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 17, 2022

IVERIC bio, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36080**	**20-8185347**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 IVERIC bio, Inc. (the "Company")'s future expectations, plans and prospects 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 ACP in geographic atrophy, its development and regulatory strategy for ACP, including its plans to complete its submission of a new drug application to the U.S. Food and Drug Administration, the impact of FDA designations and the potential approvability and timelines for review of ACP, 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 Information

On November 17, 2022, the Company announced that it received from the U.S. Food and Drug Administration ("FDA") breakthrough therapy designation for avacincaptad pegol ("ACP", also known as Zimura®), its novel investigational complement C5 inhibitor, for the treatment of geographic atrophy ("GA") secondary to age-related macular degeneration ("AMD").

Breakthrough therapy designation is designed to accelerate the development and regulatory review of potential new medicines that are intended to treat a serious condition and address a significant unmet medical need. The new medicine needs to show preliminary clinical evidence that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, and in general, should show a clear advantage. The FDA will review the full data submitted to support approval of drugs designated as breakthrough therapies to determine whether the drugs are safe and effective for their intended use before they are approved for marketing.

The FDA's breakthrough therapy designation was based on the 12-month primary efficacy endpoint data from the Company's GATHER1 and GATHER2 clinical trials evaluating ACP for GA secondary to AMD. The Company believes that the FDA will assess the efficacy of ACP based on the 12-month primary efficacy endpoint data from GATHER1 and GATHER2; this belief is based on the Company's interactions with the FDA, including its pre-new drug application ("NDA") meeting.

The Company also expects priority review of the NDA; however, that determination will be made by the FDA after the filing of the application. The Company is on track to complete the submission of its NDA of ACP for the treatment of GA secondary to AMD to the FDA by the end of 2022.

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 17, 2022

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