

EMILY: Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our second 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 2018;
- payer coverage, timing of revenues from payers 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 March 31, 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
- Steve Shak, our Chief Scientific Officer.

Additionally,

- Fred Pla, our Chief Business and Product Development 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 second quarter, we delivered 9 percent test growth and 5 percent revenue growth **on a constant currency basis**, consistent with the guidance we provided during our first quarter call. With our continued commitment to profitability, we delivered operating leverage for the eighth consecutive quarter, improved net loss by 9 million dollars in the first half of the year, and, as guided today, expect to deliver a profit for the full-year on revenue between 345 and 355 million dollars.

Importantly, our unmatched clinical evidence and commercial channel continue to drive strong demand and market leadership. In the first half of the year, we achieved our goal to continue to grow our **global** invasive breast cancer and U.S. prostate cancer business. Specifically, we:

- Increased the number of U.S. invasive breast cancer tests delivered by more than 3 percent, compared with the prior year, maintaining our significant leadership position with approximately 90 percent share of this market segment;
- Generated 14 percent test growth and 20 percent revenue growth across international markets on a constant currency basis; **and**
- Continued to accelerate prostate test adoption with 39 percent volume growth and 52 percent revenue growth, compared to the same period last year. With these strong results, we believe we continue to lead the market in low- and intermediate-risk prostate cancer test adoption.

In prostate cancer, which is a key driver of our near- and long-term growth, we continue to generate compelling data, including the new Kaiser validation study, that support increased utilization and reimbursement for the Oncotype DX[®] GPS[™] test in low- and intermediate-risk patients.

With our planned launch of the Oncotype DX AR-V7 prostate test with Epic Sciences later this year, we will achieve an important milestone in partnering with industry leaders to deliver innovative products through our commercial channel. This is the first test to accurately identify which metastatic prostate cancer patients will not respond to androgen receptor-targeted therapies. The availability of Oncotype DX AR-V7 will allow men with late-stage prostate cancer to avoid wasting time on both costly and potentially ineffective treatments.

While the global reimbursement landscape has delayed our 2017 revenue growth, there is no doubt that demand across our key businesses is strong and growing. Looking ahead, we see significant upside in 2018 with the anticipated January implementation of both PAMA reimbursement rates and AJCC staging criteria, along with the TAILORx intermediate study results. Combined, we believe these milestones will have a significant impact on U.S. invasive breast penetration and international reimbursement, and further solidify our market differentiation. In addition, we will have the benefit of a full year of CMS intermediate prostate coverage and expect private reimbursement to follow, leading to strong revenue growth in 2018.

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

Brad

Thanks Kim.

In the second quarter of 2017, we continued to generate strong test growth, delivering a 9 percent increase in volume, or more than 31,550 Oncotype™ tests compared with the same period in 2016, which was in-line with our expectations. We increased year-over-year demand across each of our key markets including sequential double-digit growth in prostate following a very strong first quarter. In the first half of 2017, we delivered more than 63,140 tests, an increase of 8 percent, compared with the same period in 2016.

Total revenue was 85.5 million dollars in the second quarter of 2017, an increase of 4 percent and as guided with the exception of, what we believe is, a temporary post-election hold on funding in France until later this year. Total revenue for the six months ended June 30, 2017 was 169.5 million dollars, an increase of 4 percent, compared with the same period in 2016. On a constant currency basis, revenue increased 5 percent in both the quarter and six months ended June 30, 2017, compared with the same periods in 2016.

In the first half of 2017, we delivered operating leverage of nearly 50 percent through expense control, excluding the termination of PCR licensing fees. We delivered more than 100 percent of our growth in revenue to the bottom line whereby operating income improvement in dollars exceeded revenue growth in dollars during the first half of 2017. We continue to remain focused on improving the bottom line.

Over the past couple of years, we have been committed to improving profitability. In 2016, we improved our operating loss by 20 million dollars, and this year we

plan to further improve our operating loss by approximately 15 million dollars as part of our goal to deliver a full-year net profit. We made continued improvements in the second quarter with favorable year-to-date operating and net loss comparisons over last year.

Specifically, operating loss improved by approximately 8 million dollars to a 6 million dollar operating loss for the six months ended June 30, 2017, compared to the same period last year. Net loss was 3.5 million dollars for the six months ended June 30, 2017, compared with a net loss of 12.5 million dollars for the same period last year. We delivered 13.1 million dollars in positive adjusted EBITDA in the first half of 2017.

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

- **U.S. invasive breast cancer** test volume was up 5 percent and revenue was up 2 percent in the second quarter, compared to last year. Specifically, U.S. invasive breast revenue was 65.6 million dollars. Accrual revenue tracked test volume. As expected, cash revenue in the quarter of approximately 19 million dollars was similar to the second quarter 2016 and up 1.7 million dollars sequentially. For the six months ended June 30, 2017, U.S. invasive breast test volume increased more than 3 percent and revenue grew 2 percent compared to the same period in 2016. Importantly, we continue to grow our U.S. invasive breast cancer business, increasing market penetration and maintaining clear market leadership.

As a reminder, we received a new CPT code and price for DCIS in the second quarter of 2016. Although DCIS revenue and tests were down year-over-year, we delivered sequential growth in tests this quarter, and, as expected, ASP

normalized on a comparison basis. DCIS revenue was under 2 million dollars in the second quarter.

- **International** test volume increased 12 percent, representing 24 percent of total test volume in the second quarter, and revenue grew 6 percent compared to the same period last year. On a constant currency basis, international revenue was up 10 percent. We estimate the temporary funding hold in France was approximately five hundred thousand dollars in revenue in the quarter. For the six months ended June 30, 2017, international test volume increased 14 percent and revenue grew 16 percent compared to the same period last year. On a constant currency basis, international revenue for the first half of 2017 was up 20 percent.
- Our **U.S. prostate** business continued to accelerate in the second quarter with 38 percent test growth and 83 percent revenue growth. Specifically, U.S. prostate revenue was 4.1 million dollars and contributed approximately half of the total global product revenue growth. For the six months ended June 30, 2017, U.S. prostate tests delivered grew 39 percent and revenue grew 52 percent compared with the same period in the prior year. Specifically, U.S. prostate revenue was 7.4 million dollars and contributed just under half of the year-to-date global product revenue growth. It is important to note, in the first half of 2017, we successfully met our commitment on prostate test growth and expect to see further growth in prostate revenue with finalized CMS reimbursement for intermediate patients and progress with private payors later this year.

As you look to calculate relative market share it is important to remember that Genomic Health reports test results delivered to physicians for treatment decisions rather than the orders received. Additionally, the opportunity for the utilization of the Oncotype DX Genomic Prostate Score™ test is 160,000 patients in the United States each year who are designated as either very-low, low or favorable intermediate risk, and does not include high-risk patients or other intermediate-risk patients. As Kim mentioned, we believe we continue to be the market leader in low- and intermediate-risk prostate cancer based on test volume performance over the last several quarters and recent market research. Prostate volume represented approximately 11 percent of total test volume in the second quarter of 2017. Looking ahead, we expect prostate test volume to continue to lead overall test growth and thereby be an increasingly larger portion of our test volume.

Cash revenue in the second quarter increased sequentially to 25.6 million dollars in the range of thirty percent of total product revenue and an increase of 2.3 million dollars as compared to the first quarter 2017.

59 percent of tests delivered and 70 percent of product revenue were recorded on an accrual basis in the second quarter of 2017.

Our gross margin rate was 83.9 percent in the second quarter, consistent with levels in recent years and an improvement over the second quarter of 2016. We continue to expect gross margin rate to range between 83 and 84 percent for the remainder of the year.

Turning now to guidance:

For the full year ending December 31, 2017, we now expect to deliver total revenue of between 345 million dollars and 355 million dollars; formerly the range was between 355 and 370 million dollars. We have adjusted the guidance range for revenue to reflect the unknown timing of TAILORx intermediate results and reimbursement delays. Specifically:

- Delays in CMS intermediate coverage, which is now expected later in the year compared to early Q2, as well as private prostate coverage;
- An unexpected hold on French payments following the recent presidential election; **and**
- Lighter than expected DCIS revenue.

It is important to note we remain pleased with the pace of adoption in our key markets globally, which continues to track as expected with growth for the year above 8 percent.

We are committed to delivering a full-year profit at either end of the new revenue guidance, which represents an improvement in our net income outlook from February. This commitment to the bottom line requires spending adjustments across the year and across our organization of nearly 16 million dollars compared with our plans from when we entered the year. We expect our net income results in both the third and fourth quarter to exceed that of 2016. By delivering these strong bottom line results in the second half, we will have achieved 10 consecutive quarters of bottom line improvement by the end of 2017 and a full-year profit.

Looking ahead to the third quarter, we expect revenue of approximately 87 million dollars. We anticipate we will return to double-digit revenue growth in the

fourth quarter, with finalization of expanded CMS coverage for intermediate-risk prostate cancer patients and continued growth in our global breast business.

Importantly, and as Kim mentioned, we expect several key catalysts will drive strong revenue growth in 2018, positioning us for long-term success with continued improvements in full-year profitability.

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

Steve

Thank you Brad.

Our recent scientific presentations and publications emphasize the continuous nature of cancer biology and the best-in-class performance of our Oncotype IQ[®] portfolio of tests.

In breast cancer, five studies were presented at the ASCO Annual Meeting, including new analyses from our collaboration with the Surveillance, Epidemiology, and End Results (or SEER) Registry program focused on outcomes in more than 49,000 women who received an Oncotype DX Breast Recurrence Score[®] test. One of these analyses evaluating the risk of breast cancer-specific mortality across the full range of Recurrence Score[®] results is consistent with previous validation studies indicating that women with Recurrence Score results less than 25 have limited benefit from chemotherapy, whereas those with scores greater than 25 appear to benefit. As we await the full results and definitive conclusions from the prospective, randomized TAILORx trial, these new SEER findings suggest that TAILORx will not only more precisely define the effect of chemotherapy in breast cancer, but that it will also identify a larger group of women who can be treated confidently with hormonal therapy alone.

In July, the St. Gallen International Breast Cancer Conference Expert Panel published updated guidelines endorsing Oncotype DX for guiding chemotherapy treatment decisions in both node-negative and node-positive breast cancer patients. Importantly, Oncotype DX was the only test supported by a majority of

panelists for its value in providing information that can help physicians decide to omit chemotherapy in patients with up to three positive nodes.

In addition to these updated guidelines and positive studies presented during the quarter, it is encouraging to see recently published data reinforcing that there is a spectrum of continuous biology in breast cancer and growing evidence from all research groups on the importance of more precise estimates of risk and chemotherapy benefit. This is exactly the intelligence that the Oncotype DX individualized Recurrence Score result has provided to more than 750,000 **breast** cancer patients over the past 13 years.

In Urology, we presented important new data validating the Oncotype DX Genomic Prostate Score (or GPS) to predict long-term outcomes, including metastasis and prostate cancer death in a large community-based, multi-center clinical validation study conducted at Kaiser Permanente. Importantly, in this study presented at AUA, no patient with NCCN very-low, low-, or intermediate-risk disease and a GPS result of less than 20 developed metastasis or died due to prostate cancer. At ASCO, another presentation looking back at earlier studies confirmed that men with a GPS result of less than 20 are at extremely low risk of developing metastatic disease or dying from prostate cancer in the 10-year period following radical prostatectomy.

Given the strength of these Kaiser study results and their expected impact on clinical practice, in late May we updated our GPS patient report to incorporate these additional, critical endpoints. The new report now includes an easy-to-interpret risk assessment based on the NCCN framework that captures clinical and pathological features, and an individual's tumor biology revealed by GPS, providing personalized risk for prostate cancer-specific death, the development of

metastasis and adverse pathology. We have received positive feedback on the new report, confirming that comprehensive risk assessments for both the current state of a man's prostate cancer and the future risk for each man diagnosed with prostate cancer enhances the ability of urologists and their patients to make the important decision between active surveillance or definitive treatment.

We believe the compelling Kaiser validation study results, our ongoing clinical utility projects with payors, and increasing demand for the Oncotype DX Genomic Prostate Score test will lead to additional reimbursement, beginning with expanded CMS coverage for intermediate patients when the LCD becomes final later this year. We expect subsequent private coverage to follow.

Finally, in preparation for the commercial launch of the new Oncotype DX AR-V7 Nucleus Detect™ test in collaboration with Epic Sciences, we recently initiated an early access Clinical Utility Program for select centers around the country. As a reminder, Oncotype DX AR-V7 is the first test to accurately identify which metastatic prostate cancer patients will not respond to androgen receptor-targeted therapies. This early utility program with oncologists and urologists aims to get feedback to ensure that, as we scale up, we continue to deliver consistent, high quality tests and the exceptional customer service that people expect from Genomic Health and Epic Sciences. We will make the test widely available in the United States later this year.

I will now turn the call back over to Kim to conclude...

Kim:

Thanks, Steve.

By providing clinically actionable insights, our growing Oncotype IQ portfolio of tests enable patients to experience the immediate value of precision medicine, addressing both the overtreatment and optimal treatment of cancer.

Our focus for the remainder of the year is clear as we work to:

- Improve revenue growth, including double-digit growth in the fourth quarter; and
- Deliver full-year profitability at either end of the adjusted revenue guidance.

Importantly, there are multiple catalysts on the horizon that we expect to fuel future revenue growth. Specifically, in 2018 we anticipate:

- 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 in January;
- Impact of intermediate Recurrence Score results from the TAILORx study; and
- Further reimbursement traction in Europe;

In closing, as August marks our seventeenth anniversary, it is timely to reflect on our bold vision to revolutionize the treatment of cancer through genomic testing. Once clinically unproven and scientifically challenging, we pursued this vision

with passion, determination and substantial investment. Today, we are proud to share that more than 800,000 actionable test results have now been delivered to patients, generating more than 2 billion dollars in revenue and more than 4 billion dollars in savings to the healthcare system, proving that we have pioneered a successful and sustainable business that is leading the revolution of precision medicine.

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 upcoming conferences this quarter.

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