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 9, 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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2021, IVERIC bio, Inc. (the "Company") announced its financial results for the three months and nine months ended September 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Items 2.02 and 9.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated November 9, 2021

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 9, 2021

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

Iveric Bio Reports Third Quarter 2021 Operational Highlights and Financial Results

– Zimura® GATHER2 Enrollment Complete; Retention Exceeding Expectations, with Injection Fidelity Rate Target of Greater than 90% -

- Preparations of a New Drug Application (NDA) and Building Commercial Infrastructure are Underway for a Potential Launch of Zimura for the Treatment of Geographic Atrophy Secondary to Age-Related Macular Degeneration –

– FDA Agreement Under Special Protocol Assessment (SPA) Received for GATHER2 Phase 3 Clinical Trial of Zimura in Geographic Atrophy Secondary to Age-Related Macular Degeneration –

– Zimura Phase 3 Clinical Trial for Intermediate AMD to Initiate in 2022 –

- Conference Call and Webcast Today, November 9, 2021, at 8:00 a.m. ET -

NEW YORK, NY, Nov. 9, 2021 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the quarter ended September 30, 2021 and provided a general business update.

“2021 has been a pivotal year for Iveric Bio as we set in motion our plans to accelerate the opportunity for Zimura to be first-in-class and best-in-class for the treatment of geographic atrophy secondary to age-related macular degeneration,” stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. “With recruitment complete, the main priorities for us today are the retention of patients in GATHER2, our second Phase 3 clinical trial of Zimura for geographic atrophy secondary to age-related macular degeneration, and preparation for the potential U.S. commercialization of Zimura in GA secondary to AMD. If approved, we believe Zimura can make a profound impact in treating this debilitating retinal disease.”

“The patient retention rate in GATHER2 is exceeding our expectations and is on track to achieve a 12-month injection fidelity rate of greater than 90%. In parallel, preparations of a New Drug Application and building a commercial infrastructure are well underway for a potential launch of Zimura in GA secondary to AMD,” stated Pravin U. Dugel, President of Iveric Bio. “As we look to 2022, we expect to receive GATHER2 topline data in the second half of the year. We are also accelerating the development plan for Zimura in patients with intermediate AMD, a stage prior to the occurrence of GA, with plans to initiate a Phase 3 clinical trial in 2022 and invest in additional lifecycle initiatives such as sustained release delivery technologies for Zimura. We believe we have the opportunity to become the leader in the development and commercialization of safe and effective treatments for all stages of AMD.”

Therapeutics Programs Targeting Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- ***GATHER2 Enrollment, Retention, and Injection Fidelity Rate***
  On July 26, 2021, the Company announced the completion of enrollment in GATHER2, four months ahead of the Company's original schedule. Based on this timeline, the Company expects topline GATHER2 data to be available in the second half of 2022, approximately one year after the enrollment of the last patient plus the time needed for database lock and analysis. Patient retention for the trial, as measured by the injection fidelity rate, continues to exceed the Company's expectations. The Company is targeting an injection fidelity rate for the GATHER2 trial, as measured through month 12, of greater than 90%. Injection fidelity is calculated by dividing the total number of actual injections (drug and sham) by the total number of expected injections (drug and sham). The Company considers injection fidelity to be the most important and stringent measure of patient retention because it reflects the timely administration of the drug or sham into the patient's eye.

- ***New Drug Application (NDA) and Commercial Infrastructure***
  Preparations of an NDA and building a commercial infrastructure are underway for a potential launch of Zimura for the treatment of GA secondary to AMD, if approved. In August 2021, Iveric Bio welcomed Christopher Simms as Senior Vice President and Chief Commercial Officer and the hiring of the commercial leadership team has begun. Mr. Simms is an accomplished healthcare leader with more than 20 years of diverse commercial leadership experience at Johnson & Johnson, Genentech, and Novartis, including focused experience in retina, ophthalmology, and optometry.

- ***Special Protocol Assessment (SPA) for GATHER2***
  The Company announced on July 6, 2021 that it received a formal agreement from the U.S. FDA under a SPA for the overall design of GATHER2, the Company's second pivotal clinical trial of Zimura in development for the treatment of GA secondary to AMD. The agreement further solidifies the Company's plans to file an application with the FDA for marketing approval of Zimura for GA secondary to AMD, if the ongoing GATHER2 clinical trial meets its primary endpoint at 12 months. Zimura met its pre-specified primary efficacy endpoint at 12 months with statistical significance in the previously completed GATHER1 pivotal clinical trial.

  In parallel discussions with those for the GATHER2 SPA, the FDA indicated to the Company that, as part of a future NDA submission for Zimura, the GATHER1 results will be considered using the original prespecified primary efficacy endpoint analysis, together with a post-hoc analysis using the same FDA preferred method that will be used for the GATHER2 trial (mean rate of growth (slope) estimated based on GA area measured by fundus autofluorescence (FAF) in the relevant timepoints). The GATHER 1 results, when analyzed using the FDA preferred analysis, are highly consistent with and strongly supportive of the results from the original prespecified analysis.

- ***Intermediate AMD***
  Following a GATHER1 post-hoc analysis in earlier stages of AMD, the Company expects to initiate an intermediate AMD clinical trial in 2022. The Company expects the intermediate AMD trial to be a Phase 3 international, randomized, double-masked, sham-controlled, multi-center trial with approximately 200 patients per treatment group. The Company expects to treat and follow all patients for 24 months. The Company expects data from this trial, if positive, together with other supportive data, may be sufficient to file a supplemental new drug application with the U.S. FDA and supplemental marketing authorization application with the European Medicines Agency.

- ***Autosomal Recessive Stargardt Disease (STGD1)***
  Patient enrollment in the Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease, referred to as the STAR trial, is ongoing with the goal of enrolling approximately 25 additional patients, for a total of approximately 120 patients. The results of this study are expected after the topline results of GATHER2.

IC-500: HtrA1 (high temperature requirement A serine peptidase 1 protein) Inhibitor

- The Company initiated a number of preclinical tolerability and pharmacokinetic and target engagement studies for IC-500 and is planning additional preclinical studies. The Company expects to submit an investigational new drug application (IND) to the FDA for IC-500 in GA secondary to AMD in the second half of 2022.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- ***IC-100: Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP) and IC-200: BEST1-Related IRDs***
  With the Company focusing its efforts and resources on the development and potential commercialization of Zimura, the Company has been considering the development options for IC-100 and IC-200 and plans to seek collaboration or out-licensing opportunities for further development and potential commercialization of IC-100 and IC-200.

- ***Minigene Research Programs***
  The Company is transitioning the Stargardt Disease (ABCA4) and USH2A minigene research programs from the University of Massachusetts Medical School to the Company with plans to continue these programs internally. The Company has identified a lead construct for its Leber Congenital Amaurosis Type 10 (LCA10) miniCEP290 program and is considering development options for this program.

Third Quarter Financial Results and 2021 Cash Guidance

- As of September 30, 2021, the Company had $242.0 million in cash, cash equivalents and marketable securities.

- In October 2021, the Company raised approximately $162.6 million in net proceeds in an underwritten public offering of common stock. The Company now estimates its year-end 2021 cash, cash equivalents and available for sale securities to range between $375 million and $385 million. The Company also estimates that its cash, cash equivalents and available for sale securities will be sufficient to fund its planned capital expenditure requirements and operating expenses through at least mid-2024. These estimates are based on the Company's current business plan, including the continuation of its ongoing clinical development programs for Zimura in GA and STGD1 and the initiation of an intermediate AMD clinical trial, preparation and potential filing of a new drug application and a marketing authorization application for Zimura in GA secondary to AMD, continuing preparations for potential commercial launch of Zimura in GA secondary to AMD, investing in sustained release delivery technologies for Zimura, and the advancement of its IC-500 development program. Excluded from these estimates are any potential approval or sales milestones payable to Archemix Corp. or any potential expenses for actual commercial launch of Zimura, such as associated sales force expenses, any additional expenditures related to potentially studying Zimura in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue.

2021 Q3 Financial Highlights

- **R&D Expenses**: Research and development expenses were $17.9 million for the quarter ended September 30, 2021, compared to $18.8 million for the same period in 2020. For the nine months ended September 30, 2021, research and development expenses were $60.0 million compared to $45.3 million for the same period in 2020. Research and development expenses increased year over year primarily due to the ongoing progress of the GATHER2 clinical trial, increased manufacturing activities for Zimura and increases in additional research and development staffing.

- **G&A Expenses:** General and administrative expenses were $6.6 million for the quarter ended September 30, 2021 and for the same period in 2020. For the nine months ended September 30, 2021, general and administrative expenses were $21.7 million compared to $17.9 million for the

same period in 2020. General and administrative expenses increased year over year primarily due to an increase in personnel costs, an increase in share-based compensation and an increase in professional service and consulting fees.

- **Income Tax Benefit**: The Company recorded no income tax benefit for the three months ended September 30, 2021 and 2020 and the nine months ended September 30, 2021. The Company recognized an income tax benefit of $3.7 million for the nine months ended September 30, 2020 to reflect a favorable settlement of a state corporate income tax audit.

- **Net Loss**: The Company reported a net loss for the quarter ended September 30, 2021 of $24.6 million, or ($0.23) per diluted share, compared to a net loss of $25.5 million, or $(0.27) per diluted share, for the same period in 2020. For the nine months ended September 30, 2021, the Company reported a net loss of $81.5 million or ($0.84) per diluted share, compared to a net loss of $59.1 million or ($0.87) for the same period in 2020.

Conference Call/Web Cast Information

Iveric Bio will host a conference call/webcast to discuss the Company's financial and operating results and provide a business update. The call is scheduled for November 9, 2021 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 1-888-317-6003 (USA) or 1-412-317-6061 (International), passcode 0259351. 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) or 1-412-317-0088, passcode 10161071.

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 retina diseases including all stages of age-related macular degeneration.

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 availability of topline data from and patient retention in its second Phase 3 trial (GATHER2) of Zimura in geographic atrophy secondary to AMD, its ability to use its completed clinical trial of Zimura for the treatment of geographic atrophy secondary to AMD (GATHER1) as a Phase 3 trial for purposes of seeking regulatory approval, its development and regulatory strategy for Zimura and its other product candidates, including its plans to submit a new drug application to the U.S. Food and Drug Administration and a marketing authorization application to the European Medicines Agency for Zimura if the results from GATHER2 are positive, and its plans for additional indications, such as intermediate AMD, that the Company may pursue for the development of Zimura, its ability to obtain the first marketing approval for the treatment of geographic atrophy and its expectations regarding the market dynamics for the treatment of geographic atrophy and other commercial matters, the implementation of its business and hiring plan, its projected use of cash, cash equivalents and available for sale securities and the sufficiency of its cash resources, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, the potential utility of its product candidates, the clinical meaningfulness of clinical trial results, statements regarding the potential for the Company's business development strategy and its personnel and human capital resources. 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, expectations for regulatory matters, 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, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, establishment of manufacturing capabilities, developments from the Company's competitors and the marketplace for the Company's products, human capital matters, 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 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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IVERIC bio, Inc.
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 17,935	$ 18,841	$ 59,972	$ 45,311
General and administrative	6,648	6,643	21,688	17,930
Total operating expenses	24,583	25,484	81,660	63,241
Loss from operations	(24,583)	(25,484)	(81,660)	(63,241)
Interest income	42	33	184	437
Other income (expense), net	(10)	1	(13)	(6)
Loss before income tax benefit	(24,551)	(25,450)	(81,489)	(62,810)
Income tax benefit	—	—	—	3,695
Net loss	$ (24,551)	$ (25,450)	$ (81,489)	$ (59,115)
Net loss per common share:				
Basic and diluted	$ (0.23)	$ (0.27)	$ (0.84)	$ (0.87)
Weighted average common shares outstanding:				
Basic and diluted	105,217	92,675	97,370	67,931

	September 30, 2021	December 31, 2020
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 241,970	$ 210,047
Total assets	$ 247,790	$ 216,754
Total liabilities	$ 21,304	$ 25,191
Additional paid-in capital	$ 872,955	$ 756,543
Accumulated deficit	$ (646,562)	$ (565,073)
Total stockholders' equity	$ 226,486	$ 191,563