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): September 6, 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. ☐

Item 8.01. Other Events.

On September 6, 2022, IVERIC bio, Inc. (the "Company") issued a press release announcing the top-line results of GATHER2, its Phase 3 clinical trial of Zimura® (avacincaptad pegol), the Company's complement protein C5 inhibitor, in patients with geographic atrophy ("GA"). A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company is providing the following additional and supportive data for the GATHER2 trial:

Baseline Characteristics

The Company collected baseline characteristics for all patients participating in the GATHER2 trial, which are presented below for each treatment group. These baseline characteristics include the ITT, or intent-to-treat, population, which includes all patients who were randomized in the trial and who received at least one dose of study drug in the relevant treatment group. For patients within each treatment group, where a numerical measurement was collected, the Company calculated the mean and standard deviation ("SD") for each measurement. SD is a statistical measure of the variability of a particular measurement within a patient population. Generally, two-thirds of all patients fall within approximately one SD, plus or minus, of the mean for any particular measurement. Based on these data, the Company believes that the baseline characteristics were generally balanced across the treatment groups.

	Treatment Group	
Baseline Characteristic	**Zimura 2 mg** (N = 225)	**Sham** (N = 222)
Mean age, years (SD)	76.3 (8.6)	76.7 (8.8)
Female gender, number (%)	154 (68.4%)	156 (70.3%)
Active smokers, number (%)	106 (47.1%)	107 (48.2%)
Caucasian race, number (%)	182 (80.9%)	186 (83.8%)
Iris color, number (%):		
Light	93 (41.3%)	109 (49.1%)
Medium	96 (42.7%)	79 (35.6%)
Dark	36 (16.0%)	34 (15.3%)
Mean intraocular pressure, mmHg (SD)	15.2 (2.5)	14.9 (2.6)
Non-subfoveal GA, number (%)	225 (100%)	222 (100%)
Multifocal GA, number (%)	178 (79.1%)	178 (80.2%)
GA size of greater than or equal to 4 disc areas, number (%)	54 (24.0%)	64 (28.8%)
Mean GA area, mm^2 (SD)	7.48 (4.01)	7.81 (3.89)
Mean Sq. Root of GA area, mm (SD)	2.641 (0.714)	2.707 (0.696)
Bilateral GA, number (%)	212 (94.0%)	210 (95.0%)
Mean BCVA, ETDRS letters (SD)	70.9 (8.9)	71.6 (9.4)
Mean LL BCVA, ETDRS letters (SD)	41.0 (19.7)	39.6 (19.6)
Patients with Hyperautofluorscence - Banded/Diffuse, number (%)	217 (96.4%)	218 (98.2%)
Height, cm (SD)	164.6 (10.6)	164.0 (9.4)
Weight, kg (SD)	75.9 (18.3)	75.0 (15.8)

Additional Safety Data

As the Company disclosed in its press release, in GATHER2, there were no events of endophthalmitis, no intraocular inflammation events, and no ischemic optic neuropathy events through month 12. The most frequently reported ocular adverse events were related to the injection procedure. The numbers below are based on investigator-reported adverse events occurring up through the month 12 time point for all patients.

The number of patients having treatment emergent adverse events ("TEAEs") organized by MedDRA system organ class, a standard method of reporting adverse events, for which there are two percent or greater of such TEAE among the patients in any treatment group, are set forth in the table below:

Patients with TEAEs in any Organ Class for which TEAE Comprises 2% or Greater of Patients in any Treatment Group

	Treatment Group	
Organ Class	**Zimura 2 mg** (N = 225)	**Sham** (N = 222)
Blood and lymphatic system disorders	4 (1.8%)	5 (2.3%)
Cardiac disorders	22 (9.8%)	16 (7.2%)
Ear and labyrinth disorders	1 (0.4%)	5 (2.3%)
Eye disorders	110 (48.9%)	84 (37.8%)
Gastrointestinal disorders	16 (7.1%)	13 (5.9%)
General disorders and administration site conditions	7 (3.1%)	10 (4.5%)
Infections and infestations	59 (26.2%)	58 (26.1%)
Injury, poisoning and procedural complications	36 (16.0%)	32 (14.4%)
Investigations	31 (13.8%)	10 (4.5%)
Metabolism and nutrition disorders	9 (4.0%)	8 (3.6%)
Musculoskeletal and connective tissue disorders	22 (9.8%)	24 (10.8%)
Benign, malignant and unspecified neoplasms (including cysts and polyps)	9 (4.0%)	16 (7.2%)
Nervous system disorders	14 (6.2%)	28 (12.6%)
Psychiatric disorders	6 (2.7%)	4 (1.8%)
Renal and urinary disorders	10 (4.4%)	5 (2.3%)
Respiratory, thoracic and mediastinal disorders	10 (4.4%)	8 (3.6%)
Skin and subcutaneous tissue disorders	8 (3.6%)	10 (4.5%)
Vascular disorders	14 (6.2%)	13 (5.9%)

The number of patients having ocular TEAEs in the study eye for which there are two percent or greater of such TEAE among the patients in any treatment group, are set forth in the table below:

Ocular TEAEs in any Organ Class in Study Eyes for which TEAE Comprises 2% or Greater of Patients in any Treatment Group

	Treatment Group	
Organ Class	**Zimura 2 mg** (N = 225)	**Sham** (N = 222)
Eye disorders	104 (46.2%)	80 (36.0%)
Infections and infestations	3 (1.3%)	5 (2.3%)
Injury, poisoning and procedural complications	5 (2.2%)	1 (0.5%)
Investigations	21 (9.3%)	2 (0.9%)

Discontinuation Rate At 12 Months

The number of patients who withdrew or otherwise discontinued from the GATHER2 trial during the first 12 months was 25 (11.1%) in the Zimura 2 mg group and 17 (7.7%) in the sham control group.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated September 6, 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: September 6, 2022

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

Iveric Bio Announces Positive Topline Data from Zimura GATHER2 Phase 3 Clinical Trial in Geographic Atrophy

- Primary Endpoint Met with 14.3% Reduction (p-value = 0.0064) in Mean Rate of Growth (Slope) in GA Area Over 12 Months Using Square Root Transformation; 17.7% Reduction (p-value = 0.0039) Using Observed GA Area -

- Statistically Significant Result with Favorable Safety Profile -

- Post-hoc Analysis of U.S. Patients: 25.5% Reduction (p-value = 0.0037) Using Square Root Transformation; 32.0% Reduction (p-value = 0.0033) Using Observed GA Area -

- Plan to Submit New Drug Application to the FDA by the End of the First Quarter 2023 -

- Conference Call and Webcast Today, September 6, 2022 at 8:00am ET -

Parsippany, New Jersey – September 6, 2022-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced positive topline results from GATHER2, the Company's second Phase 3 clinical trial of Zimura® (avacincaptad pegol), a novel investigational complement C5 inhibitor, for the treatment of geographic atrophy (GA). GATHER2 met its prespecified primary endpoint of mean rate of growth (slope) in GA area at 12 months with statistical significance and a favorable safety profile.

"We are thrilled to see for the first time an investigational therapy with a statistically significant reduction in the rate of GA progression at the 12-month primary endpoint across two Phase 3 clinical trials," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "The results from GATHER1 and GATHER2 and our Special Protocol Assessment with the FDA provide the basis for an NDA, which we are planning to submit by the end of first quarter of 2023. We look forward to engaging with the FDA throughout the review process. I want to thank the many patients, physicians and their staffs for their participation in the Zimura clinical program along with the employees of Iveric Bio for their dedication to achieve this important milestone."

Safety Overview

In GATHER2, there were no events of endophthalmitis, no intraocular inflammation events, and no ischemic optic neuropathy events through month 12. The most frequently reported ocular adverse events were related to the injection procedure.

The incidence of choroidal neovascularization (CNV) in the study eye through month 12 was 15 patients (6.7%) in the Zimura 2 mg group and 9 patients (4.1%) in the sham control group. Similar to GATHER1, the Company's first Phase 3 clinical trial of Zimura in GA, an independent masked reading center assessed the CNV cases in GATHER2 at the 12-month timepoint for exudative macular

neovascularization (eMNV) and non-exudative macular neovascularization (neMNV). The accompanying table summarizes this analysis:

Month 12	eMNV* (%)	neMNV* (%)	Peripapillary CNV	Total CNV
Zimura 2mg (N=225)	11 (4.9%)	1 (0.5%)	3 (1.3%)	15 (6.7%)
Sham (N=222)	7 (3.2%)	0	2 (0.9%)	9 (4.1%)

* Please reference the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on April 4, 2022 for the assessment criteria.

Efficacy Overview

The pre-specified primary endpoint, mean rate of growth (slope) in GA area over 12 months, was measured by fundus autofluorescence (FAF) based on readings at three time points (baseline, month 6, and month 12) and was calculated using the square root transformation of the GA area. The FAF images were assessed by an independent masked reading center. The Company also analyzed the mean rate of growth (slope) in GA area without square root transformation (observed GA area). Detailed data for the primary endpoint and observed GA analysis are shown in the accompanying table:

Mean Rate of Growth (Slope) in GA Area from Baseline to Month 12

MMRM Analysis (mixed model of repeated measures)	Zimura 2 mg (N = 225)	Sham (N = 222)	Difference	% Difference	P-Value
Mean Rate of GA Growth (Slope) (mm) (Square Root Transformation)	0.336	0.392	0.056	14.3%	0.0064[(a)]
Mean Rate of GA Growth (Slope) (mm^2) (Observed)	1.745	2.121	0.376	17.7%	0.0039[(b)]

[(a)] Pre-specified primary endpoint; statistically significant.
[(b)] Descriptive p-value.

The Company also analyzed the mean change in GA area from baseline to month 12 in GATHER2 using a point analysis, which was the pre-specified primary endpoint in GATHER1. This analysis was performed based on FAF readings at the same three time points as the primary efficacy analysis (baseline, month 6, and month 12) using the square root transformation and the observed GA area. The results for the 12-month point analysis were consistent with the slope analysis. Details are provided in the accompanying supplement.

"Geographic Atrophy is a devastating and life-altering disease that severely impacts my patients, limiting their ability to drive, read and see the faces of friends and family," stated Arshad M. Khanani, MD, MA, FASRS, Director of Clinical Research at Sierra Eye Associates, Reno, Nevada. "In addition to GATHER1, GATHER2 also meeting the primary efficacy endpoint is great news for patients suffering from geographic atrophy. Additionally, I am impressed with the safety profile of Zimura in both the GATHER1 and GATHER2 trials, as safety is critically important when evaluating potential treatment options."

As part of the pre-specified statistical analysis plan for GATHER2, the Company also analyzed the mean rate of growth (slope) in GA area for Zimura 2 mg as compared to sham for pre-specified patient subgroups based on baseline lesion size, baseline visual acuity, baseline autofluorescence pattern, age, and gender. Zimura 2 mg showed a reduction in the mean rate of growth (slope) in GA area for all analyzed subgroups.

The pre-specified supportive endpoints in GATHER2 included the mean change in best corrected visual acuity (BCVA) and the mean change in low luminance best corrected visual acuity (LL BCVA) from baseline to month 12. For BCVA, a favorable trend for Zimura 2 mg was observed consistent with GATHER1. For LL BCVA, a favorable trend was not observed.

Additional Efficacy Analysis

In a post-hoc analysis of GATHER2, the Company analyzed the reduction in mean rate of growth (slope) in GA area over 12 months for patients receiving Zimura by geographic region (U.S. versus rest of world). The reduction for patients receiving Zimura in the U.S. was 25.5% (descriptive p-value = 0.0037) using square root transformation and 32.0% (descriptive p-value = 0.0033) using observed GA area. Patients in the U.S., who accounted for 42.7% of enrolled patients, had a mean baseline lesion size that was 13% smaller than patients outside the U.S. The Company's preliminary hypothesis for regional variation is disease stage. The Company previously hypothesized that Zimura may be more impactful in earlier stages of GA, based on post-hoc analysis of the GATHER1 data. Consistent with this finding, patients in the U.S. in GATHER2 may have been recruited at an earlier stage of the disease as evidenced by the smaller baseline lesion size. The Company plans to continue to explore this hypothesis.

"We are delighted that both GATHER1 and GATHER2 have met their primary endpoint with statistical significance and a consistently favorable safety profile," said Pravin U. Dugel, MD, President of Iveric Bio. "We believe Zimura has the potential to benefit GA patients by altering the natural course of their disease. With our GATHER2 SPA agreement, we plan to submit our NDA as expeditiously as possible. Our highest priority now is to make Zimura available to physicians and their patients as soon as possible."

Attached to this press release is a supplement containing tables summarizing the 12-month efficacy and safety data from the GATHER1 and GATHER2 clinical trials. The Company plans to make additional supportive information regarding the GATHER2 topline results available in a Current Report on Form 8-K to be filed with the U.S. Securities and Exchange Commission.

GATHER2 results are scheduled for presentation at the *American Academy of Ophthalmology Annual Meeting (AAO 2022)* beginning on September 30, 2022 in Chicago, Illinois.

About Geographic Atrophy

Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in aging adults, affecting both eyes in the majority of patients. The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of retinal cells and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue. Geographic atrophy, the advanced stage of AMD, leads to further irreversible loss of vision in these patients. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy.

About Zimura

Zimura (avacincaptad pegol) is an investigational drug not approved in any country. Zimura is a novel complement C5 protein inhibitor. Overactivity of the complement system and the C5 protein are suspected to play a critical role in the development and growth of scarring and vision loss associated with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). By blocking the activity of C5, Zimura may decrease activity of the complement system that causes the degeneration of retinal cells and potentially slow the progression of GA.

About the GATHER Clinical Trials
The Company previously reported that Zimura met its primary endpoint in the completed international, randomized, double-masked, sham-controlled, multicenter GATHER1 clinical trial, in which 286 patients with GA were enrolled. In GATHER2, 448 participants were enrolled in the international, randomized, double-masked, sham-controlled, multicenter clinical trial to measure the efficacy and safety of monthly 2 mg intravitreal administration of Zimura in patients with GA. For the first 12 months, patients were randomized to receive either Zimura 2 mg or sham monthly. At 12 months, participants in the Zimura arm were re-randomized to either receive Zimura 2mg once monthly or every other month until month 23 of the study. The final evaluation will take place at month 24.

About Iveric Bio
Iveric Bio is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe and effective treatments designed to address debilitating retinal diseases including earlier stages of age-related macular degeneration. For more information on the Company, please visit www.ivericbio.com.

Iveric Bio Conference Call/Web Cast Information
Iveric Bio's management team will host a conference call/webcast today at 8:00 a.m. Eastern Time to discuss the positive Zimura GATHER2 data. To participate in the conference call, dial 1-888-317-6003 (USA) or 1-412-317-6061 (International), passcode 5213988. A live, listen-only audio webcast of the conference call can be accessed on the Investors section of the Iveric Bio website at www.ivericbio.com. A replay will be available approximately two hours following the live call for two weeks. The replay number is 1-877-344-7529 (USA Toll Free), passcode 5014160.

Forward-looking Statements

Any statements in this press release about 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 press release, the Company's forward looking statements include statements about its expectations regarding the robustness and clinical relevance of the clinical data from its GATHER1 and GATHER2 trials of Zimura in geographic atrophy, its development and regulatory strategy for Zimura, including its ability to use the data from the GATHER1 and GATHER2 clinical trials for purposes of seeking regulatory approval of Zimura for geographic atrophy and its plans to submit a new drug application to the U.S. Food and Drug Administration, its hypotheses regarding exploratory post-hoc analyses of the GATHER1 and GATHER2 results and the potential impact of Zimura on earlier stages of disease, and the potential utility of Zimura 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 press release. 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.

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SUPPLEMENT

GATHER1 and GATHER2 12-Month Results

The accompanying tables contain the 12-month results for GATHER1 (Zimura 2 mg group as compared to its sham group) and GATHER2 (Zimura 2 mg group as compared to sham).

Efficacy Results

The efficacy results presented provide both (A) the mean rate of change in GA area from baseline to month 12 using a point analysis and (B) the mean rate of growth (slope) in GA area over 12 months. These results are provided using both the square-root transformation and the observed GA areas.

GATHER1

MMRM Analysis	Zimura 2 mg (N = 67)	Sham (N = 110)	Difference	% Difference	P-Value
Sq. Rt. Transformation					
Mean Change in GA Area (mm)	0.292	0.402	0.110	27.4%	0.0072[a]
Mean Rate of GA Growth (Slope) (mm)	0.283	0.392	0.109	27.7%	0.0063[b]
Observed Area					
Mean Change in GA Area (mm^2)	1.592	2.290	0.697	30.5%	0.0059[b]
Mean Rate of GA Growth (Slope) (mm^2)	1.221	1.889	0.668	35.4%	0.0050[b]

The estimates for the GATHER1 Zimura 2 mg group vs. sham are from the MMRM model, drawing on all available data, including data from groups with different randomization ratios in Part 1 and Part 2 of the trial, and should not be interpreted as directly observed data.

GATHER2

MMRM Analysis	Zimura 2 mg (N = 225)	Sham (N = 222)	Difference	% Difference	P-Value
Sq. Rt. Transformation					
Mean Change in GA Area (mm)	0.333	0.392	0.059	15.0%[c]	0.0056[b]
Mean Rate of GA Growth (Slope) (mm)	0.336	0.392	0.056	14.3%	0.0064[a]
Observed Area					
Mean Change in GA Area (mm^2)	1.936	2.341	0.405	17.3%	0.0027[b]
Mean Rate of GA Growth (Slope) (mm^2)	1.745	2.121	0.376	17.7%	0.0039[b]

Explanatory notes - in the above presentation:

[a] Indicates pre-specified primary endpoint; statistically significant;
[b] Indicates descriptive p-value; and
[c] The reduction at 6 months for patients receiving Zimura was 14.1% (descriptive p-value = 0.0293).

Safety Results

The safety results presented provide data for the following adverse events of interest in the study eye: (1) endophthalmitis, (2) intraocular inflammation events, (3) ischemic optic neuropathy events, and (4) choroidal neovascularization cases (eMNV, neMNV, peripapillary CNV and total CNV), in each case, through month 12. Please reference the Company's Form 8-K filed with the U.S. Securities and Exchange Commission on April 4, 2022 for the CNV assessment criteria.

Reported Adverse Events of Interest

	Endophthalmitis	Intraocular Inflammation	Ischemic Optic Neuropathy
GATHER1			
Zimura 2 mg (N=67)	0	1*	0
Sham (N = 110)	0	0	0
GATHER2			
Zimura 2mg (N=225)	0	0	0
Sham (N=222)	0	0	0

* Transient and mild; reported as related to injection procedure.

Reported Choroidal Neovascularization Cases

	eMNV (%)	neMNV (%)	Peripapillary CNV (%)	Total CNV (%)
GATHER1				
Zimura 2 mg (N=67)	4 (6.0%)	2 (3.0%)	0	6 (9.0%)
Sham (N = 110)	*	*	*	3 (2.7%)
GATHER2				
Zimura 2mg (N=225)	11 (4.9%)	1 (0.5%)	3 (1.3%)	15 (6.7%)
Sham (N=222)	7 (3.2%)	0	2 (0.9%)	9 (4.1%)

* Not available.