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 12, 2026

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)

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 2.02 Results of Operations and Financial Condition.

On May 12, 2026, Opus Genetics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the first quarter ended March 31, 2026. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 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 May 12, 2026.
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: May 12, 2026

OPUS GENETICS, INC.

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

Exhibit 99.1

Opus Genetics Announces Financial Results for First Quarter 2026 and Provides Corporate Update

Opus Genetics Virtual R&D Science Forum Scheduled for Tuesday, June 16, 2026, at 10:00 am ET

Upcoming Data Readout for Cohort 1 of OPGx-BEST1 Gene Therapy Study Expected in September 2026

LCA5 Accepted to FDA's Rare Disease Evidence Principles (RDEP) Program and Enrolling Pivotal Trial

RDH12, MERTK and RHO Programs Expected to Advance to Clinical Testing in the Next 12 Months

Cash Runway into 2029 Expected to Support Multiple Clinical Inflection Points, Potential Product Approvals and Opportunities for Priority Review Vouchers

RESEARCH TRIANGLE PARK, N.C. – May 12, 2026 - Opus Genetics, Inc. (Nasdaq: IRD) (the "Company" or "Opus Genetics"), a clinical-stage biopharmaceutical company developing gene therapies to restore vision and prevent blindness in patients with inherited retinal diseases (IRDs), today announced financial results for the first quarter ended March 31, 2026, and provided a corporate update.

"With encouraging momentum across both our LCA5 and BEST1 gene therapy programs, Opus Genetics is entering a defining stretch where we believe our precision targeted approach can reshape what's possible for patients with inherited retinal diseases," said George Magrath, M.D., Chief Executive Officer of Opus Genetics. "Our upcoming BEST1 Cohort 1 clinical data and June R&D Science Forum will provide key opportunities to showcase the depth and maturity of our science and pipeline. Backed by a strong balance sheet and disciplined capital strategy, we are well-positioned to advance our lead programs toward pivotal trials, and accelerate our earlier-stage RDH12, MERTK, and RHO programs into the clinic."

Pipeline Updates

Research & Development (R&D) Science Forum

- Opus Genetics plans to host an R&D Science Forum on Tuesday, June 16, 2026, from 10:00 am – 12:00 pm ET, with management and key opinion leaders (KOLs) highlighting earlier-stage gene therapy programs entering clinical testing and IRD global market opportunities. Registration for the event will be available on the Events page of the Opus Genetics website.

OPGx-BEST1

- Enrollment completed in Cohort 1 of the Phase 1/2 trial (BIRD-1) including participants with both dominant and recessive forms of BEST disease, with the final participant scheduled for dosing this month.
- Baseline demographics were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2026 Annual Meeting with the related poster presentation available on the Publications & Presentations page of the Opus Genetics website. Additionally, a slide presentation and video summary recording titled "OPGx-BEST1 Cohort 1 Baseline Demographics and Key Endpoints for IRDs" are provided on the IR Presentations page of the Opus Genetics website.
- Opus Genetics expects to announce three-month topline data from Cohort 1 of the Phase 1/2 trial in September 2026.

OPGx-LCA5

- Positive six-month pediatric cohort data was presented at ARVO 2026; robust and consistent improvements were observed in cone-mediated function with average gains of approximately 1.5 log unit in cone sensitivity, reaching normal ranges after a single dose. Improvements were also observed in objective measures, visual acuity, and functional vision. The therapy was well tolerated, with most adverse events anticipated, mild, and not related to OPGx-LCA5.
- The U.S. Food and Drug Administration (FDA) granted acceptance of the LCA5 program into the Rare Disease Evidence Principles (RDEP) program, which is designed to provide guidance on the types of evidence that can be used to demonstrate substantial evidence of effectiveness, including the potential use of a single adequate and well-controlled study supported by confirmatory evidence.

- Recruitment is ongoing in the run-in period for the pivotal Phase 3 trial. In parallel, the clinical and commercial batch of drug product is being manufactured. Dosing with OPGx-LCA5 is expected to start in the fourth quarter of 2026.

OPGx-RDH12
- OPGx-RDH12 is being developed to deliver a functional RDH12 gene to photoreceptors using an AAV vector.
- This program is expected to enter the clinic in the fourth quarter of 2026. Funding is supported by the RDH12 Alliance.

OPGx-MERTK
- OPGx-MERTK is being developed for retinal degeneration caused by mutations in the MERTK gene, which plays a critical role in phagocytosis of photoreceptor outer segments by RPE cells.
- Clinical development activities are underway. Funding is supported by a consortium led by Abu Dhabi's Healthcare Research and Innovation Fund.

OPGx-RHO
- Preclinical data presented at ARVO 2026 and the Foundation Fighting Blindness Retinal Therapeutics Innovation Summit 2026 provided safety and efficacy data on the use of OPGx-RHO in two large animal models of autosomal-dominant retinitis pigmentosa (adRP). This preclinical work was co-funded by the Foundation Fighting Blindness and the National Institutes of Health.
- This program is expected to enter the clinic in 2027.

Recent Medical Presentations
- ARVO 2026 Annual Meeting:
  - "Restoration of Cone-Mediated Vision After Gene Augmentation in Children with LCA5"
  - "Preliminary Results from Adult Participant in a Phase 1b/2a Clinical Study of OPGx-BEST1 Gene Therapy for ARB and BVMD Due to BEST1 Mutations"
  - "Development of Cell-Based Expression and Functional Potency Assays for OPGx-BEST1 Gene Therapy"
  - "Nonclinical Efficacy and Toxicity Study of GMP-Grade Vector OPGx-RHO (Scaav2/5-RHO820-Shrna820) Delivered by Subretinal Injection in a Canine Model of RHO-adRP"
  - "Therapeutic Efficacy of a Mutation-Independent AAV Knockdown and Replacement Approach in a Swine Animal Model of Autosomal-Dominant Retinitis Pigmentosa (adRP)"
- Foundation Fighting Blindness Retinal Therapeutics Innovation Summit 2026: "Safety and Efficacy of OPGx-RHO Silence-and-Replace Gene Therapy for RHO-adRP: Evidence Across Two Large Animal Models"
- The Macula Society Annual Meeting: "Preliminary Results from Sentinel Patient in a Phase 1b/2a Clinical Study of OPGx-BEST1 Gene Therapy for the Treatment of BVMD and ARB Due to BEST1 Mutations"
- Asia-Pacific Academy of Ophthalmology Congress (APAO): "Gene Therapy for BEST1 Inherited Retinal Disease"
- Advanced Therapies Week: "Building Scalable Viral Vector Manufacturing Models"

Financial Results for the First Quarter Ended March 31, 2026

Cash Position: As of March 31, 2026, Opus Genetics had cash and cash equivalents of $60 million. Subsequent to the end of the period, the Company entered into a strategic financing agreement with Oberland Capital Management, which included funding of a principal amount of $35 million of senior secured notes and a commitment to a $5 million equity investment, which is expected to close on or about May 22, 2026, subject to the satisfaction of customary closing conditions. With approximately $90 million in current cash, and potential future fundings under the facility with Oberland Capital Management, the Company believes its aggregate cash resources will fund operations into 2029. This estimate excludes any potential proceeds from callable warrants or future milestone payments.

Revenue: License and collaborations revenue totaled $2.2 million for the quarter ended March 31, 2026, compared to $4.4 million for the same period in 2025. Revenue in both periods came primarily from reimbursement of research and development (R&D) services based on the Company's collaboration with Viatris, Inc.

Research and Development (R&D) Expenses: R&D expenses were $10.6 million for the quarter ended March 31, 2026, compared to $8.0 million for the same period in 2025. The increase was primarily attributable to higher manufacturing costs associated with the Company's IRD programs, partially offset by lower clinical costs associated with the Company's

phentolamine-related programs. R&D expenses included $0.4 million and $0.3 million in stock-based compensation expense for the three months ended March 31, 2026 and 2025, respectively.

General and Administrative (G&A) Expenses: G&A expenses were $5.9 million for the quarter ended March 31, 2026, compared to $6.3 million for the same period in 2025. The decrease was primarily attributable to lower legal costs, partially offset by higher employee compensation-related costs. G&A expenses included $1.1 million and $0.6 million in stock-based compensation expense for the three months ended March 31, 2026 and 2025, respectively.

Net Loss: Net loss for the quarter ended March 31, 2026 was $65.5 million, or ($0.75) per basic and diluted share, compared to a net loss of $8.2 million, or ($0.24) per basic and diluted share, for the same period in 2025. The increase in net loss was primarily due to a non-cash expense, driven by the increase in the fair value change in warrant liabilities associated with the Company's March 2025 Warrants, and higher R&D expenses as discussed above.

About Opus Genetics

Opus Genetics is a clinical-stage biopharmaceutical company developing gene therapies to restore vision and prevent blindness in patients with inherited retinal diseases (IRDs). The Company is developing durable, one-time treatments designed to address the underlying genetic causes of severe retinal disorders. The Company's pipeline includes seven AAV-based programs, led by OPGx-LCA5 for LCA5-related mutations and OPGx-BEST1 for BEST1-related retinal degeneration, with additional candidates targeting RDH12, MERTK, RHO, CNGB1 and NMNAT1. 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 cash runway and future financing availability, potential future funding under the Oberland facility, potential product approvals, and Priority Review Voucher opportunities, the clinical development, clinical results, preclinical data and future plans for Phentolamine Ophthalmic Solution 0.75%, OPGx-LCA5, OPGx-BEST1, OPGx-MERTK, OPGx-RDH12, OPGx-RHO and earlier stage programs, 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 most recent Annual Report on Form 10-K 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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-Financial Tables Follow-

Opus Genetics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share amounts and par value)

	As of	
	March 31, 2026	**December 31, 2025**
Assets	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 59,959	$ 45,091
Accounts receivable	1,731	1,995
Contract assets and unbilled receivables (Note 10)	984	1,170
Prepaids and other current assets	3,927	1,788
Total current assets	66,601	50,044
Property and equipment, net	186	199
Total assets	$ 66,787	$ 50,243
Liabilities, convertible preferred stock and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 4,422	$ 3,293
Accrued expenses	4,918	4,488
Total current liabilities	9,340	7,781
Warrant liabilities	77,349	25,985
Funding agreement, related party	1,198	1,129
Total liabilities	87,887	34,895
Commitments and contingencies (Note 3 and Note 9)		
Series B preferred stock, par value $0.0001; 7,374,632 shares and no shares were designated as of March 31, 2026 and December 31, 2025, respectively; 7,374,632 shares and no shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively.	24,736	—
Stockholders' (deficit) equity:		
Preferred stock, par value $0.0001; 2,625,368 shares and 10,000,000 shares authorized as of March 31, 2026 and December 31, 2025, respectively; no shares issued and outstanding at March 31, 2026 and December 31, 2025.	—	—
Common stock, par value $0.0001; 125,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 71,402,472 and 69,894,507 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively.	7	7
Additional paid-in capital	208,281	203,930
Accumulated deficit	(254,124)	(188,589)
Total stockholders' (deficit) equity	(45,836)	15,348
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 66,787	$ 50,243

Opus Genetics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended March 31,	
	2026	**2025**
License and collaborations revenue	$ 2,157	$ 4,370
Operating expenses:		
Research and development	10,577	7,953
General and administrative	5,944	6,346
Total operating expenses	16,521	14,299
Loss from operations	(14,364)	(9,929)
Fair value change in warrant liabilities	(51,364)	2,805
Financing costs	(582)	(1,372)
Interest expense	(69)	—
Other income, net	844	302
Loss before income taxes	(65,535)	(8,194)
Benefit (provision) for income taxes	—	—
Net loss	(65,535)	(8,194)
Other comprehensive loss, net of tax	—	—
Comprehensive loss	$ (65,535)	$ (8,194)
Net loss per share:		
Basic and diluted	$ (0.75)	$ (0.24)
Number of shares used in per share calculations:		
Basic and diluted	86,891,352	33,884,920

Source: Opus Genetics, Inc.