

GENOMIC HEALTH INC

FORM 8-K (Current report filing)

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Address	301 PENOBSCOT DRIVE REDWOOD CITY, CA 94063
Telephone	650-556-9300
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Symbol	GHDX
SIC Code	8071 - Medical Laboratories
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 1, 2017

GENOMIC HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51541
(Commission
File Number)

77-0552594
(IRS Employer
Identification No.)

301 Penobscot Drive, Redwood City, California
(Address of principal executive offices)

94063
(Zip Code)

Registrant's telephone number, including area code: **(650) 556-9300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of Regulation S-K of the Securities Act (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2):

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 1, 2017, Genomic Health, Inc. issued a press release announcing financial results for its second fiscal quarter ended June 30, 2017. The full text of the press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by Genomic Health, Inc. dated August 1, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 1, 2017

GENOMIC HEALTH, INC.

By /s/ G. Bradley Cole
Name: G. Bradley Cole
Title: Chief Financial Officer

**GENOMIC HEALTH, INC.
EXHIBIT INDEX**

Exhibit Number	Description
99.1	Press release issued by Genomic Health, Inc. dated August 1, 2017



Investor and Media Contact:

Emily Faucette
 Genomic Health
 650-569-2824
 EFaucette@genomichealth.com

Genomic Health Announces Second Quarter 2017 Financial Results and Reports Recent Business Progress

Delivered 9 Percent Increase in Test Volume; 4 Percent Increase in Revenue

Continued to Generate Strong Test Demand with 5 Percent Increase in U.S. Invasive Breast Cancer, 38 Percent Increase in U.S. Prostate and 12 Percent Increase in International Growth

Improved Earnings Per Share by \$0.10

Company Adjusts 2017 Revenue Guidance; Expects Profit for the Full Year

REDWOOD CITY, Calif., August 1, 2017 -- Genomic Health, Inc. (NASDAQ: GHDX) today reported financial results and business progress for the quarter ended June 30, 2017.

Total revenue was \$85.5 million in the second quarter of 2017, compared with \$82.0 million in the second quarter of 2016, an increase of 4 percent, and an increase of 5 percent on a constant currency basis.¹

U.S. product revenue was \$72.4 million in the second quarter of 2017, compared with \$69.6 million in the second quarter of 2016. U.S. invasive breast revenue from Oncotype DX Breast Recurrence Score[®] test sales was \$65.6 million in the second quarter of 2017, compared with \$64.4 million in the second quarter of 2016. U.S. prostate revenue from Oncotype DX[®] Genomic Prostate Score[™] (GPS[™]) test sales was \$4.1 million in the second quarter of 2017, compared with \$2.3 million in the second quarter of 2016.

International product revenue was \$13.1 million in the second quarter of 2017, compared with \$12.3 million in the second quarter of 2016, an increase of 6 percent, and an increase of 10 percent on a constant currency basis.¹

“In the second quarter, we continued to deliver solid results reflecting both the strength and differentiation of our clinical data and unmatched commercial channel, generating a 9 percent increase in test volume and a 4 percent increase in revenue,” said Kim Popovits, chairman of the board, chief executive officer and president of Genomic Health. “Importantly, we delivered operating leverage and made significant progress toward our goal of delivering full-year profitability, having improved net loss by \$9 million in the first half of the year.”

More than 31,550 Oncotype[™] test results were delivered in the second quarter of 2017, an increase of 9 percent, compared with more than 29,060 test results delivered in the same period in 2016. Oncotype DX Breast Recurrence Score tests delivered in the U.S. grew 5 percent and Oncotype DX Genomic Prostate Score tests delivered in the U.S. grew 38 percent compared with the second quarter of the prior year. International tests delivered grew 12 percent compared with the same period of the prior year and represented approximately 24 percent of total test volume in the second quarter of 2017.

Operating loss for the second quarter of 2017 improved to \$3.1 million, compared with \$5.1 million for the second quarter of 2016. Net loss was \$2.7 million, or 8 cents per share, for the second quarter of 2017, compared with a net loss of \$6.1 million, or 18 cents per share, for the second quarter of 2016. Basic and diluted net loss per share was \$0.08 for the second quarter of 2017, compared with basic and diluted net loss per share of \$0.18 for the second quarter of 2016.

Total revenue for the six months ended June 30, 2017 was \$169.5 million compared with \$162.9 million for the six months ended June 30, 2016, an increase of 4 percent. On a constant currency basis, revenue increased 5 percent compared with the same period in the prior year.¹

International product revenue was \$26.5 million for the six months ended June 30, 2017, compared with \$22.7 million for the six months ended June 30, 2016, an increase of 16 percent, and an increase of 20 percent on a constant currency basis.¹

Operating loss improved to \$6.0 million for the six months ended June 30, 2017 compared with an operating loss of \$13.9 million for the six months ended June 30, 2016. Net loss was \$3.5 million for the six months ended June 30, 2017 compared with a net loss of \$12.5 million for the six months ended June 30, 2016.

Cash and cash equivalents and short-term marketable securities at June 30, 2017 were \$109.8 million, compared with \$87.7 million at December 31, 2016 excluding the fair value of the company's investment in a marketable security of \$9.3 million.

2017 Financial Outlook

The company is providing the following adjusted financial guidance for the full year ending December 31, 2017:

- Total revenue of between \$345 to \$355 million (formerly \$355 to \$370 million); and
- Profit for the full-year at either end of revenue range (formerly profit at revenue above \$362.5 million).

“While the timing of important reimbursement drivers has delayed the pace of revenue growth, we expect to deliver full-year profitability at these revised revenue levels, including double-digit revenue growth in the fourth quarter,” said Brad Cole, chief operating officer and chief financial officer of Genomic Health. “We expect full-year CMS intermediate prostate coverage and the implementation of both PAMA reimbursement rates and AJCC staging criteria, along with increased global market penetration, to drive strong revenue growth in 2018.”

Recent Business Highlights

- Presented new results from a large, community-based, multi-center clinical validation study conducted at Kaiser Permanente at the American Urological Association (AUA) 2017 Annual Meeting. The results confirmed that the Oncotype DX GPS test is a strong independent predictor of prostate cancer-specific death and disease progression (metastases) at 10 years in men with localized prostate cancer.
 - Data from two Oncotype DX GPS test analyses based on a prospective, multi-center, 1,200-patient study were also presented at AUA, including results that represent the first-ever prospective validation of a tissue-based molecular marker in prostate cancer. The second analysis, presented at AUA and published online in *Urology*, reinforced that the GPS test significantly increases use of and persistence on active surveillance.
 - Initiated an early access Clinical Utility Program for select centers around the country in preparation for the commercial launch of the Oncotype DX AR-V7 Nucleus Detect™ test in collaboration with Epic Sciences.
 - The 15th St. Gallen International Breast Cancer Conference Expert Panel published updated guidelines endorsing the Oncotype DX Breast Recurrence Score test for guiding treatment decisions on adjuvant chemotherapy in both node-negative and node-positive patients (up to three nodes).
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- *Breast Cancer Research and Treatment* published positive five-year clinical outcome results from the PlanB study led by the West German Study Group (WSG) in 93 centers across Germany. The study showed that women with Recurrence Score[®] results of 11 or less who were treated with hormonal therapy alone had excellent outcomes with 94 percent disease-free survival rates at five years despite having high-risk disease by traditional parameters.
- Presented results from eight studies across breast, prostate and kidney cancers that provide additional evidence of the value of Oncotype DX tests in predicting clinically meaningful endpoints and outcomes across cancer types at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Conference Call Details

To access the live conference call today, August 1 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 call ID is 47057890. 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 web site at <http://investor.genomichealth.com>. Please connect to the web site at least 15 minutes prior to the presentation 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 help optimize cancer care, including addressing the overtreatment of the disease, 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 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ[®] Liquid Select™ test. 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 financial guidance for the full year 2017; 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 risk that the company may not achieve its updated 2017 guidance estimates and the assumptions underlying such guidance; 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, 2017. 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, Liquid Select, Genomic Prostate Score, GPS Oncotype DX AR-V7 Nucleus Detect 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.

ⁱ Constant currency is a non-GAAP measure that is calculated by comparing the company's quarterly average foreign exchange rates for the three and six months ended June 30, 2017. The constant currency disclosures take current local currency revenue and translate it into U.S. dollars based upon the foreign currency exchange rates used to translate the local currency revenue for the applicable comparable period in the prior year, rather than the actual exchange rates in effect during the current period. It does not include any other effect of changes in foreign currency rates on the company's results or business. The company believes this non-GAAP financial measure is useful to investors in assessing the operating performance of the business. This non-GAAP measure should not be considered in isolation or as an alternative to GAAP measures.

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,	
	2017	2016	2017	2016
REVENUES:				
Product revenues - United States	\$ 72,409	\$ 69,556	\$ 142,998	\$ 140,051
Product revenues - Outside of the United States	13,078	12,330	26,469	22,729
Total product revenues	85,487	81,886	169,467	162,780
Contract revenues	—	88	—	88
Total revenues	85,487	81,974	169,467	162,868
OPERATING EXPENSES (1)(2):				
Cost of product revenues	13,798	15,598	27,471	31,752
Research and development	15,781	14,948	30,655	30,557
Selling and marketing	40,656	37,989	82,163	77,489
General and administrative	18,395	18,537	35,146	36,975
Total operating expenses	88,630	87,072	175,435	176,773
Loss from operations	(3,143)	(5,098)	(5,968)	(13,905)
Interest income	206	87	364	165
Gain on sales of marketable securities	—	676	2,807	2,009
Other income (expense), net	357	(150)	452	(63)
Loss before income taxes	(2,580)	(4,485)	(2,345)	(11,794)
Income tax expense	159	1,615	1,200	657
Net loss	<u>\$ (2,739)</u>	<u>\$ (6,100)</u>	<u>\$ (3,545)</u>	<u>\$ (12,451)</u>
Basic and diluted net loss per share	<u>\$ (0.08)</u>	<u>\$ (0.18)</u>	<u>\$ (0.10)</u>	<u>\$ (0.38)</u>
Shares used in computing basic and diluted net loss per share	<u>34,428</u>	<u>33,130</u>	<u>34,219</u>	<u>33,015</u>

- (1) Included in operating expenses for the three months ended June 30, 2017 were non-cash charges of \$8.2 million, including \$5.2 million of stock-based compensation expense and \$3.0 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of \$7.0 million, including \$4.8 million of stock-based compensation expense and \$2.2 million of depreciation and amortization expenses.
- (2) Included in operating expenses for the six months ended June 30, 2017, were non-cash charges of \$15.7 million, including \$10.3 million of stock-based compensation expense and \$5.4 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of \$13.8 million, including \$9.4 million of stock-based compensation expense and \$4.4 million of depreciation and amortization expenses.

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

	As of June 30, 2017 <u>(Unaudited)</u>	As of December 31, 2016 <u>(1)</u>
Cash and cash equivalents	\$ 42,200	\$ 40,404
Short-term marketable securities (2)	67,599	56,585
Accounts receivable, net	32,427	35,179
Prepaid expenses and other current assets	12,278	13,796
Total current assets	154,504	145,964
Property and equipment, net	48,908	45,688
Other assets	9,518	9,462
Total assets	\$ 212,930	\$ 201,114
Accounts payable	\$ 5,322	\$ 2,864
Accrued expenses and other current liabilities	33,762	38,311
Other liabilities	3,899	3,834
Stockholders' equity	169,947	156,105
Total liabilities and stockholders' equity	\$ 212,930	\$ 201,114

- (1) The condensed consolidated balance sheet at December 31, 2016, 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, 2016.
- (2) Included in short-term marketable securities as of December 31, 2016 is \$9.3 million of corporate equity securities, representing the Company's investment in Invitae Corporation. All remaining shares of Invitae Corporation were sold during the quarter ended March 31, 2017.

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