ILMN Q4 & Full Year 2020 Earnings Call

Prepared Remarks – February 11, 2021

Juliet Cunningham, *VP, Investor Relations*

Good afternoon everyone, and welcome to our earnings call for the fourth quarter and full year 2020.

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, Juliet. Good afternoon everyone.

Illumina had a strong finish to 2020, with both revenue and orders setting new records. Fourth quarter revenue of $953 million, was up 20% sequentially from the third quarter. Sequencing Instruments grew 29% quarter-over-quarter. We also booked the second highest NovaSeq units during the fourth quarter, primarily driven by the August launch of our V 1.5 reagents. V1.5 resulted in higher new customer growth, as well as additional HiSeq conversions. NovaSeq continues to be the market-leading sequencer as it enters its fifth year since launch.

Full year 2020 revenue of $3.2 billion declined 9% year-over-year with the largest impact from the pandemic in the second quarter. Our business accelerated in the second half of the year, growing 17% compared to the first half. In 2020, we shipped more than 2,000 sequencing systems, set another record for mid-throughput shipments and added more than 700 new customers, which exceeded our expectations.

I'd like to share some fourth quarter highlights by platform, starting with our high-throughput systems:
NovaSeq consumable pull-through was at its highest level of the year at over $1.2 million per instrument. We expect NovaSeq pull-through to continue at pre-pandemic levels of $1.1 to $1.2 million per year in 2021.

The NovaSeq v1.5 reagent introduction is catalyzing a new wave of high-throughput customers as the $600 genome became a reality for labs of any size. In fact, over half of our NovaSeq system orders in 2020 were to new high throughput customers. This includes customers like Argentina's Ministry of Health, who purchased NovaSeq for infectious disease research. The V 1.5 introduction also accelerated the purchasing timeline for CellCarta, a contract research organization and a new-to-high throughput customer, who plans to use their NovaSeq to support oncology clinical trials. The V 1.5 reagents are also strengthening the economic case for legacy HiSeq customers to upgrade – like the University of Oregon, who is using NovaSeq for large, single cell and epigenetics studies.

We ended the year with about 1,000 active HiSeq units and in 2021, we expect continued HiSeq to NovaSeq adoption among the 320 customers yet to transition.

Moving to mid-throughput, 2020 marked the second consecutive year of record placements, and the mid-throughput segment continues to provide durable growth in our core business. Fourth quarter strength was primarily driven by the successful launches of NextSeq 1000 and 2000, which also drove an increase in mid-throughput consumable revenue for the full year. Looking ahead, we expect continued NextSeq expansion in 2021, particularly in the clinical segment. Notably, we received NMPA approval in China for NextSeq Dx, driving demand in local hospitals in applications like oncology and infectious disease testing. We expect this approval to drive NextSeq Dx placements and further increase our clinical presence in 2021.

We added more than 500 new low-throughput customers in 2020, bringing our total to more than 6,100 customers worldwide. Our platforms hold the largest set of flow cell configurations and enable the most expansive set of supported methods with run times as fast as five hours. In the fourth quarter, we had record low-throughput consumable revenue driven by customers like Invitae, who has products in development using the MiSeq Dx.

I'll now provide updates on our Clinical and Research and Applied segments:

Total sequencing consumables revenue of $2 billion was down 2% year-over-year reflecting the impact of the pandemic on academic and research institutions. By the fourth quarter of 2020, clinical sequencing run-rates actually *exceeded* pre-pandemic levels and research run-rates also returned to normalized pre-pandemic volumes – it was great to see how our customers successfully rebounded under these challenging circumstances.

More than 43% of our sequencing consumable shipments in 2020 were to clinical customers, which includes testing for Oncology, Reproductive Health, and Genetic Disease. Clinical testing proved durable during the pandemic with clinical consumables growing about 8% year-over-year to approximately $890 million in 2020. And in the fourth quarter, clinical consumables growth accelerated to over 20% year-over-year.

In Clinical, I'll highlight first the tremendous progress made in market access and reimbursement. We believe recent landmark coverage decisions will drive greater adoption of next generation sequencing to new levels over the next several years:

- In Oncology – 205 million lives are now covered for tumor comprehensive genomic profiling in the U.S., and with an increasing number of targeted oncology therapies, we expect CGP to grow to be a $1 billion plus market by 2026. Additionally, Germany recently started covering tumor CGP and whole exome and whole genome for rare and undiagnosed genetic disease without restrictions. This means that 73 million lives will have better access to CGP and whole exome and whole genome testing.

- In Reproductive Health, with multiple large payors expanding coverage for all pregnancies – we expect NIPT coverage in the U.S. to exceed 3 million pregnancies by the end of 2021.

- And finally, whole genome sequencing coverage for genetic disease testing increased 10-fold in 2020 and we expect WGS to become the standard of care in genetic disease as awareness and reimbursement continues to grow.

With these positive reimbursement trends as a backdrop, I'll now discuss our clinical focus areas in a little more detail:

Oncology testing continues to represent approximately 20% of total sequencing consumables, and it grew year-over-year driven by companies like Guardant Health, who expanded its mobile phlebotomy services to help patients access its Guardant360 liquid biopsy test during the pandemic. This also includes Genomic Hubs in the NHS that adopted NovaSeq comprehensive genomic profiling as the standard of care in the UK, and oncology centers like Florida Cancer Specialists, a private community oncology and hematology practice with nearly 100 offices throughout Florida. Florida Cancer Specialists purchased multiple NextSeq Dx systems in 2020 to run Illumina's Trusight Oncology 500 assay in its new lab.

Reproductive Health represented about 12% of sequencing consumables, with revenue and samples for our end-to-end VeriSeq NIPT solution growing over 20% in 2020.

Lastly, about 10% of our sequencing consumables revenue is related to genetic disease testing. Customers continue to choose Illumina's highly accurate and scalable sequencers as their platform of choice in this area. For example, the recent collaboration between Weill Cornell Medicine and New York-Presbyterian Hospital, in partnership with the New York Genome Center, will use Illumina technology for clinical WGS in areas like cardiovascular, metabolic and neurodegenerative diseases.

Turning to our Research and Applied segment, revenue of approximately $1.2 billion represented just under 57% of our sequencing consumable shipments and was lower by about 6% year-over-year as customers were impacted by the pandemic. Research accelerated in the second half, growing 20% compared to the first half as researchers returned to their labs.

This segment includes research in oncology and genetic disease, as well as Population Genomic and Research initiatives. Our sequencers enable programs like KDNA – a large scale Korean project aiming to sequence 1 million genomes by 2030. A service provider consortium, standardized on Illumina technology, won the competitive tender based on NovaSeq's superior technical evaluation. The program plans to complete its 7,500-genome 'phase-one' by the end of the year.

The NHS commenced a phased rollout for whole genome sequencing in the fourth quarter for selected rare disease and cancer patients as part of their routine care. Once this "Live Clinical Testing" phase is complete, we expect the whole genome sequencing service to further ramp in the Spring.

We expect the All of Us program to continue to scale this year, and the NIH anticipates releasing de-identified data from 100,000 sequenced and array genotyped samples to its research portal by the end of 2021.
Finally, as a leading innovator, Illumina remains steadfast in the defense of our intellectual property globally. We received injunctions against BGI for patent infringement in the U.S., Germany, U.K., Spain, Sweden and Finland. We remain confident that our IP portfolio affords strong protection for Illumina's innovations now and well into the future.
And now, I'll turn it over to Sam.

Sam Samad, *Chief Financial Officer*

Thank you.

As Francis discussed, we had record fourth quarter revenue that grew slightly year-over-year to $953 million, driven by 1% growth in sequencing offset by an 8% decline in microarrays.

Total sequencing revenue reached a record of $846 million, which represented 89% of total revenue in the fourth quarter of 2020 and grew 19% sequentially. Sequencing consumables revenue grew 5% compared to the prior year period and 20% sequentially. Sequencing instruments revenue was roughly flat year-over-year and grew 29% sequentially and sequencing service and other was down 15% compared to the prior year period due to IVD partnership revenue recognized last year.

Moving to regional results, the Americas revenue grew 14% sequentially. Revenue in the region was 2% lower compared to the prior year quarter, which was primarily driven by one-time technology access fees for an IVD partnership and lower DTC revenue. These items were partially offset by sequencing consumables. The Americas had record sequencing product revenue in the fourth quarter, driven by clinical customers.

EMEA delivered record revenue of $285 million representing 34% sequential growth and 2% growth year-over-year driven by strong instrument revenue from NovaSeq. We also saw certain customers in emerging countries taking their first NovaSeq shipments.

Greater China grew 16% sequentially and 3% year-over-year to $96 million and had its highest sequencing instrument revenue quarter since 2017, driven in part by growing demand in hospitals. Subsequent to Q4, we also announced the Sequoia Capital China Genomics Incubator, which builds on our other incubator efforts in Silicon Valley and the U.K. Together, we will partner with leading entrepreneurs in China to build genomics startup companies to create breakthrough genomics applications and clinical sequencing solutions.

Finally, APJ revenue of $77 million was up 24% sequentially and up 5% from the prior year period. For the full year, the region was roughly flat compared to 2019 with full year growth in sequencing consumables.

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. Please note that all subsequent references to net income and earnings per share refer to the results attributable to Illumina shareholders.

As expected, non-GAAP gross margin of 66.9% decreased approximately 50 basis points sequentially. Year-over-year, fourth quarter non-GAAP gross margin was down 330 basis points primarily due to a one-time inventory write down in Q4, one-time IVD partnership revenue in the year ago quarter, and higher freight costs related to COVID-19 .

Non-GAAP operating expenses of $439 million were up $74 million sequentially, as expected, reflecting the extra week in the fourth quarter, variable compensation expenses and other investments.

Non-GAAP operating margin was 20.9%, down from 21.4% in the third quarter.

Non-GAAP other income of $20 million was $13 million higher sequentially due to gains on short term investments sold as we repositioned our investment portfolio for the anticipated funding of the GRAIL acquisition.

The non-GAAP tax rate of 18.4% was up from last quarter due to a discrete charge related to a tax structure initiative in the fourth quarter. The sequential increase of our tax rate in Q4 was also impacted by discrete tax benefits in the third quarter of 2020 related to prior year return adjustments.

For the fourth quarter of 2020, GAAP net income was $257 million, or $1.75 per diluted share, and non-GAAP net income was $179 million, or $1.22 per diluted share.

Moving to cash flow and balance sheet items:

- Cash flow from operations was $406 million
- DSO of 50 days compared to 53 days last quarter driven by revenue linearity
- Fourth quarter capital expenditures were $62 million and free cash flow was $344 million
- We repurchased $280 million of stock in the fourth quarter

We ended the year with approximately $3.5 billion in cash, cash equivalents, and short-term investments.

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

Moving now to 2021 guidance:

We expect full year 2021 revenue to grow in the range of 17 to 20% or 3.79 to 3.89 billion dollars representing an increase of approximately $599 million at the midpoint.

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

- Sequencing revenue to grow approximately 20%;
- This includes sequencing consumable growth of around 20%;
- We expect sequencing system revenue to grow 33% year-over-year driven by placements of NovaSeq due to continued HiSeq conversions, and the adoption of V 1.5 reagents, as well as placements of NextSeq due to NextSeq 2000 and Dx demand; and
- Arrays to grow approximately 5% compared to 2020.

We expect full year non-GAAP gross margin to modestly improve from 2020 reflecting increased leverage from higher volumes and cost saving initiatives partially offset by product mix, and IVD partnership revenue in the first quarter of 2020.

We expect 2021 operating margin to be approximately 24%;

As volumes increase and freight charges normalize, we expect both gross and operating margins to improve in the second half of 2021 and be above the full year average.

We expect other income to be about $40 million lower than 2020 due to the gains in the fourth quarter of 2020, lower interest rates, and shorter duration investments in anticipation of the close of the GRAIL acquisition.

We expect GAAP earnings per share to be in the range of $4.76 to $5.01, and non-GAAP earnings per share in the range of $5.10 to $5.35. And we expect diluted shares outstanding in 2021 to be approximately 147 million.

Moving to the first quarter of 2021:

- We are raising our previous expectations, and we now expect high-single digit revenue growth compared to the first quarter of 2020.
- We expect sequential improvement in non-GAAP gross margin;
- Sequential decline in non-GAAP operating expenses similar to historical seasonality;
- Non-GAAP Other income to be significantly lower compared to the fourth quarter of 2020 due to the one-time gain on short term investments previously discussed; and
- As a result, we expect non-GAAP EPS to be slightly higher compared to the fourth quarter of 2020.

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

Francis deSouza, *President & Chief Executive Officer*

We're off to a strong start in 2021. We're seeing strength in our core business and are playing an essential role in the emerging surveillance effort necessary to fight the pandemic.

In the past couple of months, as new, more dangerous SARS-Cov-2 variants have emerged, there has been a growing recognition of the need for COVID surveillance around the globe, with countries like U.K., Australia, Canada and Germany leading the way in deploying national surveillance infrastructures. In the U.S., the proposed budget package, contains $1.75 billion for the CDC to conduct, expand, and improve activities to sequence genomes, identify mutations, and survey the transmission of viruses including SARS-CoV-2.

Sequencing-based surveillance is one of the key elements in the fight against this pandemic, and it's also becoming clear that sequencing and surveillance are becoming mainstream in the defense against infectious disease. This global surveillance infrastructure being built right now will be instrumental in identifying future outbreaks – including coronaviruses, antimicrobial resistance and bioterrorism.

Illumina is proud to be at the forefront of this important work.

We'd also like to congratulate Nobel Laureate and Illumina Board member, Dr. Frances Arnold, who was named as Co-Chair of the U.S. President's Council of Advisors on Science and Technology. We believe the recent appointments of highly experienced scientists signal the Administration's focus on science, including genomics, to improve life in the U.S. for everyone.

Finally, we continue to expect to close the GRAIL acquisition in the second half of this year, enabling us to help accelerate the adoption of early cancer detection screening, and open up the largest application for genomics by far. We are looking forward to GRAIL launching Galleri in Q2.

We see a vast number of opportunities ahead of us and there has never been a more exciting time to be in genomics at Illumina.

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, 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, Inc. (the "Company") intends to file with the SEC a registration statement on Form S-4 that will include a preliminary prospectus with respect to the Company'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 Company 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 registration statement or any other document which the Company may file with the SEC. INVESTORS AND SECURITY HOLDERS OF GRAIL ARE URGED TO READ THE REGISTRATION STATEMENT, WHICH WILL INCLUDE 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 on Form S-4 (when available), which will include the consent solicitation statement/prospectus, and other documents filed with the SEC by the Company through the website maintained by the SEC at www.sec.gov, through the Company'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 the Company'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 the Company's common stock and on the Company'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 the Company to integrate, GRAIL's business successfully and to achieve anticipated synergies, (viii) the risks and costs associated with the development and commercialization of, and the Company's ability to develop and commercialize, GRAIL's products; (ix) the risk that disruptions from the proposed transaction will harm the Company's business, including current plans and operations, (x) legislative, regulatory and economic developments, (xi) the other risks described in the Company'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, will be more fully discussed in the consent solicitation statement/prospectus that will be included in the registration statement on Form S-4 that will be filed with the SEC in connection with the proposed transaction. While the list of factors presented here is, and the list of factors to be presented in the registration statement on Form S-4 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 the Company's financial condition, results of operations, credit rating or liquidity. The Company 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.