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 26, 2025

Opus Genetics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34079**	**11-3516358**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8 Davis Drive **Durham, NC**	**27713**
(Address of principal executive offices)	(Zip Code)

(248) 957-9024
(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 8.01 Other Events

VEGA-3 Phase 3 Trial Topline Results

On June 26, 2025, Opus Genetics, Inc. (the "***Company***") announced topline results from VEGA-3, its second pivotal Phase 3 trial evaluating Phentolamine Ophthalmic Solution 0.75% for the treatment of presbyopia. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein. As announced in the press release, the Company is hosting a webcast and conference call this morning at 8:00 a.m. Eastern Time to discuss recent clinical results and provide a corporate update. The live and archived webcast may be accessed on the Company's website under the Investors section.

Cash Runway

As previously disclosed by the Company on June 23, 2025, the Company expects that its cash on hand will be sufficient to fund operations into the second half of fiscal year 2026.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to certain risks and uncertainties posed by many factors and events that could cause the Company's actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, and in the Company's other filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. These forward-looking statements are based upon the Company's 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. The Company undertakes no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 26, 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.

OPUS GENETICS, INC.

Date: June 26, 2025

By: /s/ Dr. George Magrath
Name: Dr. George Magrath
Title: Chief Executive Officer

Exhibit 99.1

Opus Genetics Announces VEGA-3 Phase 3 Trial Met its Primary Endpoint for Phentolamine Ophthalmic Solution 0.75% for the Treatment of Presbyopia

- Study met its primary and key secondary endpoints, demonstrating rapid and sustained improvement in near visual acuity
- Safety profile consistent with previous clinical trials and no treatment-related serious adverse events reported in the study
- No evidence of tachyphylaxis was observed in this study over the 6-week period
- Management to Host Webcast and Conference Call Today at 8:00 A.M. ET

Research Triangle Park, NC June 26, 2025 - Opus Genetics, Inc. (Nasdaq: IRD), a clinical-stage biopharmaceutical company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and small molecule therapies for other ophthalmic disorders, today announced positive topline results from VEGA-3, its second pivotal Phase 3 trial evaluating Phentolamine Ophthalmic Solution 0.75% for the treatment of presbyopia. Presbyopia is an ophthalmic disorder that involves the progressive loss of ability to focus on close objects that results in blurred near vision, difficulty seeing in dim light, and eye strain.

The VEGA-3 trial met its primary endpoint, with a statistically significant 27.2% of participants treated with Phentolamine Ophthalmic Solution 0.75% achieving a ≥15-letter improvement in binocular distance-corrected near visual acuity (DCNVA), with less than a 5-letter loss in binocular best-corrected distance visual acuity (BCDVA) at 12 hours post-dose on Day 8, compared to 11.5% of patients on placebo ($p<0.0001$). The trial also met key secondary efficacy endpoints, reinforcing the benefit observed.

“The results of the VEGA-3 trial reinforce our belief that Phentolamine Ophthalmic Solution 0.75% could offer an option to improve near vision for millions of adults affected by presbyopia,” said George Magrath, M.D., CEO, Opus Genetics. “The positive results from both our Phase 3 VEGA-2 and VEGA-3 trials support the submission of an application to the U.S. Food and Drug Administration (FDA), which we plan to file in the second half of 2025. I want to thank the participants and clinical teams who participated in VEGA-3 and who have helped us bring Phentolamine Ophthalmic Solution 0.75% to this point in development.”

“These findings provide further validation of Phentolamine Ophthalmic Solution 0.75% as a differentiated approach to managing presbyopia, reflected by its ability to improve near vision while preserving distance vision without compromising low contrast vision,” said Jay Pepose, M.D., Ph.D., Chief Medical Advisor, Opus Genetics.

VEGA-3 Phase 3 Study

VEGA-3 is the second Phase 3 clinical trial evaluating the safety and efficacy of Phentolamine Ophthalmic Solution 0.75% in subjects with presbyopia. VEGA-3 is a multicenter, randomized, double-masked, placebo-controlled Phase 3 study that enrolled 545 participants across 40 sites in the United States. Subjects were randomized in a 3:2 ratio to receive either Phentolamine Ophthalmic Solution 0.75% or placebo, administered once daily in the evening.

Top-Line Results:

- The primary endpoint was defined as the proportion of participants achieving a ≥15-letter Early Treatment Diabetic Retinopathy Study (ETDRS) (≥3-line) improvement in binocular DCNVA and with less than 5 letters of loss in binocular BCDVA from baseline at 12 hours post-dose on Day 8, as compared to placebo.

- 27.2% of participants treated with Phentolamine Ophthalmic Solution 0.75% achieved a ≥15-letter improvement in DCNVA, with less than a 5-letter loss in BCDVA at 12 hours post-dose on Day 8, compared to 11.5% of patients on placebo ($p<0.0001$).

- 20.6% of patients in the Phentolamine arm achieved ≥15-letter ETDRS (≥3-line) gain in DCNVA at 1-hour post-dose on Day 1 compared to 6.1% of those receiving placebo ($p=0.0002$).

- Significant patient-reported functional benefit at Days 3 and 8 and Week 6 were observed with patients reporting satisfaction with near vision upon awakening ($p<0.0001$) and improvement in their near vision ($p<0.0001$).

- There was no evidence of tachyphylaxis observed after 6 weeks compared to the primary endpoint at Day 8 12 hours post-dose.

- Phentolamine Ophthalmic Solution 0.75% demonstrated a safety profile consistent with previous trials, with no new safety signal identified and no treatment-related serious adverse events reported in this study. The most common (≥5%) treatment-emergent adverse events included conjunctival hyperemia, instillation site irritation, and dysgeusia and all of which were predominantly mild. A low rate of headache (2.6%) was reported over the study period.

VEGA-3 patients will continue to be monitored for long-term safety over 48 weeks. Additional information on the VEGA-3 study design is available on ClinicalTrials.gov (NCT06542497).

Opus Genetics and Viatris (through its affiliate) are parties to a global licensing agreement which provides for the development of Phentolamine Ophthalmic Solution 0.75% and grants exclusive rights to Viatris to commercialize Phentolamine Ophthalmic Solution 0.75% in the United States.

Conference Call & Webcast Details

Opus Genetics management will host a webcast and conference call today at 8:00 a.m. Eastern Time to discuss the VEGA-3 results and provide a corporate update. The live and archived webcast may be accessed on the Opus Genetics website under the Investors section: Events. The live call can be accessed by dialing 888-506-0062 (domestic) or 973-528-0011 (international) and entering conference code: 936860. Opus Genetics suggests participants join 15 minutes in advance of the event.

About Phentolamine Ophthalmic Solution 0.75%

Phentolamine Ophthalmic Solution 0.75% is a non-selective alpha-1 and alpha-2 adrenergic antagonist to reduce pupil size, administered as an eye drop. It works by uniquely blocking the alpha-1 receptors found on the radial iris dilator muscles, which are activated by the alpha-1 adrenergic receptors, without affecting the ciliary muscle. Phentolamine Ophthalmic Solution 0.75% is currently being evaluated in two Phase 3 programs for the treatment of presbyopia and dim (mesopic) light vision disturbances after keratorefractive surgery (LYNX clinical program) and presbyopia (VEGA clinical program).

About Presbyopia

Presbyopia is the progressive loss of ability to focus on near objects that typically becomes noticeable in the early to mid-40s. As the eye ages, the ability to focus for reading and other tasks that require clear vision at near distances decreases. Presbyopia patients experience blurred near vision, difficulty seeing in dim light and eye strain. This ubiquitous condition leads to the widespread use of reading glasses or bifocals. It is estimated that 128 million Americans, and over 2 billion people worldwide, have presbyopia, and this number is expected to grow as the population ages.

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 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 is being studied in two Phase 3 programs for presbyopia and dim light vision disturbances. The company 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. Such statements include, but are not limited to, statements related to the clinical development, clinical results, and future plans for Phentolamine Ophthalmic Solution 0.75% and expectations regarding 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. 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 in our other filings with the U.S. Securities and Exchange Commission. 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.

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