ILMN Q320 Earnings Call

Prepared Remarks – October 29, 2020

Juliet Cunningham, VP, Investor Relations:

Good afternoon everyone, and thanks for joining us for our third quarter 2020 results conference call.

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 share an update on our business and Sam will review our financial results. Similar to last quarter, we are hosting our call from a number of different locations, so please bear with us if there are any technical challenges or pauses.

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'll turn the call over to Francis.

Francis deSouza, President and CEO:

Thank you, Juliet. Good afternoon everyone and thank you for joining us today.

We saw a strong rebound in our business in the third quarter, with a faster recovery than we expected in both our Clinical and Research customers. Total revenue for the third quarter was $794 million, up 26% sequentially and down 12% compared to the prior year period. I'll share the third quarter highlights and Sam will provide more detailed financials.

Sequencing revenue grew 25% compared to the second quarter of 2020. Sequencing consumables grew 29% sequentially with strength across our high-, mid-, and low-throughput product portfolio. NextSeq's momentum continued to build, with mid-throughput consumables growing both sequentially and 3% year-over-year, and we expect continued growth in the fourth quarter.

Sequencing Instruments also outperformed expectations, with revenue up 24% sequentially. This growth was primarily driven by increased shipments of NovaSeq and NextSeq platforms. NovaSeq purchases have rebounded nicely from Q1 when some customers delayed purchases as shelter-in-place policies took effect. We have been pleased with the sequential growth in NovaSeq shipments in each quarter since Q1. We're entering the fourth quarter with a strong NovaSeq pipeline and expect this sequential growth to continue in Q4.

In addition, we had another successful quarter for our mid-throughput portfolio with both NextSeq 2000 and NextSeq 550 exceeding our expectations. Strong demand for these flexible sequencers led to record mid-throughput shipments in the third quarter. We are especially pleased with the success of the NextSeq 2000 launch reflecting positive customer feedback and demand. Approximately one-third of NextSeq 2000 placements are coming from new-to-Illumina customers. Consistent with our expectations, we've seen little cannibalization of NovaSeq conversions among the remaining HiSeq customers.

Sequencing Service and Other revenue grew 9% sequentially and was 28% lower compared to the prior year, due to one-time, IVD licensing and development revenue of over $30 million in the third quarter of last year.

Total microarray revenue of $86 million was up 28% sequentially as Direct to Consumer customers and other applications began recovering from pandemic-related headwinds.

Turning to our customer segments, we saw solid improvement in both clinical and research activity. As a reminder we track sequencing run-rates as an indicator of general activity. Run volumes are based on a sampling and do not directly correlate with revenue. The intent of providing this metric is to help investors understand customer sequencing activity.

Clinical sequencing run volumes increased from an average of 84% in the second quarter to 96% during the third quarter compared to pre-pandemic levels.

In Oncology, we're encouraged by signs that point to continued adoption of NGS in cancer treatment. The European Society for Medical Oncology, or ESMO became the first scientific society to issue recommendations for the use of NGS in oncology. Depending on the cancer type, the Society recommends NGS for large, multi-gene panels, for the determination of Tumor Mutation Burden, and to screen patients for clinical trials. To date, TSO 500, which is for research use only, provides comprehensive genomic profiling and has been adopted by approximately 250 customers. We are excited to release a CE IVD marked TSO comprehensive assay in 2021 to ensure labs can follow ESMO guidelines and continue to improve cancer patient outcomes.

Growing payer adoption will continue to broaden the availability of these tests. Last month, Aetna, covering 19 million lives, announced coverage for large panel comprehensive genomic profiling - for both solid and liquid, including testing for TMB.

We're also encouraged by the increasing availability and adoption of NGS-based liquid biopsy tests. The recent FDA approval of Guardant360 and FoundationOne Liquid CDx demonstrates the clinical utility of these technologies that detect cell free DNA from the tumor in the blood and can provide comprehensive genomic profiling when tumor tissue is not available. Liquid biopsy panels like these broaden access to more patients who can benefit from NGS in their cancer treatment.

Reproductive Health showed strength in the quarter, growing sequentially and year-over-year. In fact, during the third quarter Reproductive Health averaged over 100% of its pre-pandemic run rate. We expect sustained growth as reimbursement prospects have never looked more promising. Recently, ACOG updated its guidance to recommend that NIPT be made available to all pregnant women, regardless of maternal age or baseline risk. This is a major milestone, and we expect payers to continue to follow ACOGs guidance, adding to the already 130 million plus lives covered for average risk in the U.S. Centene, for example, recently aligned its guidelines, adding average risk coverage to an additional 23 million lives in the U.S. Centene is also the largest Medicaid managed care organization in the U.S. – meaning this coverage decision will bring NIPT as an option to more medically underserved areas and populations.

In Genetic Disease Testing - physicians, insurance companies and governments around the globe are increasingly adopting sequencing to diagnose children suspected of having genetic conditions. We are seeing solid progress on the reimbursement front. Payer adoption in the U.S. continues to grow, with more than double the lives covered for whole genome sequencing than at the start of the year. And Australia recently announced that it will reimburse whole exome or genome sequencing to identify the genetic cause of intellectual disabilities. These positive developments give us confidence in sustained long-term growth in this underpenetrated market.

Turning to Research, sequencing runs show continued improvement and increased from an average of 65% in the second quarter to 82% in the third quarter compared to its pre-pandemic run volumes. We're encouraged to see researchers returning to their labs and reopening, and this level of improvement exceeded our expectations.

Within Research, we're seeing the role of NGS take shape in infectious disease. We believe the most likely near-term use case for sequencing is in research and surveillance for projects like Australia's First National COVID-19 Tracking System – which aims to sequence the virus genomes of all positive COVID-19 tests in Australia and track COVID-19 using genomics across the country. NIH is also increasing its funding for understanding COVID-19 and the transmission pathway using genomic testing. We continue to believe COVID-19 testing will be primarily served by PCR and antigen tests, with NGS providing supplemental testing capacity. As such, we are not factoring in a material contribution to revenue in the fourth quarter from COVID-19 testing.

On the Population Genomics front, we're seeing promising signs of progress. All of Us, received its IDE approval from the FDA in the second quarter and, as expected, samples started to flow from the biobank to partner genome centers. We expect the project to ramp in the fourth quarter and into 2021.

During the third quarter, sequencing for the UK Bio bank continued, and we expect levels to gradually return to normal and sequencing to continue into 2021.

And, we expect whole genome sequencing services for the NHS Genomic Medicine Service to commence later this quarter. Given the NHS's current focus on COVID, we expect this program to gradually ramp over the next few quarters.

Perhaps one of the most resilient PopGen programs in the face of the pandemic has been the Million Veteran Program – or MVP. The project aims to provide insights on how genetics, lifestyle, and military exposures affect health and illness, and, has recently expanded its targeted enrollment from one million to two million veterans. The U.S. Department of Veteran's Affairs, through its sequencing partner Personalis, expects to cross the 100,000 whole genome milestone before the end of the year.

We believe these and other initiatives will expand our markets and create exciting new opportunities for Illumina. We are committed to continue to lead through innovation with new product launches to support the markets and customers we serve, including:

- NovaSeq 6000 v1.5 reagents, which were launched during the third quarter. This release offers increased shelf-life, improved quality scores, longer indexes, and most importantly, it makes the $600 genome more broadly available to help smaller labs be successful – and provides additional incentives for labs to upgrade from HiSeqs to NovaSeq. NovaSeq 6000 v1.5 reagents have been extremely well received by our customers.
    - For example, the Princess Máxima Center, the largest national pediatric oncology center in Europe, was outsourcing its genome sequencing to a collaborator, but with the new reagents, they were able to purchase a NovaSeq and can now start to perform testing in house – meaning potential care-altering genomic information will reach children with cancer faster and be performed closer to the patient.
    - The longer read lengths combined with high throughput scale enabled a Canadian biotech company to adopt the NovaSeq 6000 for the development of antibody products for potential COVID19 therapy.
- We are preparing to launch NextSeq 1000 this quarter. NextSeq 1000 enables lower throughput customers to adopt our newest platform as an entry point with the ability to field-upgrade to the NextSeq 2000.
- We're also launching the P3 flow cell this quarter. Early access P3 customers, including academic core labs, are already using the flow cell for routine sequencing methods in mid-sized research projects to enable faster turnaround times. Other customers are using P3 to develop workflows in single cell, epigenetics, and spatial transcriptomics.

These are examples of how we continue to execute on our current and future plans, throughout these challenging times, to advance our mission and create long-term shareholder value.

Now, I'll hand the call over to Sam to discuss the third quarter financials.

Sam Samad, CFO:

Thanks, Francis.

As discussed, third quarter 2020 revenue was $794 million, a 12% decline year-over-year, but a 26% increase compared to the second quarter of 2020. While the global pandemic continued to impact our business, we saw encouraging signs of recovery within both clinical and research customers.

Sequencing consumables revenue of $500 million was up 29% sequentially and down 5% compared to the prior year period. Quarter over quarter growth of $113 million reflected significant improvement across high-, mid-, and low-throughput platforms with NovaSeq pull through returning to over 1 million per system per year. Our mid-throughput sequencing consumables grew in the quarter vs. the same period last year.

Total sequencing system revenue of $109 million was ahead of our expectations with both NovaSeq and our mid throughput platforms exceeding our expectations at the start of the quarter. The third quarter was also a record quarter for mid-throughput shipments driven by customer demand for NextSeq 2000 and the NextSeq 550 Dx platform. In fact, NextSeq Dx shipments represented over 40% of NextSeq 550 shipments year-to-date. Since 2013, Illumina has shipped over 1,000 Dx instruments, reflecting the growing clinical nature of our customer base.

Sequencing Service and Other revenue of $99 million was lower compared to the third quarter of 2019. Total sequencing revenue was $708 million and represented 89% of total revenue.

Finally, total microarray revenue of $86 million was down 16% from the third quarter of 2019, reflecting lower consumables and services revenue primarily driven by COVID-19 related headwinds.

Turning to the regions, Americas revenue of $436 million was ahead of expectations and grew over $100 million, or 30%, compared to the second quarter of 2020. Sequential growth was driven by both research and clinical customers as labs continued to reopen and clinical activity increased. In fact, clinical sequencing consumables grew modestly compared to the prior year period as demand started to recover after delays in testing in the second quarter.

EMEA revenue of $213 million was up $45 million compared to the second quarter of 2020 with strength in sequencing consumables, which grew compared to the third quarter of 2019 driven by a strong rebound in both clinical and research customers.

China revenue grew sequentially to $83 million – driven by strength in instrument placements.

APJ revenue was roughly flat year-over-year at $62 million and increased $11 million compared to the second quarter of 2020, with NIPT helping to lead the recovery with sequential and year over year growth.

Moving through the P&L, I will highlight non-GAAP results that 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.

Non-GAAP gross margin of 67.4% was lower, as expected, on both a year-over-year and sequential basis. The year-over-year decline was driven by IVD partnership revenue in the third quarter of 2019 not repeating this year, and lower volume and higher freight costs associated with the pandemic.

Non-GAAP operating expenses of $365 million were higher compared to the second quarter of 2020 and the same quarter last year. Sequential growth was driven, as expected, by an increase in R&D project spend, and higher compensation expenses. Compared to the third quarter of 2019, operating expenses were higher primarily due to compensation related expenses, and increased project spend, partially offset by decreased travel.

Non-GAAP operating margin was 21.4%, up from 15.8% last quarter.

The non-GAAP tax rate of 14.8% was lower compared to last quarter and prior year due to discrete tax benefits related to prior year return adjustments and release of tax reserves.

For the third quarter of 2020, GAAP net income was $179 million, or $1.21 per diluted share, and non-GAAP net income was $150 million, or $1.02 per diluted share. Other Income was the main driver for the difference between GAAP and non-GAAP net income due to net gains from mark-to-market adjustments on our strategic investments, primarily from our marketable equity securities.

Additionally, in the third quarter:

- Cash flow from operations was $153 million.
- Capital expenditures were $48 million and free cash flow was $105 million.
- DSO of 53 days compared to 55 days last quarter, in part, due to increased collections.
- We repurchased $125 million of common stock in the third quarter with $295 million remaining for repurchase under our current plan.

We ended the quarter with approximately $3.3 billion in cash, cash equivalents, and short-term investments.

Our weighted average diluted share count for the quarter was approximately 148 million.

As we continue to navigate this pandemic, there are still uncertainties around the virus resurgence and rate of recovery, and, therefore, we will not provide guidance for the remainder of the year. Additionally, we are closely monitoring developments in the pandemic given the risk of new shutdowns in the U.S. and Europe.

In the fourth quarter, we expect that sequencing run volumes will continue to improve modestly for clinical and research customers from the 96% and 82% levels, respectively, in the third quarter. Again, we caution that this does not directly correlate to revenue, but data from the third quarter suggests customers are steadily returning to their labs which will lead to increased activity.

Consistent with the third quarter, we expect fourth quarter sequential growth across all regions with China and APJ showing flat to modest growth year over year.

For the fourth quarter of 2020, we currently expect:

- Continued sequential improvement in revenue, resulting from:
    - Sequencing consumables being up modestly on a sequential basis as clinical and research activity continues to gradually improve.
    - Sequencing instruments increasing sequentially and the fourth quarter is expected to be the strongest quarter of the year for instrument placements.
    - Sequencing Service and Other flat sequentially,
    - And Microarrays up modestly on a sequential basis as we continue to see a gradual recovery in direct to consumer and genotyping applications
- For the rest of the P&L, we expect -
    - Sequential decline in non-GAAP gross margin, in part, driven by product mix with higher contribution from instrument sales.

- Sequential increase in non-GAAP operating expenses, primarily driven by R&D project-related expenses, compensation related expenses, and an extra week in the fourth quarter compared to the prior quarter and prior year.

- Non-GAAP EPS to be roughly flat compared to the third quarter of 2020, reflecting revenue improvement offset by lower gross margins and a sequential increase in operating and tax expenses.

With that, I'll hand the call back over to Francis for some closing remarks.

Francis deSouza, President & CEO:

Thanks, Sam. As the global leader for sequencing platforms and consumables, we've seen our products enable groundbreaking research programs and transformative clinical tests that have the potential to shift the paradigm in patient care. One of the largest opportunities for patient impact and revenue potential for years to come is the ability for NGS to detect cancer early.

Last month, we announced a definitive agreement to acquire GRAIL and we expect the acquisition to close in the second half of 2021. We believe our planned acquisition of GRAIL will accelerate a new era of early cancer detection, transforming cancer survivability and opening up the largest clinical application of genomics we've seen. We look forward to welcoming our GRAIL colleagues to Illumina when the acquisition closes. Upon close we expect to operate GRAIL as a division within Illumina. We remain committed to supporting all of Illumina's customers, and ensuring that innovators who wish to develop NGS-based tests have continued access to our technologies.

To conclude, the recovery of our business accelerated in the third quarter with significant sequencing consumables revenue growth compared to the second quarter of 2020 and we expect continued consumables growth in the fourth quarter. Importantly, we're also making good progress incorporating genomics into the standard of care in oncology therapy selection, NIPT, and genetic disease testing. And, most importantly, we believe that we are laying a strong foundation for Illumina's near- and long-term growth.

With that, we'll open the call up to 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.