

EMILY: Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our third quarter 2017 financial results. Please note, a copy of the prepared remarks we are about to make is available to download on the Investors section of our corporate website, genomichealth.com.

Before we begin, I'd like to remind you that various remarks that we make on this call that are not historical, including those about:

- our future and full-year financial and operating results
- our guidance for 2017 and key drivers and expectations for 2017 and 2018
- payer coverage, timing of revenues from payors and progress in reimbursement and patient access
- our plans and prospects
- our ability to leverage our existing commercial channel and infrastructure
- the success and focus of our business strategy
- economic benefits and value of our tests
- growth opportunities
- future products, product launches and our product pipeline
- demand for our tests and drivers of demand, as well as correlations between test demand to present or future revenue
- effects of foreign currency exchange rates
- international expansion
- clinical outcomes and timing of clinical studies and publications; and
- expectations regarding potential FDA or other regulation

constitute forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act.

We refer you to our quarterly report on Form 10-Q for the quarter ended June 30, 2017 filed with the SEC, in particular to the section entitled Risk Factors, for additional information on factors that could cause actual results to differ materially from our current expectations. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these forward-looking statements.

Joining me today to make prepared remarks are:

- Kim Popovits, our Chairman of the Board, Chief Executive Officer and President;
- Brad Cole, our Chief Operating Officer and Chief Financial Officer; and
- Phil Febbo, our Chief Medical Officer.

Additionally,

- Steve Shak, our Chief Scientific Officer will be available during Q&A at the end of the call.

I'll now turn it over to Kim.

Kim:

Thanks, Emily. Good afternoon everyone, and welcome.

In the third quarter, we delivered solid results including a 2 percent increase in revenue and a 5 percent increase in tests delivered, despite disruption in U.S. regions affected by the hurricanes, which impacted revenue by approximately 3 million dollars and volumes by approximately 3 percent. Importantly, we delivered our ninth consecutive quarter of improved profitability and a 1-million-dollar profit on a non-GAAP basis in the quarter, which excludes Biocartis transaction costs.

As we approach the end of the year, I'd like to take a moment to highlight the important progress and impact we are making.

In invasive breast cancer, Oncotype DX is included in all clinical guidelines for node-negative disease and broadly available, with orders from over 90 countries serving more than 800,000 patients to-date. Adding to this strong adoption, we now have outcomes of more than 60,000 women for whom our test was ordered through prospective, randomized trials including TAILORx low-risk and PlanB; as well as leading patient registries like SEER and the Clalit healthcare system in Israel. These unprecedented, published outcomes facilitate a deeper understanding of the practice-changing impact of Oncotype DX across multiple breast cancer populations. Importantly, we believe the TAILORx intermediate results – the largest adjuvant breast cancer treatment study ever conducted – will be a significant catalyst in driving future growth and penetration when reported, establishing a new standard of care.

In prostate cancer, we continue to generate strong data, demand and market leadership for our Oncotype DX Genomic Prostate Score test in low- and

intermediate-risk patients. Importantly, we are beginning to close the gap between volume and revenue with new reimbursement, including the final coverage decision to expand Medicare coverage to qualified U.S. patients with intermediate-risk prostate cancer. With this coverage effective October 9th, we now have Medicare reimbursement across the full spectrum of prostate cancer patients for whom our test was developed, and for which we have robust validation and clinical utility data. We expect prostate revenue to continue to accelerate in 2018, with a full year of complete Medicare coverage.

As our International momentum continues to grow, we feel this is the right time to evolve and expand our business model to develop an IVD version of the Oncotype DX invasive breast cancer test that can be performed locally by laboratory partners, and in hospitals around the world, through our exclusive agreement with Biocartis.

In Europe, where we have pioneered the commercialization of our Oncotype DX breast cancer test over the last several years, there is increasing demand for genomic testing, and a related need for broad-based reimbursement by private and public payors. This positive trend led to our recent investment in a platform to reach even more customers through a localized, distributed IVD system where there is an established pathway for reimbursement. Through a comprehensive review of potential partners worldwide, the Biocartis Idylla cartridge emerged as the best-in-class option with the capability to meet our rigorous quality and reproducibility standards, requirements for ease-of-use, short turnaround time, and varying needs of customers for scalability.

Our collaboration with Biocartis positions us to accelerate adoption and global patient access to standard of care breast cancer testing with Oncotype DX,

beginning with France and Germany in 2019. Additionally, we think it will facilitate broader collaboration opportunities with pharmaceutical companies seeking diagnostic partner solutions with the ability to develop and offer tests globally through decentralized settings.

I will now turn the call over to Brad and Phil to provide further detail on our third quarter financial results, our worldwide commercial and operations progress, and recent scientific updates.

Brad...

Brad

Thanks Kim.

In the third quarter of 2017, we delivered more than 31,580 Oncotype tests, an increase of 5.4 percent, compared to the same period in 2016. The disruption from the hurricanes in certain regions of the U.S. is estimated to have negatively impacted domestic test volume by approximately 3 percent. On a worldwide basis, test volume without this disruption would have increased by approximately 7.6 percent.

Total revenue was 83.8 million dollars in the third quarter of 2017, an increase of 2 percent compared to the prior year. Revenue is estimated to have increased by approximately 5 percent without the hurricane disruption. The revenue impact in the third quarter is estimated to be approximately 3 million dollars, and was two-fold:

- First, there was a loss of revenue on test volume estimated to be approximately two million dollars due to delays in treatment planning or delays in diagnoses in these regions.
- Second, payors in the affected regions were delayed in payment processing as cash revenue was less than expected by approximately one million dollars.

We are pleased to have delivered 1.1 million dollars in profit on a non-GAAP basis, which excludes the transaction costs from the Biocartis collaboration. We continue our commitment to profitability as evidenced by the operating leverage delivered through improved efficiencies and spending controls, which resulted in

the non-GAAP profit in the quarter. This important result represents our ninth consecutive quarter of improved profitability.

For the nine months ended September 30, 2017, we delivered more than 94,730 tests, an increase of 7 percent, compared with the same period in 2016.

Total revenue for the nine months ended September 30, 2017 was 253.3 million dollars, an increase of 3 percent, compared with the same period in 2016. On a constant currency basis, revenue increased 4 percent in the nine months ended September 30, 2017, compared with the same period in 2016.

For the nine months ended September 30, 2017, operating expenses increased at a slower rate than revenue, and gross margin rate improved by 2.3 points, delivering operating leverage for the year. The 8-million-dollar revenue increase dropped directly to the bottom line where we delivered an 8-million-dollar improvement in operating loss.

We delivered 15 million dollars in adjusted EBITDA for the nine months ended September 30, 2017. Adjusting for the Biocartis transaction costs in the third quarter, this would have been 18 million dollars in adjusted EBITDA.

I will now walk you through the results across each of our key markets:

- U.S. invasive breast cancer test volume was consistent with the third quarter of the prior year and revenue decreased by 1.5 million dollars, primarily due to lower cash revenue this year. Accrual revenue continues to track test volume as expected. Specifically, we delivered 18,700 U.S. invasive breast cancer tests. Through the first half of 2017, U.S. invasive breast cancer tests delivered grew approximately 3 percent, and in the third quarter, excluding the

hurricane impact, test volume would have been up by approximately 3 percent. Importantly, we have continued to grow our U.S. invasive breast cancer test volume and market penetration, while maintaining our clear market leadership this year. We expect test growth in the fourth quarter to again be in range of 3 percent on a year over year basis and up sequentially in the historically strong fourth quarter.

- Our international business continues to accelerate with test volume growing in double digits for the third consecutive quarter this year. This quarter, test volume was 8,160, an increase of 14 percent, representing 26 percent of total test volume in the third quarter, and revenue grew to 12.9 million dollars or a 7 percent increase compared to the same period last year. For the nine months ended September 30, 2017, international test volume was up 13 percent and revenue of 39.4 million dollars grew 13 percent compared to the same period last year. On a constant currency basis, international revenue for the nine months ended September 30, 2017 grew 16 percent. We again expect double-digit test growth in the fourth quarter from our international business as well as double digit revenue growth for the year. We expect our full-year international revenue to exceed 50 million dollars for the first time in 2017.
- U.S. prostate test volume was 3,430, an increase of 39 percent despite the hurricane impact. Prostate revenue was 5.5 million dollars, more than doubling from last year. For the nine months ended September 30, 2017, U.S. prostate tests delivered grew 39 percent and revenue grew 79 percent compared with the same period in the prior year. Specifically, U.S. prostate revenue for the first nine months of the year was 12.9 million dollars and this

increase in prostate revenue has contributed to two-thirds of our global year-to-date product revenue growth. Looking ahead, we expect prostate test volume to continue to lead overall test growth and to grow again sequentially in the fourth quarter. Importantly, class penetration should exceed 20 percent in the fourth quarter with the Oncotype DX GPS test continuing to lead the market in low- and intermediate-risk prostate cancer test adoption.

Cash revenue in the third quarter was just under 24 million dollars, down by approximately 1 million, compared to a year ago, and, in the range of 28 percent of total product revenue.

57 percent of tests delivered and 72 percent of product revenue were recorded on an accrual basis in the third quarter of 2017.

Our gross margin rate was 84 percent in the third quarter, an improvement from 83.7 percent in the third quarter of 2016. We continue to expect gross margin rate to range between 83 and 84 percent.

Cash and cash equivalents and short-term marketable securities at September 30, 2017 were 119.0 million dollars, an increase of 22 million dollars, compared with 97 million dollars at December 31, 2016.

Turning now to guidance:

We continue to expect to deliver a profit for the full year excluding the Biocartis transaction costs recorded during the third quarter. Fourth quarter net income is expected to exceed 2.5 million dollars, an improvement over third quarter results, and will represent our 10th consecutive quarter of improved profitability. In addition, we expect to deliver more than 10 million dollars in adjusted EBITDA.

We expect to meet the low end of our full-year revenue guidance, which is 345 million dollars, excluding the estimated 3-million-dollar hurricane impact in the third quarter. Fourth quarter revenue is expected to be approximately 89 million dollars and to grow approximately 9 percent over the fourth quarter of 2016. Our global breast cancer business is expected to be a major contributor to this characteristically strong fourth quarter. In addition, prostate tests and revenue growth should again be more than 30 percent.

As we look ahead to 2018, we expect several key catalysts will drive strong revenue growth, including the anticipated implementation of both PAMA reimbursement at a higher level than our 2017 invasive breast rate, and AJCC staging criteria that becomes effective in January, as well as the TAILORx intermediate study results anticipated at ASCO in June.

Combined, we believe these milestones will have a significant impact on our U.S. invasive breast penetration and international reimbursement, and further solidify our global market leadership in early stage breast cancer. In addition, we will have the benefit of a full year of CMS intermediate-risk prostate coverage and expect private reimbursement to follow, leading to strong revenue growth in 2018.

I will now turn the call over to Phil to discuss recent clinical milestones.

Phil:

Thanks Brad.

Advanced molecular diagnostics are improving the quality of care and outcomes for cancer patients. Our Oncotype IQ Genomic Intelligence Platform plays an important role in delivering precision medicine with tests that optimize treatment decisions for early- and late-stage cancer patients. During the third quarter, we made significant clinical progress, presenting and publishing data to support continued strong uptake in adoption and reimbursement of our Oncotype tests.

New data presented at the ESMO Congress in Madrid, Spain, reinforced the value of the Oncotype DX Breast Recurrence Score test in accurately predicting outcomes across patient populations. Specifically, results from a SEER analysis of more than 1,700 patients younger than 40 – an age that is generally associated with a poor prognosis and intensive treatment – showed a wide range of Recurrence Score results, demonstrating that not all young women with breast cancer have aggressive disease. Importantly, in this study, those with a Recurrence Score below 18 experienced excellent outcomes at five years, even among the more than 80 percent foregoing chemotherapy.

In another study, results from the West German Study Group's PlanB study, one of the largest contemporary adjuvant breast cancer trials in Europe, showed very low rates of distant recurrence in clinically high-risk patients with node-negative and node-positive breast cancer who had a Recurrence Score less than or equal to 11 following five years of hormone therapy alone.

Another recent publication is also advancing the level of evidence supporting the use of Oncotype DX in node-positive breast cancer. This includes results from a large prospectively designed registry conducted by Clalit representing a large genomically-characterized cohort of node-positive breast cancer patients. These results, published in the journal *nature publication group Breast Cancer*, demonstrate excellent 5-year clinical outcomes across multiple subgroups including age, tumor size, and tumor grade.

Collectively, these studies once again support the ability of the Oncotype DX test to accurately identify patients who are not likely to benefit from chemotherapy despite being considered high risk based on age or other traditional clinical factors. We are confident that this real-world evidence, now in over 8,000 breast cancer patients with up to 3 positive nodes who were treated based on Recurrence Score results, will lead to more consistent guideline recommendations, continued adoption, and improved reimbursement and access for women with node positive disease.

In prostate cancer, we continued to make important progress delivering actionable results to urologists to increase adoption while further strengthening evidence to support private reimbursement. Just last month, *European Urology* published results from our collaboration with Kaiser validating the Oncotype DX Genomic Prostate Score test's ability to predict prostate cancer death and the development of metastases at 10 years. With this study, the Oncotype DX GPS test is now uniquely validated to predict both these long-term endpoints, as well as the risk of adverse pathology. No other test has the strength of evidence supporting an association with adverse pathology and no other test provides a comprehensive risk assessment that combines clinical, pathological, and

biological elements for both the current state and future risk of a man's prostate cancer. Our patient report has been updated to reflect this and we are already receiving feedback that it is enhancing decision making for urologists and their patients.

While the addition of 10-year risk of prostate cancer death and metastasis are important, understanding a man's risk for adverse pathology remains a critical factor when deciding between immediate treatment or active surveillance. This is supported by another recent publication in *Urology* that found 62 percent of patients who received an Oncotype DX GPS score chose active surveillance, compared to 40 percent of untested patients. This absolute increase in active surveillance adoption of over 20 percent aligns patient management with NCCN and AUA guidelines, is consistent with our three previously published studies, and results in 1 of 5 tested men avoiding the side effects of treatment and significant cost savings for the healthcare system. Importantly, nearly 90 percent of tested men remained on active surveillance at one year, reflecting both the urologists' and patients' confidence in their decision to choose active surveillance, and the ability of GPS to identify men with less aggressive tumors who are unlikely to require treatment.

Turning now to our collaboration with Epic Sciences. Together, we have made significant progress on the Clinical Utility Program that is providing select centers access to the Oncotype DX AR-V7 Nucleus Detect test. Feedback has been outstanding and demand is steadily growing. AR-V7 positive status is becoming regarded as an actionable disease subtype for metastatic prostate cancer given its prognostic and predictive importance in identifying patients who do not benefit from costly AR-inhibitors. Our Oncotype DX AR-V7 Nucleus Detect test identifies

patients who are AR-V7 positive with unmatched specificity and predictive value. Importantly, a dossier for Medicare coverage has been submitted in preparation for broad commercial access next year. We believe we are well positioned to obtain a positive coverage decision in early 2018.

It has always been essential to Genomic Health's mission to show how our tests reduce health care costs by optimizing treatment. This is even more important today as health care costs and premiums continue to rise unsustainably. To strengthen our capabilities in the field of health economic analyses, and engage meaningfully with private payors, we recently hired Dr. John Hornberger. A physician with a health economics degree from Stanford, John has led the industry in developing many of the most compelling health economic analyses for value-based diagnostics, including Oncotype DX. He joins additional new hires from the in vitro diagnostics, managed care, and payer community to ensure our tests align with the values and needs of patients, physicians, and payors, which are intended to be reflected in both policy and pricing decisions.

I will now turn the call back over to Kim.

Kim.

Kim:

Thanks, Phil.

As we continue to lead a revolution in precision medicine with our differentiated Oncotype IQ portfolio of tests that address both the overtreatment and optimal treatment and close 2017, we remain laser-focused on:

- Generating revenue growth; and
- Delivering full-year profitability, excluding the transaction costs from the Biocartis collaboration.

Further, looking ahead to 2018, there are multiple catalysts on the horizon that we expect to fuel future growth including:

- A full year of CMS intermediate prostate coverage and expanded private reimbursement;
- Implementation of both the PAMA market-based pricing and AJCC staging criteria for the Breast Recurrence Score test in January;
- Global impact of intermediate Recurrence Score results from the practice-changing TAILORx study
- Further reimbursement traction in Europe; and
- Broad commercial launch of our Oncotype DX AR-V7 Nucleus Detect test.

In closing, we remain committed to our mission to improve the quality of treatment decisions for cancer patients around the world through our practice-changing Oncotype tests. We will achieve this by leveraging our existing business model and unmatched commercial channel, while proactively pursuing opportunities – developed at Genomic Health and through partners - to evolve

our business strategy in driving long-term shareholder value. I would now like to open the line for your questions.

OPERATOR: [Instructions] We ask that you limit your questions to two. If time permits, we will come back to those who have re-entered the question queue.

[Q&A Session]

KIM: Thank you for joining us today and for your interest in Genomic Health. We look forward to seeing some of you at SABCS next month.

OPERATOR: And this concludes today's third quarter conference call for Genomic Health. You may now disconnect.