

EMILY: Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our second quarter 2018 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 are not historical, including those about:

- our future financial and operating results;
- key drivers and expectations for revenue growth in 2018;
- demand for our tests and drivers of demand, as well as correlations between test demand to present or future revenue;
- payor coverage, timing of revenues from payors and progress in reimbursement and patient access;
- clinical outcomes and the timing and impact of clinical studies and publications
- 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 the value of our tests;
- growth opportunities, including international expansion;
- future products, product launches and our product pipeline;
- effects of changes in the new ASC 606 accounting standard and comparisons against prior periods;
- effects of foreign currency exchange rates;
- the new tax law; and
- expectations regarding potential FDA or other regulation of our tests.

These 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 period ended March 31, 2018, 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 Financial Officer; and
- ✓ Steve Shak, our Chief Scientific Officer and Chief Medical Officer.

Additionally,

- ✓ Fred Pla, our Chief Operating Officer, will be available during Q&A at the end of the call.

I'll now turn the call over to Kim.

Kim:

Thanks, Emily. Good afternoon, everyone, and welcome.

We delivered record results in the first half of 2018, including 14 percent revenue growth, an 8.3 million-dollar profit on a GAAP basis, and a 9.4 million-dollar profit on a non-GAAP basis in the second quarter. Importantly, we delivered our 12th consecutive quarter of improved non-GAAP profitability. These strong results were driven by:

- ✓ Successful execution across our entire business;
- ✓ Enhanced operational efficiency and greater leverage;
- ✓ Strong reimbursement for the Oncotype DX Breast Recurrence Score[®] test including PAMA; and
- ✓ Increasing private payor reimbursement for the Oncotype DX[®] Genomic Prostate Score[™] (or GPS[™]) test.

We believe we will continue to accelerate adoption and reimbursement of our Oncotype IQ[®] portfolio of proprietary tests with the recent achievement of key catalysts, including:

- ✓ **Presentation and publication of the landmark TAILORx study results in early June.** We anticipate these positive results will be transformative in increasing global adoption, reimbursement and penetration of the Oncotype DX Breast Recurrence Score. We are already seeing the impact of the TAILORx results in global invasive breast test volume following ASCO. Additionally, both NICE in the UK and G-BA in Germany announced plans to incorporate TAILORx results as they prepare to make reimbursement decisions later this year; and

- ✓ **Multiple private reimbursement decisions for the Oncotype DX GPS test**, including a top five national payor. With these new policies and existing Medicare coverage, the total number of covered lives for the GPS test in the United States is now more than 92 million.

Additionally, we reached an important milestone in our Biocartis IVD collaboration, demonstrating feasibility to perform the Oncotype DX Breast Recurrence Score test on the proprietary Idylla™ platform. We are now in the process of building the global infrastructure, including supply chain and technical and clinical support, to enable rapid deployment of our IVD solution to increase access in Europe and other markets where localized testing is critical for adoption and reimbursement.

As part of these efforts, we are identifying early access sites to conduct validation studies and are making good progress with European IVD Regulatory requirements. We remain on track to launch the Oncotype DX IVD test in late 2019 beginning with France and Germany. Based on this rapid progress, we are accelerating R&D feasibility studies with the goal of moving additional and future Oncotype DX tests to the Idylla platform to expand our international offering.

Separately, while we continue to actively develop our urology pipeline, we made a business decision to discontinue our early-stage development of the IsoPSA assay and terminate our milestone-based licensing agreement with Cleveland Diagnostics.

As we look to expand our future growth through pipeline development, we continue to actively evaluate licensing, collaboration and acquisition opportunities

to complement our internal R&D in driving leverage across our established oncology and urology channels.

I will now turn the call over to Brad and Steve to provide further detail on our second quarter financial results, as well as our worldwide commercial and clinical progress.

Brad:

Thanks, Kim.

We are very pleased with our second quarter financial results, during which we delivered double-digit revenue growth across all our key product lines.

As a reminder, effective January 1, 2018, we adopted the new ASC 606 accounting standard for revenue, using the modified retrospective method, which applies the new standard prospectively and does not impact prior years' financial statements. Since the as-reported 2017 quarterly and annual financial statements will not be restated to reflect the new accounting standard, we have provided a supplemental financial schedule in the non-GAAP tables in our press release, reflecting an estimate of revenue as if the new standard had been applied as of January 1, 2017, which we will refer to as pre-ASC 606 adjusted figures in our comparative comments.

In the second quarter of 2018, total revenue was 95.6 million dollars, an increase of 14 percent, compared to the pre-ASC 606 adjusted revenue of 83.8 million dollars for the second quarter of 2017. On a constant currency basis, revenue increased 13 percent.

For the six months ended June 30, 2018, total revenue was 188.2 million dollars, compared with pre-606 adjusted revenue of 166.1 million dollars for the same period in 2017, an increase of 13 percent.

In the second quarter of 2018, we delivered an 8.3 million-dollar profit, an improvement of 11 million dollars compared with the same period in 2017. On a non-GAAP basis, profit was 9.4 million dollars. These strong results mark our 12th

consecutive quarter of improved profitability on a year-over-year non-GAAP basis.

For the six months ended June 30, 2018, we delivered a 4.5 million-dollar profit, an improvement of 8 million dollars. On a non-GAAP basis, profit was 14 million dollars for the first six months ended June 30, 2018.

We delivered more than 33,590 Oncotype™ test results in the second quarter of 2018, an increase of 6 percent, compared to the same period in 2017. Revenue growth of 14 percent was driven about equally by test volume -- up over 6 percent -- and reimbursement improvements and collection efficiency increasing realized average selling price by 8 percent.

85 percent of tests delivered and 93 percent of product revenue were recorded on an accrual basis in the second quarter of 2018.

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

- **U.S. invasive breast cancer** revenue was 72.5 million dollars in the second quarter of 2018, an increase of 13 percent, compared to pre-ASC 606 adjusted revenue for the same period in 2017. Revenue was up 12 percent for the six months ended June 30, 2018. This accelerated revenue growth in the second quarter was driven by:
 - Increased test volume resulting in revenue growth of 4 percent and contributing more than 30 percent of total growth;
 - PAMA implementation adding 3 percent to revenue growth and contributing approximately 20 percent of total growth;

- Stronger ASP overall from private payors, a result of contract renewals and collection efficiency, contributing nearly 3 percent to growth and more than 30 percent of total growth; and
- The move to the new revenue standard positively impacting growth as well and contributing approximately 10 percent of total growth.

U.S. invasive breast cancer test volume increased 4 percent year-over-year in the quarter and 4 percent year-over-year for the six-month period.

Early positive impact in June following the presentation of TAILORx results was reflected in strong test demand, up 7 percent in June compared with May 2018, and up 7 percent compared with June 2017.

- **International** product revenue was 14.2 million dollars in the second quarter of 2018, an increase of 11 percent, compared to pre-ASC 606 adjusted revenue. On a constant currency basis, revenue grew 6 percent. International revenue increased 8 percent for the six-month period ended June 30, 2018. On a constant currency basis, revenue grew 4 percent. The number of international tests delivered in the second quarter of 2018 was consistent with the same period in 2017, and represented approximately 23 percent of total test volume in the quarter. International test volume declined 3 percent for the six-month period ended June 30, 2018, compared to the same period in 2017.

Excluding Germany where we changed the ordering model late last year to require committed payment prior to accepting orders, and the conclusion of

certain studies for which we provided tests, international volume was up 16 percent year-over-year in the second quarter. While these changes have impacted tests delivered, as expected, we are beginning to see progress in both payor engagement and coverage, contributing to this double-digit revenue growth.

Additionally, similar to the U.S., the TAILORx results have had an early impact internationally. Test demand was up 14 percent in June compared with May 2018, and up 10 percent compared with June 2017.

Looking ahead, with these TAILORx results and anticipated reimbursement decisions in the UK and Germany later this year, we expect international revenue to continue to grow in double digits.

- In **U.S. prostate**, we delivered record revenue for our GPS test of 6.7 million dollars, an increase of 63 percent, which contributed more than 20 percent to total revenue growth in the quarter. This higher revenue was equally driven by:
 - higher test volume, which grew 32 percent, and
 - increased payments for qualified billable tests and coverage from private payors.

Oncotype DX GPS test volume growth was as expected with continued market leadership in low- and intermediate-risk prostate cancer. We are starting to see an uptick in private coverage with more than 42 million U.S. private lives now covered, in addition to the 50 million lives covered by

Medicare. For the six months ended June 30, 2018, GPS revenue was up 72 percent and tests delivered were up 29 percent. We continue to expect full-year GPS revenue growth to be approximately 50 percent and test volume to be approximately 30 percent as originally planned.

While it is still early, we are encouraged by the initial response to our launch of the Oncotype DX AR-V7 Nucleus Detect™ test, and anticipate it will provide a more meaningful impact on both test and revenue growth following the finalization of the Medicare LCD, which we expect to occur in the third quarter.

Gross margin rate increased to 85 percent in the second quarter due to:

- Stronger average selling price for our U.S. invasive breast test and continued benefit of PAMA;
- Stronger average selling price and revenue growth for our GPS test;
- Our new international payment model; and
- Further operating efficiencies.

Moving forward, we expect gross margin rate to be 84 percent, in line with our year-to-date gross margin rate.

Cash and cash equivalents and short-term marketable securities at June 30, 2018, were 152.9 million dollars, an increase of 23.3 million dollars from December 31, 2017.

In the second quarter, non-GAAP adjusted EBITDA was 17.6 million dollars. For the first six months of the year, non-GAAP adjusted EBITDA was 30.5 million

dollars, on track to exceed the more than 50 million dollars for the year we expected.

Looking ahead at the remainder of the year, we reiterate our full-year guidance. Specifically, in 2018, we are guiding to:

- Total revenue of between 366 and 382 million dollars, representing growth between 10 and 15 percent compared with 2017. Given our strong first half performance and revenue beat, we currently expect to deliver revenue at the higher end of revenue guidance for the year. As a reminder, the positive TAILORx results at ASCO were assumed in our 382 million dollar revenue guidance
- Net income, or profit, between 14 and 20 million dollars on a non-GAAP basis, which excludes:
 - clinical and commercial development milestone expense, and
 - the first quarter realignment charge.

We are very pleased with our first half results including record revenue levels and continued operating leverage, having delivered our 12th consecutive quarter of improved non-GAAP operating results. Based on this strong performance, we expect the street will raise revenue and non-GAAP net income projections, and are comfortable with the high-end of both our revenue and net income guidance ranges. As a reminder, to achieve the high-end of our revenue guidance we must deliver:

- U.S invasive breast revenue growth of greater than 10 percent, contributing to over 50 percent of expected revenue growth for the year;

- Prostate GPS revenue growth of approximately 50 percent and increasing reimbursement from private payors, contributing approximately 20 percent of expected revenue growth for the year;
- Improved revenue growth in international markets with expanded test volume globally and reimbursement coverage in Western Europe, contributing approximately 20 percent of expected revenue growth for the year; and
- A fourth quarter contribution from the Oncotype DX AR-V7 Nucleus Detect test.

As planned, in the second half of the year, we anticipate increased spend associated with the ramp-up of our IVD product development and business process enhancements globally.

We remain committed and well-positioned to deliver double-digit revenue growth and continued improvement in profitability in 2018.

I will now turn the call over to Steve to discuss one of our key growth drivers – the recent TAILORx results.

Steve:

Thanks Brad.

June 3rd marked the day that we, and thousands of physicians and hundreds of thousands of breast cancer patients around the world, had been waiting for with the reporting of positive TAILORx results assessing the effect of chemotherapy in women with early-stage breast cancer and Oncotype DX Breast Recurrence Score results of 11 to 25. In meeting its primary endpoint, this study – presented in the plenary session at ASCO and simultaneously published in *The New England Journal of Medicine* – provides the highest level of clinical evidence for Oncotype DX. With these results, physicians can now tell every patient, with precision, what their magnitude of chemotherapy benefit will be.

Before I review the TAILORx results in detail, on behalf of all of us at Genomic Health, I want to thank the thousands of people around the world who made this landmark study possible – especially the 10,273 patients whose selfless participation enables a new global standard of care in breast cancer diagnosis and treatment.

As a reminder, the TAILORx trial was independently designed and led by ECOG-ACRIN under the sponsorship of the National Cancer Institute, or NCI. It is the largest breast cancer treatment trial ever conducted, and thousands of investigators enrolled more than 10,000 women across approximately 1,200 sites in six countries. All five adult cancer research groups in the NCI's network enrolled patients, and leading breast cancer advocacy organizations, including the Breast Cancer Research Foundation, Susan G. Komen and the National Breast Cancer Coalition, supported the trial.

TAILORx provides the most definitive answer about how to treat women with early-stage breast cancer using the Oncotype DX test. These Phase 3 trial results provide an unprecedented level of precision supporting the use of the test to guide adjuvant chemotherapy use in this population, which accounts for about one-half of all breast cancers.

With regard to the primary endpoint, TAILORx enrolled approximately 7,000 women with Oncotype DX Breast Recurrence Score results of 11 to 25. This primary study group was randomized to receive hormonal therapy with or without chemotherapy in order to more precisely define the benefit of chemotherapy, if any. These randomized patients with Recurrence Score results of 11 to 25 comprised approximately two-thirds of all TAILORx patients and were followed long-term, with nine-year outcomes reported. This group of women represents approximately 260,000 breast cancer patients diagnosed in major global markets each year.

The TAILORx study definitively established that chemotherapy can be spared in at least 70 percent of patients. The relationship between the Recurrence Score result and chemotherapy benefit is clear. Tumor size or tumor grade did not predict chemotherapy benefit, proving that the biology revealed by the Recurrence Score is essential in determining chemotherapy benefit. Thus, the unique TAILORx trial has established that chemotherapy treatment should be guided by the Recurrence Score result. Only the Oncotype DX test finds the patients with high Recurrence Scores who should be treated with chemotherapy to prevent distant recurrences, and the patients with low Recurrence Scores who can safely avoid chemotherapy.

Media coverage of the TAILORx results was extraordinary, with compelling quotes from highly regarded key opinion leaders and advocacy groups around the world. The broad media dissemination of these practice changing results, including key countries where there remains significant opportunity for increasing patient access, inspired a positive global reaction.

We are also encouraged by the continuing flow of information and interest in the TAILORx results, including:

- a positive editorial published in *The New England Journal of Medicine* last month;
- continued media coverage in the United States and Europe; and
- a record number of educational sessions hosted by our medical team and thought leaders around the world in June and July to educate physicians as they appropriately apply these landmark results to clinical practice.

We, along with key opinion leaders, believe the significant TAILORx results warrant immediate review and inclusion in clinical guidelines. As Dr. William Gradishar, an oncologist at Northwestern University and chair of the NCCN cancer treatment guidelines committee has stated, “Clearly, this is a landmark study. I think it will cause some changes in the guideline language.”

As a reminder, TAILORx, as well as the completed NSABP B-20 and the SWOG-8814 Oncotype DX studies, are unparalleled in their specific design to formally identify those patients who benefit from chemotherapy, as well as those who do not, using randomization to treatment. While other prospective studies have looked at prognosis, TAILORx was uniquely designed to answer the most important question regarding the prediction of chemotherapy benefit. Large

randomized clinical trials like TAILORx provide the gold standard of clinical evidence and come along once in a decade at best. We are proud that Oncotype DX is the only genomic test to have been studied in such depth and believe it will be uniquely indispensable to clinical practice moving forward.

I'll now turn the call back over to Kim.

Kim:

Thanks, Steve.

Through effective execution across our entire business and publication of the practice changing TAILORx results, the first half of 2018 was critical to both our short- and long-term growth. As we look ahead, we believe we are well-positioned to drive further adoption and reimbursement of our portfolio globally. Importantly, we are on track to deliver double-digit revenue growth and a full year of profitability.

Our remaining 2018 priorities include:

- Leveraging the strong prospective evidence that TAILORx provided to encourage more clinicians to use the Oncotype DX breast cancer test for all eligible patients worldwide;
- Driving further adoption of the Oncotype DX GPS test while leveraging a full year of CMS intermediate-risk coverage and expanding private reimbursement; and
- Furthering reimbursement success in large European markets for our invasive breast cancer test.

We are on a path to deliver both near-term growth and profitability, while continuing to develop and deliver high-value tests that improve treatment decisions and outcomes for cancer patients around the world.

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 investor conferences and medical meetings.

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