

**EMILY:** Thank you. Good morning, everyone, and welcome to Genomic Health's conference call to review our fourth quarter and year-end 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](http://genomichealth.com), and a reconciliation to historical non-GAAP adjusted EBITDA is included at the end of the prepared remarks.

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
- our guidance for 2018 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
- effects of changes in accounting standards and the new tax law
- international expansion
- clinical outcomes and timing of clinical studies and publications; 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-Q for the quarter ended September 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
- Fred Pla, our Chief Business and Product Development Officer.

Additionally,

- Phil Febbo, our Chief Medical 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 morning, everyone, and welcome.

In 2017, we continued to improve profitability, including a 1.9 million dollar profit in the fourth quarter, representing our tenth consecutive quarter of improved profitability. Importantly, we achieved our goal to deliver a full-year profit on a non-GAAP basis, excluding business development transaction costs.

In positioning our business to deliver near-term growth and increased profitability, we are directing our focus and resource allocation toward catalysts that will drive further adoption and reimbursement of our portfolio globally with greater operational efficiency. Specifically, we are directing resources to expand our Oncotype DX offering through the development of IVD solutions to increase global access in markets where localized testing is critical for adoption and reimbursement. In doing so, we will no longer provide the Oncotype SEQ Liquid Select test or further invest in non-proprietary NGS-based panels. Accordingly, we are reducing positions by approximately 10 percent and taking a charge of approximately 10 million dollars in the first quarter for costs associated with personnel reductions and the write-off of certain assets associated with NGS-based panels.

With this strengthened focus on generating consistent profitable growth and shareholder value, I'd like to take a moment to highlight the important progress we have made, as well as the catalysts that will drive our business forward. To date, we have served more than 850,000 cancer patients in more than 90 countries and have generated more than 2 billion dollars in revenue, including double-digit revenue compound annual growth rate since 2010.

In our core U.S. invasive breast cancer business, where we have 60 percent market penetration, three key catalysts position us to drive higher utilization and revenue, including:

- The recent implementation of AJCC breast cancer staging criteria, which name Oncotype DX specifically;
- PAMA market-based pricing, representing more than a 10 percent increase to our Medicare rate, or an estimated six to eight million dollars to the topline in 2018; and
- Likely the most important, the expected near-term read-out of the TAILORx intermediate results. As a reminder, TAILORx is the largest adjuvant breast cancer treatment study ever conducted having enrolled more than 10,000 women with early-stage breast cancer across approximately twelve hundred trial sites in six countries. Led by ECOG, the primary objective of this independent study is to more precisely define the effect of chemotherapy for women considered to be at intermediate risk. Nearly 7,000 patients with Recurrence Score results from 11 to 25 were randomized to receive hormonal therapy with or without chemotherapy. When reported, we believe these landmark study results will drive future growth and penetration, establishing a new standard of care. As a reference point, when the secondary endpoint of TAILORx in patients with Recurrence Score results less than 11 was published in *The New England Journal of Medicine* in 2015, we saw a five percent increase in tests delivered. We expect the results for patients with Recurrence Scores of 11 to 25 to be reported by study investigators in the first half of the year.

Outside of the United States, where approximately 220 million lives are covered for the Oncotype DX invasive breast cancer test, and we have approximately 11 percent market penetration, we expect TAILORx to have a significant impact on increasing international utilization and reimbursement.

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. Last month NCCN published its 2018 prostate cancer guidelines, which now recommend considering molecular testing, including the Oncotype DX GPS test for men with low- and favorable intermediate-risk prostate cancer to help choose between active surveillance or definitive treatment. This update is a significant advancement for genomics in prostate cancer and should enhance access to our GPS test for newly diagnosed prostate cancer patients. Importantly, 2018 will represent our first full year of Medicare coverage to qualified U.S. patients with intermediate-risk prostate cancer. We believe this coverage, combined with the recent strengthening of the NCCN guidelines, will support our efforts to secure additional private reimbursement and revenue in 2018.

We are expanding our impact in prostate cancer care and commercial channel leverage with last week's U.S. commercial launch of Oncotype DX AR-V7 Nucleus Detect - a liquid biopsy test to help physicians select the most effective treatment for metastatic castration-resistant prostate cancer that will be sold by both our Oncology and Urology sales force. And, we have a significant opportunity to reduce unnecessary biopsies and spending in the pre-diagnosis stage through our IsoPSA collaboration with Cleveland Diagnostics that Fred will talk about further.

We are confident the changes we are implementing - to deliver near-term growth and increased profitability - will firmly set us on a path to maximize profitable growth and shareholder value, while continuing to pursue a mission defined 18 years ago - to develop and deliver high value tests that improve treatment decisions and outcomes for cancer patients around the world.

I will now turn the call over to Brad and Fred to provide further detail on our fourth quarter and year-end financial results, our worldwide commercial and operations progress, and recent business development efforts.

**Brad:**

Thanks Kim.

In the fourth quarter of 2017, we delivered more than 31,990 Oncotype tests, an increase of 7 percent, compared to the same period in 2016. Notably, the fourth quarter represented our strongest quarter of U.S. invasive breast cancer growth for the year with continued market leadership.

Total revenue was 87.5 million dollars in the fourth quarter of 2017, an increase of 6 percent compared to the prior year. This included 300 thousand dollars of contract revenue from our collaboration with Janssen.

As Kim mentioned, in 2017 we delivered improved profitability, which included a 1.9 million dollar profit in the fourth quarter. This important result represents our tenth consecutive quarter of improved profitability. And as expected, we delivered a full-year non-GAAP profit, excluding transaction costs of 4.2 million dollars from our collaborations with Biocartis and Cleveland Diagnostics.

60 percent of tests delivered and 71 percent of product revenue were recorded on an accrual basis in the fourth quarter and for the year of 2017.

Our gross margin rate was 84 percent in the fourth quarter, an improvement from 83.4 percent in the fourth quarter of 2016. For the full year, gross margin rate improved by 1.9 percent. We continue to expect gross margin rate to range between 83 and 84 percent.

Now turning to our full-year 2017 results. We delivered more than 126,740 Oncotype tests, an increase of 7 percent, compared to the same period in 2016.

Total revenue was 340.8 million for the full-year 2017, an increase of 4 percent, compared with the same period in 2016. On a constant currency basis, revenue increased 5 percent for the full-year 2017, compared with the same period in 2016.

Our net loss for the full year narrowed to 3.9 million dollars, compared with 13.9 million dollars in 2016. We continue our commitment to profitability as evidenced by the operating leverage delivered through improved efficiencies and spending controls in 2017, which resulted in the .4 million dollar full-year non-GAAP profit, excluding business development transactions.

We delivered approximately 30 million dollars in adjusted EBITDA for the full year, excluding our business development transaction costs in the second half consistent with our expectation for 2017<sup>1</sup>.

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

- **U.S. invasive breast cancer** test volume increased 3 percent for the full year, consistent with our low single-digit expectations, despite the hurricane impact in the third quarter of the year. Accrual revenue continues to track test volume as expected, as our accrual ASP across the year has been consistent. Specifically, we delivered more than 76,970 U.S. invasive breast cancer tests in 2017 - our strongest volume growth of the year in the fourth quarter. In 2018, we expect U.S. invasive breast cancer growth to start off in the low single digits, with a lift in volume following the TAILORx intermediate results anticipated later this year. As a reminder, after

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<sup>1</sup> See table at end of script



reporting the low-risk results back in 2015 we experienced an additional 5 percent increase in US invasive breast volume in the following few quarters.

- Our **international** business continues to grow with an 11 percent increase in test volume for the year, which represented 25 percent of total test volume. International revenue was 53.1 million dollars for the full year, an increase of 13 percent compared with 2016. On a constant currency basis, international revenue for the full year grew 15 percent.

In the fourth quarter, revenue grew to 13.7 million dollars, or a 14 percent increase compared to the same period in 2016. We are pleased with our continued double-digit international revenue growth. Specifically, we delivered more than 20 percent growth in EMEA and saw strong growth in Japan and Korea during the quarter.

International test volume increased by 3 percent in the fourth quarter. With the exception of Germany where we implemented changes in test ordering to require reimbursement, international test volume grew 10 percent in the fourth quarter as compared to the previous year.

Looking ahead to 2018, we expect double-digit revenue and test growth with resumed interim funding in France and improved coverage in Germany later in the year.

- In **U.S. Prostate**, we delivered more than 13,380 GPS tests, an increase of 37 percent for the full year, and 17.9 million dollars in revenue, an increase of 66 percent compared with 2016. This revenue contributed to more than half of our global revenue growth in the year. As expected, in the fourth quarter, GPS test and revenue growth were strong again at 33 and 39 percent, respectively. Also as anticipated, class penetration exceeded 20 percent in the fourth quarter with the Oncotype DX GPS test continuing to be the market leader in low- and intermediate-risk prostate cancer test adoption and revenue, with 5 million dollars in GPS revenue in the fourth quarter. Looking ahead to 2018, we expect prostate test volume and revenue growth over 30 percent, and GPS test growth to continue to lead overall company test growth.

Cash and cash equivalents and short-term marketable securities at December 31, 2017 were 129.6 million dollars, which included the fair value of the company's investment in Biocartis, a marketable security of 3.5 million dollars, an increase of 32.6 million dollars compared to 2016.

We are continuing to evaluate the provisions of the Tax Act and its impact to the company. The reduction to the corporate tax rate will result in re-measuring our deferred tax assets and liabilities and a corresponding adjustment to our valuation allowance. We do not anticipate any material impact.

Turning now to 2018 guidance. Revenue now includes the new revenue recognition accounting standard under ASC 606. The impact of this accounting change will reduce reported revenue by about 2.5 percent, primarily through bad debt expense now being effectively booked as a contra-revenue account. There is no impact to income measures, including operating and net income.

Specifically, in 2018 we are guiding to:

- Total revenue of between 366 and 382 million dollars including the adoption of ASC 606, representing growth between 10 and 15 percent compared with 2017 revenue. An equivalent figure for revenue prior to the application of ASC 606 would have been revenue between 375 and 392 million dollars.
- Importantly, net income between 14 and 20 million dollars on a non-GAAP basis, which excludes:
  - possible clinical and commercial development milestone expense of up to 10 million dollars associated with our Biocartis and Cleveland Diagnostics collaborations; and
  - a first quarter charge of approximately 10 million dollars for cost of personnel reductions and the write-off of assets associated with development and offering of NGS panels.

It's important to point out that the mid-point of our 2018 revenue guidance range is at Street consensus when you take into account the adoption of ASC 606.

The high end of our 2018 revenue guidance range is based on the following:

- In our U.S invasive breast business -- the implementation of PAMA and AJCC which both began in January; and continued low- to mid-single-digit growth with an acceleration later in the year following anticipated TAILORx results. These three factors result in revenue growth of 8 to 10 percent, contributing to over 40 percent of expected revenue growth for the year.
- For prostate GPS – continued volume growth above 30 percent and increasing reimbursement from private payers following strengthened

NCCN guidelines, contributing approximately 20 percent of expected revenue growth for the year.

- Continued double-digit revenue growth in international markets with expanded reimbursement coverage in Western Europe; contributing approximately 20 percent of expected revenue growth for the year; and
- The recent launch of our Oncotype DX AR-V7 Nucleus Detect test with CMS coverage anticipated at mid-year, contributing over 15 percent of expected revenue growth for the year.

We expect many of these catalysts will impact second half revenue, leading to an acceleration in revenue growth in the back half of the year. With this in mind and applying the new ASC 606 revenue standard, we anticipate revenue of approximately 89 million dollars in the first quarter, representing approximately 8 to 9 percent revenue growth.

Additionally, in the first quarter, we expect non-GAAP operating income to be either break-even or at a small loss, an improvement over the 2.8 million dollar operating loss in 2017, delivering the eleventh consecutive quarter of improved profitability. Non-GAAP operating income in the first quarter does not include the expected charge for realignment of our business or any other non-GAAP items, such as development milestone expenses.

Our strategic decision to realign focus and resource allocation to deliver catalysts for near-term growth will result in a reduction of approximately 10 percent of our positions and the write-off of certain assets associated with NGS panels and our Oncotype SEQ Liquid Select product. The expected charge of approximately 10

million dollars will be taken in the first quarter. We believe this strategic direction to maximize profitable growth in the short term will:

- result in approximately 3 million dollars in expense savings per quarter beginning in the second quarter; and
- enable us to enhance operational efficiency and deliver leverage above 50 percent in 2018, improved over our 40 percent leverage target of the past few years.

Together with revenue performance, leading to double-digit operating income as a percent of revenue in the fourth quarter, we expect to deliver approximately 50 million dollars in adjusted EBITDA.

I will now turn the call over to Fred to discuss Oncotype IQ portfolio updates.

**Fred:**

Thanks Brad.

Our Oncotype IQ Genomic Intelligence Platform plays an important role in delivering precision medicine with innovative tests that optimize treatment decisions for early- and late-stage cancer patients. We are focused on customizing the development and delivery of additional tests to meet the unique needs of an expanding customer base by offering proprietary content on multiple platforms. In doing so, we will continue to pursue organic development, licensing agreements and collaboration opportunities as part of our mission to address critical questions across the cancer patient journey.

In prostate cancer, we have a growing portfolio of actionable tests that are defining us as the Urology business partner of choice. Just last week, we launched the Oncotype DX AR-V7 Nucleus Detect test to predict treatment response for the 50,000 men in the United States with metastatic disease who will benefit from knowing their AR-V7 status prior to selecting further treatment.

Developed and performed by Epic Sciences at its centralized, CLIA-certified lab in San Diego and sold by Genomic Health's Oncology and Urology commercial channels, this new liquid biopsy test helps extend the lives of men with the most advanced form of prostate cancer by accurately detecting a splice variant of the AR-V7 protein in the nucleus of circulating tumor cells. This knowledge enables physicians to confidently decide whether men treated with an androgen receptor-signaling inhibitor, or ARSI therapy, such as enzalutamide and abiraterone, need to start another type of ARSI or switch to chemotherapy.

With new data presented at ASCO GU last month, the predictive power of the Oncotype DX AR-V7 Nucleus Detect test is now supported by two clinical studies that collectively confirm patients who are AR-V7 positive and treated with chemotherapy survive longer than those on costly ARSI therapy. Importantly, a dossier for Medicare coverage has been submitted and the expected draft LCD will be reviewed shortly. NCCN guidelines already include AR-V7 as a biomarker for consideration. We believe our Oncotype DX AR-V7 Nucleus Detect test is well positioned to obtain a positive Medicare coverage decision in mid-2018. This test demonstrates our ability to leverage Genomic Health's unique commercial channel to deliver proprietary tests with clear paths to reimbursement and profitable growth for our business.

In December, we announced a multi-year research collaboration agreement with Janssen Pharmaceuticals to evaluate the Oncotype DX GPS test for their prostate cancer drug pipeline. As part of the agreement, we began testing samples from Janssen studies to examine the association of GPS results with clinical outcomes. Janssen is a recognized leader in oncology and urology, and their selection of the Oncotype DX GPS test reflects the best-in-class value that the test delivers in stratifying patient risk and its potential to reveal additional insights for guiding treatment selection for prostate cancer patients in the future.

Shifting to the diagnosis of prostate cancer, at the end of 2017 we announced an exclusive licensing agreement with Cleveland Diagnostics to develop and commercialize a high-PSA reflex test to improve the diagnosis of prostate cancer with greater specificity while eliminating unnecessary biopsies for the more than four million screened men who receive a PSA score between 2 and 10 each year in the United States.

Today, PSA screening leads to more than 900,000 biopsies each year in the U.S. Seventy-five percent of these biopsies are negative or indicate a low likelihood of high-grade cancer, resulting in unnecessary burden to patients and unnecessary costs to the U.S. healthcare system. We believe Cleveland Diagnostics' IsoPSA reagents and technology will represent a best-in-class option based on positive results from a development study, published by Dr. Eric Klein in *European Urology*, that demonstrated it significantly improved diagnostic accuracy over standard PSA testing alone. We estimate that it could reduce the total number of biopsies performed each year by one-third.

This technical accuracy and precision, combined with the potential for simple integration into the current workflow of any urology laboratory practice, makes Cleveland Diagnostics the ideal partner for us to leverage our urology channel to address this critical large unmet need. Additionally, we believe this IsoPSA test will get reimbursed at a value-based rate when you consider the health economics of reducing unnecessary biopsies and overtreatment.

As we continue to expand our commitment to urology and leverage our commercial capabilities, we expect we will soon have multiple tests to answer critical questions about prostate cancer treatment decisions from early diagnosis to late-stage disease. With the Oncotype DX GPS test for low- and intermediate-risk patients considering active surveillance, the Oncotype DX AR-V7 Nucleus Detect test for metastatic patients considering androgen receptor-therapy, and now the IsoPSA platform, Genomic Health is well positioned to be the diagnostic partner of choice in urology.

Turning now to our IVD efforts to increase global access to Oncotype tests in markets where a local offering is critical for adoption and reimbursement. Our



collaboration with Biocartis is progressing rapidly as we design a best-in-class sample-to-answer solution and work toward our goal of completing the transfer of the Oncotype DX Breast Recurrence Score test to its proprietary Idylla platform this year. We plan to start with France and Germany – countries where there is a reimbursement path – and are in the process of identifying early access sites to conduct validation studies to support launching in these countries in 2019.

Beyond these first two markets, the IVD technology allows us to consider entering even larger markets in the future, like China. It also opens the doors to expanded pharmaceutical collaborations to partner on global clinical trials.

Additionally, we are building out our IVD capabilities including infrastructure needed to commercialize and support decentralized testing in the field, as well as expanding our regulatory and quality systems, and obtaining ISO 13485 certification. We intend to leverage these capabilities to support a rapid expansion of our IVD offering, both geographically and across our product line including our future IsoPSA test for prostate cancer patients.

We are excited about these collaborations to facilitate the development of IVD solutions to increase global access to our Oncotype tests and the potential long-term impact this will have on our ability to reach more patients worldwide.

I will now turn the call back over to Kim.

**Kim:**

Thanks, Fred.

We are already executing near-term milestones to deliver double-digit revenue growth and increasing profitability in 2018 with the implementation of PAMA and AJCC in invasive breast cancer, strengthened NCCN prostate cancer guidelines, and our U.S. commercial launch of Oncotype DX AR-V7.

We see further runway for profitable growth as additional milestones are achieved this year, including:

- Global impact of intermediate Recurrence Score results for our Oncotype DX invasive breast cancer test from the practice-changing TAILORx study;
- A full year of CMS intermediate-risk prostate coverage and expanded private reimbursement;
- Further reimbursement traction in Europe; and
- Anticipated Medicare coverage for Oncotype DX AR-V7 mid-year.

Looking beyond 2018, we plan to continue to balance organic and partnered pipeline investments to expand our Oncotype IQ Genomic Intelligence Platform with a suite of actionable tests that can be delivered through our Oncology and Urology commercial channels. We believe our technical flexibility and ability to develop and deliver proprietary content on multiple platforms will further strengthen our position as a leader in the molecular diagnostics industry.

Identifying the right partners to help us expand our worldwide reach and provide us with new tools to answer additional clinical questions, combined with our

established brand, global channels and expanding portfolio, will position us for continued leadership in precision medicine.

With multiple catalysts on the horizon in 2018 and the evolution of our business strategy, we plan to drive both short- and long-term shareholder value while continuing to make cancer care smarter for physicians, payers and 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.

	<b>Year Ended December 31, 2017</b>
	<u>(In thousands)</u>
<b>Adjusted EBITDA reconciliation:</b>	
GAAP loss from operations	\$ (6,450)
Add:	
Stock-based compensation expense	20,256
Depreciation and amortization	11,730
Adjusted EBITDA	<u>25,536</u>
Non-GAAP adjustments:	
Research and development – discount on convertible promissory note	671
Research and development – discount for lack of marketability during lock up period	322
Research and development – collaboration expense: upfront license and option fee	3,248
Adjusted EBITDA, excluding transaction costs	<u>\$ 29,777</u>