
**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 28, 2022

IVERIC bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36080
(Commission
File Number)

20-8185347
(IRS Employer
Identification No.)

8 Sylvan Way
Parsippany, NJ 07054
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(609) 474-6455**

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 (*see* General Instruction A.2. below):

- 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, \$0.001 par value per share	ISEE	The Nasdaq Global Select Market

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.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about the future expectations, plans and prospects of IVERIC bio, Inc. (the "Company") constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this Current Report on Form 8-K, the Company's forward-looking statements include statements about its expectations regarding the results and implications of the clinical data from its GATHER1 and GATHER2 trial of avacincaptad pegol in geographic atrophy, its development and regulatory strategy for avacincaptad pegol, including its plans to complete its submission of a new drug application to the U.S. Food and Drug Administration, its plans to use data from GATHER1 and GATHER2 to support treatment of geographic atrophy associated with earlier stage disease, including in patients with intermediate age-related macular degeneration, and the potential utility of ACP in treating geographic atrophy. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to expectations for regulatory matters, interpretation of clinical trial results by the scientific and medical community, developments from the Company's competitors and the marketplace for the Company's products, and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments may cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

Item 8.01 Other Events

The Company is providing the following business updates:

- The Company has submitted to the U.S. Food and Drug Administration ("FDA") the second part of its New Drug Application ("NDA") for avacincaptad pegol ("ACP") for the treatment of geographic atrophy ("GA") secondary to age-related macular degeneration ("AMD"). Consistent with the Company's agreement with the FDA for rolling NDA review, the Company previously submitted the first part of its NDA on November 3, 2022, which included the full ACP clinical data package from the GATHER1 and GATHER2 clinical trials. The recently submitted second part of the NDA included nonclinical data. The remaining, final part of the NDA will include chemistry, manufacturing and controls data. The Company remains on track to complete the submission of its NDA to the FDA by the end of 2022.
- Based on formal feedback received from the FDA, the Company intends to pursue further discussions with the FDA about utilizing the GATHER1 and GATHER2 clinical trial data included in the current NDA submission to support treatment of GA associated with earlier stage disease, including in patients with intermediate AMD ("iAMD"). As a result of these ongoing discussions, the Company does not believe it needs to conduct a new clinical trial of ACP in patients with iAMD.

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.

IVERIC bio, Inc.

Date: November 28, 2022

By: /s/ David F. Carroll
David F. Carroll
Senior Vice President, Chief Financial Officer and Treasurer