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 7, 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”) announced top-line results of GATHER2, its second Phase 3 clinical trial of Zimura® (avacincaptad pegol), the Company’s complement protein C5 inhibitor, in patients with geographic atrophy ("GA").

The Company is providing the following additional supplemental data regarding reported safety events in the GATHER2 trial:

Among the eye disorder ocular treatment emergent adverse events ("TEAEs") reported in GATHER2 (104 cases in Zimura 2 mg (46.2%); 80 cases in sham (36.0%)), two of the TEAEs were reported as serious in the Zimura 2 mg group, as compared to three TEAEs in the sham group. In the Zimura 2 mg group, both serious TEAEs were cases of choroidal neovascularization ("CNV"), the overall incidence of which was previously reported with the GATHER2 top-line results. In the sham group, one serious TEAE was a CNV case, one was a case of visual acuity reduced and one was a case of visual acuity reduced transiently.

Among the ocular cases of injury, poisoning and procedural complications reported in GATHER2 (5 cases in Zimura 2 mg (2.2%); 1 case in sham (0.5%)), all were procedural complications of intravitreal injection or sham administration. None of these cases were serious.

All 23 ocular investigation cases reported in GATHER2 (21 cases in Zimura 2 mg (9.3%); 2 cases in sham (0.9%)) were cases of increased intraocular pressure ("IOP"). None of these cases were serious. Of the 21 cases in the Zimura 2 mg group, 20 of them were transient in nature; of the 20 transient cases, 19 of them resolved the same day. The single non-transient case in the Zimura 2 mg group was for a patient with glaucoma at baseline. The increased incidence of increased IOP is expected for an intravitreal injection as compared to a sham procedure. Patients in the sham group had a barrel of a syringe placed against the eye to simulate the pressure of an injection but no needle penetrates the eye.

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.

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 7, 2022

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