GENOMIC HEALTH INC

FORM 8-K
(Current report filing)

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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 2, 2018

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 2, 2018, Genomic Health, Inc. issued a press release announcing financial results for its first fiscal quarter ended March 31, 2018. 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 2, 2018.

GENOMIC HEALTH, INC.
EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Genomic Health, Inc. dated May 2, 201 8

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 2, 2018

GENOMIC HEALTH, INC.

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

Exhibit 99.1

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Genomic Health Announces First Quarter 2018 Financial Results and Reports Recent Business Progress

Reported Record Revenue of $92.6M and Delivered 13 Percent Revenue Growth on a Pre-606 Adjusted Basis

Reported Net Loss of $3.8M Including First Quarter Charge of $8.5M for Realignment of Resources

Delivered $4.6M Profit on a Non-GAAP Basis

REDWOOD CITY, Calif., May 2, 2018 -- Genomic Health, Inc. (NASDAQ: GHDX) today reported financial results and business progress for the quarter ended March 31, 2018.

"In the first quarter of 2018, we delivered 13 percent growth in revenue and delivered a non-GAAP profit demonstrating continued operating leverage for the 11 th consecutive quarter of improved profitability," said Kim Popovits , chairman of the board, chief executive officer and president of Genomic Health . "We delivered a strong start to the year with multiple revenue drivers, including the implementation of PAMA and AJCC breast cancer staging criteria, and the recent strengthening of NCCN prostate cancer guidelines. With several additional catalysts on the near-term horizon, including ECOG's presentation of TAILORx results at ASCO and the anticipated finalization of the Medicare LCD for the Oncotype DX AR-V7 Nucleus Detect test, we expect strong revenue growth in the second half of the year."

Pre-606 Adjusted Revenue
Effective January 1, 2018, the company adopted the new ASC 606 accounting standard for revenue, using the modified retrospective method, which applies the new standard prospectively and does not impact prior years' financial statements. Since the as-reported 2017 quarterly and annual financial statements will not be restated to reflect the new accounting standard, the company has provided a supplemental financial schedule in the non-GAAP tables at the end of this release, reflecting an estimate of revenue as if the new standard had been applied as of January 1, 2017 referred to herein as "pre-606 adjusted revenue."

First Quarter Financial Results
Total revenue was $92.6 million in the first quarter of 2018, compared with pre-606 adjusted revenue of $82.3 million for the first quarter of 2017, an increase of 13 percent, and an increase of 12 percent on a non-GAAP constant currency basis. Revenue was $84.0 million in the first quarter of 2017.

U.S. product revenue was $78.9 million in the first quarter of 2018, compared with pre-606 adjusted revenue of $69.2 million for the first quarter of 2017, an increase of 14 percent. U.S. product revenue was $70.6 million in the first quarter of 2017. U.S. invasive breast revenue from Oncotype DX Breast Recurrence Score ® tests was $71.0 million in the first quarter of 2018, compared with U.S. invasive breast pre-606 adjusted revenue of $63.4 million for the first quarter of 2017, an increase of 12 percent. U.S. invasive breast revenue was $64.8 million in the first quarter of 2017. U.S. prostate test revenue from Oncotype DX ® Genomic Prostate Score™ (GPS™) tests was $5.8 million in the first quarter of 2018, compared with $3.3 million in the first quarter of 2017, an increase of 75 percent.

International product revenue was $13.8 million in the first quarter of 2018, compared with pre-606 adjusted revenue of $13.1 million for the first quarter of 2017, an increase of 5 percent, and a 1 percent increase on a non-GAAP constant currency basis. International product revenue was $13.4 million in the first quarter of 2017.

Net loss was $3.8 million, or $0.11 per share on a basic and diluted basis, in the first quarter of 2018, compared with a net loss of $0.8 million, or $0.02 per share on a basic and diluted basis, in the first quarter of 2017. Operating loss was $4.4 million in the first quarter of 2018, compared with an operating loss of $2.8 million in the first quarter of 2017.

On a non-GAAP basis, excluding the $8.5 million one-time charge for the realignment of resources that was completed in the quarter and certain other one-time charges, net income was $4.6 million in the first quarter of 2018, compared with a $2.8 million non-GAAP net loss in the first quarter of 2017. On a non-GAAP basis, operating income was $4.2 million in the first quarter of 2018, compared with a non-GAAP operating loss of $2.8 million in the first quarter of 2017.

More than 32,440 Oncotype™ test results were delivered in the first quarter of 2018, an increase of 3 percent, compared with more than 31,580 test results delivered in the same period in 2017. Oncotype DX Breast Recurrence Score tests delivered in the U.S. grew 4 percent in the first quarter of 2018 compared with the same period in 2017. Oncotype DX Genomic Prostate Score tests delivered in the U.S. grew 25 percent in the first quarter of 2018 compared with the same period in 2017. International tests delivered decreased by 7 percent compared with the same period in 2017 and represented approximately 22 percent of total test volume in the first quarter of 2018.

Cash and cash equivalents and short-term marketable securities at March 31, 2018 were $130.4 million, which included the fair value of the company's investment in marketable equity securities of $3.8 million, compared with $129.6 million at December 31, 2017, which included the fair value of the company's investment in marketable equity securities of $3.5 million.

Recent Business Highlights

- Results from the landmark ECOG-ACRIN Cancer Research Group TAILORx study were accepted for presentation at the Plenary Session at the 2018 American Society of Clinical Oncology Annual Meeting (ASCO) on Sunday, June 3.
- Multiple private insurers established new coverage for the Oncotype DX Genomic Prostate Score test, bringing the total number of U.S. covered lives to more than 71 million.
- Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies, issued a draft local coverage determination (LCD) for the Oncotype DX AR-V7 Nucleus Detect ™ test.
- The National Institute for Health and Care Excellence (NICE) in the United Kingdom issued a revised Diagnostics Consultation Document (DCD) including the Oncotype DX Breast Recurrence Score test for continued use to guide adjuvant chemotherapy decisions for patients with hormone receptor-positive, HER2-negative, node-negative early-stage breast cancer.

- Secured tender with the UNICANCER hospital group in France for the Oncotype DX Breast Recurrence Score test increasing access to approximately 20 percent of the French market.
- Established new public coverage for the Oncotype DX Breast Recurrence Score test in Germany, bringing the total number of German covered lives to more than 17 million.
- Secured public coverage with the province of Manitoba for the use of the Oncotype DX Breast Recurrence Score test in early-stage breast cancer patients with node-negative disease, increasing the total number of covered lives in Canada to 35 million.
- *The Oncologist* published positive results from a study conducted by Sunnybrook Health Sciences Centre in Canada, demonstrating a 37 percent reduction in chemotherapy among breast cancer patients with up to three positive nodes, as well as an increase in physicians' and patients' confidence (49 and 54 percent, respectively) when Oncotype DX was used to make adjuvant treatment decisions.
- Presented results from three studies at the 11th European Breast Cancer Conference (EBCC-11) in March.
- Received acceptance to present two studies utilizing the Oncotype DX Genomic Prostate Score test at the American Urological Association Annual Meeting in May.

Non-GAAP Disclosure

The company makes reference in this press release to "non-GAAP operating income (loss)" which excludes 2018 expenses resulting from the restructuring charges for the cessation of Oncotype SEQ, including the Oncotype SEQ Liquid Select™ test, and Oncotype SEQ product development and commercialization activities (restructuring charges). Additionally, the company references "non-GAAP net income (loss)" which excludes the Q1 2018 restructuring charges as well as fair value adjustments related to its collaborations with Biocartis and Cleveland Diagnostics in the first quarter of 2018 and the gain on sale of marketable equity securities in the first quarter of 2017. 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. The company also considers the impact of foreign currency exchange rates on its global business as described in the constant currency table accompanying this press release. 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 or net income (loss) information prepared in accordance with GAAP. An explanation and reconciliation of the non-GAAP financial measures to the most directly comparable GAAP financial measures is included in the tables accompanying this press release.

Conference Call Details

To access the live conference call today, May 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 call ID is 2186716. 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 900,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ 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 the company's beliefs regarding its revenue growth for the remainder of 2018 and the drivers of growth; the commercial performance of its tests, including the recent launch of AR-V7 Nucleus Detect; the anticipated Medicare coverage of AR-V7 Nucleus Detect; 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 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; the ability of the company to increase worldwide access through the development of in vitro diagnostic tests; expectations regarding additional public and private reimbursement coverage for our tests worldwide and the ability of additional coverage to result in additional revenue; and the company's methodology for calculating financial performance under the new ASC 606 accounting standard as compared against prior periods under the previously applicable ASC 605 accounting standard. 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 revenue growth in for the remainder of 2018; 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 Annual Report on Form 10-K for the year ended December 31, 2017. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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

	Three Months Ended March 31,	
	2018	**2017**
REVENUES:		
Product revenues - United States	$ 78,867	$ 70,587
Product revenues - Outside of the United States	13,758	13,392
Total revenues	92,625	83,979
OPERATING EXPENSES (1):		
Cost of product revenues	18,733	13,672
Research and development	16,807	14,874
Selling and marketing	41,755	41,507
General and administrative	19,718	16,751
Total operating expenses	97,013	86,804
Loss from operations	(4,388)	(2,825)
Interest income	417	158
Gain on sales of marketable securities	—	2,807
Other income (expense), net	436	95
Income (loss) before income taxes	(3,535)	235
Income tax expense	240	1,041
Net loss	$ (3,775)	$ (806)
Basic and diluted net loss per share	$ (0.11)	$ (0.02)
Shares used in computing basic and diluted net loss per share	35,198	34,009

(1) Included in operating expenses for the three months ended March 31, 2018 were non-cash charges of $8.3 million, including $5.2 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 2017 of $7.5 million, including $5.1 million of stock-based compensation expense and $2.4 million of depreciation and amortization expenses.

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

	As of March 31, 2018 (Unaudited)	As of December 31, 2017 (1)
Cash and cash equivalents	$ 42,085	$ 45,518
Short-term marketable securities (2)	88,302	84,057
Accounts receivable, net	46,567	31,161
Prepaid expenses and other current assets	14,035	13,524
Total current assets	190,989	174,260
Property and equipment, net	40,824	46,440
Other assets	11,126	10,917
Total assets	$ 242,939	$ 231,617
Accounts payable	$ 4,744	$ 156
Accrued expenses and other current liabilities	33,904	39,360
Other liabilities	3,899	3,810
Stockholders' equity	200,392	188,291
Total liabilities and stockholders' equity	$ 242,939	$ 231,617

(1) The condensed consolidated balance sheet at December 31, 2017, 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, 2017.

(2) Included in short-term marketable securities as of March 31, 2018 and December 31, 2017 is $3.8 million and $3.5 million, respectively, of corporate equity securities, representing the company's investment in Biocartis N.V.

GENOMIC HEALTH, INC.
GAAP to Non-GAAP Reconciliations
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Loss from operations reconciliation:		
GAAP loss from operations	$ (4,388)	$ (2,825)
Cost of product revenues – cessation of Oncotype SEQ	3,576	—
Research and development – cessation of Oncotype SEQ	3,063	—
Selling and marketing – cessation of Oncotype SEQ	995	—
General and administrative – cessation of Oncotype SEQ	909	—
Non-GAAP income (loss) from operations	$ 4,155	$ (2,825)
Net income (loss) reconciliation:		
GAAP net loss	$ (3,775)	$ (806)
Cost of product revenues – cessation of Oncotype SEQ	3,576	—
Research and development – cessation of Oncotype SEQ	3,063	—
Selling and marketing – cessation of Oncotype SEQ	995	—
General and administrative – cessation of Oncotype SEQ	909	—
Other income – Biocartis - change in fair value	(127)	—
Other income – Cleveland Diagnostics - note discount accretion	(62)	—
Non-recurring gain on sale of marketable securities	—	(2,807)
Reduced income tax expense from the sale of marketable securities	—	821
Non-GAAP net income (loss)	$ 4,579	$ (2,792)

GENOMIC HEALTH, INC.
Non-GAAP Constant Currency Reconciliations
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Constant currency reconciliations:		
International Revenue:		
International revenue (1)	$ 13,758	$ 13,124
Currency exchange adjustments (2)	(476)	—
Non-GAAP International revenue	$ 13,282	$ 13,124
Period over period constant currency increase	158	
Period over period constant currency increase percentage	1%	
Total Revenue:		
Total revenue (1)	$ 92,625	$ 82,305
Currency exchange adjustments (2)	(476)	—
Non-GAAP total revenue	$ 92,149	$ 82,305
Period over period constant currency increase	9,844	
Period over period constant currency increase percentage	12%	

(1) For the three months ended March 31, 2018, International revenue and total revenue is based on GAAP under ASC 606 and for the three months ended March 31, 2017, International revenue and total revenue is based on the Pre-606 Adjusted revenue on the following table.

(2) Constant currency is a non-GAAP measure that is calculated by comparing the company's quarterly average foreign exchange rates for the three months ended March 31, 2018 and 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.
Non-GAAP Supplemental Financial Information (1)
(In thousands)
(Unaudited)

	First Quarter 2017	Second Quarter 2017	Third Quarter 2017	Fourth Quarter 2017	Full Year 2017
U.S. Product revenue, under ASC 605:					
Invasive breast test revenue	$ 64,838	$ 65,629	$ 63,050	$ 66,210	$ 259,727
Prostate test revenue	3,315	4,124	5,501	4,990	17,930
All other test revenue	2,434	2,656	2,330	2,286	9,706
Total U.S. product revenue	70,587	72,409	70,881	73,486	287,363
Adjustment related to new ASC 606 accounting standard:					
Invasive breast test revenue	1,406	1,432	1,404	1,465	5,707
Prostate test revenue	—	—	—	—	—
All other test revenue	—	—	—	—	—
Total ASC 606 adjustment to U.S. product revenue	1,406	1,432	1,404	1,465	5,707
Pre-606 Adjusted U.S. Product revenue, net of adjustments:					
Invasive breast test revenue	63,432	64,197	61,646	64,745	254,020
Prostate test revenue	3,315	4,124	5,501	4,990	17,930
All other test revenue	2,434	2,656	2,330	2,286	9,706
Total Pre-606 Adjusted U.S. product revenue	$ 69,181	$ 70,977	$ 69,477	$ 72,021	$ 281,656
International product revenue, under ASC 605:					
Invasive breast test revenue	$ 13,220	$ 12,888	$ 12,811	$ 13,517	$ 52,436
Prostate test revenue	35	30	41	23	129
All other test revenue	137	160	88	138	523
Total International product revenue	13,392	13,078	12,940	13,678	53,088
Adjustment related to new ASC 606 accounting standard:					
Invasive breast test revenue	268	273	267	279	1,087
Prostate test revenue	—	—	—	—	—
All other test revenue	—	—	—	—	—
Total ASC 606 adjustment to International product revenue	268	273	267	279	1,087
Pre-606 Adjusted International product revenue, net of adjustments:					
Invasive breast test revenue	12,952	12,615	12,544	13,238	51,349
Prostate test revenue	35	30	41	23	129
All other test revenue	137	160	88	138	523
Total Pre-606 Adjusted International product revenue	$ 13,124	$ 12,805	$ 12,673	$ 13,399	$ 52,001
Total Product Revenue, under ASC 605:					
Invasive breast test revenue	$ 78,058	$ 78,517	$ 75,861	$ 79,727	$ 312,163
Prostate test revenue	3,350	4,154	5,542	5,013	18,059
All other test revenue	2,571	2,816	2,418	2,424	10,229
Total product revenue	83,979	85,487	83,821	87,164	340,451
Adjustment related to new ASC 606 accounting standard:					
Invasive breast test revenue	1,674	1,705	1,671	1,744	6,794
Prostate test revenue	—	—	—	—	—
All other test revenue	—	—	—	—	—
Total ASC 606 adjustment to total product revenue	1,674	1,705	1,671	1,744	6,794
Pre-606 Adjusted Total product revenue, net of adjustments:					
Invasive breast test revenue	76,384	76,812	74,190	77,983	305,369
Prostate test revenue	3,350	4,154	5,542	5,013	18,059
All other test revenue	2,571	2,816	2,418	2,424	10,229
Total Pre-606 Adjusted total product revenue	$ 82,305	$ 83,782	$ 82,150	$ 85,420	$ 333,657

(1) Effective January 1, 2018, the company adopted new accounting guidance ASC Topic 606 ("ASC 606"), related to revenue from contracts with customers, using a modified retrospective method. Since the 2017 annual and quarterly financial statements will not be restated to reflect ASC 606, the company is providing this supplemental schedule to present 2017 revenue reflecting an estimate as if ASC 606 had been applied effective January 1, 2017. This Pre-606 adjusted revenue information is intended to provide investors with a basis for considering the potential directional impact the adoption of ASC 606 might have on the company's financial information that will be reported in 2018. The Pre-606 adjusted revenue information is provided only for illustrative purposes and does not constitute a restatement of the company's historical financial statements previously filed with the SEC, which should be considered by investors in their entirety as filed.

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