GENOMIC HEALTH INC

FORM 8-K
(Current report filing)

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Address	301 PENOBSCOT DRIVE REDWOOD CITY, CA, 94063
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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): November 8, 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 November 8, 2017, Genomic Health, Inc. issued a press release announcing financial results for its third fiscal quarter ended September 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 November 8, 2017.

GENOMIC HEALTH, INC.
EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Genomic Health, Inc. dated November 8, 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: November 8, 2017

GENOMIC HEALTH, INC.

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

Exhibit 99.1

Investor and Media Contact:

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

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

Delivered 2 Percent Increase in Revenue; 5 Percent Increase in Test Volume

Reported Net Loss of $2.2M; Delivered $1.1M Profit on a Non-GAAP Basis

Announced Collaboration with Biocartis to Develop IVD Version of Oncotype DX Breast Cancer Test with a $3.2M Transaction Cost in the Third Quarter

Reiterates Full-year Revenue Guidance, Excluding Impact from Hurricane Disruption

Expects Full-year Profitability, Excluding Cost of Biocartis Transaction

REDWOOD CITY, Calif., November 8, 2017 -- Genomic Health, Inc. (NASDAQ: GHDX) today reported financial results and business progress for the quarter ended September 30, 2017.

Total revenue was $83.8 million in the third quarter of 2017, compared with $82.3 million in the third quarter of 2016, an increase of 2 percent. Revenue was negatively impacted by approximately $3 million due to the hurricane disruption in certain regions of the United States.

U.S. product revenue was $70.9 million in the third quarter of 2017, compared with $70.0 million in the third quarter of 2016. U.S. invasive breast revenue from Oncotype DX Breast Recurrence Score ® tests was $63.1 million in the third quarter of 2017, compared with $64.6 million in the third quarter of 2016. U.S. prostate revenue from Oncotype DX ® Genomic Prostate Score™ (GPS™) tests was $5.5 million in the third quarter of 2017, compared with $2.3 million in the third quarter of 2016.

International product revenue was $12.9 million in the third quarter of 2017, compared with $12.1 million in the third quarter of 2016, an increase of 7 percent.

“ In the third quarter, we generated solid results including a 2 percent increase in revenue and a 5 percent increase in test volume, despite disruption in U.S. regions affected by hurricanes. We also reported a net loss of $2.2 million, and on a non-GAAP basis delivered a $1.1 million profit in the third quarter. Importantly, we expect to deliver full-year profit, excluding transaction costs from our collaboration with Biocartis,” said Kim Popovits, chairman of the board, chief executive officer and president of Genomic Health . “We look forward to significant revenue drivers in 2018 including a new higher Medicare rate under PAMA and anticipated TAILORx results, while we expand our business model to increase worldwide access through the development of an in vitro diagnostic, or IVD, version of the Oncotype DX breast cancer test.”

More than 31,580 Oncotype™ test results were delivered in the third quarter of 2017, an increase of 5 percent, compared with more than 29,990 test results delivered in the same period in 2016. U.S. test volume was negatively impacted by approximately 3 percent due to the hurricane disruption in certain regions of the country. Oncotype DX Breast Recurrence Score tests delivered in the U.S. were consistent with the third quarter of the prior year. Oncotype DX Genomic Prostate Score tests delivered in the U.S. grew 39 percent compared with the third quarter of the prior year. International tests delivered grew 14 percent compared with the same period of the prior year and represented approximately 26 percent of total test volume in the third quarter of 2017.

Operating loss for the third quarter of 2017 improved to $2.6 million, compared with $3.0 million for the third quarter of 2016. Net loss was $2.2 million, or $0.06 per share, for the third quarter of 2017, compared with a net loss of $2.8 million, or $0.08 per share, for the third quarter of 2016. Basic and diluted net loss per share was $0.06 for the third quarter of 2017, compared with basic and diluted net loss per share of $0.08 for the third quarter of 2016.

Total revenue for the nine months ended September 30, 2017 was $253.3 million compared with $245.1 million for the nine months ended September 30, 2016, an increase of 3 percent. On a constant currency basis, revenue increased 4 percent compared with the same period in the prior year. [i]

International product revenue was $39.4 million for the nine months ended September 30, 2017, compared with $34.8 million for the nine months ended September 30, 2016, an increase of 13 percent, and an increase of 16 percent on a constant currency basis [i]

Operating loss improved to $8.6 million for the nine months ended September 30, 2017, compared with an operating loss of $16.9 million for the nine months ended September 30, 2016. Net loss was $5.7 million, or $0.17 per share, for the nine months ended September 30, 2017, compared with a net loss of $15.3 million, or $0.46 per share, for the nine months ended September 30, 2016.

Cash and cash equivalents and short-term marketable securities at September 30, 2017 were $119.0 million, compared with $97.0 million at December 31, 2016 which included the fair value of the company's investment in a marketable security of $9.3 million at December 31, 2016.

The non-GAAP financial measures used adjust for specified items that can be highly variable or difficult to predict. A reconciliation of the non-GAAP financial measures to the most directly comparable GAAP financial measures is included in the tables accompanying this release.

2017 Financial Outlook

- The company expects to deliver full-year profit, excluding the $3.2 million cost of the Biocartis transaction.
- The company expects to meet the low end of its full year revenue guidance, which is $345 million, excluding the estimated hurricane impact on revenue of approximately $3 million in the third quarter .

Recent Business Highlights

- Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies, issued a positive final Local Coverage Determination (LCD) that became effective on October 9, 2017 to expand Medicare coverage of the Oncotype DX Genomic Prostate Score test to qualified patients with favorable intermediate-risk prostate cancer throughout the U.S.
- Established additional private coverage for the Oncotype DX Genomic Prostate Score test, bringing the total number of U.S. covered lives to more than 66 million.
- Established new private coverage for the Oncotype DX Breast Recurrence Score test in Germany, bringing the total number of German private covered lives to 15 million.

- Announced an exclusive agreement with Biocartis Group NV to develop an IVD version of the Oncotype DX Breast Recurrence Score test on Biocartis' Idylla platform that can be performed locally by laboratory partners and in hospitals around the world to broaden future global patient access.
- *European Urology* published results from a large, community-based, multi-center clinical validation study conducted at Kaiser Permanente. The results confirmed that the Oncotype DX GPS test is a strong independent predictor of prostate cancer-specific death and metastases at 10 years in men with localized prostate cancer.
- Presented results from four studies that provide additional evidence of the unmatched value of the Oncotype DX Breast Recurrence Score test in accurately predicting outcomes in early-stage breast cancer patients at the European Society for Medical Oncology (ESMO) 2017 Congress.
- *Nature Partner Journals Breast Cancer* , a peer-reviewed journal published by *Nature* , published two articles highlighting results from a large prospectively designed registry conducted by Clalit Health Services, the largest Health Maintenance Organization in Israel. The results reinforce the ability of the Oncotype DX Breast Recurrence Score test to predict clinical outcomes in both node-negative and node-positive patients.
- Received acceptance to present nine studies at the 2017 San Antonio Breast Cancer Symposium (SABCS) in December.

Conference Call Details
To access the live conference call today, November 8, 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 5697809. 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 achieving its financial guidance for the full year 2017; the commercial performance of its tests; the ability of new Medicare rates under PAMA to result in additional revenue in 2018; the favorable impact of TAILORx results on revenue in 2018; the estimated impact of the recent hurricanes on the company's business; the attributes and focus of the company's product pipeline; the ability of any potential tests the company may develop to optimize cancer treatment; the ability of the company to develop and commercialize, and collaborate with third parties to commercialize, additional tests in the future; and the ability of the Company to increase worldwide access through the development of an in vitro diagnostic version of its tests. 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 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 June 30, 2017. 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 is a non-GAAP measure that is calculated by comparing the company's quarterly average foreign exchange rates for the nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
REVENUES:				
Product revenues - United States	$ 70,881	$ 70,041	$ 213,878	$ 210,092
Product revenues - Outside of the United States	12,940	12,095	39,409	34,824
Total product revenues	83,821	82,136	253,287	244,916
Contract revenues	—	122	—	210
Total revenues	83,821	82,258	253,287	245,126
OPERATING EXPENSES (1)(2):				
Cost of product revenues	13,433	13,425	40,904	45,177
Research and development	17,212	14,746	47,868	45,303
Selling and marketing	38,303	38,838	120,464	116,327
General and administrative	17,505	18,268	52,651	55,243
Total operating expenses	86,453	85,277	261,887	262,050
Loss from operations	(2,632)	(3,019)	(8,600)	(16,924)
Interest income	263	117	627	282
Gain on sales of marketable securities	—	—	2,807	2,009
Other income (expense), net	340	(111)	792	(174)
Loss before income taxes	(2,029)	(3,013)	(4,374)	(14,807)
Income tax expense	162	(193)	1,362	464
Net loss	$ (2,191)	$ (2,820)	$ (5,736)	$ (15,271)
Basic and diluted net loss per share	$ (0.06)	$ (0.08)	$ (0.17)	$ (0.46)
Shares used in computing basic and diluted net loss per share	34,675	33,391	34,373	33,141

(1) Included in operating expenses for the three months ended September 30, 2017 were non-cash charges of $8.1 million, including $5.0 million of stock-based compensation expense and $3.1 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of $7.0 million, including $4.7 million of stock-based compensation expense and $2.3 million of depreciation and amortization expenses.

(2) Included in operating expenses for the nine months ended September 30, 2017, were non-cash charges of $23.8 million, including $15.2 million of stock-based compensation expense and $8.6 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of $20.8 million, including $14.1 million of stock-based compensation expense and $6.7 million of depreciation and amortization expenses.

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

	As of September 30, 2017 (Unaudited)	As of December 31, 2016 (1)
Cash and cash equivalents	$ 43,019	$ 40,404
Short-term marketable securities (2)	75,942	56,585
Accounts receivable, net	35,584	35,179
Prepaid expenses and other current assets	11,506	13,796
Total current assets	166,051	145,964
Property and equipment, net	47,411	45,688
Other assets	9,522	9,462
Total assets	$ 222,984	$ 201,114
Accounts payable	$ 8,475	$ 2,864
Accrued expenses and other current liabilities	35,947	38,311
Other liabilities	3,867	3,834
Stockholders' equity	174,695	156,105
Total liabilities and stockholders' equity	$ 222,984	$ 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.

GENOMIC HEALTH, INC.
GAAP to Non-GAAP Reconciliations
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Income (loss) from operations reconciliation:				
GAAP (loss) from operations	$ (2,632)	$ (3,019)	$ (8,600)	$ (16,924)
Research and development – collaboration with Biocartis, upfront license and option fee	3,249	—	3,249	—
Selling and marketing – impairment charge for previously capitalized software	—	2,600	—	2,600
Non-GAAP income (loss) from operations	$ 617	$ (419)	$ (5,351)	$ (14,324)
Interest and other income (expense), net reconciliation :				
GAAP interest and other income (expense), net	$ 603	$ 6	$ 4,226	$ 2,117
Non-recurring gain on sale of marketable securities	—	—	(2,807)	(2,009)
Non-GAAP interest and other income (expense), net	$ 603	$ 6	$ 1,419	$ 108
Income tax (benefit) expense reconciliation:				
GAAP income tax (benefit) expense	$ 162	$ (193)	$ 1,362	$ 464
Reduced income tax expense from the sale of marketable securities	—	—	(821)	(347)
Non-GAAP income tax (benefit) expense	$ 162	$ (193)	$ 541	$ 117
Net income (loss) reconciliation:				
GAAP net (loss)	$ (2,191)	$ (2,820)	$ (5,736)	$ (15,271)
Research and development – collaboration with Biocartis, upfront license and option fee	3,249	—	3,249	—
Selling and marketing – impairment charge for previously capitalized software	—	2,600	—	2,600
Non-recurring gain on sale of marketable securities	—	—	(2,807)	(2,009)
Reduced income tax expense from the sale of marketable securities	—	—	821	347
Non-GAAP net income (loss)	$ 1,058	$ (220)	$ (4,473)	$ (14,333)

GENOMIC HEALTH, INC.
GAAP to Non-GAAP Reconciliations (continued)
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Non-GAAP adjustment summary:				
Research and development expense adjustments	$ 3,249	$ —	$ 3,249	$ —
Selling and marketing expense adjustments	—	2,600	—	2,600
Gain on sale of marketable securities	—	—	(2,807)	(2,009)
Total non-GAAP adjustments before tax	3,249	2,600	442	591
Income tax effect	—	—	821	347
Total non-GAAP adjustments after tax	$ 3,249	$ 2,600	$ 1,263	$ 938

The Company makes reference in this press release to "non-GAAP net income" which excludes research and development expense recorded for a one-time upfront license and option fee, for the Company's collaboration with Biocartis N.V.; and certain other non-recurring income and expenses. The Company believes that excluding these items and their related tax effects from its financial results reflects operating results that are more indicative of the Company's ongoing operating performance while improving comparability to prior periods, and, as such may provide investors with an enhanced understanding of the Company's past financial performance and prospects for the future. In addition, the Company's management uses such non-GAAP measures internally to evaluate and assess its core operations and to make ongoing operating decisions. This information is not intended to be considered in isolation or as a substitute for income (loss) from operations, net loss or other income (expense) information prepared in accordance with GAAP.

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