in greater detail at our inaugural ESG Investor Event on November 16th, and we hope you will join us.

To close, we saw remarkable performance and broad-based strength across our business in the third quarter, and we are both inspired and excited to see this momentum continuing into Q4. We again raised our annual revenue guidance, and with our record instrument backlog, we are on pace for a strong finish to an exceptional 2021. We will build upon this strength as we seize opportunities to expand existing markets, including oncology testing and infectious disease, along with new applications. Sequencing data will enable this expansion as we usher in the era of genomic medicine, and Illumina will be at the forefront of these innovations, supporting our customers as we collectively advance human health.

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

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, 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.