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): July 12, 2021

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.)

Five Penn Plaza, Suite 2372
New York, NY 10001
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(212) 845-8200**

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

This Current Report on Form 8-K contains forward-looking statements of IVERIC bio, Inc. (the "Company"). Any statements in this Form 8-K 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," "future", "may", "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this Form 8-K, the Company's forward looking statements include statements about the timing, progress and results of clinical trials, including expectations regarding patient enrollment in and the availability of top-line data from GATHER2 and the initiation of a Phase 1/2 clinical trial of IC-200 for autosomal recessive bestrophinopathy, and other research and development activities and expectations regarding human capital. 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 the progression and duration of the COVID-19 pandemic and responsive measures thereto and related effects on the Company's research and development programs, operations and financial position, the initiation and the progress of research and development programs and clinical trials, including enrollment and retention in clinical trials, availability of data from these programs, expectations for regulatory matters, reliance on clinical trial sites, contract research organizations and other third parties, need for additional financing and negotiation and consummation of business development transactions 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 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 updates relating to its business:

GATHER2 Enrollment

The Company is expecting to enroll approximately 440 patients in GATHER2, its ongoing Phase 3 clinical trial evaluating Zimura® (avacincaptad pegol) for the treatment of geographic atrophy secondary to age-related macular degeneration, and it expects to complete patient enrollment during the week beginning July 19, 2021. The Company expects top-line data from GATHER2 to become available during the second half of 2022, approximately one year after the enrollment of the last patient plus the time needed for database lock and analysis.

IC-200

The Company has completed a preclinical toxicology study of IC-200, the Company's gene therapy product candidate for *BEST1*-related inherited retinal diseases, in a naturally occurring canine disease model of Best disease. Subject to regulatory review, the Company plans to initiate a Phase 1/2 clinical trial of IC-200 during the fourth quarter of 2021. The first IC-200 clinical trial will focus on patients with the autosomal recessive form of the disease, autosomal recessive bestrophinopathy.

IC-100

As previously disclosed, the Company was planning to discuss with the U.S. Food and Drug Administration, or FDA, the results from its toxicology studies of IC-100, the Company's gene therapy product candidate for rhodopsin-mediated autosomal dominant retinitis pigmentosa, and the design of its first-in-human clinical trial, before submitting an investigational new drug application, or IND. The FDA advised, in lieu of this meeting, additional discussion should be conducted during the 30-day IND review period following IND submission. The Company is considering its development options for this product candidate.

Massachusetts Lab Space and Minigene Programs

The Company recently hired four individuals who were previously at the University of Massachusetts Medical School, UMMS, including the principal investigator for the Company's miniCEP290, miniABCA4 and miniUSH2A sponsored research programs at UMMS. The Company is working to transition the research and preclinical development activities for these programs from UMMS to the Company. The Company is also preparing to establish laboratory space for these employees to continue working on these programs and other preclinical research and development activities for the Company.

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: July 12, 2021

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