
**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 2, 2017

MYRIAD GENETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

0-26642
(Commission
File Number)

87-0494517
(IRS Employer
Identification No.)

**320 Wakara Way
Salt Lake City, Utah 84108**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (801) 584-3600

Not Applicable
(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

- ☐ 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 the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 November 2, 2017, Myriad Genetics, Inc. (“Myriad” or the “Company”) issued a press release relating to the GeneSight® Psychotropic Results from a Large Prospective Trial in Patients with Major Depressive Disorder. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

FORWARD-LOOKING STATEMENTS

Exhibits 99.1 may contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our business, goals, strategy and financial and operational outlook. These “forward-looking statements” are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that sales and profit margins of our existing molecular diagnostic tests and pharmaceutical and clinical services may decline or will not continue to increase at historical rates; risks related to our ability to transition from our existing product portfolio to our new tests; risks related to changes in the governmental or private insurers reimbursement levels for our tests or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests; risks related to increased competition and the development of new competing tests and services; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and pharmaceutical and clinical services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and pharmaceutical and clinical services, including our ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying our molecular diagnostic tests and pharmaceutical and clinical services tests and any future tests are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities; risks related to public concern over our genetic testing in general or our tests in particular; risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems; risks related to our ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license or acquire; risks related to our projections about the potential market opportunity for our products; the risk that we or our licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying our tests; the risk of patent-infringement claims or challenges to the validity of our patents; risks related to changes in intellectual property laws covering our molecular diagnostic tests and pharmaceutical and clinical services and patents or enforcement in the United States and foreign countries, such as the Supreme Court decision in the lawsuit brought against us by the Association for Molecular Pathology et al; risks of new, changing and competitive technologies and regulations in the United States and internationally; and other factors discussed under the heading “Risk Factors” contained in Item 1A of our most recent Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. All information in the exhibits is as of the date of the exhibits, and Myriad undertakes no duty to update this information unless required by law.

ITEM 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description
99.1	Press Release dated November 2, 2017.

The exhibit(s) may contain hypertext links to information on our website or other parties' websites. The information on our website and other parties' websites is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

In accordance with General Instruction B-2 of Form 8-K, the information set forth in Item 7.01 and in Exhibits 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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.

MYRIAD GENETICS, INC.

Date: November 2, 2017

By: /s/ R. Bryan Riggsbee
R. Bryan Riggsbee
Executive Vice President, Chief Financial Officer



News Release

Media Contact: Ron Rogers Investor Contact: Scott Gleason
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Myriad Announces GeneSight® Psychotropic Results from a Large Prospective Trial in Patients with Major Depressive Disorder

GeneSight Demonstrated Statistically Significant Improvement In the Gold Standard Clinical Outcomes of Remission and Response

SALT LAKE CITY, Nov. 2, 2017 – Assurex Health, a wholly-owned subsidiary of Myriad Genetics, Inc. (NASDAQ:MYGN), today announced positive results from a double-blind, multi-center, randomized controlled trial assessing the impact of the GeneSight® Psychotropic test (GeneSight) on psychiatric treatment response in 1,200 patients with major depressive disorder (MDD). GeneSight is the leading pharmacogenomic test to help guide medication selection for mental health disorders.

This was the largest ever pharmacogenomics depression trial and primarily assessed Hamilton Depression Rating Scale 17 (HAM-D-17) scores from baseline to eight weeks in patients receiving GeneSight-guided therapy compared to those receiving treatment-as-usual. The study was designed to evaluate three key endpoints relative to HAM-D-17 scores: remission (HAM-D-17 score ≤ 7), response (HAM-D-17 reduction $>50\%$), and symptom reduction.

Patients receiving the GeneSight test achieved a clinically meaningful and statistically significant improvement in both remission rates ($p < 0.01$) and response rates ($p = 0.01$) at eight weeks compared to the treatment-as-usual group. In addition, patients who received the GeneSight test had a greater reduction in HAM-D-17 scores after eight weeks, compared to the treatment-as-usual group, with the difference approaching statistical significance ($p = 0.1$). Lastly, the improvement in remission, response, and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period. The data will be submitted for presentation at the upcoming American Psychiatric Association's (APA) annual meeting in May 2018.

"From a clinician's perspective, better but not well is not good enough and significant improvements in response and remission are always the most-desired endpoints," said John Greden, M.D., Founding Chair of the National Network of Depression Centers (NNDC). "We are

eager to discuss complete results from this study as well as potential future applications of pharmacogenomics at the upcoming APA annual meeting in May 2018.”

“The robustness of the results are attributed to the unique algorithm developed by our scientists that appropriately weights and combines multiple pharmacogenetic factors impacting mental health medication efficacy,” said Bryan Dechairo, Ph.D., executive vice president of Clinical Development, Myriad Genetics. “Improving remission and response rates are key treatment goals of clinicians because they directly improve patients’ lives and reduce healthcare costs. These endpoints also align with payer goals, and we look forward to having those discussions in the coming months.”

About the study design

The study is a 24 week, double-blind, multi-center, randomized controlled trial that evaluated 1,200 patients with moderate or severe MDD to assess the impact of the GeneSight test on psychiatric treatment response [NCT02109939]. Patients were randomized in a 1:1 ratio to the study group (those receiving the GeneSight test) or the treatment-as-usual group. Assessments were completed at baseline and at 4, 8, 12, and 24 weeks, with patients and raters completely blinded at the 4 and 8 week time points. Unblinding occurred during week 12 of the study, when treatment-as-usual patients were allowed to switch to GeneSight-guided therapy for the remaining 12 weeks of the study.

Assurex Milestone Payments

The sole endpoint to trigger a clinical trial milestone payment to the former stockholders of Assurex was a statistically significant ($p < 0.05$) greater reduction in HAMD-17 score from baseline to week eight of the study in the GeneSight arm compared to the treatment-as-usual arm. That clinical trial milestone payment will not be due because this endpoint did not achieve statistical significance in the entire study population. However, we continue to expect that a revenue growth milestone payment (calendar year 2017 revenue compared to calendar year 2016 revenue) will be paid to the former stockholders of Assurex in our fiscal third quarter.

About GeneSight

GeneSight is a laboratory-developed pharmacogenomic test that uses cutting edge technology to measure and analyze clinically important genomic variants in the treatment of psychiatric disorders. The results of the GeneSight report can help a clinician understand the way a patient’s unique genomic makeup may affect certain psychiatric drugs. The analysis is based on pharmacogenomics, the study of genomic factors that influence an individual’s

response to drug treatments, manufacturers' FDA approved drug labels, peer reviewed scientific and clinical publications, and proven drug pharmacology. Quick turnaround time, combined with a customized report of the patient's genomic makeup, clinical experience, and other factors can provide information to help a physician make personalized drug treatment choices for each patient. For more information about GeneSight, please visit www.genesight.com.

About Assurex Health

Assurex Health, a wholly-owned subsidiary of Myriad Genetics, Inc. is a personalized medicine company that specializes in pharmacogenomics and is dedicated to helping physicians determine the right medication for individual patients with neuropsychiatric and other disorders. Assurex Health was founded to commercialize industry-leading personalized medicine technology for neuropsychiatric disorders. For more information about Assurex Health, please visit <https://genesight.com/about-assurex-health/>.

About Myriad Genetics

Myriad Genetics Inc., is a leading personalized medicine company dedicated to being a trusted advisor transforming patient lives worldwide with pioneering molecular diagnostics. Myriad discovers and commercializes molecular diagnostic tests that: determine the risk of developing disease, accurately diagnose disease, assess the risk of disease progression, and guide treatment decisions across six major medical specialties where molecular diagnostics can significantly improve patient care and lower healthcare costs. Myriad is focused on three strategic imperatives: maintaining leadership in an expanding hereditary cancer market, diversifying its product portfolio through the introduction of new products and increasing the revenue contribution from international markets. For more information on how Myriad is making a difference, please visit Myriad's website: www.myriad.com.

Myriad, the Myriad logo, BART, BRACAnalysis, Colaris, Colaris AP, EndoPredict, myPath, myRisk, Myriad myRisk, myRisk Hereditary Cancer, myChoice, myPlan, BRACAnalysis CDx, Tumor BRACAnalysis CDx, myChoice HRD, Vectra DA, GeneSight, EndoPredict and Prolaris are trademarks or registered trademarks of Myriad Genetics, Inc. or its wholly owned subsidiaries in the United States and foreign countries. MYGN-F, MYGN-G

Safe Harbor Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to submitting the data at the upcoming American Psychiatric Association's (APA) annual meeting in May 2018;

the importance of response and remission endpoints in a pharmaceutical study for any antidepressant; the robustness of the results being attributed to the unique algorithm developed by scientists that appropriately weights and combines multiple pharmacogenetic factors impacting mental health medication efficacy; significant improvements in response and remission always being key endpoints; the endpoints of response and remission also aligning with payer goals; anticipated future discussions with payers in the coming months; the expectation that no clinical trial milestone payment will be due because the primary study endpoint did not achieve statistical significance; the continued expectation that a revenue growth milestone payment (calendar year 2017 revenue compared to calendar year 2016 revenue) will be paid in Myriad's fiscal third quarter; and the strategic directives described under the captions "About GeneSight," "About Assurex Health," and "About Myriad Genetics." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described or implied in the forward-looking statements. These risks include, but are not limited to: the risk that sales and profit margins of our existing molecular diagnostic tests and pharmaceutical and clinical services may decline or will not continue to increase at historical rates; risks related to our ability to transition from our existing product portfolio to our new tests; risks related to changes in the governmental or private insurers' reimbursement levels for our tests or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests; risks related to increased competition and the development of new competing tests and services; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and pharmaceutical and clinical services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and pharmaceutical and clinical services, including our ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying our molecular diagnostic tests and pharmaceutical and clinical services tests and any future tests are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities; risks related to public concern over genetic testing in general or our tests in particular; risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems; risks related to our ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license or acquire, including but not limited to our acquisition of Assurex Health, Sividon Diagnostics

GmbH, and Privatklinik Dr. Robert Schindlbeck GmbH & Co. KG; risks related to our projections about the potential market opportunity for our products; the risk that we or our licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying our tests; the risk of patent-infringement claims or challenges to the validity of our patents; risks related to changes in intellectual property laws covering our molecular diagnostic tests and pharmaceutical and clinical services and patents or enforcement in the United States and foreign countries, such as the Supreme Court decision in the lawsuit brought against us by the Association for Molecular Pathology et al; risks of new, changing and competitive technologies and regulations in the United States and internationally; the risk that we may be unable to comply with financial operating covenants under our credit or lending agreements; the risk that we will be unable to pay, when due, amounts due under our credit or lending agreements; and other factors discussed under the heading "Risk Factors" contained in Item 1A of our most recent Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

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