ILMN Q2 2021 Earnings Call

Prepared Remarks – August 5, 2021

Brian Blanchett, *Investor Relations*

Good afternoon everyone, and welcome to our earnings call for the second 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. Francis will provide an update on the state of Illumina's business and Sam will review our 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 will now turn the call over to Francis.

Francis deSouza, *President & Chief Executive Officer*

Thank you and good afternoon everyone.

Illumina delivered Q2 revenues of $1.126 billion, representing 78% year-over-year growth, significantly exceeding expectations across all geographic regions and market segments. Our clinical markets, including oncology, reproductive health and genetic disease testing are expanding as reimbursement coverage increases, patient awareness grows and more sequencing applications enter the clinic. Ramping population sequencing programs are contributing to the robust growth in our research business. Additionally, genomic surveillance has emerged as a critical tool in the global fight against the pandemic, with over 70 countries now using Illumina platforms for COVID-19 surveillance. Looking forward, there is momentum for this global surveillance infrastructure to be the backbone of a durable, global genomic epidemiology capability to combat future outbreaks, including zoonotic transmissions, anti-microbial resistance, and bioterrorism.

Q2 was the second consecutive quarter of record instrument sales, with revenue up 113% year-over-year and we ended the quarter with the highest instrument backlog since launching NovaSeq. Now looking at our performance by platform.

Our high throughput portfolio continued its spectacular run, with NovaSeq achieving its highest order volume since launch in Q1 2017. Demand for high throughput sequencing capacity continues to expand, with over half of the orders in Q2 coming from customers who are new to high-throughput. Additionally, our customers are continuing to use these systems at a high rate to meet demand in oncology testing, genetic disease testing, and population sequencing programs.

Our mid-throughput platforms continue to drive growth with record placements in Q2. The strength of the NextSeq 2000, with almost 3x the output of NextSeq550, is enabling exciting new applications for customers like Cold Spring Harbor Labs in single cell analysis. Clinical customers drove new NextSeq 550 placements. NextSeqDx again set a record for shipments as we see a trend toward decentralization of clinical sequencing outside the US.

Benchtop platforms also had an excellent quarter, with instrument revenue up over 50% year-over-year. We shipped more MiSeq instruments this quarter than any prior quarter in the last five years. This record demand has been driven by our core business as well as emerging areas like preimplantation genetic screening and COVID surveillance.

Turning to our Clinical and Research and Applied segments:

Sequencing consumables revenue of $704 million was up 82% year-over-year, driven by demand in both our Clinical and our Research segments.

Starting with our Clinical business, our focus on market access and collaborations are expanding reimbursement, powering new and existing testing providers, and benefiting patients around the world. There are now over one billion covered lives globally across NIPT, WGS for RUGD, and CGP in Oncology, demonstrating the expertise and impact of Illumina's market access team to drive coverage, and also the enormous opportunity in our clinical segment.

Oncology testing, our largest market segment, recorded its third consecutive quarter of outstanding year-over-year growth as our customers announced additional offerings for therapy selection and MRD tests. In therapy selection, expanding reimbursement for comprehensive genomic profiling is fueling the shift from small to large panels. With 74% of lives now covered for CGP in the US and additional indications approved, new customers are entering the oncology testing field and existing customers, like Caris, are expanding their footprint. TruSight Oncology 500, Illumina's RUO comprehensive genomic profiling assay, achieved its 100,000th sample milestone in Q2, and added over 40 additional customers so far this year across 23 countries. In addition, over the last year, MRD testing has emerged as a key driver of future growth in the oncology segment, with positive reimbursement decisions, more customers, and multiple approaches entering the market. It is also exciting to see pharma invest in MRD based clinical trials to bring proven drugs to early-stage disease and improve patient outcomes.

Reproductive Health consumables shipments continued to benefit from the revised ACOG guidelines. In January, we expected that NIPT would be covered for approximately three million pregnancies in the US by the end of 2021. We have already surpassed that milestone and we expect coverage to continue to expand. We're also making progress outside the US to ensure all expecting families have access to NIPT. In Germany for example, national coverage will be implemented in 2022. Additionally, we are seeing continued growth from our CE-IVD marked VeriSeq NIPT Solution in Europe and Asia. In Q2, Next Generation Genomic in Thailand adopted our VeriSeq NIPT Solution v2, broadening access to expanded NIPT for expectant parents in Southeast Asia.

Genetic Disease testing delivered another outstanding quarter driven by reimbursement coverage increasing across Europe and lower sequencing prices enabling an accelerated shift from exomes to genomes. In the quarter, we also saw promising research and guidelines recognizing the diagnostic yield and cost effectiveness of whole genome sequencing for genetic disease. In June, Rady Children's Hospital and the State of California published the results of Project Baby Bear, a groundbreaking program that showcases the significant benefits of rapid whole genome sequencing in decreasing both time to diagnosis and healthcare spending for critically-ill infants. More than 30% of these patients had a change of care due to the diagnosis enabled by WGS. This rapid whole genome sequencing protocol is now available through Rady's growing network of over 60 hospital partners as well as other hospital networks across the country.

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

Momentum from population genomics programs continued to grow in Q2. In the US, All of Us is now operating at full scale running thousands of genomes a week. We also saw multiple initiatives ramp internationally, providing an on-going pipeline of new PopGen opportunities. We expect revenue from over 30 different PopGen initiatives in the second half of the year.

Multi-omic, spatial, and single cell approaches are gaining traction in many our research segments, driving high intensity sequencing. The success of Illumina's partnerships with companies such as Olink, Nanostring, and 10x will enable novel discoveries and expanded applications to enter the clinic.

The emergence of the delta variant has renewed focus on and heightened awareness for genomic surveillance in the fight against COVID-19 and future pathogens. The launch of the RUO 96-sample COVIDSeq Assay and the expanded EUA for COVIDSeq on NextSeq2000 this quarter demonstrate our continued commitment to provide the workflows, instruments, and bioinformatics to meet this challenge. We are now working with governments and testing labs on COVID surveillance initiatives in over 70 countries. These efforts have driven increased COVID consumable revenue in Q2 relative to Q1 and at this time we expect the consumable revenue in the second half to remain relatively steady to the first half.

Through our philanthropic efforts, we are working to ensure that countries with high needs for Covid surveillance, but limited resources also have access to our sequencers and consumables. Earlier this week we announced a donation of $1M in sequencing capabilities, including two NextSeq 2000s, to the Molecular Diagnostic Reference Laboratory at Kasturba Hospital. This will enable COVID surveillance in Mumbai, an epicenter of India's devasting second wave.

Before I hand the call over to Sam, I'll provide a brief update on GRAIL. In Q2 GRAIL launched the first-of-it-kind multi-cancer screening test Galleri. We made this test available to our employees and are encouraged by the positive feedback we've received. It is exciting to see the promise of genomics come to fruition in oncology screening, and we are committed to supporting all companies innovating in this space. As we shared in late July, we remain committed to closing this pro-competitive deal and believe with this acquisition, Illumina will be uniquely positioned to help save tens of thousands of lives.

And now, I'll turn the call over to Sam.

Sam Samad, *Chief Financial Officer*

As Francis outlined, second quarter revenue exceeded our expectations, growing 78% year-over-year to $1.126 billion, driven by 80% growth in sequencing and 57% growth in microarrays. For the first time in company history, total quarter sequencing revenue exceeded one-billion dollars, growing 4% sequentially to $1.021 billion and representing 91% of total revenue.

Our core business continued to accelerate across all regions in the quarter driven by growth in clinical, as well as strong demand from our research customers who were particularly impacted by the pandemic in the second quarter of 2020 and are continuing to resume and expand their sequencing.

Sequencing consumables revenue grew 82% year-over-year to $704 million, led by record NovaSeq consumables shipments, with robust demand driven by V1.5 flow cells. Sequencing instruments revenue grew 115% year-over-year to $189 million, reflecting another quarter of significant strength across all instrument categories. NovaSeq shipments more than doubled from the second quarter of 2020, driven by continued adoption by new to high-throughput customers. Mid-throughput system shipments reached a new high, driven by record NextSeqDx shipments and demand for NextSeq 1000 and 2000. Since launch, 25% of NextSeq 1000 and 2000 have been shipped to new-to-Illumina customers.

Revenue contributions from COVID-19 surveillance testing exceeded our expectations, contributing approximately $40 million in sequencing consumables revenue and $20 million in incremental instrument revenue.

Sequencing service and other revenue was also higher than expected, growing 41% year-over-year to $128 million, primarily due to approximately $20M of one-time revenue recognized from NIPT royalties received related to a patent litigation settlement.

Moving to regional results, revenue for the Americas region was $589 million, growing 76% compared to the prior year period. Revenue growth in the region was driven by record sequencing product revenue related to demand for clinical oncology testing and genetic disease testing. The regional performance was also driven by strength in genetic disease research from population genomic initiatives, as well as contributions from COVID surveillance testing.

EMEA delivered revenue of $320 million, representing 90% growth year-over-year. EMEA's performance was driven by both a recovery in research and an acceleration of the clinical business, including a record quarter for genetic disease testing, due to momentum from expanded market access and reimbursement. COVID surveillance testing also contributed to the strong performance in the region.

Greater China revenue was $132 million, representing growth of 67% year-over-year due to continued strength in sequencing led by clinical growth in the region. Sequencing instrument shipments more than doubled year-over year driven by growing demand for NextSeqDx in hospitals, given the superior ease of use, accuracy, and quality of outputs from Illumina sequencers.

Finally, APJ revenue of $85 million grew 67% year-over-year, driven by sequencing consumables revenue growth across clinical applications in Reproductive Health and Genetic Disease Testing, as well as strong utilization by research customers. As expected, APJ revenue decreased sequentially due to timing of fiscal year-end purchases and normal seasonality in Japan in the first quarter of 2021.

Moving to gross margin and operating expenses, I will highlight 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.

Non-GAAP gross margin of 71.8% improved sequentially by 130 basis points mainly due to favorable utilization on strong demand as well as one-time revenue from a patent litigation settlement. On a year-over-year basis, non-GAAP gross margin increased 320 basis points due to increased fixed cost leverage on higher volumes, as well as a positive impact from the patent litigation settlement, partially offset by product mix.

Non-GAAP operating expenses of $471 million increased $51 million sequentially due to higher compensation related expenses and increased project related spend but were lower than expected due to the timing of certain investments shifting to the second half of 2021. As expected, non-GAAP operating expenses were up $137 million year-over-year, due to increased performance-based compensation expenses and headcount growth, as well as additional investments to support the growth of our business.

Non-GAAP operating margin was 30.0%, compared to 32.1% in the first quarter of 2021. Operating margins were better than expected due to higher revenues and favorable gross margin, driven by higher volumes and the one-time patent litigation settlement.

Non-GAAP other expense of $2 million was flat sequentially and $15 million lower year-over-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 for the anticipated funding of the GRAIL acquisition.

The non-GAAP tax rate of 17.9% decreased from last quarter due to a tax expense recognized in the first quarter of 2021 on certain foreign subsidiary earnings that are no longer indefinitely reinvested. The decrease in the non-GAAP tax rate year-over-year was due to a higher mix of earnings in jurisdictions with a lower tax rate.

For the second quarter, GAAP net income was $185 million, or $1.26 per diluted share, and non-GAAP net income was $276 million, or $1.87 per diluted share.

Moving to cash flow and balance sheet items:

- Cash flow from operations was $253 million, which included $105 million in continuation payments made to Grail pursuant to the Merger Agreement;

- DSO of 44 days compared to 43 days last quarter driven by revenue linearity;

- Second quarter 2021 capital expenditures were $44 million and free cash flow was $209 million;

- We did not repurchase any common stock in the second quarter.

We ended the quarter with approximately $4.3 billion in cash, cash equivalents and short-term investments. During the second quarter, we used $491 million to repay the outstanding principal of our 2021 Convertible Notes, which matured in June.

Our weighted average diluted share count for the quarter was approximately 147 million.

Moving now to 2021 guidance:

We now expect full year 2021 revenue to grow in the range of 32% to 34% or $4.28 billion to $4.34 billion. At the mid-point, this represents an increase of approximately $1.07 billion compared to 2020.

For the full year 2021, at the midpoint of our revenue guidance range, we now expect:

- Total sequencing revenue to grow approximately 35% year-over-year driven by accelerating strength in our core business and higher than expected contributions from COVID surveillance testing;

- We now expect 2021 non-GAAP operating margin to be approximately 27.5% reflecting our higher revenue expectations and our ongoing commitment to continued innovation in R&D. We continue to maintain our focus on improving our core business operating margin leverage over time;

- We expect our non-GAAP tax rate to increase approximately 200 to 250 basis points from the prior year, which is higher than our previous expectations

- We now expect non-GAAP earnings per share in the range of $6.30 to $6.50, and GAAP earnings per share in the range of $4.69 to $4.89

Moving to the third quarter of 2021:

- We expect revenue to increase approximately 30% year-over-year

- We expect non-GAAP earnings per share in the range of $1.30 to $1.35, and GAAP earnings per share in the range of $1.23 to $1.28

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

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

Thank you, Sam.

It is clear from our strong first half results that Illumina, and our customers, are firing on all cylinders.

Our clinical markets are all growing as expanded reimbursement gives more patients access to existing genomic tests, and evidence generation brings new genomic applications into the clinic. In oncology, more cancer patients have access to CGP for therapy selection. And emerging MRD and early cancer detection tests will drive significant long-term growth for sequencing. In genetic disease testing, the speed to diagnosis and treatment benefits that rapid WGS offers is catalyzing awareness and adoption. In NIPT, while coverage has expanded dramatically in the US there is still a significant need internationally representing a tremendous growth opportunity.

Research funding and overall investor capital deployment in life sciences continues to be incredibly robust, which will drive innovation and new use cases for sequencing for decades to come. Single-cell, spatial and multi-omic approaches to complex problems are driving larger scale, novel research and clinical solutions. The benefit of population genomics

programs in national health systems is driving more governments to take up these initiatives further broadening the reach of sequencing across the globe. COVID surveillance initiatives are laying the foundation for a permanent, global genomic epidemiology infrastructure.

Illumina is playing a central role central in these advancements in genomics and human health. I am very proud of the execution of our fantastic teams around the world.

This is an incredible time for our field, and we have the most exciting technology road map in development that I've seen in my time at the company. I am honored to work alongside my colleagues to fulfill Illumina's instrumental role in improving human health by unlocking the power of the genome.

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, operating margins, other income, and free cash flow 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. Additionally, non-GAAP net income attributable to Illumina stockholders and diluted earnings per share attributable to Illumina stockholders 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 and consumables, to deploy new products, services, and applications, and to expand the markets for our technology platforms; (x) our ability to obtain regulatory clearance for our products from government agencies; (xi) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business; (xii) our ability to successfully identify and integrate acquired technologies, products, or businesses; and (xiii) the application of generally accepted accounting principles, which are highly complex and involve many subjective assumptions, estimates, and judgments, 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.

Additional Information and Where to Find It

In connection with the proposed transaction, Illumina filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 (File No. 333-250941) (as amended, the "Registration Statement"), which includes a prospectus with respect to Illumina's common stock and contingent value rights to be issued in the proposed transaction and a consent solicitation statement of GRAIL, Inc. ("GRAIL") in connection with the proposed transaction (the "Consent Solicitation Statement/Prospectus"). The Registration Statement was declared effective by the SEC on February 9, 2021. The Consent Solicitation Statement/Prospectus was first distributed to GRAIL stockholders on or about February 17, 2021. On March 4, 2021, Illumina filed with the SEC Prospectus Supplement No. 1 to the Consent Solicitation Statement/Prospectus and a registration statement on Form S-4 (File No. 333-253891) pursuant to Rule 462(b) of the Securities Act of 1933, as amended (the "462(b) Registration Statement"). The 462(b) Registration Statement relates to the Registration Statement and was declared effective automatically upon filing with the SEC. Illumina may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the Consent Solicitation Statement/Prospectus or the Registration Statement or any other document which Illumina may file with the SEC. INVESTORS AND SECURITY HOLDERS OF GRAIL ARE URGED TO READ THE REGISTRATION STATEMENT, WHICH INCLUDES THE CONSENT SOLICITATION STATEMENT/PROSPECTUS, AND ANY OTHER RELEVANT DOCUMENTS THAT ARE FILED OR WILL BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and security holders may obtain free copies of the Registration Statement, which includes the Consent Solicitation Statement/Prospectus, and other documents filed with the SEC by Illumina through the website maintained by the SEC at www.sec.gov, through Illumina's Investor Relations page (investor.illumina.com) or by writing to Illumina Investor Relations, 5200 Illumina Way, San Diego, CA 92122.

No Offer or Solicitation

This communication is for informational purposes only and is not intended to and does not constitute an offer to subscribe for, buy or sell, or the solicitation of an offer to subscribe for, buy or sell, or an invitation to subscribe for, buy or sell any securities or a solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which such offer, invitation, sale or solicitation would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Cautionary Notes on Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In this context, forward-looking statements often address expected future business and financial performance and financial condition, and often contain words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "see," "will," "would," "may," "target," similar expressions and variations or negatives of these words. Forward-looking statements by their nature address matters that are, to different degrees, uncertain, such as statements about the consummation of the proposed transaction and the anticipated benefits thereof. These and other forward-looking statements are not guarantees of future results and are subject to risks, uncertainties and assumptions that could cause actual results to differ materially from those expressed in any forward-looking statements, including the failure to consummate the proposed transaction or to make any filing or take other action required to consummate such transaction in a timely matter or at all. Important risk factors that may cause such a difference include, but are not limited to: (i) the proposed transaction may not be completed on anticipated terms and timing, (ii) a condition to closing of the transaction may not be satisfied, including obtaining regulatory approvals, (iii) the potential impact of unforeseen liabilities, future capital expenditures, revenues, costs, expenses, earnings, synergies, economic performance, indebtedness, financial condition and losses on the future prospects, business and management strategies for the management, expansion and growth of Illumina's business after the consummation of the transaction, (iv) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction, (v) any negative effects of the announcement, pendency or consummation of the transaction on the market price of Illumina's common stock and on Illumina's operating results, (vi) risks associated with third-party contracts containing consent and/or other provisions that may be triggered by the proposed transaction, (vii) the risks and costs associated with the integration of, and the ability of Illumina to integrate, GRAIL's business successfully and to achieve anticipated synergies, (viii) the risks and costs associated with the development and commercialization of, and Illumina's

ability to develop and commercialize, GRAIL's products; (ix) the risk that disruptions from the proposed transaction will harm Illumina's business, including current plans and operations, (x) legislative, regulatory and economic developments, (xi) the other risks described in the Consent Solicitation Statement/Prospectus that is included in the Registration Statement, as well as in Illumina's most recent annual reports on Form 10-K and quarterly reports on Form 10-Q and in the registration statement on Form S-1 filed with the SEC by GRAIL on September 9, 2020, as amended on September 17, 2020, and (xii) management's response to any of the aforementioned factors.

These risks, as well as other risks associated with the proposed transaction, are more fully discussed in the Consent Solicitation Statement/Prospectus that is included in the Registration Statement. While the list of factors presented here is, and the list of factors presented in the Registration Statement are, considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Consequences of material differences in results as compared with those anticipated in the forward-looking statements could include, among other things, business disruption, operational problems, financial loss, legal liability to third parties and similar risks, any of which could have a material adverse effect on Illumina's financial condition, results of operations, credit rating or liquidity. Illumina does not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, should circumstances change, except as otherwise required by securities and other applicable laws.