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): **September 13, 2017 (September 12, 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 7.01 Regulation FD Disclosure.

On September 13, 2017, Genomic Health, Inc. ("Genomic Health" or the "Company") and Biocartis Group NV issued a press release related to the agreement described below. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Item 7.01 is not intended to, and does not, constitute a determination or admission by the Company that this information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 8.01 Other Events.

On September 12, 2017, Genomic Health entered into a license and development agreement (the "Agreement") with Biocartis NV ("Biocartis") for an exclusive license to Biocartis' Idylla platform technology and related intellectual property to develop and commercialize an in vitro diagnostic ("IVD") version of its Oncotype DX Breast Recurrence Score test, along with certain options to expand its exclusive license to develop additional IVD versions of Genomic Health tests on the Biocartis Idylla platform. As part of the agreement, Genomic Health will make an up-front payment of approximately $3.3 million to Biocartis, which the Company expects to expense in the third quarter of 2017. Additional payments to Biocartis will be made as certain developmental and commercial milestones are achieved in the future. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales of the IVD tests developed on the Biocartis Idylla platform.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to Genomic Health's ability to successfully develop and commercialize in vitro diagnostic ("IVD") versions of its tests including initially its Oncotype DX Breast Recurrence Score test, and the timing and amounts of any future payments or investments in connection with the collaboration. 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 regulation of Genomic Health's tests or any tests offered through its commercial channel; the applicability of clinical study results to actual outcomes; Genomic Health's ability to develop, commercialize or collaborate to offer any new test, including IVD versions of its tests, in new markets domestically and internationally; the risk that sufficient levels of reimbursement may not be obtained or maintained, domestically or abroad, for Genomic Health's tests; competition; unanticipated costs or delays in research and development efforts; Genomic Health's ability or the ability of its collaborators to obtain capital when needed to support the activities contemplated by the collaboration; and the other risks and uncertainties set forth in Genomic Health's filings with the Securities and Exchange Commission, including the risks set forth in Genomic Health'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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by Genomic Health, Inc. and Biocartis Group NV dated September 13, 2017.

GENOMIC HEALTH, INC.
EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release issued by Genomic Health, Inc. and Biocartis Group NV dated September 13, 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: September 13, 2017

GENOMIC HEALTH, INC.

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

Exhib it 99.1

PRESS RELEASE

Genomic Health and Biocartis Announce Agreement to Develop an Idylla™ IVD Oncotype DX ® Breast Cancer Test to Broaden Global Patient Access

Strategic Collaboration Aimed at Exclusive Test Development and Commercialization of Proprietary Genomic Health Tests on the Idylla™ Platform

REDWOOD CITY, Calif., and MECHELEN, Belgium, September 13, 2017 — Genomic Health, Inc. (NASDAQ: GHDX) , the world's leading provider of genomic-based diagnostic tests and Biocartis Group NV (Euronext Brussels: BCART), an innovative molecular diagnostics company, today announced an exclusive agreement to develop an in vitro diagnostic (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.

The Oncotype DX Breast Recurrence Score test examines the activity of 21 genes in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of their individual disease. As the only test proven to predict chemotherapy benefit, the Oncotype DX Breast Recurrence Score test is included in all major cancer guidelines worldwide and is now considered standard of care for early-stage breast cancer.

Biocartis' proprietary Idylla™ platform offers a unique solution that is currently unmatched in the localization of complex molecular diagnostics. With the fully automated sample-to-answer, real-time polymerase chain reaction (PCR)-based cartridge of the Idylla platform, Genomic Health intends to enable local pathology labs to generate Oncotype DX Breast Recurrence Score results with minimal labor, efficient turnaround time, and the consistent high quality and clinical utility that physicians and patients have come to expect when making treatment decisions with Oncotype DX.

"We are excited to augment our successful U.S. centralized laboratory business model with an IVD system that can be implemented by local laboratories to increase global patient access to standard of care testing with the Oncotype DX Breast Recurrence Score test planned for launch in Europe beginning with France and Germany, in 2019," said **Frederic Pla, Ph.D., chief business and product development officer, Genomic Health.** "We believe our strategic collaboration with Biocartis positions us to accelerate adoption and market access around the world, as well as to broaden partnership opportunities with pharmaceutical companies seeking diagnostic solutions with the ability to develop and offer tests globally through decentralized settings."

Herman Verrelst, chief executive officer of Biocartis , commented: "Adding world-leading assays such as the Oncotype DX test to our Idylla platform is an essential step in our strategy to rapidly expand the

menu offering on our platform. Today's announcement demonstrates how we can assist providers of proprietary molecular tests in making their offering available to local labs across the globe, without the need for a highly specialized molecular diagnostics infrastructure. This demonstrates the true strength and ambition of the Idylla technology: enabling the best molecular diagnostics for all patients, worldwide. We are impressed by what Genomic Health has realized so far, and our team looks forward to making this strategic collaboration a success."

The strategic collaboration will provide Genomic Health with exclusive worldwide rights to develop and commercialize its Oncotype DX Breast Recurrence Score test on the Idylla platform, with the option to expand the collaboration to include additional tests in oncology and urology. Development of the Oncotype DX ® IVD test is expected to begin in late 2017, with the aim of providing initial access to patients in Europe, beginning with France and Germany, in 2019.

As part of the agreement, Genomic Health will make a payment of approximately $3.3 million to Biocartis, which is expected to be expensed in the third quarter of 2017. Additional payments to Biocartis will be made as certain developmental and commercial milestones are achieved in the future. Genomic Health continues to expect to be profitable for the full year 2017, excluding these transaction costs. Upon commercialization, Genomic Health will make royalty payments to Biocartis based on net sales of the IVD tests developed on the Biocartis Idylla platform.

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.

About Biocartis
Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis launched the Idylla™ platform in September 2014. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis offers ten oncology tests and two infectious disease tests in Europe. More information: www.biocartis.com. Press Photo Library available here. Follow us on Twitter: @Biocartis_.

Genomic Health Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to Genomic Health's beliefs regarding its future performance, including its guidance of profitability for the full year 2017 and the factors that may

impact such guidance; the company's ability to successfully develop and commercialize an IVD test; the expected benefits of an IVD version of the company's breast cancer test, and its expectations regarding timing and geographic rollout of any such test; the company's belief that the collaboration will allow it to accelerate adoption, reimbursement and access to the test and broaden other partnership opportunities; the commercial performance of its tests; the attributes and focus of the company's product pipeline; the ability of any potential tests the company may develop to optimize cancer treatment; and the ability of the company to develop and commercialize, and collaborate with third parties to commercialize, additional tests in the future. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to Genomic Health's ability to execute its business model; the regulation of Genomic Health's tests or any tests offered through its commercial channel; the applicability of clinical study results to actual outcomes; Genomic Health's ability to develop, commercialize or collaborate to offer any new test, including an IVD version of its breast cancer test, in new markets domestically and internationally; the risk that sufficient levels of reimbursement may not be obtained or maintained, domestically or abroad, for Genomic Health's tests or tests offered through its commercial channel; competition; unanticipated costs or delays in research and development efforts; Genomic Health's ability or the ability of its collaborators to obtain capital when needed to support the activities contemplated by the collaboration described in this press release; and the other risks and uncertainties set forth in Genomic Health's filings with the Securities and Exchange Commission, including the risks set forth in Genomic Health'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.

Biocartis Forward-Looking Statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Biocartis' or, as appropriate, the Biocartis directors' or managements' current expectations and projections concerning future events such as the Biocartis' results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Biocartis operates. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. As a result, the Biocartis expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Biocartis nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

The Biocartis trademark and logo are trademarks of Biocartis and are used and registered in Europe. Idylla™ is a registered trademark in the United States and other countries. The Idylla™ trademark and logo are trademarks of and used by Biocartis. This press release is not for distribution, directly or indirectly, in any jurisdiction where to do so would be unlawful. Any persons reading this press release should inform themselves of and observe any such restrictions. Biocartis takes no responsibility for any violation of any such restrictions by any person. Please refer to the product labeling for applicable intended uses for each individual Biocartis product. This press release does not constitute an offer or invitation for the sale or purchase of securities in any jurisdiction. No securities of Biocartis may be offered or sold in the United States of America absent registration with the United States Securities and Exchange Commission or an exemption from registration under the U.S. Securities Act of 1933, as amended.

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