Emily:

Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our fourth quarter and year-end 2018 financial results.

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.

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 some of the information presented today may contain projections or other forward-looking statements regarding future events or the future financial performance of the company, including our financial guidance for 2019. These statements are based on management's current expectations, and the actual events or results may differ materially and adversely from these expectations. We refer you to our most recent annual report on Form 10-K, and quarterly report on Form 10-Q, as 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.

I'll now turn the call over to Kim.

Kim:

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

2018 was a record year for Genomic Health. We delivered 394.1 million dollars in revenue -- or growth of 18 percent; and 39.7 million dollars in profit on a non-GAAP basis -- compared to a 1.6 million dollar loss in 2017. In doing so, we exceeded both top and bottom line expectations for the year and delivered our 14th consecutive quarter of improved non-GAAP profitability.

This strong performance reflects increasing global demand and revenue for our Oncotype DX Breast Recurrence Score® test and continued adoption and growing reimbursement for our Oncotype DX® Genomic Prostate Score®, or GPS™ test, as well as success in driving operational efficiencies across our business.

In collaboration with physicians around the world, we have now delivered more than one million Oncotype DX® tests to cancer patients. Since launching in 2004, more than 53,000 physicians in 90 countries have used Oncotype DX to optimize treatment decisions for patients with breast, prostate and colon cancers. With this impressive and rewarding achievement, we are delivering on the promise of precision medicine by improving outcomes for cancer patients, while saving healthcare systems around the world billions of dollars.

I'd like to take a moment to highlight the important accomplishments that drove this year's strong performance and position us for continued growth in 2019.

In our core invasive breast cancer business, we reached a long-awaited clinical milestone and business catalyst with the publication of the landmark TAILORx trial that used Oncotype DX to precisely define the effect of chemotherapy for all early-stage breast cancer patients. These practice-changing results are already making an impact on elevating Oncotype DX to a new global standard of care with increasing traction among physicians with high-growth potential to use Oncotype DX more consistently for all medically eligible patients. Additionally, exclusive guideline endorsements from NCCN and IQWiG in Germany; and an expanded recommendation from NICE in the UK, globally distinguish Oncotype DX from other genomic tests based on clinical evidence and the critical importance of predicting chemotherapy benefit. With an anticipated reimbursement decision from GBA in Germany in the coming months, combined with continued TAILORx momentum, we expect to drive meaningful growth in our core invasive breast cancer business in 2019.

I'd now like to turn to our urology franchise, where we have two market-leading prostate cancer tests representing a growth opportunity greater than 500 million dollars. With strengthened NCCN guidelines for the Oncotype DX GPS test, and additional data reinforcing its clinical utility, we secured multiple private reimbursement decisions this year, including a top 5 national payor. This brings the total number of U.S. covered lives to more than 100 million.

In early 2018, we launched the Oncotype DX AR-V7 Nucleus Detect™ test to help physicians select the most effective treatment for patients with metastatic castrate-resistant prostate cancer. Medicare's final local coverage determination,

or LCD, became effective in December, establishing coverage for approximately half of the 50,000 eligible patients in the United States each year. We expect this to have a positive impact on both test and revenue growth in 2019.

Now, updating our progress to broaden global access and expand our business through the development of a sample-to-answer version of the Oncotype DX Breast Recurrence Score test on the Idylla™ platform: In 2018, we completed and met our goals for technical feasibility, and recruited clinical validation sites in France and Germany and expect to place IVD instruments at those sites in 2019.

Based on this successful progress, in December we expanded our exclusive collaboration with Biocartis to include urology for the development of an IVD version of our Oncotype DX GPS test here in the United States. This decision reflects our confidence in the Idylla platform as a best-in-class solution to accelerate access to Oncotype™ tests around the world and diversify our test portfolio for longer-term growth.

Finally, I would like to highlight an exciting appointment to our executive management team with the promotion of Dr. Rick Baehner to Chief Medical Officer. Rick has served cancer patients for more than 20 years at the University of California, San Francisco and began his career at Genomic Health 17 years ago. He has held various leadership roles at Genomic Health, most recently as Vice President of Oncology and Pathology Development. As Chief Medical Officer, Rick will oversee our global medical and pathology organizations, reporting directly to Fred Pla, our Chief Operating Officer.

I will now turn the call over to Brad to provide further details on our fourth quarter and year-end financial results.

Brad:

Thanks, Kim.

We are very pleased with our fourth quarter and full-year 2018 financial results. We delivered double-digit revenue growth across all key product lines and significantly improved our profitability and operational efficiency. And with our strong fourth quarter results, we exceeded expectations for the year, while achieving our 14th consecutive quarter of improved non-GAAP profitability.

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.

I will begin with our full year results. Total revenue was 394.1 million dollars in 2018, an increase of 18 percent, compared with pre-ASC 606 adjusted revenue of 334 million dollars for 2017. The implementation of PAMA, a positive driver for our U.S. invasive breast price in particular and the new revenue recognition accounting standard under ASC 606, positively impacted full year 2018 revenue by approximately 4 percent. Excluding these effects, overall revenue growth on

an adjusted basis was 14 percent in 2018. Test volume drove 8 points of growth and reimbursement improvements contributed another 6 points of growth.

GAAP net income for the full year was 25.7 million dollars, an improvement of 29.6 million dollars, compared with a net loss of 3.9 million dollars in 2017.

Non-GAAP net income was 39.7 million dollars for the year, an improvement of 41.3 million dollars, compared with a 1.6 million dollar non-GAAP net loss in 2017.

In 2018, our gross margin rate was 84 percent, consistent with 2017 and our expectations for the full year 2019.

Now turning to our fourth quarter 2018 results. Total revenue was 104.6 million dollars for the quarter, an increase of 22 percent, compared with pre-ASC 606 adjusted revenue of 85.7 million dollars for the fourth quarter of 2017. This fourth quarter revenue result includes approximately 3.5 million dollars on a year-to-date basis to reflect ASC-606 portfolio adjustments. Without this adjustment, fourth quarter revenue would have been 101.1 million dollars, in line with our recent expectations, and revenue growth would have been 18 percent.

GAAP net income for the quarter was 8.9 million dollars, an improvement of 7 million dollars compared with the same period in 2017.

Non-GAAP net income was 12.4 million dollars for the quarter, an increase of 9.5 million dollars, compared with the fourth quarter of 2017.

In the fourth quarter, we delivered more than 35,530 Oncotype tests, an increase of 11 percent compared to a year ago, following the third quarter, which also posted year-over-year double-digit test growth. The double-digit test growth is a

result of global invasive breast strength following TAILORx results, and strength in U.S. GPS prostate test growth, which increased 19 percent as compared to the fourth quarter last year. And sequentially, GPS test growth was up by 9 percent, lifted by early contributions from our recent Urology salesforce expansion. For the full year, we delivered more than 136,380 Oncotype tests, an increase of 8 percent, compared to 2017, led by GPS growth of 23 percent.

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

- U.S. invasive breast cancer revenue was 299.4 million dollars for the year, an increase of 18 percent, compared to pre-ASC 606 adjusted revenue of 254 million dollars for 2017. In the fourth quarter, revenue was 79.3 million dollars, an increase of 22 percent, compared to pre-ASC 606 adjusted revenue of 64.7 million dollars for the same period in 2017. U.S. invasive breast cancer test volume increased 7 percent for the year and 9 percent year-over-year for the quarter. This strong growth in the back half of the year was driven by TAILORx.

- International Oncotype DX product revenue was 59.4 million dollars for the year, an increase of 14 percent, compared with pre-ASC 606 adjusted revenue of 52 million dollars for 2017. On a non-GAAP constant currency basis, international revenue for the year grew 12 percent.

  In the fourth quarter, international revenue increased 19 percent to 16 million dollars, compared to pre-ASC 606 adjusted revenue of 13.4 million dollars for the same period in 2017. On a non-GAAP constant currency basis, international revenue for the quarter increased 21 percent.

As we experienced in the U.S., TAILORx results continued to have a strong impact internationally. The number of international tests delivered in the fourth quarter grew 15 percent compared with the same period in 2017 and represented 24 percent of total test volume in the quarter.

For the full year, international test volume increased by 4 percent, which represented 24 percent of total test volume in 2018. Excluding Germany and Italy, annual international test growth was up 13 percent for the year.

- U.S. prostate revenue was 26.8 million dollars for the year, an increase of 50 percent, compared with pre-ASC 606 adjusted revenue of 17.9 million dollars for 2017, and led overall company test growth in 2018. During the fourth quarter, revenue grew to 7.4 million dollars, increasing 48 percent, compared to pre-ASC 606 adjusted revenue of 5 million dollars for the same period in 2017. U.S. prostate test volume increased by 23 percent for the year and 19 percent year-over-year for the quarter. We believe class penetration now exceeds 30 percent and growing with the Oncotype DX GPS test continuing to be the market leader in low- and intermediate-risk prostate cancer test adoption and revenue.

We delivered more than 72 million dollars in adjusted EBITDA for the full year, significantly exceeding expectations from the beginning of 2018. These improved financial results have further translated into a significant increase in our cash position at the end of 2018.

Cash, cash equivalents and short-term marketable securities at December 31, 2018, were 209.8 million dollars, an increase of 80.2 million dollars from last year.

Turning now to 2019 guidance, we are guiding to:

- Total revenue of between 436 and 448 million dollars, representing growth between 11 and 14 percent compared with 2018. It is important to note that without the effect of PAMA and the new revenue recognition standard, full year revenue growth in 2018 would have been 14 percent, consistent with the high-end of our 2019 revenue guidance.

- Non-GAAP net income between 54 and 60 million dollars, representing growth between 35 and 50 percent compared with 2018. This level of net income growth is consistent with our commitment to 40 percent operating leverage.

With our anticipated double-digit revenue growth range and even greater net income growth in 2019, we expect to deliver more than 90 million dollars in adjusted non-GAAP EBITDA for the full year 2019.

The high-end of our 2019 revenue guidance range is based on the following:

- In our U.S invasive breast business, mid-to-high single-digit volume growth, contributing to approximately 30 percent of expected company revenue growth for the year;
- For prostate GPS – continued volume growth of approximately 20 percent and additional pricing strength from the new CMS PLA code, driving revenue growth above 30 percent, altogether contributing approximately 20 percent of expected company revenue growth for the year;
- For our international business - revenue growth above 50 percent driven by test volume growth above 25 percent and expanded public reimbursement

coverage in Germany beginning in the second half. This would contribute to approximately 40 percent of expected revenue growth for the year;

- Additionally, we expect our AR V-7 test for metastatic prostate cancer will make its first contribution to revenue with our first full year of Medicare coverage.

The low-end of our 2019 revenue guidance range is based on volume growth below high-end guidance estimates and a delay in German public reimbursement.

We expect greater year-over-year revenue growth in the first half of 2019 when compared to our expectations for the second half of 2019. This is a result of the strong uptake in the second half of 2018 following the publication of TAILORx results in June. We expect to deliver our 15th consecutive quarter of year-over-year improved non-GAAP profitability in the first quarter.

I'd like to remind you the expected increase in expenses from the fourth quarter of 2018 to the first quarter of 2019 is in line with our historical trend, primarily due to personnel costs being reset in the new year, and training and education programs that are more concentrated in the early part of each year.

We have entered 2019 with strong momentum in our business and expect to deliver revenue growth between 11 and 14 percent, significantly greater improvement in profitability for the full year with continued operating leverage, and non-GAAP operating income as a percent of revenue above 10 percent. Additionally, we expect 2019 operating margin expansion to deliver net income growth between 35 and 50 percent for the year on a non-GAAP basis.

We believe we are well-positioned to drive further adoption and reimbursement across our Oncotype IQ® portfolio globally and even greater improvement in profitability for the full year.

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

Steve:

Thanks, Brad.

The positive TAILORx results made 2018 a momentous year for the advancement of personalized breast cancer treatment. 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, defining a new standard of care. TAILORx established that Oncotype DX definitively identifies the vast majority of women with early-stage breast cancer who receive no benefit from chemotherapy, and also, the important minority for whom chemotherapy can be life-saving.

In addition, TAILORx also confirmed that patients will be frequently mistreated when decisions are based on clinical risk features alone. Specifically, 25 percent of patients with a low Recurrence Score – from 0 to 25 – had high clinical risk. Therefore, based on clinical risk alone, patients would be significantly overtreated without Oncotype DX. Conversely, 43 percent of patients with a high Recurrence Score – from 26 to 100 – had low clinical risk. Therefore, based on clinical risk alone, patients would be significantly undertreated despite their cancer having a high likelihood of a preventable distant recurrence that is much more difficult and expensive to treat.

The practice changing impact of this largest-ever breast cancer treatment trial is further supported by rapid guideline updates, including exclusive endorsements from NCCN, now recommending Oncotype DX as a "preferred test," and IQWiG,

which we expect will lead to broad national reimbursement later this year in Germany.

Applying the patient criteria from TAILORx, NCI-sponsored investigators recently conducted a new analysis in 569 patients from its previously completed NSABP B-20 study, reconfirming that Oncotype DX predicts which patients with early-stage, HER2-negative breast cancer will derive life-saving benefit from chemotherapy treatment. The new results, published in the *Nature Partner Journals Breast Cancer*, show a large statistically significant benefit from the addition of chemotherapy to hormonal therapy in patients with Recurrence Score results of 26-100.

With unparalleled evidence from randomized patients in this NSABP analysis and the landmark TAILORx trial, physicians can now tell every patient more confidently, based on Oncotype DX, whether they should receive chemotherapy or not. It has never been as clear.

In addition, Oncotype DX is the only test that improves outcomes and lowers costs compared to other prognostic tests or to no testing at all. Multiple studies have consistently shown that Oncotype DX is cost-saving, and its use has delivered billions of dollars in healthcare savings globally to date. When we started offering Oncotype DX, more than 70 percent of women were being treated with chemotherapy, and we now know – based on TAILORx – that a great many patients were being overtreated. With the use of Oncotype DX over the past 15 years, we are seeing increasing de-escalation of unnecessary chemotherapy in clinical practice, and the associated cost savings to the

healthcare system. Just this month, a health economics analysis was published in the *Journal of Comparative Effectiveness Research* indicating that Oncotype DX is the only genomic breast cancer test associated with both a reduction in distant recurrences and a decrease in chemotherapy utilization, lowering both unnecessary toxicities and healthcare costs.

At the San Antonio Breast Cancer Symposium in December, results from multiple presentations reinforced the value of Oncotype DX in optimizing treatment and outcomes in patients with both node-negative and node-positive disease. This new data included:

- Two independent analyses led by TAILORx investigators which provided further information about the value of the Recurrence Score result regardless of race or ethnicity and highlighted the negative impact of chemotherapy on patient quality of life;
- Real-world evidence from an analysis of more than 70,000 patients with node-negative disease in the SEER registry who were treated based on Oncotype DX Breast Recurrence Score results were consistent with the findings of TAILORx. Importantly, an analysis of more than 10,000 patients with node-positive disease in the SEER registry who were treated based on Recurrence Score results indicated that node-negative results can be extrapolated to node-positive disease. Specifically, low Recurrence Score results identify node-positive patients for whom hormonal therapy alone is an appropriate option;
- And finally, a multi-center, prospective study in 500 young women with node-positive and node-negative breast cancer demonstrated very good outcomes for those with a Recurrence Score up to 25 who were not treated

with chemotherapy, reinforcing the value of testing in patients age 40 or younger.

It is notable at San Antonio that there were many presentations by leaders in the field that highlighted the importance of the updated NCCN guidelines and the preference for Oncotype DX over other prognostic tests. In addition, over the last six months, dozens of independent medical education programs around the world have highlighted the TAILORx results and Oncotype DX as practice-changing, setting the new standard of care. And several leading organizations, including the *New England Journal of Medicine* and the National Cancer Institute, have identified the TAILORx study as one of the top medical advances in the year 2018.

Turning now to prostate cancer, last month the journal *Urology* published results of a multi-center study in men who elected immediate radical prostatectomy after receiving the Oncotype DX Genomic Prostate Score. With these results, GPS became the first genomic test with prospective validation for predicting adverse pathology in newly diagnosed patients. This also represents the third published validation study of the Oncotype DX GPS test to predict adverse pathology at the time of radical prostatectomy, as well as the first truly prospective validation of this critical endpoint. In providing more precise estimates of disease aggressiveness beyond clinical factors, the GPS test can help physicians increase the number of men who are appropriate for active surveillance, while importantly identifying men with more aggressive disease who may consider immediate surgery with more confidence. In fact, 90 percent of both physicians

and patients reported that GPS testing provided increased confidence in treatment decision-making.

With this unparalleled suite of evidence supporting Oncotype DX tests in both our Oncology and Urology franchises, we believe we are well-positioned to continue increasing physician adoption and patient access to our tests around the world.

I'll now turn the call back to Kim.

Kim:

Thanks, Steve.

We founded Genomic Health nearly 20 years ago with the goal of improving the quality of treatment decisions for cancer patients by ending a “one size fits all treatment approach.” In delivering our one millionth Oncotype DX test, we have spared cancer patients around the world from either over-treatment or under-treatment of their disease.

Looking ahead to 2019, we expect to deliver double-digit revenue growth and even greater improvement in profitability for the full year by continuing to increase penetration of our Oncotype DX tests and broadening global access with national reimbursement.

We expect the TAILORx publication to have a practice-changing impact globally, and we look forward to national reimbursement progress in key European markets, including Germany. We plan to increase adoption and private reimbursement of our Oncotype DX AR-V7 Nucleus Detect test now that we have Medicare coverage. And finally, we intend to continue to diversify our portfolio and expand the menu of tests that we deliver globally through multiple platforms and partnerships, leveraging our established oncology and urology channels.

With these catalysts, we are well-positioned to continue to drive both near- and long-term shareholder value as we continue to pursue our mission of developing and delivering high-value tests to help physicians and the next million cancer patients around the world make confident, individualized treatment decisions that result in improved outcomes.

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 are pleased with the progress we made across our business in 2018, and we're very excited about our growth opportunities in the year ahead. We look forward to seeing some of you at upcoming investor conferences and medical meetings, and we look forward to continuing to update you throughout the year. Thank you.

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

# # #