

**EMILY:** Thank you. Good afternoon, everyone, and welcome to Genomic Health's conference call to review our third 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).

Please note 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;
- our financial guidance for 2018 and the company's beliefs regarding its performance for the remainder of 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;
- global growth opportunities, including through the deployment of our tests on a sample-to-answer IVD platform;
- 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; and
- expectations regarding 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 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.

Joining me today to make prepared remarks are:

- ✓ Kim Popovits, our Chairman of the Board, Chief Executive Officer and President; and
- ✓ Brad Cole, our Chief Financial Officer.

I'll now turn the call over to Kim.

**Kim:**

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

We continue to deliver record top and bottom-line results in 2018. In the third quarter specifically, we generated 23 percent revenue growth and a 13 million-dollar profit on a non-GAAP basis. Importantly, we achieved our 13<sup>th</sup> consecutive quarter of improved non-GAAP profitability.

This strong performance reflects:

- ✓ Increasing global demand and revenue for the Oncotype DX Breast Recurrence Score<sup>®</sup> test;
- ✓ Continued adoption and growing reimbursement for the Oncotype DX<sup>®</sup> Genomic Prostate Score<sup>™</sup> (or GPS<sup>™</sup>) test; and
- ✓ Success in driving operational efficiencies across our business.

With three quarters of record results this year, we are raising our full-year 2018 revenue and net income guidance, and now expect to deliver approximately 17 percent revenue growth for the year, surpassing the top-end of our original full year revenue guidance of 15 percent.

We believe we are well-positioned to continue accelerating adoption, reimbursement and revenue growth across our business in the near-term, with the achievement of several recent milestones, including:

- ✓ Positive guideline recommendations that demonstrate global support for the Oncotype DX Breast Recurrence Score test following publication of the landmark TAILORx results. Specifically, NCCN updated its 2018 breast cancer guidelines, elevating Oncotype DX to its “preferred” category with a

"strongly consider" designation as the only multi-gene test to predict chemotherapy treatment benefit for patients with node-negative early-stage breast cancer. In addition to this guideline inclusion with level 1 evidence for node-negative breast cancer, NCCN also elevated Oncotype DX into the chemotherapy treatment pathway for patients with micro metastases and for patients with up to three positive lymph nodes.

Guideline momentum also continued in Europe as the German Institute for Quality and Efficiency in Health Care, or IQWiG, concluded in its updated assessment of breast cancer gene expression profiling tests that only the Oncotype DX test has sufficient evidence to guide breast cancer adjuvant chemotherapy treatment decisions. As IQWiG's positive technical assessment informs G-BA's official national reimbursement decision, we believe we are one step closer to gaining reimbursement for tens of thousands of breast cancer patients diagnosed in Germany each year.

Together, these new exclusive guidelines globally distinguish Oncotype DX from other genomic tests based on clinical evidence and the critical importance of predicting chemotherapy benefit. We continue to expect decisions from GBA as well as NICE in the UK in the coming months.

- ✓ Important reimbursement wins across our urology franchise, including Medicare's final local coverage determination, or LCD, that will become effective in December for use of the Oncotype DX AR-V7 Nucleus Detect™ test for men with castrate resistant metastatic prostate cancer. As a

reminder, of the 50,000 eligible patients in the United States, approximately 25,000 are covered by Medicare.

In early-stage prostate cancer, Blue Shield of California established reimbursement for the Oncotype DX GPS test bringing the total number of U.S. covered lives to more than 100 million.

- ✓ Importantly, we continue to make progress in our development of a sample-to-answer version of the Oncotype DX Breast Recurrence Score test on the Idylla™ platform with the successful completion of technical feasibility and the selection of validation study sites.

We believe the development of this unique and highly scalable sample-to-answer IVD capability positions us for further long-term growth and diversification by:

- Accelerating access in key European markets where a localized solution is required;
- Opening global access to emerging large markets such as China, Brazil and India;
- Providing us with a proprietary platform to build a menu of locally distributed tests to be offered through our global commercial channel; and
- Facilitating broader collaboration opportunities with pharmaceutical companies seeking localized diagnostic solutions.

I will now turn the call over to Brad to provide further detail on our third quarter financial results and updated annual guidance.

**Brad:**

Thanks, Kim.

We are very pleased with our third quarter financial results, during which we delivered revenue growth above 22 percent in all of our key product lines, continuing the strong revenue growth throughout 2018.

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 third quarter of 2018, total revenue was 101.3 million dollars, an increase of 23 percent, compared to the pre-ASC 606 adjusted revenue of 82.2 million dollars for the third quarter of 2017.

For the nine months ended September 30, 2018, total revenue was 289.5 million dollars, compared with pre-606 adjusted revenue of 248.2 million dollars for the same period in 2017, an increase of 17 percent.

In the third quarter of 2018, we delivered a non-GAAP profit of 13.3 million dollars, an improvement of 12.2 million dollars compared with the same period in

2017. These strong results mark our 13<sup>th</sup> consecutive quarter of improved non-GAAP profitability.

For the nine months ended September 30, 2018, we delivered a non-GAAP profit of 27.3 million dollars, an improvement of nearly 32 million dollars, compared with a non-GAAP loss of 4.5 million dollars for the same nine-month period in 2017. These strong non-GAAP net income results represent continued and improving operating leverage above our stated annual target of 40 percent.

Third quarter revenue growth of 23 percent was driven primarily by test volume -- up over 10 percent compared to the third quarter of 2017 to more than 34,810 tests delivered, and improved average selling price from reimbursement improvements and collection efficiencies, which had a 13 percent impact on revenue growth. The increased realized price was boosted by PAMA pricing effective January and improved collection levels from process and system changes and enhancements implemented throughout the year. As payors require additional payment criteria, we have invested to meet the needs of these requirements and are seeing the results in improved average selling prices across product lines.

The third quarter revenue result of 101.3 million dollars and 23 percent growth includes approximately 2 million dollars of revenue from upgrading payors into higher revenue recognition portfolios as we continue to see strong payment performance. Without this year-to-date effect on third quarter results, revenue would have been 99.3 million dollars and revenue growth would have been 20 percent.

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

- U.S. invasive breast cancer revenue was 76.7 million dollars in the third quarter of 2018, an increase of 24 percent, compared to pre-ASC 606 adjusted revenue for the same period in 2017. Revenue was up 17 percent for the nine months ended September 30, 2018. The accelerated revenue growth in the third quarter was driven by:
  - Increased test volume of 12 percent compared to last year as a result of the TAILORx presentation and publication driving further demand. We estimate an increase of 6 percent test growth based on these definitive 10-year results. Test volume growth contributed half of total revenue growth;
  - CMS pricing has increased through PAMA adding 3 percent to revenue growth and contributing to approximately 12 percent of total revenue growth;
  - Stronger ASP overall from private payors, a result of contract renewals and collection efficiency through process change and system enhancements, contributing 5 percent to revenue growth and to more than 20 percent of total revenue growth; and
  - Upgrading certain payors to higher revenue portfolio rates on a year-to-date basis a result of improved payment performance above their initial portfolio rate estimates. This contributed to approximately 4 percent to revenue growth, and to approximately 15 percent of total revenue growth.

U.S. invasive breast cancer test volume increased 12 percent year-over-year in the quarter and 7 percent year-to-date.



Looking ahead to fourth quarter we expect U.S. invasive breast cancer revenue to continue to grow in the mid-to-high teens.

- International product revenue was 15.5 million dollars in the third quarter of 2018, an increase of 22 percent, compared to pre-ASC 606 adjusted revenue. On a constant currency basis, revenue grew 20 percent. International revenue increased 13 percent for the nine-month period ended September 30, 2018. On a constant currency basis, revenue grew 9 percent.

Similar to the U.S., the TAILORx results have had a positive impact internationally. The number of international tests delivered in the third quarter of 2018 grew 6 percent compared with the same period in 2017 and represented approximately 25 percent of total test volume in the quarter.

Excluding Germany and Italy 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 15 percent year-over-year in the third quarter. While these changes have impacted tests delivered, as expected, we are seeing progress in both payor engagement and coverage.

Looking ahead to the fourth quarter, we expect international test growth in the mid-to-high teens and revenue growth above 20 percent.

- In U.S. prostate, our GPS test continues to contribute to strong test and revenue growth, increasing 15 percent and 28 percent, respectively. GPS revenue of 6.9 million dollars in the third quarter was equally driven by higher test volume and increased payments for qualified billable tests with Medicare and further coverage and increased payment from private payors. For the nine months ended September 30, 2018, GPS tests delivered were up 24 percent and revenue grew 54 percent.

It's important to note that GPS revenue in the third quarter of 2017 included reimbursement payments from prior periods, and when adjusting for this occurrence, growth would have been 70 percent in the third quarter of 2018.

Additionally, with our sales force expansion complete and the full team now in place we continue to expect full-year GPS revenue growth above 50 percent and test volume growth to be approximately 25 percent. We believe we are continuing to lead the market for low- and intermediate-risk prostate cancer patients using genomic tests for treatment decisions.

And with the Oncotype DX AR-V7 Nucleus Detect test, finalization of the Medicare LCD is expected to have a positive impact on both test and revenue growth beginning in 2019. The final LCD coverage posted by Palmetto is expected to take effect in December once the notice period ends.

Gross margin was 85 percent in the third quarter. Moving forward, we expect our 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 September 30, 2018, were 183.3 million dollars, an increase of 53.7 million dollars from December 31, 2017.

In the third quarter, non-GAAP adjusted EBITDA was 22 million dollars. For the first nine months of the year, non-GAAP adjusted EBITDA was 52 million dollars.

Based on our strong performance during the first nine months of the year, we are raising our guidance for the year ending December 31, 2018, as follows:

- Total revenue of between 389 and 391 million dollars, representing growth of 17 percent compared with 2017. In the fourth quarter, we expect revenue growth of between 17 and 19 percent or between 100 and 102 million dollars.
- Net income, or profit, between 26 and 28 million dollars on a GAAP basis, up from our original guidance of between zero and 5 million dollars.
- Non-GAAP net income of between 37 and 39 million dollars, up from our original guidance of between 14 and 20 million dollars. As a reminder, our non-GAAP estimate excludes:
  - clinical and commercial development milestone expense, and
  - program cessation charges.

Delivering revenue growth in our new guidance range of 17 percent for the full year will exceed our annual growth goal of 15 percent. Delivering net income in our new guidance range will exceed our operating leverage target.

Looking ahead to the fourth quarter and 2019, we anticipate increased spending associated with post-TAILORx sales and marketing activities and the ramp-up of our IVD product development.

Additionally, as our business continues to diversify with multiple products, new testing platforms and expanding geography, we are investing in state-of-the-art systems to enhance order processing, test delivery and revenue collection, which includes:

- online ordering with automated prior authorization support and real-time insurance verification;
- central lab test result processing with maximum efficiency and quality,
- delivery of a best-in-class test report; and
- infrastructure to support a sample-to-answer platform for global markets.

Reflected in our 2018 financial results, we are seeing the benefits of these investments with consistent reimbursement traction, strong collections and greater internal efficiencies. Moving forward, it is our goal to leverage these capabilities to seamlessly integrate new products into our commercial channel.

I will now turn the call over to Kim to provide closing remarks.

**Kim:**

Thanks, Brad.

At the beginning of 2018 we made a commitment to deliver near-term growth and increased profitability, with a focus on catalysts to drive further adoption and reimbursement of our portfolio globally. With our third consecutive quarter of double-digit revenue growth and profitability, it's clear our strategy is working. Furthermore, the achievement of several milestones laid out in January position us for further growth, including:

- ✓ Presentation and publication of the landmark TAILORx study results that used Oncotype DX to precisely define the effect of chemotherapy for all early-stage breast cancer patients;
- ✓ Achieving a 10 percent increase to our Medicare rate for the Oncotype DX Breast Recurrence Score test through PAMA market-based pricing;
- ✓ Strengthened NCCN guidelines for both the Oncotype DX Breast Recurrence Score and GPS tests;
- ✓ Increasing reimbursement for our Genomic Prostate Score test;
- ✓ International reimbursement traction with decisions in Germany and the UK expected soon; and
- ✓ The U.S. commercial launch and final Medicare LCD for the Oncotype DX AR-V7 test.

And, certainly for us, the most rewarding milestone of the year is expected to occur in the fourth quarter when we deliver our one millionth Oncotype DX test, an impressive accomplishment demonstrating Genomic Health's pioneering impact in delivering precision medicine to 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 the upcoming Canaccord conference next week and at the San Antonio Breast Cancer Symposium in December.

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

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