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): November 6, 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, Suite 220 **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 7.01 Regulation FD Disclosure.

On November 6, 2025, Opus Genetics, Inc. (the "Company") issued a press release announcing a $23 million registered direct offering (the "Offering"), a copy of which is furnished as Exhibit 99.1 hereto.

Also on November 6, 2025, the Company issued a press release announcing the successful completion of a Type B Regenerative Medicine Advanced Therapy ("RMAT") meeting with the U.S. Food and Drug Administration ("FDA") regarding OPGx-LCA5, its gene therapy candidate for Leber congenital amaurosis ("LCA") caused by mutations in the LCA5 gene, a copy of which is furnished as Exhibit 99.2 hereto.

The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

The Company announced the successful completion of a Type B RMAT meeting with the FDA regarding OPGx-LCA5, its gene therapy candidate for LCA caused by mutations in the LCA5 gene. The meeting provided constructive feedback from the FDA on key elements of the Company's registration strategy, including Chemistry, Manufacturing and Controls (CMC) and the pivotal trial design. The FDA acknowledged the significant unmet medical need for individuals with LCA5-related blindness and reaffirmed its commitment to regulatory flexibility for rare genetic diseases. To date in the Phase 1/2 portion of the trial, six late-stage participants have been treated with OPGx-LCA5, all of whom have experienced clinically meaningful improvements in vision, providing evidence of biological activity with the potential for functional restoration of vision in individuals with advanced disease.

The Company will incorporate the FDA's feedback into its updated clinical development and CMC plans for the Phase 3 portion of the study, which will include enrolling as few as eight participants in a single-arm, 12-month study utilizing an adaptive design and provides flexibility regarding endpoints and number of participants, reflective of LCA5 as a rare condition with an urgent medical need.

The Company expects the Phase 3 portion of the trial will include a run-in period prior to dosing to evaluate the natural history of each participant to serve as their own control in the study. The Company is actively identifying patients for this segment and has enrolled the first participant for ongoing disease monitoring. Efficacy and safety will be assessed using measures such as visual acuity, full-field stimulus testing, microperimetry, and the Multi-Luminance Orientation and Mobility Test (MLoMT). Following availability of validated clinical drug supply manufactured with the intended commercial processes, dosing with OPGx-LCA5 is anticipated in the second half of 2026, with topline clinical data expected approximately one year later.

In September 2025, the FDA introduced the Rare Disease Evidence Principles (RDEP) review process to facilitate the approval of drugs intended to treat rare diseases with very small patient populations, a significant unmet medical need and a known genetic defect that is the major driver of the pathophysiology. With a patient population of fewer than 1,000 individuals, the Company believes that its LCA5 program meets the eligibility criteria for the RDEP process and plans to submit an application.

Including expected proceeds from the Offering and based on current operating plans, the Company expects its cash resources will fund operations into the second half of 2027, excluding any potential proceeds from callable warrants or future milestone payments.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Opus Genetics, Inc., dated November 6, 2025.
99.2	Press Release of Opus Genetics, Inc., dated November 6, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, the intended use of proceeds of the Offering and other statements relating to the Offering. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "designed", "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should,", "strive", "target," "will," "would," or the negative thereof and similar words and expressions. Forward-looking statements are based on management's current expectations, beliefs and assumptions and on information currently available to the Company. Such statements are neither promises nor guarantees, and involve a number of known and unknown risks, uncertainties and assumptions. Actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, without limitation, risks and uncertainties associated with the consummation of the Offering, uncertainties related to market conditions, the satisfaction of customary closing conditions, the completion of the Offering on the anticipated terms or at all, general economic conditions and other risks identified from time to time in the reports the Company files with the SEC, including the Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as such factors may be updated from time to time in its other filings with the SEC, accessible on the SEC's website at *www.sec.gov*. The forward-looking statements in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update or revise any of the statements. The Company's business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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.

OPUS GENETICS, INC.

Date: November 6, 2025

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

Exhibit 99.1

FINAL FOR GLOBENEWSWIRE

Opus Genetics Announces $23 Million Registered Direct Offering

- Financing led by Perceptive Advisors and Balyasny Asset Management -

- Proceeds targeted to fund rapid development of ophthalmic gene therapy clinical programs -

RESEARCH TRIANGLE PARK, N.C. – November 6, 2025 - Opus Genetics, Inc. (Nasdaq: IRD) (the "Company" or "Opus Genetics") 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 that it has entered into a securities purchase agreement to sell securities in a registered direct offering (the "offering") for gross proceeds of approximately $23 million, before deducting offering expenses. The financing, which included new and existing institutional investors, was led by Perceptive Advisors and Balyasny Asset Management, with participation by Nantahala Capital.

Opus intends to use the net proceeds to advance its LCA5 and BEST-1 gene therapy clinical programs, as well as for working capital and general corporate purposes. Including expected proceeds from this offering and based on current operating plans, the Company expects its cash resources will fund operations into the second half of 2027, excluding any potential proceeds from callable warrants or future milestone payments.

"We appreciate the support of these respected healthcare investors, which reflects strong confidence in our clinical pipeline," said George Magrath, M.D., Chief Executive Officer, Opus Genetics. "Following the successful outcome of our U.S. Food and Drug Administration (FDA) meeting for OPGx-LCA5, this financing positions us to advance our LCA5 and BEST-1 programs with the ultimate goal of restoring vision and preventing blindness in patients with inherited retinal diseases."

In the offering, Opus is selling an aggregate of 3,827,751 shares of its common stock at a price of $2.09 per share and, in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 7,177,033 shares of common stock at a purchase price of $2.0899 per pre-funded warrant. Each pre-funded warrant has an exercise price of $0.0001 per share of common stock, will be immediately exercisable and may be exercised at any time until exercised in full. The offering is expected to close on November 7, 2025, subject to customary closing conditions. Sidley Austin LLP served as counsel to Opus in connection with the transaction. The Company did not use a placement agent in connection with the offering.

The offering, including the shares of common stock issuable from time to time upon exercise of the pre-funded warrants, is being made pursuant to an effective shelf registration statement on Form S-3 (File No. 333-276462) filed with the U.S. Securities and Exchange Commission (the "SEC") on January 10, 2024 and declared effective by the SEC on January 23, 2024. The offering is being made only by means of a prospectus supplement and accompanying prospectus, which form a part of the registration statement. Copies of the prospectus supplement and accompanying prospectus will be filed with the SEC and will be available free of charge on the SEC's website at www.sec.gov.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Opus Genetics

Opus Genetics is a clinical-stage biopharmaceutical company developing gene therapies for the treatment of inherited retinal diseases (IRDs) and small molecule therapies for other ophthalmic disorders. The Company's pipeline features AAV-based gene therapies targeting inherited retinal diseases including Leber congenital amaurosis (LCA), bestrophinopathy, and retinitis pigmentosa. Its lead gene therapy candidates are OPGx-LCA5, which is in an ongoing Phase 1/2 trial for LCA5-related mutations, and OPGx-BEST1, a gene therapy targeting BEST1-related retinal degeneration. Opus Genetics 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 reduced low light vision and nighttime visual 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our other filings with the 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.

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Source: Opus Genetics, Inc.

FINAL FOR GLOBENEWSWIRE

Opus Genetics Announces Successful FDA Meeting Supporting Advancement of OPGx-LCA5 Toward Pivotal Trial for LCA5-Related Inherited Retinal Disease

- Outcome of Regenerative Medicine Advanced Therapy (RMAT) meeting provides the potential for an accelerated regulatory pathway to approval of OPGx-LCA5
- First participant enrolled in run-in period for planned adaptive Phase 3 trial
- Company intends to apply for the FDA's new Rare Disease Evidence Principles (RDEP) review process
- OPGx-LCA5 has the potential to be the first gene therapy and one-time treatment for Leber congenital amaurosis (LCA) type 5
- Recent $23 million financing led by Perceptive Advisors and Balyasny Asset Management to advance LCA5 and BEST1 programs and fund current operating plans into second half of 2027

RESEARCH TRIANGLE PARK, N.C. - November 6, 2025 - Opus Genetics, Inc. (Nasdaq: IRD) (the "Company" or "Opus Genetics"), a clinical-stage biopharmaceutical company developing gene therapies for inherited retinal diseases (IRDs) and small-molecule therapies for other ophthalmic disorders, today announced the successful completion of a Type B Regenerative Medicine Advanced Therapy (RMAT) meeting with the U.S. Food and Drug Administration (FDA) regarding OPGx-LCA5, its gene therapy candidate for Leber congenital amaurosis (LCA) caused by mutations in the LCA5 gene.

The meeting provided constructive feedback from the FDA on key elements of Opus's registration strategy, including Chemistry, Manufacturing and Controls (CMC), and the pivotal trial design. The FDA acknowledged the significant unmet medical need for individuals with LCA5-related blindness and reaffirmed its commitment to regulatory flexibility for rare genetic diseases.

"The FDA's guidance provides confidence in our path to approval for OPGx-LCA5," said George Magrath, M.D., Chief Executive Officer, Opus Genetics. "Importantly, we expect to be able to advance our ongoing trial using an adaptive design that includes a Phase 3 portion which will avoid the requirement for a separate registrational trial. Given the severe nature of the disease, we are actively identifying patients who may qualify for the Phase 3 and enrolling them into the planned run-in period to monitor their disease. This productive RMAT interaction represents an important milestone as we continue working closely with the FDA to bring sight-restoring gene therapies to patients who currently have no approved treatment options. We look forward to meeting with the FDA again in the coming months."

To date in the Phase 1/2 portion of the trial, six late-stage participants have been treated with OPGx-LCA5, and all six have experienced clinically meaningful improvements in vision, providing evidence of biological activity with the potential for functional restoration of vision in individuals with advanced disease.

Opus will incorporate the FDA's feedback into its updated clinical development and CMC plans for the Phase 3 portion of the study to include enrolling as few as 8 participants in a single arm, 12-month study utilizing an adaptive design, which provides flexibility on endpoints and number of participants, reflective of LCA5 as a rare condition with an urgent medical need.

The Company expects the Phase 3 portion of the trial will include a run-in period prior to dosing to evaluate the natural history of each participant to serve as their own control in the study. Opus is actively identifying patients for this segment and has enrolled the first participant. Efficacy and safety will be assessed using measures such as visual acuity, full-field stimulus testing, microperimetry, and Multi-Luminance Orientation and Mobility Test (MLoMT). Following availability of validated clinical drug supply manufactured with the intended commercial processes, dosing with OPGx-LCA5 is anticipated in the second half of 2026, with topline clinical data expected approximately one year later.

"With recent financing secured, we are strongly positioned to advance our LCA5 program with the rigor and urgency this patient community deserves. As we progress into our LCA5 pivotal trial and initiate clinical testing in our second gene therapy program for the treatment of BEST1-related disease, we are entering the next stage of growth as we build the world's leading portfolio of gene therapies for inherited retinal diseases," concluded Dr. Magrath.

In September 2025, the FDA introduced the Rare Disease Evidence Principles (RDEP) review process to facilitate the approval of drugs to treat rare diseases with very small patient populations with significant unmet medical need and with a known genetic defect that is the major driver of the pathophysiology. With a patient population of less than 1,000, Opus believes that its LCA5 program meets the eligibility criteria for the RDEP process and plans to submit an application.

About OPGx-LCA5

OPGx-LCA5 is designed to address a form of Leber congenital amaurosis (LCA) due to biallelic mutations in the LCA5 gene (LCA5), which encodes the lebercilin protein. LCA5-associated inherited retinal disease is an early-onset severe inherited retinal dystrophy. Studies in patients with this mutation have reported evidence for the dissociation of retinal architecture and visual function in this disease, suggesting an opportunity for therapeutic intervention through gene augmentation. OPGx-LCA5 uses an adeno-associated virus 8 (AAV8) vector to precisely deliver a functional LCA5 gene to the outer retina. OPGx-LCA5 is currently being evaluated in a Phase 1/2 clinical trial at the University of Pennsylvania. Data from pediatric participants demonstrated large gains in cone-mediated vision, and the therapy remains well tolerated with no ocular serious adverse events or dose-limiting toxicities. The adult cohort showed durable improvements in cone sensitivity and visual function out to 18 months. OPGx-LCA5 has received Rare Pediatric Disease, Orphan Drug and Regenerative Medicine Advanced Therapy (RMAT) designations from the FDA.

About Leber Congenital Amaurosis (LCA) and LCA5

Leber congenital amaurosis (LCA) is a group of inherited retinal diseases characterized by severely impaired vision or blindness at birth. Some retinal experts consider LCA to be a severe form of retinitis pigmentosa (RP). The condition is caused by degeneration and/or dysfunction of photoreceptors, the cells in the retina that make vision possible. Mutations in one of more than two dozen genes can cause LCA.

LCA5 is an ultra-rare disease caused by mutations in the LCA5 gene, which encodes lebercilin, a protein essential for photoreceptor structure and function. LCA5 accounts for roughly 2% of all LCA cases, or approximately 200 patients. There are currently no approved therapies for LCA5-related inherited retinal degeneration, making gene therapy a potentially transformative approach.

About Opus Genetics

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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, the clinical development of, and clinical results and future plans for, OPGx-LCA5, potential meetings with the FDA regarding our OPGx-LCA5 program, 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 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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