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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Sector	Healthcare
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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): **May 9, 2017**

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-51541**	**77-0552594**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

301 Penobscot Drive, Redwood City, California	**94063**
(Address of principal executive offices)	(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 May 9, 2017, Genomic Health, Inc. issued a press release announcing financial results for its first fiscal quarter ended March 31, 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 May 9, 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: May 9, 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 May 9, 2017

Exhibit 99.1

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

Delivered 7 Percent Increase in Test Volume; 4 Percent Increase in Revenue

Generated 17 Percent Test Growth and 29 Percent Revenue Growth Across International Markets

Continued to Accelerate Prostate Test Adoption with 40 Percent Volume Growth and 26 Percent Revenue Growth

Improved Earnings Per Share by $0.17

Conference Call Today at 4:30 p.m. ET

REDWOOD CITY, Calif., May 9, 2017 — Genomic Health, Inc. (Nasdaq: GHDX) today reported financial results and business progress for the quarter ended March 31, 2017.

Total revenue was $84.0 million in the first quarter of 2017, compared with $80.9 million in the first quarter of 2016, an increase of 4 percent.

U.S. product revenue was $70.6 million in the first quarter of 2017, compared with $70.5 million in the first quarter of 2016. U.S. invasive breast revenue was $64.8 million in the first quarter of 2017, compared with $64.1 million in the first quarter of 2016. U.S. prostate revenue was $3.3 million in the first quarter of 2017, compared with $2.6 million in the first quarter of 2016.

International product revenue was $13.4 million in the first quarter of 2017, compared with $10.4 million in the first quarter of 2016, an increase of 29 percent, and an increase of 33 percent on a constant currency basis. [i]

“Strong demand for our Oncotype tests in the first quarter of 2017 was due, in part, to growth across our U.S. prostate and global invasive breast business, including four percent sequential growth in U.S. invasive breast cancer. Importantly, for the seventh consecutive quarter, we delivered operating leverage and improved operating income by $6 million in the first quarter,” said Kim Popovits, chairman of the board, chief executive officer and president of Genomic Health. “Additionally, last week Palmetto GBA issued a draft local coverage determination that recommends Medicare coverage expansion for the Oncotype DX Genomic Prostate Score to include intermediate-risk patients. Reimbursement progress remains a critical growth driver as we aim to deliver double-digit revenue growth in the second half of the year with continued profitability improvement.”

Operating loss for the first quarter of 2017 improved to $2.8 million, compared with $8.8 million for the first quarter of 2016. Net loss was $0.8 million, or 2 cents per share, for the first quarter of 2017, compared with a net loss of $6.4 million, or 19 cents per share, for the first quarter of 2016. Basic and diluted net loss per share was $0.02 for the first quarter of 2017, compared with a basic and diluted net loss per share of $0.19 for the first quarter of 2016.

More than 31,580 Oncotype™ test results were delivered in the first quarter of 2017, an increase of 7 percent, compared with more than 29,510 test results delivered in the same period in 2016. Oncotype DX Breast Recurrence Score ® tests delivered in the U.S. grew 1 percent and Oncotype DX ® Genomic Prostate Score™ tests delivered in the U.S. grew 40 percent compared with the prior year. International tests delivered grew 17 percent compared with the prior year and represented approximately 25 percent of total test volume in the first quarter of 2017.

Cash and cash equivalents and short-term marketable securities at March 31, 2017 were $94.4 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.

Recent Business Highlights

- Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies, issued a draft local coverage determination (LCD) for the Oncotype DX Genomic Prostate Score (GPS) expanding Medicare coverage to include qualified patients with favorable intermediate-risk prostate cancer throughout the United States.

- Presented results from four studies evaluating the clinical validation and utility of the GPS in the management of early-stage prostate cancer at the 2017 Genitourinary (GU) Cancers Symposium. Collectively, these new data highlight the test’s ability to predict disease aggressiveness and refine risk stratification across National Comprehensive Cancer Network (NCCN) clinical risk groups.

- Presented results from a large multi-center clinical validation study that used a longitudinal patient database from Kaiser Permanente’s Northern California region demonstrating that the GPS predicts 10-year risk of developing metastatic prostate cancer. Designated one of the ‘Best Posters’ at the 32 nd Annual European Association of Urology (EAU) Congress, results highlight the expanded value of the test in assessing risk and long-term outcomes in newly diagnosed prostate cancer patients.

- Later this week, additional results from the Kaiser validation study, which also analyzed the GPS performance in predicting prostate cancer-specific death, will be presented at the American Urological Association (AUA) 2017 Annual Meeting.

- Three additional Oncotype DX GPS studies demonstrating prospective and additional clinical utility, including persistence on active surveillance, will also be presented at AUA.

- The German Association of Gynecological Oncology’s (AGO’s) updated treatment guidelines reconfirm Oncotype DX with the highest 1A level of evidence and recognize it as the only multi-gene

breast cancer test available to predict chemotherapy benefit for women with early-stage, hormone-receptor positive, HER2-negative invasive breast cancer.

- Established an agreement with an additional German public health insurance fund, covering 2.5 million lives, to begin offering Oncotype DX to early-stage breast cancer patients.

- Presented results at the 15 th St. Gallen International Breast Cancer Conference from 15 Oncotype DX Breast Recurrence Score studies conducted in 12 countries that provide real-world evidence of the test's ability to change treatment decisions for breast cancer patients.

- The journal *Breast Cancer Research and Treatment* published results from the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Registry, which demonstrated that many node-positive breast cancer patients can avoid chemotherapy based on their Oncotype DX Breast Recurrence Score.

- The *Journal of Surgical Oncology* published results from a multicenter trial, which demonstrated that the Oncotype DX Breast Recurrence Score can guide neoadjuvant therapy to help facilitate breast-conserving surgery for hormone receptor-positive breast cancer patients.

- Received acceptance to present eight Oncotype DX studies at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in June.

Conference Call Details

To access the live conference call today, May 9 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 10366777. 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 help optimize cancer care by 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 750,000 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™. 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 its guidance; the commercial performance of its tests; the attributes and focus of the company's product pipeline; the risk that the company may not obtain or maintain adequate levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop including Medicare coverage for its Oncotype DX Genomic Prostate Score test in favorable intermediate-risk prostate cancer patients; the ability of the company to achieve expanded coverage of reimbursement for its existing tests and the ability of any such expanded coverage to result in additional revenue;the ability of any potential tests the company may develop to optimize cancer

treatment; and the ability of the company to develop, commercialize or collaborate to offer 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 estimates and assumptions underlying future financial and business performance; 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 has all rights necessary to commercialize its tests; 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 and uncertainties set forth in our filings with the Securities and Exchange Commission, including our most recent report on Form 10-K for the year ended December 31, 2016. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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[i] Constant currency was calculated by comparing the company's quarterly average foreign exchange rates for the three months ended March 31, 2017 with the comparable three month period in 2016.

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

	Three Months Ended March 31,	
	2017	2016
	(Unaudited)	
REVENUES:		
Product revenues — United States	$ 70,587	$ 70,495
Product revenues — Outside of the United States	13,392	10,399
Total revenues	83,979	80,894
OPERATING EXPENSES (1):		
Cost of product revenues	13,672	16,153
Research and development	14,874	15,610
Selling and marketing	41,507	39,500
General and administrative	16,751	18,438
Total operating expenses	86,804	89,701
Loss from operations	(2,825)	(8,807)
Interest income	158	78
Gain on sales of marketable securities	2,807	1,333
Other income (expense), net	95	87
Income (loss) before income taxes	235	(7,309)
Income tax expense (benefit)	1,041	(958)
Net loss	$ (806)	$ (6,351)
Basic and diluted net loss per share	$ (0.02)	$ (0.19)
Shares used in computing basic and diluted net loss per share	34,009	32,900

(1) Included in operating expenses for the first quarter of 2017 were non-cash charges of $7.5 million, including $5.1 million of stock-based compensation expense and $2.4 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of $6.7 million, including $4.5 million of stock-based compensation expense and $2.2 million of depreciation and amortization expenses.

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

	As of March 31, 2017 (Unaudited)	As of December 31, 2016 (1)
Cash and cash equivalents	$ 40,774	$ 40,404
Short-term marketable securities (2)	53,648	56,585
Accounts receivable, net	34,593	35,179
Prepaid expenses and other current assets	13,079	13,796
Total current assets	142,094	145,964
Property and equipment, net	49,459	45,688
Other assets	10,321	9,462
Total assets	$ 201,874	$ 201,114
Accounts payable	$ 5,238	$ 2,864
Accrued expenses and other current liabilities	31,527	38,311
Other liabilities	3,941	3,834
Stockholders' equity	161,168	156,105
Total liabilities and stockholders' equity	$ 201,874	$ 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.