

MYRIAD GENETICS INC
Form 8-K
December 26, 2018

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): December 22, 2018

MYRIAD GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	0-26642	87-0494517
(State or other jurisdiction of	(Commission	(IRS Employer
incorporation)	File Number)	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

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(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 December 22, 2018, Myriad was notified by the editor of the Journal of Psychiatric Research that the GUIDED study manuscript has been accepted for publication. The Company will include the accepted manuscript in its clinical dossier which will be submitted for reimbursement assessment by both commercial insurance companies and Medicare. The Company anticipates that the online version of the accepted manuscript will be available within a few weeks.

Safe Harbor Statement

This communication contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to inclusion of the accepted manuscript in the Company’s clinical dossier; submission of the clinical dossier for reimbursement assessment by both commercial insurance companies and Medicare; and the Company’s anticipation that the online version of the accepted manuscript will be available within a few weeks. 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 the Company’s existing molecular diagnostic tests and pharmaceutical and clinical services may decline or will not continue to increase at historical rates; risks related to the Company’s ability to transition from its existing product portfolio to its new tests; risks related to changes in the governmental or private insurers’ reimbursement levels for the Company’s tests or the Company’s ability to obtain reimbursement for its new tests at comparable levels to its existing tests; risks related to increased competition and the development of new competing tests and services; the risk that the Company 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 the Company may not successfully develop new markets for its molecular diagnostic tests and pharmaceutical and clinical services, including the Company’s ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying the Company’s 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 the Company’s laboratory testing facilities; risks related to public concern over the Company’s genetic testing in general or the Company’s 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 the Company’s ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to the Company’s ability to successfully integrate and derive benefits from any technologies or businesses that it licenses or acquires, including but not limited to the Company’s acquisition of Counsyl, Assurex, Sividon and the Clinic; risks related to the Company’s projections about the potential market opportunity for the Company’s products; the risk that the Company or its licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying the Company’s tests; the risk of patent-infringement claims or challenges to the validity of the Company’s patents; risks related to changes in intellectual property laws covering the Company’s 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 the Company may be unable to comply with financial operating covenants under the Company’s credit or lending agreements; the risk that the Company will be unable to pay, when due, amounts due under the Company’s credit or lending agreements; and other factors discussed under the heading “Risk Factors” contained in Item 1A of the Company’s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in the Company’s Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

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: December 26, 2018 By: /s/ R. Bryan Riggsbee
R. Bryan Riggsbee
Executive Vice President, Chief Financial Officer

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