

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): July 22, 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)

(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 1.01 Entry into a Material Definitive Agreement.

On July 22, 2025, Opus Genetics, Inc., together with its wholly owned subsidiary, OpusTX, LLC (collectively, the “*Company*”), entered into a funding and license agreement (the “*Agreement*”) with Eyes on the Future (“*EOTF*”), and RDH12 Fund for Sight (the “*Fund*,” and together with EOTF, the “*Funding Parties*”), relating to the Company’s program to develop gene therapies that treat patients with inherited retinal degeneration associated with mutations in the RDH12 gene (the “*RDH12 Program*”). The Agreement provides for funding by the Funding Parties of up to \$1,600,000 to support the development of the RDH12 Program. The Company is required to use the funding to conduct development activities in accordance with a mutually agreed development plan.

Under the Agreement, the Company is subject to certain diligence obligations to develop a product under the RDH12 Program. If the Company is unable to achieve certain milestones by the specified dates or if certain other events occur (a “*License Trigger Event*”), then the Funding Parties may exercise their rights under a non-exclusive, global, royalty-free and fully paid-up license granted by the Company to the Funding Parties to develop products under the RDH12 Program. If the Funding Parties exercise such license rights, then the Company will receive a non-exclusive license under the data and other intellectual property generated by the Funding Parties to develop products under the RDH12 Program, and the right to negotiate an exclusive license to such data and intellectual property to commercialize products under the RDH12 Program. The Agreement includes certain restrictions on the Company’s ability to out-license rights to the RDH12 Program, and during the term of the Agreement the Company may not grant a third party an exclusive license to develop or commercialize products under the RDH12 Program in the United States without the prior written consent of the Funding Parties.

The term of the Agreement continues until the earlier of (a) dosing by the Company of three patients in a Phase 1a/2b clinical trial prior to a License Trigger Event, and (b) the first commercial sale of a product under the RDH12 Program following receipt of regulatory approval in the United States or certain other European countries. The Agreement will also terminate if an exclusive, global licensee of the Company for the RDH12 Program assumes the Company’s obligations under the Agreement. The Agreement may be terminated by either party for cause, including material breach or bankruptcy, subject to a cure period, or by the Funding Parties for convenience following a License Trigger Event.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the Agreement, which will be filed with the Company’s next Quarterly Report on Form 10-Q for the quarter ended September 30, 2025.

Item 7.01 Regulation FD Disclosure.

On July 23, 2025, the Company issued a press release announcing entry into the Agreement. A copy of the press release is furnished herewith as Exhibit 99.1.

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 July 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: July 23, 2025

OPUS GENETICS, INC.

By: /s/ Dr. George Magrath

Name: Dr. George Magrath

Title: Chief Executive Officer

Opus Genetics and the Global RDH12 Alliance Partner to Advance RDH12 Gene Therapy for Inherited Childhood Blindness

- *Collaboration aims to accelerate development of OPGx-RDH12, a gene therapy for RDH12-associated Leber congenital amaurosis (RDH12-LCA)*

RESEARCH TRIANGLE PARK, N.C., July 23, 2025 (GLOBE NEWSWIRE) -- 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 (“Opus”), today announced a strategic partnership with the Global RDH12 Alliance (the “Alliance”) to advance Opus’ gene therapy program for patients with vision loss due to retinol dehydrogenase 12 (“RDH12”) gene mutations. The Alliance serves as a collaborative platform uniting key advocacy groups dedicated to RDH12-related IRDs, including: (i) “RDH12 Fund for Sight” in the U.S. and (ii) “Eyes on the Future” in the UK.

This collaboration will accelerate development of OPGx-RDH12, Opus’ gene therapy program targeting the RDH12 gene mutation for the potential treatment of Leber congenital amaurosis (“RDH12-LCA”). Leber congenital amaurosis (“LCA”) is a rare IRD that causes progressive vision loss and blindness, often beginning in early childhood. Patients with RDH12 mutations often have early visual acuity loss with retinal structural changes by two years of age.

Under the agreement, the Alliance will provide up to \$1.6 million towards the development of the OPGx-RDH12 program. The partnership also includes a risk-sharing structure and performance-based milestones. Together, the parties will co-develop the OPGx-RDH12 program, including the clinical and regulatory strategy, with the goal of filing an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (the “FDA”) by late 2025.

“Since founding the RDH12 Fund for Sight more than a decade ago, our goal has always been to bring a treatment to the RDH12-LCA community,” said Mathew Pletcher, Ph.D., Board member of the RDH12 Fund for Sight and father to a 19-year-old living with the condition. “This partnership represents a significant step forward. By combining our patient community’s unique, first-hand perspectives on RDH12-LCA and resources with Opus’ gene therapy expertise, we can accelerate the transition of this promising therapy out of the laboratory and into the clinic.”

Silvia Cerolini, CEO of Eyes on the Future and mother of an 11-year-old girl affected by RDH12-LCA, added, “We are racing against time as our children’s vision continues to deteriorate. Partnering with Opus to bring this gene therapy into the clinic is an incredibly meaningful milestone, and it shows what’s possible when patients and the industry work together. It brings us one step closer to our mission: helping our kids and our community see the world for longer.”

“Opus is pleased to work directly with the patient community in true partnership,” said George Magrath, CEO of Opus Genetics. “This collaboration is much more than a financial arrangement. We value each other’s insights, experience and connections as critical to a successful co-development of this gene therapy.”

Professor Jean Bennett, MD, PhD, Opus Genetics Scientific Advisor and Board of Directors member, added, “With the understanding of how gene therapy works and the preclinical evidence so far, we see a clear path for its application to RDH12-LCA. I want to thank everybody in the RDH12 community for their indispensable support to RDH12 research over the years. This partnership is a critical enabler to accelerate the path to bringing this therapy to all of those in need.”

About RDH12-LCA and OPGx-RDH12

RDH12-LCA is an ultra-rare form of childhood blindness affecting several thousand people globally. Mutations in the RDH12 gene impair protein function in the retina, leading to early visual decline, often with structural retinal changes by age two, and rapid progression during the second decade of life. OPGx-RDH12 uses an adeno-associated virus (AAV) vector to deliver a functional copy of the RDH12 gene directly to photoreceptors in the retina. “Preclinical studies in cell and mouse models have shown restoration of RDH12 activity and functional improvements,” said Professor Jean Bennett, MD, PhD, Opus Genetics Scientific Advisor and Board of Directors member.

About RDH12 Fund for Sight

The RDH12 Fund for Sight is a U.S.-based not-for-profit organization that aims to bring together families with common concerns and worries, collect and distribute information about the form of LCA caused by RDH12, and, most importantly, ensure that significant funds are devoted to the study and development of treatments for LCA caused by RDH12. More information is available at <http://rdh12.org>.

About Eyes on the Future

Eyes on the Future is a UK-based non-for-profit organization supporting research into rare diseases and eye diseases with specific focus on RDH12 inherited retinal dystrophies. Funded by Enrico and Silvia, whose 11-year-old child is affected by RDH12-LCA, Eyes on the Future is a registered Company limited by guarantee in England and Wales, No. 13956181 and a registered Charity No. 1198330. More information is available at www.eyesonthefuture.org.uk.

About Opus Genetics

Opus Genetics is a clinical-stage biopharmaceutical company developing gene and small molecule therapies for vision-threatening eye diseases. Opus’ pipeline features AAV-based gene therapies targeting inherited retinal diseases including 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. 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. Such statements include, but are not limited to, 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 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 hereof. 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.

Contacts:

Investors

Jenny Kobin
Remy Bernarda
IR Advisory Solutions
ir@opusgtx.com

Media

Kimberly Ha
KKH Advisors
917-291-5744
kimberly.ha@kkhadvisors.com

Source: Opus Genetics
