



February 10, 2016

Genomic Health Announces 2016 Financial Outlook and Provides 2015 Fourth Quarter and Year-End Financial Results

Expects to Deliver Double-Digit Test and Revenue Growth in 2016 Plans to Launch First Liquid Biopsy Test Mid-2016 Conference Call Today at 4:30 p.m. ET

REDWOOD CITY, Calif., Feb. 10, 2016 /PRNewswire/ -- [Genomic Health, Inc.](#) (Nasdaq: GHDX) today reported financial results and business progress for the quarter and year ended December 31, 2015.

Revenue was \$74.5 million in the fourth quarter of 2015, compared with \$69.1 million in the fourth quarter of 2014, an increase of 8 percent. On a constant currency basis, revenue increased 9 percent compared with the same period in the prior year.

U.S. revenue was \$63.9 million in the fourth quarter of 2015, an increase of 9 percent compared with the same period in the prior year. International revenue was \$10.6 million in the fourth quarter of 2015, compared with \$10.3 million a year ago. International revenue was reduced by \$0.6 million from foreign exchange rate differences due to the stronger dollar as compared to a year ago.

Revenue was \$286.8 million in the full year 2015, compared with \$275.7 million in 2014, an increase of 4 percent. International revenue for the full year 2015 was \$41.4 million, compared with \$45.0 million a year ago. For the year ended December 31, 2015, international revenue was reduced by approximately \$3.0 million from foreign exchange rate differences due to the stronger dollar as compared to a year ago.

More than 107,030 Oncotype DX[®] test results were delivered for the year ended December 31, 2015, an increase of 12 percent, compared with more than 95,610 test results delivered in 2014. In the fourth quarter of 2015, more than 27,730 Oncotype DX test results were delivered, an increase of 12 percent, compared with more than 24,770 test results delivered in the same period in 2014. Prostate tests delivered in the United States for the full year grew 75 percent compared to the prior year and represented approximately 8 percent of total test volume in 2015. International tests delivered in the full-year grew 19 percent compared to the prior year and represented approximately 21 percent of total test volume in 2015.

"We expect the strong momentum generated across our business in 2015, combined with new compelling global prospective outcomes evidence for the Oncotype DX breast cancer test and recent Medicare coverage for the Oncotype DX prostate cancer test, to lead to double-digit test and revenue growth in 2016," said [Kim Popovits](#), Chairman of the Board, Chief Executive Officer and President of Genomic Health. "Additionally, we are excited to continue our impact in making cancer care smarter by launching our first liquid biopsy test, Oncotype SEQ[™], in mid-2016."

Operating loss for the fourth quarter narrowed to \$3.5 million compared with \$6.0 million for the fourth quarter of 2014. Net loss was \$3.2 million for the fourth quarter of 2015 and includes a \$0.8 million tax credit in the quarter resulting from a change in fair value of the company's investment in a marketable security. Basic and diluted net loss per share was \$0.10 for the fourth quarter of 2015 compared with basic and diluted net loss per share of \$0.20 for the same period in 2014.

Additional Year-End 2015 Financial Results

Operating loss was \$34.5 million for the year ended December 31, 2015, compared with an operating loss of \$23.6 million for the year ended December 31, 2014. The operating loss for the year ended December 31, 2015 includes a non-recurring first quarter charge of \$5.5 million in R&D associated with the wind-down of a breast cancer collaboration.

Net loss was \$33.8 million for the year ended December 31, 2015, compared with a net loss of \$24.6 million for the year ended December 31, 2014. Basic and diluted net loss per share was \$1.04 for the year ended December 31, 2015, compared with a basic and diluted net loss per share of \$0.78 for the year ended December 31, 2014.

Cash and cash equivalents and short-term investments at December 31, 2015 were \$76.8 million, excluding the fair value of the company's investment in a marketable security of \$18.1 million, compared with \$103.7 million at December 31, 2014.

2016 Financial Guidance

"In 2016 we plan to deliver double-digit test and revenue growth and improve our net loss, while delivering positive EBITDA*," said [Brad Cole](#), Chief Operating Officer and Chief Financial Officer of Genomic Health. "We expect our net loss in the first half of the year to be within the full year loss guidance of \$12 to \$18 million and to move toward profitability in the second half of the year."

The company is providing the following financial guidance for the full year ending December 31, 2016:

- | Total revenue of \$320 to \$335 million, representing growth of between 12 and 17 percent compared to 2015;
- | Net loss between \$12 and \$18 million at the mid-point of revenue guidance, excluding the effect of the company's investment in a marketable security, or basic net loss per share of between \$0.37 and \$0.55; and
- | Oncotype DX tests delivered of 117,500 to 121,000, representing growth of between 10 and 13 percent compared to 2015.

* EBITDA, or earnings before interest, taxes, depreciation and amortization, is a non-GAAP term.

Recent Business Highlights:

Oncotype DX Commercial Progress

- | Implemented new enterprise-wide platform (ERP) to add novel capabilities and provide the ability to scale the company's growing business.
- | Expanded coverage of the Oncotype DX breast cancer test for patients with 1-3 positive nodes to include 11 million additional lives through new policies with Health Net, Blue Cross Blue Shield of Florida and Independent Blue Cross. This brings the total number of node-positive covered lives to more than 161 million U.S. lives.
- | Received positive reimbursement decisions for the Oncotype DX breast cancer test in four additional regions of Spain bringing the total number of ex-U.S. lives covered to 196 million.
- | The Centers for Medicare and Medicaid Services (CMS), which administers the Medicare program, [issued its final Clinical Laboratory Fee Schedule](#) (CLFS) for 2016, which will allow the Medicare Administrative Contractor (MAC) to continue to set payment for the Oncotype DX colon cancer test through 2016, as has been done since initiation of coverage in 2011.

Pipeline, Presentations and Publications

- | Announced plans to launch [first liquid biopsy](#) test, Oncotype SEQ™, a blood-based mutation panel that uses next-generation sequencing to identify select actionable genomic alterations for the treatment of patients with late-stage lung, breast, colon, melanoma, ovarian or gastrointestinal cancer, in mid-2016. Oncotype SEQ represents the first of several liquid biopsy tests that Genomic Health plans to deliver through the introduction of its Oncotype IQ™ Genomic Intelligence Platform.
- | *Urology* published a meta-analysis of the original Oncotype DX clinical validation studies demonstrating the ability of the Genomic Prostate Score (GPS) to refine risk stratification for low- and intermediate-risk patients with greater precision compared to clinical classifiers alone.
- | Positive results from a large prospective outcomes study in Germany were accepted for publication in the *Journal of Clinical Oncology*. Led by the Women's Healthcare Study Group, the PlanB study demonstrated that women with breast Recurrence Score® results of 11 or less who were treated with hormonal therapy alone had excellent outcomes with 98 percent disease-free survival rates at three years despite having intermediate- or high-risk disease by traditional parameters.
- | Received acceptance to present five year outcomes data from the PlanB study in an oral presentation at the upcoming [European Breast Cancer Conference](#) in March.
- | Announced [results](#) from multiple Oncotype DX breast cancer test studies at the 38th CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) reconfirming that Oncotype DX accurately predicts clinical outcomes - including risk of recurrence and breast cancer survival - in early-stage patients with invasive breast cancer. Data include results from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute (NCI); complete results from a multi-center study from Clalit Health Services, the largest health maintenance organization in Israel; additional analyses from the NCI-sponsored Trial Assigning IndividuaLized Options for Treatment (Rx), or TAILORx; and the German PlanB study.

Conference Call Details

To access the live conference call today, February 10 at 4:30 p.m. Eastern Time via phone, please dial (877) 303-7208 from the United States and Canada or +1 (224) 357-2389 internationally. The conference ID is 34365800. Please dial in

approximately ten minutes prior to the start of the call. To access the live and subsequently archived webcast of the conference call, go to the [Investor Relations](http://investor.genomichealth.com/events.cfm) section of the company's website at <http://investor.genomichealth.com/events.cfm>. Please connect to the web site at least 15 minutes prior to the call to allow for any software download that may be necessary.

About Genomic Health

[Genomic Health](#), Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of cancer, one of the greatest issues in healthcare today. With its Oncotype IQ™ Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX gene expression tests that have been used to guide treatment decisions for more than 600,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests. The company is based in [Redwood City](#), California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: [@GenomicHealth](#), [Facebook](#), [YouTube](#) and [LinkedIn](#).

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating the company's beliefs regarding its liquid biopsy platform and the timing of a liquid biopsy test; the company's intent to continue its investments in DCIS, prostate cancer and international markets; the company's full year 2015 results; the attributes and focus of the company's product pipeline; the ability of any potential tests the company may develop to optimize cancer treatment; and the ability of the company to develop and commercialize additional tests in the future. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies and their impact on reimbursement and adoption; the applicability of clinical study results to actual outcomes; the company's ability to develop and commercialize new tests and expand into new markets domestically and internationally; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; unanticipated costs or delays in research and development efforts; the company's ability to obtain capital when needed and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Recurrence Score, DCIS Score, Oncotype SEQ, and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

GENOMIC HEALTH, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
	Unaudited		Unaudited	
REVENUES:				
Product revenues - United States	\$ 63,918	\$ 58,794	\$ 245,378	\$ 230,657
Product revenues - Outside of the United States	10,582	10,332	41,447	45,049
Total revenues	74,500	69,126	286,825	275,706
OPERATING EXPENSES (1)(2):				
Cost of product revenues	14,078	12,501	53,591	48,742
Research and development	12,605	12,549	59,798	53,076
Selling and marketing	35,593	35,144	143,557	137,846
General and administrative	15,755	14,919	64,348	59,669
Total operating expenses	78,031	75,113	321,294	299,333
Loss from operations	(3,531)	(5,987)	(34,469)	(23,627)
Interest income	58	48	221	192
Other income (expense), net	(291)	(227)	(498)	(764)
Loss before income taxes	(3,764)	(6,166)	(34,746)	(24,199)

Income tax expense (benefit)	(587)	101	(996)	393
Net loss	<u>\$ (3,177)</u>	<u>\$ (6,267)</u>	<u>\$ (33,750)</u>	<u>\$ (24,592)</u>
Basic and diluted net loss per share	<u>\$ (0.10)</u>	<u>\$ (0.20)</u>	<u>\$ (1.04)</u>	<u>\$ (0.78)</u>
Shares used in computing basic and diluted net loss per share	<u>32,645</u>	<u>31,791</u>	<u>32,382</u>	<u>31,453</u>

- (1) Included in operating expenses for the three months ended December 31, 2015 were non-cash charges of \$6.0 million, including \$4.0 million of stock-based compensation expense and \$2.0 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2014 of \$5.6 million, including \$3.9 million of stock-based compensation expense and \$1.7 million of depreciation and amortization expenses.
- (2) Included in operating expenses for the twelve months ended December 31, 2015 were non-cash charges of \$23.1 million, including \$16.0 million of stock-based compensation expense and \$7.1 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2014 of \$23.4 million, including \$16.5 million of stock-based compensation expense and \$6.9 million of depreciation and amortization expenses.

GENOMIC HEALTH, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	As of December 31, 2015 (Unaudited)	As of December 31, 2014 (1)
Cash and cash equivalents	\$ 32,533	\$ 29,726
Short-term marketable securities (2)	62,410	73,934
Accounts receivable, net	36,531	34,916
Prepaid expenses and other current assets	<u>10,844</u>	<u>9,944</u>
Total current assets	142,318	148,520
Property and equipment, net	39,746	21,860
Other assets	<u>1,921</u>	<u>15,541</u>
Total assets	<u>\$ 183,985</u>	<u>\$ 185,921</u>
Accounts payable	\$ 8,395	\$ 6,987
Accrued expenses and other current liabilities	33,656	31,016
Deferred revenues	431	335
Other liabilities	2,410	2,070
Stockholders' equity	<u>139,093</u>	<u>145,513</u>
Total liabilities and stockholders' equity	<u>\$ 183,985</u>	<u>\$ 185,921</u>

- (1) The condensed consolidated balance sheet at December 31, 2014, has been derived from the audited consolidated financial statements at that date included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014.
- (2) Included in short-term marketable securities as of December 31, 2015, was \$18.1 million of corporate equity securities, representing the Company's investment in Invitae Corporation.



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