August 2, 2016

Genomic Health Reports Continued Double-Digit Growth in Announcement of Second Quarter 2016 Financial Results, Raises Low End of Full-Year Test and Revenue Guidance

16% Increase in Revenue; 12% Increase in Tests Delivered
13% Growth with Record Number of Prostate Cancer Tests Delivered
More than 20% Increase in Both International Revenue and Tests Delivered
Launched Oncotype SEQ™ Liquid Biopsy Test and Announced Collaboration to Commercialize Epic Sciences' AR-V7 Test
Conference Call Today at 4:30 p.m. ET

REDWOOD CITY, Calif., Aug. 2, 2016 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today reported financial results and business progress for the quarter ended June 30, 2016.

Total revenue was $82.0 million in the second quarter of 2016 and includes $0.1 million in contract revenue, compared with $70.6 million in the second quarter of 2015, an increase of 16 percent.

U.S. product revenue was $69.6 million in the second quarter of 2016, an increase of 15 percent, compared with the same period in the prior year. Prostate test revenue in the U.S. of $2.3 million contributed to approximately 3 percent of the year-over-year growth.

International product revenue was $12.3 million in the second quarter of 2016, compared with $9.9 million a year ago, an increase of 24 percent. International revenue on a constant currency basis increased by 26 percent compared with a year ago.[i]

More than 29,060 Oncotype DX® test results were delivered in the second quarter of 2016, an increase of 12 percent, compared with more than 26,060 test results delivered in the second quarter of 2015. U.S. invasive breast tests delivered grew 8 percent and prostate tests delivered grew 13 percent compared with the prior year. International tests delivered grew 23 percent compared with the prior year and represented approximately 23 percent of total test volume in the second quarter of 2016.

"In the second quarter we delivered double-digit revenue growth of 16 percent driven by an increase in Oncotype DX tests delivered across our key markets," said Kim Popovits, Chairman of the Board, Chief Executive Officer and President of Genomic Health. "In addition, we expanded our Oncotype IQ™ Genomic Intelligence Platform with the launch of our first liquid biopsy test, Oncotype SEQ, for late stage solid tumors, and announced an exclusive collaboration to commercialize Epic Sciences' AR-V7 liquid biopsy test for metastatic prostate cancer. These achievements further reinforce both our strategy and leadership in providing genomic-based diagnostics to optimize outcomes across the cancer patient journey."

Operating loss for the second quarter of 2016 improved to $5.1 million, compared with $10.8 million for the second quarter of 2015. Net loss was $6.1 million for the second quarter of 2016 and included a tax expense in the quarter of $1.4 million from the company's investment in a marketable security. Basic and diluted net loss per share was $0.18 for the second quarter of 2016, compared with basic and diluted net loss per share of $0.29 for the same period in 2015.

Total revenue for the six months ended June 30, 2016 was $162.9 million compared with $138.8 million for the six months ended June 30, 2015, an increase of 17 percent. On a constant currency basis, revenue increased 18 percent compared with the same period in the prior year.[i]

Operating loss improved to $13.9 million for the six months ended June 30, 2016 compared with an operating loss of $25.5 million for the six months ended June 30, 2015. Net loss was $12.5 million for the six months ended June 30, 2016 compared with a net loss of $18.7 million for the six months ended June 30, 2015.

Cash and cash equivalents and short-term marketable securities at June 30, 2016 were $80.9 million excluding the fair value of the company's investment in a marketable security of $12.7 million, compared with $76.8 million at December 31, 2015 excluding the fair value of the company's investment in a marketable security of $18.1 million.

2016 Financial Outlook

The company is raising the low end of both revenue and test guidance for the full-year ending December 31, 2016:

- Raising total revenue to between $325 and $335 million (formerly $320 to $335 million); and
- Raising Oncotype DX tests delivered range to between 118,500 and 121,000 (formerly 117,500 to 121,000); and
- Maintaining net loss guidance between $12 and $18 million at the mid-point of revenue guidance, excluding gains of the company's investment in a marketable security expected to offset costs associated with the Epic Sciences collaboration, or basic net loss per share of between $0.37 and $0.55.

Recent Business Highlights

Oncotype DX Commercial Progress

- Established additional private coverage arrangements for the Oncotype DX Genomic Prostate Score™, bringing the total number of prostate cancer covered U.S. lives to more than 60 million.
- Launched an enhanced prostate cancer report to reflect an important new meta-analysis recently published in *Urology* that combined the patient-specific data from two Oncotype DX validation studies to create more precise risk estimates for high stage, high grade, and adverse pathology associated with the test results.
- The National Institute for Health and Care Excellence (NICE) published its latest quality standard guidelines recommending the use of the Oncotype DX test in eligible patients with early-stage breast cancer.
- Established NHS reimbursement for the Oncotype DX Breast Recurrence Score in Northern Ireland and Scotland.
- Launched Oncotype SEQ Liquid Select, the first non-invasive liquid biopsy test that the company will deliver through its Oncotype IQ Genomic Intelligence Platform. Oncotype SEQ is a blood-based test that uses next-generation sequencing to identify and assess actionable genomic alterations in a panel of 17 select genes to inform the treatment of stage IV solid tumors, including lung, breast, colon, melanoma, ovarian, and gastrointestinal stromal tumors.
- Entered into an exclusive agreement with Epic Sciences, Inc. to commercialize its novel AR-V7 liquid biopsy test in the United States through Genomic Health's world-class commercial channel. The blood-based test detects the V7 variant of the androgen receptor protein (AR-V7) in the nucleus of circulating tumor cells (CTC) - information that can help guide treatment selection in patients with metastatic castration-resistant prostate cancer (mCRPC). The test will be performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego, California.

Presentations and Publications

- Received acceptance to present eight abstracts at the European Society for Medical Oncology (ESMO) 2016 Congress in October including results from the Oncotype SEQ liquid biopsy analytical validation study.
- Presented results from seven Oncotype DX studies at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. Results included four new analyses from the National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Registry with more than 44,600 breast cancer patients. The SEER analyses reconfirmed through prospective outcomes data that the Oncotype DX Breast Recurrence Score result is an accurate predictor of five-year survival in patients with node-positive and node-negative disease in contemporary "real-world" clinical practice and revealed important disparities in the utilization of the test as well as patient outcomes.
- *Nature Partner Journals Breast Cancer* published five-year outcomes results from the NCI SEER Registry that demonstrated node-negative and node-positive patients with low Oncotype DX Breast Recurrence Score® results, the vast majority treated without chemotherapy, had excellent breast cancer survival.
- The *Journal of Clinical Oncology*, the official journal of ASCO, published results from a large study confirming the ability of the Oncotype DX Breast Recurrence Score results, in combination with quantitative estrogen-receptor expression, to accurately predict the risk of late distant recurrence up to 15 years in patients with early-stage, hormone receptor-positive breast cancer. These findings suggest that Oncotype DX can help identify which patients are most likely to benefit from extended hormonal treatment.
- The *Journal of Clinical Oncology* also published findings from a separate Oncotype DX study that evaluated the ability of the Breast Recurrence Score result to provide information on breast cancer progression and survival in newly diagnosed stage IV breast cancer patients.
- Results of a European meta-analysis of prospective decision-impact studies performed in France, Germany, Spain and the UK were accepted for publication in the *European Journal of Cancer*. The findings showed that the Oncotype DX Breast Recurrence Score test had a significant and consistent impact on adjuvant treatment decisions despite differences in therapeutic traditions, with an average change rate of 32 percent, resulting in an overall reduction in the recommended use of chemotherapy.
- Results from the large SUNRISE clinical validation study of the Oncotype DX Colon Recurrence Score test were published in the *Journal of Clinical Oncology*. Conducted in Japan, this study confirms that Oncotype DX accurately predicts recurrence risk in Japanese patients with stage II and III colon cancer, providing information beyond

conventional factors.

Conference Call Details
To access the live conference call today, August 2, 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 48903348. 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 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 to the company's beliefs regarding its future performance, including updated 2016 guidance; the commercial performance of its tests; 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, and collaborate with third parties to 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 commercial success of any collaborations entered into by the company; 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 March 31, 2016. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

[i] Constant currency was calculated by comparing the company's quarterly average foreign exchange rates for the three and six months ended June 30, 2016 with the comparable periods of 2015.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
REVENUES:				
Product revenues - United States	$ 69,556	$ 60,692	$ 140,051	$ 118,409
Product revenues - Outside of the United States	12,330	9,927	22,729	20,362
Total product revenues	81,886	70,619	162,780	138,771
Contract revenues	88	-	88	-
Total revenues	81,974	70,619	162,868	138,771
OPERATING EXPENSES (1)(2):				
Cost of product revenues	15,221	13,033	31,021	25,795
Research and development	15,325	14,595	31,288	33,713

Selling and marketing	37,989	37,243	77,489	72,595
General and administrative	18,537	16,580	36,975	32,169
Total operating expenses	87,072	81,451	176,773	164,272
Loss from operations	(5,098)	(10,832)	(13,905)	(25,501)
Interest income	87	55	165	109
Gain on sales of marketable securities	676	-	2,009	-
Other income (expense), net	(150)	325	(63)	(49)
Loss before income taxes	(4,485)	(10,452)	(11,794)	(25,441)
Income tax expense (benefit)	1,615	(1,215)	657	(6,711)
Net loss	$ (6,100)	$ (9,237)	$ (12,451)	$ (18,730)
Basic and diluted net loss per share	$ (0.18)	$ (0. 29)	$ (0.38)	$ (0. 58)
Shares used in computing basic and diluted net loss per share	33,130	32,324	33,015	32,191

(1) Included in operating expenses for the three months ended June 30, 2016, were non-cash charges of $7.0 million, including $4.8 million of stock-based compensation expense and $2.2 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2015 of $5.7 million, including $4.0 million of stock-based compensation expense and $1.7 million of depreciation and amortization expenses.

(2) Included in operating expenses for the six months ended June 30, 2016, were non-cash charges of $13.8 million, including $9.4 million of stock-based compensation expense and $4.4 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2015 of $11.5 million, including $8.1 million of stock-based compensation expense and $3.4 million of depreciation and amortization expenses.

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

	As of June 30, 2016	*As of* December 31, 2015
	(Unaudited)	
Cash and cash equivalents	$ 40,660	$ 32,533
Short-term marketable securities (1)	52,894	62,410
Accounts receivable, net	33,611	37,164
Prepaid expenses and other current assets	11,852	10,843
Total current assets	139,017	142,950
Property and equipment, net	39,052	39,746
Other assets	2,020	1,921
Total assets	$ 180,089	$ 184,617
Accounts payable	$ 4,796	$ 8,585
Accrued expenses and other current liabilities	34,196	33,656
Deferred revenues	235	431
Other liabilities	2,306	2,410
Stockholders' equity	138,556	139,535
Total liabilities and stockholders' equity	$ 180,089	$ 184,617

The condensed consolidated balance sheet at December 31, 2015, has been derived from the audited consolidated financial statements at that date included in the Company's Form 10-K for the fiscal year ended December 31, 2015.

(1) Included in short-term marketable securities as of June 30, 2016 and December 31, 2015 was $12.7 million and $18.1 million, respectively, of corporate equity securities, representing the Company's investment in Invitae Corporation.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/genomic-health-reports-continued-double-digit-growth-in-announcement-of-second-quarter-2016-financial-results-raises-low-end-of-full-year-test-and-revenue-guidance-300307965.html

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