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): April 4, 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.'s (the "Company") 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, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "future", "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 the Company's hypotheses underlying and the implications of the findings from a retrospective review of data from the Company's GATHER1 clinical trial, the Company's expectations to use the completed GATHER1 clinical trial and the ongoing GATHER2 clinical trial as pivotal trials for purposes of seeking regulatory approval for Zimura® (avacincaptad pegol) for the treatment of geographic atrophy, and the Company's expectations regarding and understanding of the utility and regulatory importance of fellow eye data from the GATHER1 clinical trial. 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, the initiation, progress and success of research and development programs and clinical trials, availability of data from these programs, developments from the Company's competitors, the scientific and medical community and the marketplace for the Company's products, expectations for regulatory matters 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.

Retrospective Review of Cases of Choroidal Neovascularization in the GATHER1 Trial: Exudative MNV vs. non-Exudative MNV

The Company, working with an independent reading center, recently completed a retrospective review of the cases of choroidal neovascularization ("CNV") in the Zimura® (avacincaptad pegol) 2 mg group (n=67) from GATHER1, the Company's first pivotal clinical trial evaluating the safety and efficacy of Zimura for the treatment of geographic atrophy ("GA") secondary to age-related macular degeneration ("AMD"). As previously reported, the incidence of investigator reported CNV in the study eye in the Zimura 2 mg group in the completed GATHER1 clinical trial was six (6) patients (9.0%) at 12 months and eight (8) patients (11.9%) at 18 months. GATHER2, the Company's second pivotal clinical trial evaluating the safety and efficacy of Zimura 2 mg for the treatment of GA remains ongoing, with topline data expected to be available during the second half of 2022.

The retrospective review was performed by the Center for Ocular Research and Evaluation (CORE) at Cole Eye Institute of the Cleveland Clinic (the "Reading Center"). As part of the retrospective review, the Reading Center read optical coherence tomography ("OCT") images for the eight (8) patients in the Zimura 2 mg group who developed CNV in the study eye. OCT is an ultra-high resolution imaging technology commonly used to visualize the retinal tissue. OCT is capable of rendering images in multiple dimensions and from multiple perspectives, including a cross-sectional view of the retina showing clearly defined layers of retinal tissue. OCT is the dominant imaging modality used by retinal specialists in the United States to diagnose, treat and follow patients with CNV.

OCT images were read to determine the number of CNV cases that were (1) macular neovascularization ("MNV") (versus peripapillary neovascularization, where the neovascularization is located around the optic nerve and not encroaching on the macula) and (2) exudative MNV (versus non-exudative MNV). The Reading Center classifies cases of MNV as exudative or non-exudative based on the following OCT criteria:

- Exudative MNV ("eMNV") is MNV that presents with new onset fluid in either the subretinal space or the intraretinal space. The subretinal space is the area on OCT between the retinal pigment epithelium ("RPE") and photoreceptor cells. The intraretinal space is the area on OCT containing the photoreceptors and other neurosensory cells of the retina.

- Non-exudative MNV ("neMNV") is neovascularization located in the macula but which does not present with new onset fluid in the subretinal or intraretinal spaces. In some cases, isolated fluid may be present in the sub-RPE space, which is the area between the RPE and Bruch's membrane, a layer of tissue directly beneath the RPE separating the RPE from the choroid. A case is also considered to be neMNV when the MNV may not be visible but both a double-layer sign and sub-RPE fluid are present. A double-layer sign is characterized by a shallow elevation of the RPE typically caused by the accumulation of fluid or debris in the sub-RPE space.

The table below summarizes the cases of eMNV and neMNV among GATHER1 patients with CNV in the Zimura 2 mg group at the 12-month and 18-month timepoints:

CNV cases among the Zimura 2 mg group (n=67) in the GATHER1 trial

Timepoint	eMNV (%)	neMNV (%)	Total CNV
Month 12	4 (6.0%)	2 (3.0%)	6 (9.0%)
Month 18	6 (9.0%)	2 (3.0%)	8 (11.9%)

The Reading Center also reviewed the baseline OCT images for all eight (8) patients looking for the presence of a double-layer sign at baseline. A study published in 2019 in the peer-reviewed journal *Ophthalmology Retina* found that the presence of a double-layer sign is correlated with the presence or development of neMNV in eyes with AMD, and clinical experience has shown that this type of neMNV often progresses to eMNV. Based on scientific literature and clinical understanding among the retinal community, the Company believes the presence of a double-layer sign on OCT is a useful biomarker to predict the future onset of cases of eMNV.

In this retrospective review, the Reading Center found that among the six (6) GATHER1 patients who developed eMNV over 18 months, five (5) of those patients had a double-layer sign at baseline. The Reading Center also found that neither of the two GATHER1 patients who had neMNV at the 12-month and 18-month timepoints had a double-layer sign at baseline.

For this retrospective review, OCT images were graded at the Reading Center by two masked, independent readers, with the gradings confirmed by two additional masked, independent senior readers. All OCT gradings for these patients were consistent among all readers. All of the readers remained masked to treatment condition throughout the review.

Comparison of Fellow Eye to Study Eye in the GATHER1 Trial

The Company does not plan to report data comparing the growth of GA area in the study eye to the growth of GA area in the fellow eye among patients in the GATHER1 trial. The study eye is the eye that received study drug or sham during the trial, while the fellow eye is the patient's other eye. In the GATHER1 trial, one of the key ophthalmic inclusion criteria was the presence of GA in the study eye located in whole or in part within 1500 microns of the fovea, the central portion of the macula, but which did not enter the foveal center point. These criteria did not apply to the fellow eye, and the Company has not collected measurements of the fellow eye that would enable it to determine which patients' fellow eyes would have met the study eye inclusion criteria. As the Company has previously discussed, it has been widely reported in scientific literature and observed in clinical trials that GA that is non-subfoveal (that has not impacted the foveal center), is positively correlated with a higher rate of GA area progression and growth as compared to GA that has reached the foveal center. For these reasons, the Company does not believe that a valid comparison between the growth of GA area in the study eye versus that in the fellow eye can be made for the GATHER1 trial.

In addition, in a joint endpoint workshop conducted among the U.S. Food and Drug Administration ("FDA"), the National Eye Institute, a division of the U.S. National Institutes of Health, and other participants, including several AMD imaging experts, in November 2016, the FDA expressed the view that it was not prepared to accept the use of the fellow eye as a comparator in clinical trials studying the progression of GA. A report summarizing the workshop was published in *Investigative Ophthalmology & Visual Science* in 2017. The Company is not aware that the FDA has changed its view regarding this matter.

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: April 4, 2022

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