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): March 10, 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:

☐ 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 2.02 Results of Operations and Financial Condition.

On March 10, 2026, Opus Genetics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the fiscal year ended December 31, 2025. 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 March 10, 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: March 10, 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 Full Year 2025 and Provides Corporate Update

- Favorable early safety and initial efficacy data from BEST1 program highlighted at premier gathering of global retinal experts with additional data expected mid-year 2026 -

- Reauthorization of FDA's Rare Pediatric Disease Priority Review Voucher (PRV) program provides opportunity for Opus' deep pipeline in rare inherited retinal diseases -

- FDA Prescription Drug User Fee Act (PDUFA) date in October 2026 for Phentolamine Ophthalmic Solution 0.75% for the treatment of presbyopia -

- Funding from prominent healthcare investors expected to extend cash runway into 2028 -

RESEARCH TRIANGLE PARK, N.C. - March 10, 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 year ended December 31, 2025, and provided a corporate update.

"We are delivering a steady cadence of data and milestones across our pipeline," said George Magrath, M.D., Chief Executive Officer, Opus Genetics. "With positive clinical results from both our BEST1 and LCA5 gene therapy programs, new funding for our MERTK program and an upcoming FDA PDUFA date for Phentolamine Ophthalmic Solution 0.75% in presbyopia, we are advancing therapies with both scientific promise and compelling commercial potential. The reauthorization of the U.S. Rare Pediatric Disease Priority Review Voucher program further strengthens our work, reinforcing long-term incentives that support sustainable investment in rare gene therapy development. With multiple catalysts ahead and a capital-efficient operating model, we believe Opus is positioned to create significant long-term value for shareholders."

Pipeline Updates

OPGx-BEST1 – Gene Therapy for BEST1-Related IRD

- Recruitment is ongoing at multiple U.S. sites with two participants treated to date in the Phase 1/2 trial (BIRD-1) that includes patients with both dominant and recessive forms of BEST disease.

- Positive initial three-month data from the first (sentinel) participant presented at Macula Society
    - The data demonstrated that OPGx-BEST1 was well tolerated with no ocular inflammation, no ocular or treatment-related adverse events, and no dose limiting toxicities observed to date.
    - Early signals of functional vision improvement were observed, including an equivalent 12-letter gain in Best Corrected Visual Acuity (BCVA) in the treated study eye.
    - Structural improvement in central subfield thickness (CST) was observed with a 23% decrease in the study eye.
    - Resolution of intraretinal fluid was also seen as early as 1-month in areas with less atrophy.
- Three-month results from the full Cohort 1 are expected in mid-year 2026.

OPGx-LCA5 – Gene Therapy for Leber Congenital Amaurosis (LCA5)

- Recruitment ongoing with multiple participants enrolled to date in a run-in period for the pivotal Phase 3 trial, which is targeted to enroll as few as eight participants in a single arm, 12-month study utilizing an adaptive design. Dosing with OPGx-LCA5 expected in the second half of 2026.
- Application expected to be submitted in Q1 2026 for Rare Disease Evidence Principles (RDEP) review process from the U.S. Food and Drug Administration (FDA), designed to provide greater speed and predictability in the review of therapies intended to treat rare diseases with very small patient populations with significant unmet medical need and that are driven by a known genetic defect.
- Presentation of Phase 1/2 six-month pediatric cohort data expected at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) conference in May 2026.

Preclinical Gene Therapy Pipeline

- Funding secured from Abu Dhabi's Healthcare Research and Innovation Fund to conduct a clinical trial evaluating OPGx-MERTK for MERTK-related retinitis pigmentosa (RP), a rare IRD that causes progressive vision loss and eventual blindness. Clinical development activities are underway.
- Preclinical work ongoing for Opus' broad IRD pipeline related to genetic mutations in RHO, CNGB1, RDH12-LCA, and NMNAT1, with one to two programs targeted to enter clinical testing this year.

Phentolamine Ophthalmic Solution 0.75% (PS)

- The FDA accepted the Company's supplemental New Drug Application (sNDA) for Phentolamine Ophthalmic Solution 0.75% for the treatment of presbyopia and set a PDUFA action date of October 17, 2026.
- LYNX-3, the second pivotal Phase 3 trial in keratorefractive participants with visual disturbances under mesopic, low-contrast conditions (dim light disturbances), is ongoing with topline results expected in the first half of 2026.

Recent Medical Publications and Presentations

- Presentation at The Macula Society Annual Meeting titled "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."
- Presentation at the Asia-Pacific Academy of Ophthalmology Congress (APAO) titled "Gene Therapy for BEST1 Inherited Retinal Disease."
- Presentation at the Advanced Therapies Week Conference titled "Building Scalable Viral Vector Manufacturing Models."
- Presentation at the Cell and Gene Meeting on the Mesa titled "Transformative Gene Therapies for the Treatment of Rare Inherited Retinal Diseases."
- Poster presentation at the American Academy of Optometry Annual Meeting 2025 titled "LYNX-2: A Pivotal Phase 3 Trial of Phentolamine Ophthalmic Solution in Post-Keratorefractive Surgery Subjects with Decreased Mesopic Visual Acuity."
- Presentation at Eyecelerator at the American Academy of Ophthalmology (AAO) Annual Meeting titled "Transformative Gene Therapies for the Treatment of Rare Inherited Retinal Diseases."

Financial Results for the Year Ended December 31, 2025

Cash Position: As of December 31, 2025, Opus Genetics had cash and cash equivalents of $45.1 million. Subsequent to the end of the fourth quarter, the Company raised approximately $25.0 million in gross proceeds through a private placement of equity securities. Based on current operating plans, the Company believes its aggregate cash resources of $70.1 million will fund operations into the first half of 2028, excluding any potential proceeds from callable warrants or future milestone payments.

Revenue: License and collaborations revenue totaled $14.2 million for the year ended December 31, 2025, compared to $11.0 million for the same period in 2024. Revenue in both periods was driven by the Company's collaboration with Viatris, Inc. from reimbursement of research and development (R&D) services.

Research and Development (R&D) Expenses: R&D expenses were $30.8 million for the year ended December 31, 2025, compared to $26.9 million for the same period in 2024. The increase was primarily attributable to higher costs related to clinical research, toxicology, payroll, professional services and other operating expenses, partially offset by lower manufacturing and regulatory costs. R&D expenses included $1.0 million in stock-based compensation expense during each of the years ended December 31, 2025 and 2024.

General and Administrative (G&A) Expenses: G&A expenses were $22.0 million for the year ended December 31, 2025, compared to $18.2 million for the same period in 2024. The increase was primarily attributable to higher legal and patent-related costs, payroll and public company-related costs, and professional service fees. G&A expenses included $2.4 million in stock-based compensation expense during each of the years ended December 31, 2025 and 2024.

Net Loss: Net loss for the year ended December 31, 2025 was $49.6 million, or ($0.80) per basic and diluted share, compared to a net loss of $57.5 million, or ($2.15) per basic and diluted share, for the same period in 2024. The year-over-year decrease in net loss was primarily driven by the absence of the $28.0 million acquired in-process research and development charge recognized in 2024, partially offset by an $11.5 million increase in the fair value of warrant and other derivative liabilities associated with the Company's March 2025 financings and increases to R&D and G&A expense as noted 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 RHO, CNGB1, RDH12, NMNAT1, and MERTK. Opus Genetics is also advancing a small-molecule therapy, Phentolamine Ophthalmic Solution 0.75%, beyond its approved use for pharmacologically induced mydriasis, with a supplemental new drug application under review for presbyopia and an ongoing Phase 3 pivotal trial for mesopic, low contrast conditions after keratorefractive surgery (dim light 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 cash runway, the clinical development, clinical results, preclinical data and future plans for Phentolamine Ophthalmic Solution 0.75%, OPGx-LCA5, OPGx-BEST1, RDH12 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.
Consolidated Balance Sheets
(in thousands, except share amounts and par value)

	As of December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 45,091	$ 30,321
Accounts receivable	1,995	3,563
Contract assets and unbilled receivables (Note 10)	1,170	2,209
Prepaids and other current assets	1,788	515
Short-term investments	—	2
Total current assets	50,044	36,610
Property and equipment, net	199	252
Total assets	$ 50,243	$ 36,862
Liabilities, Series A preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,293	$ 3,148
Accrued expenses and other liabilities	4,488	8,147
Total current liabilities	7,781	11,295
Warrant liabilities	25,985	—
Funding agreement, related party	1,129	—
Total liabilities	34,895	11,295
Commitments and contingencies (Note 3 and Note 9)		
Series A preferred stock, par value $0.0001; no shares and 14,146 shares were designated as of December 31, 2025 and 2024, respectively; no shares and 14,145.374 shares issued and outstanding at December 31, 2025 and 2024, respectively.	—	18,843
Stockholders' equity:		
Preferred stock, par value $0.0001; 10,000,000 and 9,985,854 shares authorized as of December 31, 2025 and 2024, respectively; no shares issued and outstanding at December 31, 2025 and 2024.	—	—
Common stock, par value $0.0001; 125,000,000 authorized as of December 31, 2025 and 2024; 69,894,507 and 31,574,657 shares issued and outstanding at December 31, 2025 and 2024, respectively.	7	3
Additional paid-in capital	203,930	145,719
Accumulated deficit	(188,589)	(138,998)
Total stockholders' equity	15,348	6,724
Total liabilities, Series A preferred stock, and stockholders' equity	$ 50,243	$ 36,862

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

	For the Year Ended December 31,	
	2025	**2024**
License and collaborations revenue	$ 14,196	$ 10,992
Operating expenses:		
Research and development	30,812	26,851
General and administrative	21,983	18,215
Acquired in-process research and development	—	28,000
Total operating expenses	52,795	73,066
Loss from operations	(38,599)	(62,074)
Fair value change in warrant and other derivative liabilities	(11,515)	72
Financing costs	(1,337)	—
Interest expense	(129)	—
Other income, net	1,989	4,470
Loss before income taxes	(49,591)	(57,532)
Provision for income taxes	—	—
Net loss	(49,591)	(57,532)
Other comprehensive loss, net of tax	—	—
Comprehensive loss	$ (49,591)	$ (57,532)
Net loss per share		
Basic and diluted	$ (0.80)	$ (2.15)
Number of shares used in per share calculations:		
Basic and diluted	62,221,901	26,715,526

Source: Opus Genetics, Inc.