

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

MYRIAD GENETICS INC

CIK: **899923** | IRS No.: **870494517** | State of Incorpor.: **DE** | Fiscal Year End: **0630**
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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, 2005**

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))

ITEM 8.01 Other Events

On May 2, 2005, Myriad Genetics, Inc. announced the preliminary results of its Phase 2 clinical trial of Flurizan™ for the treatment of patients with mild to moderate Alzheimer's disease. The press release is attached hereto as an exhibit to this Current Report on Form 8-K and is being filed pursuant to this Item 8.01 as Exhibit 99.1 to this Current Report on Form 8-K.

ITEM 9.01 Financial Statements and Exhibits.

(c) The following exhibit is filed with this report:

<u>Exhibit Number</u>	<u>Description</u>
99.1	The Registrant's press release dated May 2, 2005.

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: May 2, 2005

By: /s/ PETER D. MELDRUM
Peter D. Meldrum
President and Chief Executive Officer

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<u>Exhibit Number</u>	<u>Description</u>
99.1	The Registrant's press release dated May 2, 2005.

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FOR IMMEDIATE RELEASE

Myriad Genetics Reports Results of Phase 2 Trial of Flurizan™ in Patients with Alzheimer's Disease

–Conference Call Scheduled for 4:00 p.m. Eastern Time Today–

Salt Lake City, May 2, 2005–Myriad Genetics, Inc. (Nasdaq: MYGN), announced that preliminary results of its Phase 2 clinical trial of Flurizan did not achieve statistical significance in patients with mild to moderate Alzheimer's disease; however, a positive trend was observed on all three primary endpoints in patients with mild Alzheimer's disease, on the 800 mg twice-daily dose. Additionally, mild Alzheimer's disease patients who achieved high plasma concentrations of Flurizan demonstrated a statistically significant effect in two of the three primary endpoints. The initial findings also indicate that Flurizan was well tolerated in this 12-month, 207 patient clinical study.

The three primary endpoints of the Phase 2 study were the Alzheimer's Disease Cooperative Study–Activities of Daily Living inventory (ADCS-ADL), Clinical Dementia Rating–Sum of Boxes (CDR-sb), and the Alzheimer's Disease Assessment Scale–Cognitive function subscale (ADAS-cog). Patients with mild Alzheimer's disease who were given the 800 mg twice-daily dose of Flurizan demonstrated a 44% slowing of decline in their performance of activities of daily living, as measured by the ADCS-ADL. This assessment measures basic activities of daily living such as dressing and eating.

The 800 mg twice-daily drug-treated group with mild disease at baseline demonstrated a 41% slowing of decline during the 12-month study period in global function as measured by the CDR-sb. In this exam, the investigator performs a semi-structured interview with both the patient and the caregiver. The patient's performance is assessed in memory, orientation, judgment, problem solving, community activities, home and hobbies and personal care.

A positive trend was also seen in patients with mild disease on the 800 mg twice-daily dose for the primary cognitive endpoint, ADAS-cog. This group achieved a 29% slowing of cognitive decline. The ADAS-cog measures a patient's performance in word recall, response to directions, ability to copy geometric forms, delayed word recall, ability to name objects, memory and quality of speech.

A further analysis of data from 128 mild Alzheimer's disease patients (68% of the patients eligible for analysis) indicates that those who achieved the greatest plasma concentrations of Flurizan demonstrated a statistically significant 67% reduction in decline in activities of daily living ($p=0.017$, two-sided) as measured by ADCS-ADL, compared to patients in the placebo group. This finding was confirmed by analyzing the same group of patients versus the control group for the global function assessment, which showed a 54% slower decline ($p=0.034$, two-sided) as measured by CDR-sb. Finally, the high plasma concentration group demonstrated a 30% slowing in the rate of decline of cognitive function (not statistically significant), as measured by ADAS-cog.

"This study has been very useful and indicates that this drug may well be helpful in early stages of Alzheimer's disease," said Gordon Wilcock, M.D., Professor in Care of the Elderly, University of Bristol, United Kingdom. "It is in keeping with the evolving understanding of the relationship between amyloid deposition and Alzheimer's disease. The study has also shown a dose that is most likely to be effective. We now need further studies to confirm these findings."

In addition to efficacy measures, the Phase 2 trial assessed the safety of Flurizan in the study population. The preliminary results showed that Flurizan was well tolerated in this study. Review of the full safety data set is underway.

"Even though Flurizan did not achieve significance in the primary endpoints of the Phase 2 Alzheimer's study, we are encouraged by the statistically significant effect observed in the mild Alzheimer's disease patients," said Peter Meldrum, President of Myriad Genetics, Inc.

Based on the Phase 2 results, the Company intends to continue its Phase 3 trial, and believes that 800 mg twice daily is the preferred dose. The Company will review the protocol for the Phase 3 study with the principal investigators to determine any modifications in treatment regimens. Subject to regulatory approval, the Company will also consider modifying the Phase 3 protocol to focus future enrollment on mild Alzheimer's disease patients. Additionally, the Company will continue to analyze the data from the moderate Alzheimer's disease patients in order to better understand the effect of Flurizan in this population.

The Phase 2 trial was conducted at approximately 30 centers in the United Kingdom and Canada, with 189 patients who qualified for the intent-to-treat analysis. It was designed to study the safety and efficacy of Flurizan in altering the progression of Alzheimer's disease. The format of the trial was double blind and placebo-controlled, with a 12-month study period. Patients were randomized into one of three groups upon enrollment in the trial, and given twice-daily doses of either 400mg or 800mg of drug or placebo. At the time of enrollment, the patient group as a whole had an average Mini Mental State Exam (MMSE) score of 21 and the trial was composed of 50% men and 50% women.

About Flurizan

Flurizan is a selective amyloid beta 42 lowering agent (SALA). Flurizan has been shown to be effective in lowering levels of Abeta42 in cellular assays and animal models. Abeta42 is the primary constituent of senile plaques that accumulate in the brains of patients with Alzheimer's disease. It is thought to be the key initiator of Alzheimer's disease since this peptide has the greatest tendency to aggregate, cause neuronal damage and initiate amyloid deposits in the brain. Most genetic mutations that cause early-onset Alzheimer's disease appear to do so by increasing production of Abeta42. Myriad believes that Flurizan is the first well-tolerated drug that inhibits the production of Abeta42 to be evaluated in a clinical trial for the treatment of Alzheimer's disease.

Conference Call and Audio Web Cast

Myriad management will host a conference call at 4:00 p.m. Eastern time today, May 2, 2005, to discuss today's announcement. The call-in number for the conference call will be (888) 589-2820 or (706) 634-2173. A replay of the conference call will be available for one week following the call by dialing (800) 642-1687 or (706) 645-9291, and entering conference identification number 6051295. The call will also be available through a link on Myriad's home page at www.myriad.com.

About Myriad

Myriad Genetics, Inc. is a biopharmaceutical company focused on the development of novel healthcare products. The Company develops and markets predictive medicine products, and is developing and intends to market therapeutic products. Myriad's news and other information are available on the Company's Web site at www.myriad.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward looking statements include, the positive trend observed on all three primary end points in patients with mild Alzheimer's disease on the 800 mg twice daily dose; Flurizan's demonstrated statistically significant effect in two of the three primary endpoints; the positive trend seen in patients with mild disease on the 800 mg twice daily dose for the primary cognitive endpoint, ADAS-cog; the statistically significant reduction of 67% in the decline in activities of daily living ($p=0.017$, two sided) as measured by ADCS-ADL in patients who achieved the greatest plasma concentrations of Flurizan as compared to patients in the placebo group; the encouragement of the Company with respect to the statistically significant effect observed in the mild Alzheimer's disease patients; the toleration of Flurizan by study patients; the continuation of the Company's Phase 3 trial; the Company's belief that 800 mg twice daily is the preferred dose; the Company's review of the Phase 3 study to determine modifications of the treatment regimes; the modification the Phase 3 protocol to focus future enrollment on mild Alzheimer's disease patients; the Company's continued study and analysis of the data from the moderate Alzheimer's disease patients; and the ability of Flurizan to be helpful in early stages of Alzheimer's disease. The forward-looking statements are based on management's current expectation and are subject to certain risks and uncertainties that could cause actual results to differ materially from those set forth or

implied by forward-looking statements. These include, but are not limited to, uncertainties related to the clinical development of drugs, including that results in earlier stage clinical trials will not be repeated or confirmed in larger, later stage studies; uncertainties as to the extent of future government regulation of Myriad Genetics' business; uncertainties as to whether Myriad Genetics and its collaborators will be successful in developing, and obtaining regulatory approval for, and commercial acceptance of, therapeutic compounds; the risk that markets will not exist for therapeutic compounds that Myriad Genetics develops or if such markets exist, that Myriad Genetics will not be able to sell compounds, which it develops, at acceptable prices; and the risk that the Company will not be able to sustain revenue growth for its predictive medicine business and products. These and other risks are identified in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2004. All information in this press release is as of May 2, 2005, and Myriad undertakes no duty to update this information unless required by law.

QuickLinks

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