

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): June 23, 2025

Opus Genetics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-34079
(Commission File Number)

11-3516358
(IRS Employer Identification No.)

8 Davis Drive
Durham, NC
(Address of principal executive offices)

27713
(Zip Code)

(984) 884-6030
(Registrant's telephone number, including area code)

N/A
(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:

- ☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	IRD	The Nasdaq Stock Market LLC

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 June 23, 2025, Opus Genetics, Inc., a Delaware corporation (the “*Company*”), issued a press release announcing entry into a funding agreement (the “*Agreement*”) with the Foundation Fighting Blindness Retinal Degeneration Fund, whose sole member is Foundation Fighting Blindness, a significant stockholder of the Company. A copy of the press release is furnished herewith as Exhibit 99.1. In the press release, the Company disclosed that it now expects that its cash on hand will be sufficient to fund operations into the second half of fiscal year 2026.

The information in this Item 7.01 of this Current Report on Form 8-K, and Exhibit 99.1, is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 23, 2025.
104.1	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURE

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: June 23, 2025

OPUS GENETICS, INC.

By: /s/ Dr. George Magrath

Name: Dr. George Magrath

Title: Chief Executive Officer

Opus Genetics Awarded Non-Dilutive Funding from the RD Fund to Support Preclinical Development of OPGx-MERTK Program

RESEARCH TRIANGLE PARK, N.C., June 23, 2025 - Opus Genetics, Inc. (Nasdaq: IRD), a clinical-stage ophthalmic biopharmaceutical company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and small molecule therapies for other ophthalmic disorders, recently disclosed that the Retinal Degeneration Fund (RD Fund), the venture philanthropy arm of the Foundation Fighting Blindness, has entered into a funding agreement with Opus providing for up to \$2 million in non-dilutive funding intended to support the advancement of Opus' OPGx-MERTK program to develop gene therapies to treat patients impacted by retinitis pigmentosa caused by pathogenic variants in the Mer proto-oncogene tyrosine kinase (MERTK) gene.

"This strategic funding enables us to advance the development of OPGx-MERTK, a promising program that aims to address a retinal degenerative condition with no currently approved therapies," said George Magrath, M.D., CEO, Opus Genetics. "OPGx-MERTK is currently in preclinical development, and we expect this financial support will allow us to move this asset towards Investigational New Drug (IND) enabling studies. We are grateful to the Foundation Fighting Blindness and the RD Fund for their continued partnership as we work to bring meaningful treatments to patients suffering from vision-threatening conditions."

"This investment reflects the power of combining venture philanthropy, industry collaboration, and cutting-edge science to deliver meaningful progress for patients," said Rusty Kelley, Ph.D., managing director of the RD Fund. "Our alliance with Opus Genetics leverages the full strength of the Foundation Fighting Blindness community—our donors, mission, and team—alongside the proven expertise of Opus and gene therapy pioneers Drs. Jean Bennett and Tomas Aleman, to accelerate life-changing treatments."

The RD Fund has played a pivotal role in advancing early-stage therapeutic innovation. This funding underscores its continued commitment to supporting high-impact programs for rare diseases and will help accelerate the preclinical studies required to advance regulatory filings for the OPGx-MERTK program, further strengthening Opus' gene therapy pipeline for IRDs.

With the addition of this funding, based on current projections, Opus believes that its cash on hand will now be sufficient to fund operations into the second half of 2026.

About OPGx-MERTK

Mutations in the MERTK gene cause a rod-cone dystrophy with early macular atrophy, with retinitis pigmentosa being the most common phenotype. Opus is developing OPGx-MERTK as a modern adeno-associated virus (AAV) vector for the treatment of MERTK-associated IRD, which affects approximately 600 individuals in the U.S.

About Opus Genetics

Opus Genetics is a clinical-stage biopharmaceutical company developing gene and small molecule therapies for vision-threatening eye diseases. The company's pipeline features adeno-associated virus (AAV)-based gene therapies targeting inherited retinal diseases including Leber congenital amaurosis (LCA), bestrophinopathy, and retinitis pigmentosa. Its lead candidate, OPGx-LCA5, is in a Phase 1/2 trial for LCA5-related mutations and has shown encouraging early results. Additional programs include OPGx-BEST1, a gene therapy targeting BEST1-related retinal degeneration and a Phase 3-ready small molecule therapy for diabetic retinopathy, developed under a Special Protocol Assessment with the FDA. Opus is also advancing Phentolamine Ophthalmic Solution 0.75%, a partnered therapy currently approved in one indication and being studied in two Phase 3 programs for presbyopia and dim light vision disturbances. Opus is based in Research Triangle Park, NC. For more information, visit www.opusgtx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to us, our business prospects, and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. These forward-looking statements include statements related to the preclinical and future clinical development of OPGx-MERTK and our expected cash runway. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, and our other filings with the U.S. Securities and Exchange Commission (SEC). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. All forward-looking statements contained in this press release speak only as of the date on which they were made.

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Source: Opus Genetics, Inc.
