

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 4, 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, Suite 220  
Durham, NC  
(Address of principal executive offices)

27709  
(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

In January 2025, Opus Genetics, Inc. (the “**Company**”) received a Paragraph IV Certification Notice (the “**Notice Letter**”) from Winston & Strawn LLP, counsel to Sandoz Incorporated (“**Sandoz**”), providing notification to the Company that Sandoz has submitted an Abbreviated New Drug Application (“**ANDA**”) to the U.S. Food and Drug Administration (the “**FDA**”) seeking approval to manufacture, use or sell a generic version of RYZUMVI™ in the United States prior to the expiration of six patents listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (the “**Orange Book**”): U.S. Patent Nos. 9,795,560, 10,278,918, 10,772,829, 11,090,261, 11,844,858, and 11,400,077 (the “**Challenged Patents**”).

The Notice Letter alleges that the Challenged Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Sandoz’s ANDA. The Notice Letter does not challenge patent certification to the following RYZUMVI™ Orange Book patents: U.S. Patent Nos. 12,201,615 and 12,201,616 listed in the Orange Book.

In response to the ANDA filing, the Company or its commercial partner may choose to file a patent infringement lawsuit to defend the intellectual property rights associated with RYZUMVI™.

## Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including, without limitation, any statements related to the intention of the Company or its commercial partner to enforce their respective intellectual property rights. These forward-looking statements are based on current expectations and are not guarantees of future performance. These forward-looking statements relate to 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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 report. 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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**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: March 4, 2025

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

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