GENOMIC HEALTH INC

FORM 8-K/A

(Amended 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/A

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

Date of Report (Date of earliest event reported): **March 8, 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.

This amended Current Report on Form 8-K/A amends Item 2.02 of the Current Report on Form 8-K filed by Genomic Health, Inc. (the "Company") with the Securities and Exchange Commission on March 8, 2018, relating to a press release announcing the Company's financial results for its fourth fiscal quarter and year ended December 31, 2017. The financial table in the "2018 Financial Outlook" section describing the Company's 2018 financial guidance has been updated to correct the calculation for GAAP and non-GAAP earnings per share as well as to revise the exclusion criteria for non-GAAP net income. The full text of the amended press release is furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Amended press release issued by Genomic Health, Inc. dated March 8, 2018.

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: March 8, 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 2017 Fourth Quarter and Year-end Financial Results, Provides 2018 Financial Outlook

Achieved $1.9M Profit in the Fourth Quarter; Reported Net Loss of $3.9M for the Full Year

Delivered $0.4M Full-year Profit on a Non-GAAP Basis Excluding Business Development Transaction Costs

Delivered 7 Percent Test Growth and 6 Percent Revenue Growth in the Fourth Quarter

Guides to Double-digit Revenue Growth and Full-year Profitability in 2018

REDWOOD CITY, Calif., March 8, 2018 (Updated) — Genomic Health, Inc. (NASDAQ: GHDX) today reported financial results and business progress for the quarter and year ended December 31, 2017.

Total revenue was $340.8 million in the full year 2017, compared with $327.9 million in 2016, an increase of 4 percent.

U.S. product revenue was $287.4 million in the full year 2017, compared with $280.1 million in the full year 2016, an increase of 3 percent. U.S. invasive breast revenue from Oncotype DX Breast Recurrence Score ® tests was $259.7 million in the full year 2017, compared with $257.0 million in the full year 2016. U.S. prostate test revenue from Oncotype DX ® Genomic Prostate Score™ (GPS™) tests was $17.9 million in the full year 2017, compared with $10.8 million in the full year 2016, an increase of 66 percent.

International revenue for the full year 2017 was $53.1 million compared with $46.8 million in 2016, an increase of 13 percent, and an increase of 15 percent on a non-GAAP constant currency basis.

Operating loss improved to $6.5 million for the year ended December 31, 2017, compared with $15.4 million for the year ended December 31, 2016. Net loss was $3.9 million, or $0.11 per share on a basic and diluted basis, for the year ended December 31, 2017, compared with a net loss of $13.9 million, or $0.42 per share on a basic and diluted basis, for the year ended December 31, 2016.

On a non-GAAP basis, the company recorded $0.4 million net income for the year ended December 31, 2017.

“In 2017, we delivered improved profitability, which included a $1.9 million profit in the fourth quarter, our strongest quarter of U.S. invasive breast cancer revenue and test growth in the year. As expected, we delivered a full-year profit on a non-GAAP basis, excluding transaction costs of $4.2 million from our collaborations with Biocartis and Cleveland Diagnostics,” said Kim Popovits, chairman of the board, chief executive officer and president of Genomic Health. “With multiple revenue growth catalysts now in place, including the implementation of PAMA and AJCC breast cancer staging criteria, the recent strengthening of NCCN prostate guidelines and the launch of the Oncotype DX AR-V7 Nucleus Detect test, we expect to deliver double-digit growth in both tests delivered and revenue in 2018, along with significant improvement in profitability. In addition, we anticipate the near-term reporting of final TAILORx results to drive Oncotype DX to a new standard of care for patients diagnosed with early-stage invasive breast cancer, positioning us to deliver a record-setting performance this year.”

2018 Financial Outlook

In positioning its business to deliver near-term growth and increased profitability, the company is directing its focus and resource allocation toward catalysts that it expects will drive further adoption and reimbursement of its portfolio globally with greater operational efficiency. Specifically, the company plans to direct resources to expand its Oncotype DX offering through the development of in vitro diagnostic (IVD) test solutions, including on the Biocartis ® Idylla™ platform, to increase global access in markets where localized testing is critical for adoption and reimbursement. With this shift in focus, the company will no longer provide the Oncotype SEQ ® Liquid Select™ test or further invest in non-proprietary next-generation sequencing (NGS)-based panels. Accordingly, the company will reduce positions by approximately 10 percent and take a charge of approximately $10 million in the first quarter for costs associated with personnel reductions and the write-off of certain assets associated with NGS-based panels.

“We believe this strategic direction to maximize profitable growth in the short term will result in approximately $3 million saved per quarter, enabling us to enhance operational efficiency and deliver operating leverage above 50 percent, improved over our 40 percent leverage target of the past few years,” said Brad Cole, chief operating officer and chief financial officer of Genomic Health. “In 2018, we expect continued improvement in profitability on a non-GAAP basis and double-digit revenue growth. We expect to successfully execute on multiple revenue growth catalysts leading to an acceleration in revenue growth in the back half of the year and double-digit operating income as a percent of revenue in the fourth quarter.”

The company is providing the following guidance for the full year ending December 31, 2018 under ASC 606 revenue recognition standards:

	Low	High
Revenue [1]	$ 366	$ 382
Revenue Growth [2]	10%	15%
Net Income (GAAP) [1]	$ 0	$ 5
GAAP Basic EPS [3]	$ 0.00	$ 0.14
Net Income (Non-GAAP) [1] [4]	$ 14	$ 20
Non-GAAP Basic EPS [3]	$ 0.39	$ 0.56

(1) In millions

(2) The outlook for 10% to 15% revenue growth in 2018 represents management’s estimates for 2018 versus 2017 reported revenues adjusted to reflect the impact of ASC 606 revenue recognition rules which were effective January 1, 2018. Under the new rules, the company will report most uncollectible balances as a reduction in net revenues; historically certain uncollectible amounts were classified as bad debt expense and were approximately 2.5% of revenue and classified within selling, general and administrative expenses. The company does not expect ASC 606 to impact net income or EPS.

(3) Based on 36 million estimated shares outstanding.

(4) Non-GAAP net income excludes charges for personnel reductions and asset write-offs associated with product cessation, and clinical and commercial development milestone payments.

Additional 2017 Full Year and Fourth Quarter Financial Results

Total revenue was $87.5 million in the fourth quarter of 2017, compared with $82.7 million in the fourth quarter of 2016, an increase of 6 percent. On a non-GAAP constant currency basis, revenue increased 5 percent compared with the same period in the prior year.

U.S. product revenue was $73.5 million in the fourth quarter of 2017, compared with $70.0 million in the fourth quarter of 2016, an increase of 5 percent. U.S. invasive breast revenue from Oncotype DX Breast Recurrence Score tests was $66.2 million in the fourth quarter of 2017, compared with $63.9 million in the fourth quarter of 2016. U.S. prostate test revenue from GPS tests was $5.0 million in the fourth quarter of 2017, compared with $3.6 million in the fourth quarter of 2016, an increase of 39 percent.

International revenue was $13.7 million in the fourth quarter of 2017, compared with $12.0 million for the fourth quarter of 2016, an increase of 14 percent, and an increase of 12 percent on a non-GAAP constant currency basis.

Operating income for the fourth quarter of 2017 was $2.2 million, compared with $1.5 million for the fourth quarter of 2016. Net income was $1.9 million, or $0.05 per share on a basic and fully diluted basis, for the fourth quarter of 2017 compared with $1.4 million, or $0.04 per share on a basic and fully diluted basis, for the fourth quarter of 2016.

In the fourth quarter of 2017, more than 31,990 Oncotype™ test results were delivered, an increase of 7 percent, compared with more than 30,020 test results delivered in the same period in 2016.

More than 126,740 Oncotype test results were delivered for the year ended December 31, 2017, an increase of 7 percent, compared with more than 118,570 test results delivered in the same period in 2016. Oncotype DX Breast Recurrence Score tests delivered in the U.S. grew 3 percent in the full year 2017 compared to the prior year. Oncotype DX Genomic Prostate Score tests delivered in the U.S. grew 37 percent in the full year 2017 compared to the prior year. International tests delivered grew 11 percent for the full year compared to the prior year and represented approximately 20 percent of total test volume in 2017.

Cash and cash equivalents and short-term marketable securities at December 31, 2017 were $129.6 million, which included the fair value of the company's investment in marketable securities of $3.5 million, an increase of $32.6 million compared with $97.0 million at December 31, 2016, which included the fair value of the company's investment in marketable securities of $9.3 million.

The non-GAAP financial measures used adjust for specified items that can be highly variable or difficult to predict. 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.

Recent Business Highlights

- Launched Oncotype DX AR-V7 Nucleus Detect™, the first and only liquid biopsy test of its kind to help prolong the lives of men with metastatic castration-resistant prostate cancer (mCRPC) by accurately detecting a splice variant of the androgen receptor protein (AR-V7) in the nucleus of circulating tumor cells (CTCs).
- The National Comprehensive Cancer Network (NCCN) updated its guidelines for prostate cancer to now include molecular testing. Specifically, the updated 2018 guidelines include the Oncotype DX Genomic Prostate Score (GPS) test for men with NCCN low- and favorable intermediate-risk prostate cancer to provide prognostic information in order to choose active surveillance or definitive treatment.

- *Reviews in Urology* published real-world clinical evidence demonstrating that the Oncotype DX GPS test increases use of active surveillance by 30 percent in low-risk patients, resulting in greater adherence to guideline-based care. These findings from a large U.S. payer system are consistent with four previously published studies demonstrating the positive effect of GPS testing on active surveillance use.
- Established additional private coverage for the Oncotype DX GPS test, bringing the total number of U.S. covered lives to more than 67 million.
- Announced an exclusive licensing agreement with Cleveland Diagnostics, Inc. to develop and commercialize new prostate cancer tests based on Cleveland Diagnostics' IsoPSA™ reagents and technology. Initial efforts will focus on Genomic Health's development of a high-PSA (prostate-specific antigen) reflex test to accurately predict the presence of high-grade cancer (Gleason score >7) prior to prostate biopsy.
- Announced a multi-year research collaboration agreement with Janssen Pharmaceuticals to evaluate the GPS test for their prostate cancer drug pipeline. As part of the agreement, Genomic Health will test samples from Janssen studies to examine the association of GPS results with clinical outcomes.
- Made a $4 million equity investment in Biocartis Group NV, further strengthening the partnership between the companies to develop an IVD version of the Oncotype DX Breast Recurrence Score test on the Idylla platform that can be performed locally by laboratory partners and in hospitals around the world.
- Presented results from 10 studies that reinforce the unmatched value of the Oncotype DX Breast Recurrence Score test and Oncotype DX Breast DCIS Score™ test in optimizing patient treatment across the breast cancer disease continuum at the 2017 San Antonio Breast Cancer Symposium (SABCS).
- Received acceptance to present three studies at the 11th European Breast Cancer Conference (EBCC-11), in March.

Conference Call Details

To access the live conference call today, March 8 at 8:30 a.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 8075676. 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 850,000 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 long-term success; financial guidance and future profitability, growth and operating leverage for the full year 2018; the commercial performance of its tests including the recently announced launch 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 an in vitro diagnostic version of its tests; the company's expectations with respect to the discontinuation of next-generation sequencing based panels; and the costs and benefits of the company's reduction of its workforce and restructuring. 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 2018 guidance estimates and the assumptions underlying such guidance; the risk that the expected benefits of the restructuring will not occur, the risk that the cost of any such restructuring may be higher than expected; 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 September 30, 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 December 31,		Year Ended December 31,	
	2017	2016	2017	2016
REVENUES:				
Product revenues - United States	$ 73,486	$ 70,034	$ 287,363	$ 280,127
Product revenues - Outside of the United States	13,678	11,967	53,088	46,791
Total product revenues	87,164	82,001	340,451	326,918
Contract revenues	299	740	299	950
Total revenues	87,463	82,741	340,750	327,868
OPERATING EXPENSES (1)(2):				
Cost of product revenues	13,814	13,651	54,718	58,828
Research and development	14,944	14,855	62,811	60,158
Selling and marketing	36,536	34,715	157,001	151,042
General and administrative	20,019	18,028	72,670	73,272
Total operating expenses	85,313	81,249	347,200	343,300
Income (loss) from operations	2,150	1,492	(6,450)	(15,432)
Interest income	307	136	934	418
Gain on sales of marketable securities	—	1,199	2,807	3,208
Other income (expense), net	(436)	(558)	356	(732)
Income (loss) before income taxes	2,021	2,269	(2,353)	(12,538)
Income tax expense	142	917	1,504	1,381
Net income (loss)	$ 1,879	$ 1,352	$ (3,857)	$ (13,919)
Basic net income (loss) per share	$ 0.05	$ 0.04	$ (0.11)	$ (0.42)
Diluted net income (loss) per share	$ 0.05	$ 0.04	$ (0.11)	$ (0.42)
Shares used in computing basic net income (loss) per share	34,856	33,629	34,495	33,264
Shares used in computing diluted net income (loss) per share	35,709	34,617	34,495	33,264

(1) Included in operating expenses for the three months ended December 31, 2017 were non-cash charges of $8.2 million, including $5.0 million of stock-based compensation expense and $3.2 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of $6.5 million, including $4.2 million of stock-based compensation expense and $2.3 million of depreciation and amortization expenses.

(2) Included in operating expenses for the year ended December 31, 2017 were non-cash charges of $32.0 million, including $20.3 million of stock-based compensation expense and $11.7 million of depreciation and amortization expenses, compared with non-cash charges for the same period in 2016 of $27.2 million, including $18.3 million of stock-based compensation expense and $8.9 million of depreciation and amortization expenses.

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

	As of December 31, 2017 (Unaudited)	As of December 31, 2016 (1)
Cash and cash equivalents	$ 45,518	$ 40,404
Short-term marketable securities (2)	84,057	56,585
Accounts receivable, net	31,161	35,179
Prepaid expenses and other current assets	13,524	13,796
Total current assets	174,260	145,964
Property and equipment, net	46,440	45,688
Other assets	10,917	9,462
Total assets	$ 231,617	$ 201,114
Accounts payable	$ 156	$ 2,864
Accrued expenses and other current liabilities	39,360	38,311
Other liabilities	3,810	3,834
Stockholders' equity	188,291	156,105
Total liabilities and stockholders' equity	$ 231,617	$ 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, 2017 is $3.5 million of equity securities, representing the Company's investment in Biocartis N.V. Included in short-term marketable securities as of December 31, 2016 is $9.3 million of 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 December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Net income (loss) reconciliation:				
GAAP net income (loss)	$ 1,879	$ 1,352	$ (3,857)	$ (13,919)
Research and development — discount on convertible promissory note	671	—	671	
Research and development — discount for lack of marketability during lock up period	322	—	322	—
Research and development — collaboration expense: upfront license and option fee	—	—	3,248	—
Non-GAAP net income (loss)	$ 2,872	$ 1,352	$ 384	$ (13,919)
Constant Currency reconciliations:				
International Revenue:				
GAAP International Revenue	$ 13,678	$ 11,967	$ 53,088	$ 46,791
Currency exchange adjustments (1)	(280)	—	654	—
Non-GAAP International Revenue	$ 13,398	$ 11,967	$ 53,742	$ 46,791
Period over period constant currency increase	$ 1,431		$ 6,951	
Period over period constant currency increase percentage	12%		15%	
Total Revenue:				
GAAP Total Revenue	$ 87,463	$ 82,741	$ 340,750	$ 327,868
Currency exchange adjustments (1)	(280)	—	654	—
Non-GAAP Total Revenue	$ 87,183	$ 82,741	$ 341,404	$ 327,868
Period over period constant currency increase	$ 4,442		$ 13,536	
Period over period constant currency increase percentage	5%		4%	

(1) Constant currency is a non-GAAP measure that is calculated by comparing the Company's quarterly average foreign exchange rates for the three and twelve months ended December 31, 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.

The Company makes reference in this press release to "non-GAAP net income" which excludes certain clinical and commercial development milestone payments for the Company's collaborations with Cleveland Diagnostics and Biocartis N.V. 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. The Company has not provided a reconciliation of its full-year 2018 non-GAAP net income or non-GAAP EPS guidance to full-year 2018 GAAP net income and GAAP EPS guidance because certain items that are a component of net income cannot be reasonably predicted. In particular, sufficient information is not available to calculate certain adjustments required for such reconciliations, including the likelihood, timing and amount of clinical and commercial development milestone payments. These components of net income could significantly impact the Company's actual results. This non-GAAP information is not intended to be considered in isolation or as a substitute for comparable information prepared in accordance with GAAP.

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