

**EMILY:** Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our first 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](http://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 and full-year 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
- payer coverage, timing of revenues from payers 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

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-K for the year ended December 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 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 revenue results in the first quarter of 2018 with 13 percent revenue growth, when compared to pre-ASC 606 adjusted revenue, and a non-GAAP profit of 4.6 million dollars, representing our 11<sup>th</sup> consecutive quarter of improved profitability.

In driving our business towards near-term growth and increased profitability, we are squarely focused on catalysts that we expect will accelerate adoption and reimbursement of our Oncotype IQ<sup>®</sup> portfolio of proprietary tests. With this direction and alignment of resources, we are seeing the expected impact as evidenced by our strong performance in the first quarter, and are pleased to report the following highlights:

- We delivered 4 percent growth in our U.S. invasive breast cancer business, slightly above our expectations prior to the reporting of TAILORx results.
- Based on payments received in the first quarter, we anticipate PAMA market-based pricing, which resulted in more than a 10 percent increase to our Medicare rate, to have an eight million-dollar impact on the topline in 2018.
- New AJCC breast cancer staging criteria, which name Oncotype DX<sup>®</sup> specifically, are in place and supporting increased adoption.
- Strengthened NCCN prostate cancer guidelines and additional new data are increasing private coverage for the Oncotype DX GPS<sup>™</sup> test. Specifically, published in *Reviews in Urology*, real-world clinical evidence from the Optum Research Database of administrative claims from a large

U.S. health insurer demonstrated that the GPS test increased use of active surveillance by 30 percent in low-risk patients, resulting in greater adherence to guideline-based care. We now have published utility evidence from four studies in nearly 8,300 men, reinforcing the actionable impact of the GPS test in prostate cancer treatment planning.

- In addition, the U.S. commercial launch of Oncotype DX AR-V7 Nucleus Detect™ – a liquid biopsy test for metastatic prostate cancer– is expected to contribute to our growth this year. We were pleased that, in March, Medicare issued a draft LCD recommending coverage for use of the test throughout the United States to help identify patients who have become resistant to androgen receptor inhibitor therapy and could benefit from chemotherapy.

Most importantly, we are excited to share that TAILORx, the ECOG-ACRIN-led trial conducted under the sponsorship of the NCI, has been accepted as a late-breaking presentation at the ASCO Annual Meeting Plenary Session on Sunday, June 3rd.

We look forward to collaborating with ECOG and NCI to broadly communicate the highly anticipated TAILORx results at ASCO, and to further transforming clinical practice for women and physicians globally with the Oncotype DX Breast Recurrence Score®.

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

**Brad:**

Thanks Kim.

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 first quarter of 2018, total revenue was 92.6 million dollars, an increase of 13 percent, when compared to the pre-ASC 606 adjusted revenue of 82.3 million dollars for the first quarter of 2017. On a constant currency basis, revenue increase 12 percent. Total revenue was 84 million dollars in the first quarter of 2017.

87 percent of tests delivered and 95 percent of product revenue were recorded on an accrual basis in the first quarter of 2018.

Our net loss for the first quarter 2018 was 3.8 million dollars and included a one-time 8.5 million dollar charge for the realignment of resources that was completed in the quarter.

We delivered a 4.6 million dollar non-GAAP profit, demonstrating our continued commitment to profitability as evidenced by the operating leverage delivered this

quarter through accelerated revenue growth, improved efficiencies and spending controls. These net income results mark the 11<sup>th</sup> consecutive quarter of improved profitability on a year-over-year basis.

We delivered more than 32,440 Oncotype™ test results in the first quarter of 2018, an increase of 3 percent, compared to the same period in 2017.

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

- U.S. invasive breast cancer revenue of 71 million dollars, which was greater than anticipated, and increased 12 percent when compared to pre-ASC 606 adjusted revenue. Test volume increased 4 percent year-over-year, which is the highest reported quarterly growth in the last three quarters, and, higher than full-year 2017 growth of 3 percent. Record invasive breast test volume is indicative of continued strong demand raising overall Oncotype DX Breast Recurrence Score market adoption to nearly 60 percent. This accelerated revenue growth of 12 percent was driven by:
  - test volume resulting in revenue growth of 4 percent;
  - PAMA implementation adding more than 3 percent to revenue growth;
  - stronger ASP overall from private payers contributing nearly 3 points to growth; and,
  - the move to the new revenue standard impacting growth positively by approximately 2 points.
  
- International product revenue was 13.8 million dollars in the first quarter of 2018, an increase of 5 percent when compared to pre-ASC 606 adjusted

revenue. On a constant currency basis, revenue grew 1 percent. International invasive breast cancer tests delivered declined by 7 percent compared with the prior year.

Excluding Germany, France and Italy, international tests delivered were up 8 percent year-over-year, led by the U.K. where test growth was 11 percent. As a reminder, we have historically provided a significant number of tests in these markets through clinical trials and patient access programs. In the fourth quarter of 2017 we began requiring committed payment to be in place prior to accepting orders. While this has impacted test volume, as expected, we are beginning to see progress in both payer engagement and coverage.

In April, the National Institute for Health and Care Excellence, or NICE, in the United Kingdom issued a revised Diagnostics Consultation Document continuing to recommend the Oncotype DX invasive breast cancer test. This decision by NICE follows a large response to the earlier consultation from the clinical community and other stakeholders, with respondents resoundingly advocating for continued access to Oncotype DX testing for patients. We will continue to encourage NICE to incorporate results from TAILORx in its final guidance, which is currently expected in September 2018.

- In U.S. prostate, revenue of 5.8 million dollars delivered 75 percent revenue growth. This higher revenue was equally driven by three factors:
  - higher test volume which grew 25 percent;

- increased payments and coverage from private payers, and
- CMS coverage of intermediate-risk patients, compared to no coverage a year ago.

Our test volume was as expected with the Oncotype DX GPS test continuing to be the market leader in low- and intermediate-risk prostate cancer. We are starting to see an uptick in private coverage with more than 21 million U.S. private lives now covered, in addition to the 50 million lives covered by CMS. We plan to expand our urology sales team by mid-year. Further, we continue to expect full-year GPS test volume and revenue growth to be over 30 percent.

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.

On a non-GAAP basis, gross margin rate was 83 percent in the first quarter, and we continue to expect gross margin rate to range between 83 and 84 percent.

Cash and cash equivalents and short-term marketable securities at March 31, 2018 were 130.4 million dollars, which included the fair value of the company's investment in Biocartis, a marketable security of 3.8 million dollars.

In the first quarter, non-GAAP adjusted EBITDA was 12.9 million dollars.

Looking ahead at the remainder of the year, we continue to expect total revenue of between 366 and 382 million dollars, representing growth of between 10 percent and 15 percent as previously guided.



We are very pleased with our first quarter operating results and record revenue level. We still have important progress to make in order to achieve the high-end of our revenue guidance range. Specifically:

- U.S invasive breast revenue growth of 8 to 10 percent, contributing to over 40 percent of expected revenue growth for the year. We continue to expect an impact in the second half of the year following the TAILORx results presentation at ASCO.
- For the prostate GPS test, volume growth above 30 percent and increasing reimbursement from private payers, contributing approximately 20 percent of expected revenue growth for the year.
- Improving 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
- CMS coverage for our Oncotype DX AR-V7 Nucleus Detect test, contributing over 15 percent of expected revenue growth for the year.

In addition to delivering double digit revenue growth, we are committed to continued improvement in profitability on a non-GAAP basis in 2018.

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

**Steve:**

Thanks Brad.

We were delighted when we learned that the TAILORx study results assessing the effect of chemotherapy in women with early-stage breast cancer and Oncotype DX Breast Recurrence Score results of 11 to 25 were accepted for presentation at the ASCO Plenary Session on Sunday, June 3rd. Dr. Joseph Sparano, the Study Chair, will be presenting the results of this landmark trial on behalf of all the investigators.

As a reminder, the TAILORx trial was independently designed and led by ECOG-ACRIN under the sponsorship of the NCI. It is the largest adjuvant breast cancer treatment trial ever conducted, and thousands of investigators enrolled more than 10,000 women across approximately 1,200 sites and 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, also supported the trial.

TAILORx is a prospective randomized clinical trial designed to more precisely define the effect of chemotherapy for women considered to be at intermediate risk for recurrence based on their Oncotype DX test result. Specifically, which of these women can effectively use hormone therapy alone, sparing them the well-known side effects of chemotherapy, while identifying those who will truly benefit.

The TAILORx investigators designed the trial based on the clinical validation studies performed by NSABP which clearly showed that the Recurrence Score when high predicted a large benefit of chemotherapy and that the Recurrence

Score when low was associated with minimal to no benefit from chemotherapy. In TAILORx, the Oncotype DX test was performed for every patient enrolled in the study. Based on the NSABP results, TAILORx participants with Recurrence Score results less than 11 were treated with hormonal therapy alone while those with Recurrence Score results greater than 25 were treated with chemotherapy plus hormonal therapy.

As you may recall, results from the TAILORx secondary study group, or women with Recurrence Score results less than 11, were previously published in *The New England Journal of Medicine* in 2015. More than 99 percent of these 1,626 women who received hormonal therapy alone without chemotherapy were free of breast cancer distant recurrence after five years.

With regard to the primary endpoint, TAILORx enrolled more than 6,700 women with Oncotype DX 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 65 percent of all TAILORx patients and were followed long-term, for about nine years on average. Furthermore, this group of women represents approximately 260,000 patients diagnosed in major global markets each year.

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 the 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 is the only study specifically 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.

Further, as previous comparative studies have clearly shown, one cannot infer that a prognostic-only test result is equivalent to the Oncotype DX Recurrence Score. In fact, there is a demonstrated large lack of concordance between tests that is clinically meaningful.

As Dr. Larry Norton, the Deputy Physician-in-Chief for Breast Cancer Programs at Memorial Sloan Kettering Cancer Center has described, quote: *TAILORx results in the 11-25 Recurrence Score range will clearly inform breast cancer adjuvant treatment guidelines.* End quote.

We, along with the medical community, eagerly await Dr. Sparano's late-breaking presentation at the ASCO Plenary Session on June 3<sup>rd</sup>.

**Kim:**

Thanks, Steve.

In the year that marks our eighteenth anniversary, we believe 2018 will be momentous for Genomic Health and the hundreds of thousands of cancer patients we have the potential to serve each year.

As we lead a new era of precision cancer diagnosis and treatment, we are well positioned with multiple catalysts to drive further adoption and reimbursement of our portfolio globally.

Robust and large randomized clinical trials like TAILORx come along once in a decade at best. As we approach ASCO, and potentially a new standard of care in breast cancer diagnosis and treatment, I want to pause to reflect on the bold founding vision that continues to inspire us every day – to optimize the treatment of cancer through genomic testing. With our passion, determination, and substantial investment, Genomic Health has collaborated with the scientific community to transform this once clinically unproven and scientifically challenging vision into a reality. We have now delivered more than 900,000 test results to cancer patients in over 90 countries, generating more than 2.5 billion dollars in revenue and over 5 billion dollars in savings to the healthcare system, and we are only just getting started.

In addition to leveraging the TAILORx results to allow more patients to benefit from our Oncotype DX breast cancer test, our remaining 2018 priorities include:

- Driving further adoption of the Oncotype DX GPS test while leveraging a full year of CMS intermediate-risk coverage and expanding private reimbursement;
- Securing Medicare coverage for Oncotype DX AR-V7; and
- Furthering reimbursement success in large European markets for our invasive breast cancer test.

With the evolution of our business strategy, and the right partners and resources in place to broaden our reach, we look forward to accelerating both near- and long-term profitable growth, while continuing to bring *life, changing* value to cancer patients worldwide.

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 ASCO.

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