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): March 1, 2023

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) 474-6755**

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 March 1, 2023, IVERIC bio, Inc. (the "Company") announced its financial results for the three months and full year ended December 31, 2022. 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 March 1, 2023

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: March 1, 2023

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

Iveric Bio Reports Fourth Quarter and Full Year 2022 Operational Highlights and Financial Results

- FDA Accepts Filing of New Drug Application and Grants Priority Review for Avacincaptad Pegol (ACP) for the Treatment of Geographic Atrophy; PDUFA Goal Date is August 19, 2023 -

- Post-hoc Time-to-Event Analysis of ACP GATHER Trials Signals up to 59% Risk Reduction in Rate of Vision Loss Compared to Sham at 12 Months –

- Commercial Launch Preparations for ACP Continue to Accelerate –

- Conference Call and Webcast Today, March 1, 2023, at 8:00 a.m. ET -

PARSIPPANY, N.J. – March 1, 2023 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the fourth quarter and full year ended December 31, 2022 and provided a general business update.

"In 2022, we successfully delivered a banner year with avacincaptad pegol (ACP) achieving a statistically significant reduction in the rate of geographic atrophy (GA) progression at the 12-month pre-specified primary endpoint across two Phase 3 clinical trials," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We are excited to begin 2023 with the FDA's acceptance of the filing of our new drug application (NDA) and granting of priority review for ACP for the treatment of GA secondary to age-related macular degeneration (AMD). With the achievement of these important milestones, we move closer to our goal of providing patients with a treatment for GA, a devastating disease that leads to irreversible blindness."

"We are also excited about the new post-hoc analysis highlighting the potential signal of ACP reducing the rate of vision loss by slowing progression of GA at 12 months of treatment," stated Pravin U. Dugel, MD, President of Iveric Bio. "Our commercial leadership team brings extensive experience in launching drugs for retinal diseases with large market potential. We continue to accelerate our commercial plans and expect to have the full U.S. commercial team, including a field based sales force, hired by early April. We believe that we are well-positioned to become a leader in the development and commercialization of treatments for retinal diseases and to create long-term value for our shareholders."

Avacincaptad pegol (ACP): Complement C5 Inhibitor

- In February 2023, the Company announced that the FDA accepted for filing the Company's NDA for ACP for the treatment of GA secondary to AMD. The NDA has been granted priority review with a Prescription Drug User Fee Act (PDUFA) goal date of August 19, 2023. The Company also announced that, at the time of the FDA's acceptance letter, the FDA had not identified any potential review issues and the FDA was not currently planning to hold an Advisory Committee meeting for ACP.

- The Company announced today a post-hoc analysis from the ACP GATHER1 and GATHER2 clinical trials signaling up to a 59% reduction in the rate of vision loss for ACP 2 mg compared to sham at 12 months of treatment. Vision loss is defined as a loss of ≥ 15 letters (EDTRS) in Best Corrected Visual Acuity (BCVA) from baseline measured at two consecutive visits up to month 12. This time to event analysis will be presented at the Association for Research in Vision and Ophthalmology's annual meeting from April 23-27, 2023.

- In November 2022, the Company announced the FDA granted Breakthrough Therapy designation (BTD) for ACP for the treatment of GA secondary to AMD. To date, ACP is the first and only investigational therapy to receive BTD status for this indication, which was granted based on the 12-month results from GATHER1 and GATHER2.

- The Company intends to pursue further discussions with the FDA about utilizing the GATHER1 and GATHER2 clinical trial data included in the current NDA submission to support treatment of GA associated with earlier stage disease, including in patients with intermediate AMD (iAMD). The Company does not believe it needs to conduct a new clinical trial of ACP in patients with iAMD.

- The Company plans to submit marketing authorization applications (MAAs) to the European Medicines Agency (EMA) and the UK Medicines and Healthcare Regulatory Agency (MHRA) in 2023, subject to feedback from planned interactions with regulatory authorities in Europe, which the Company expects to have during the first half of 2023. The Company is planning to explore collaboration opportunities for the further development and potential commercialization of ACP outside the United States.

- The Company initiated an open-label extension (OLE) study for patients who completed their month 24 visits in the GATHER2 trial, with the aim of providing patients longer-term access to ACP and collecting additional safety data.

- Patient enrollment in STAR, the Company's Phase 2b screening clinical trial of ACP for the treatment of autosomal recessive Stargardt disease (STGD1), is ongoing.

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

- The Company is developing IC-500, its HtrA1 inhibitor product candidate, for GA and potentially other age-related retinal diseases. The Company is conducting additional preclinical studies to optimize formulation, dosage and delivery of IC-500 and planning for IND-enabling toxicology studies. The Company expects to submit an investigational new drug application (IND) to the FDA in the first half of 2024.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- The Company is continuing to advance its minigene programs for Leber's Congenital Amaurosis type 10 (CEP290), autosomal recessive Stargardt Disease (ABCA4) and Usher's Syndrome type 2A (USH2A).

- As part of the Company's previously stated strategy, in December 2022 the Company entered into an asset purchase agreement with Opus Genetics Inc. (Opus), pursuant to which Opus acquired all of the Company's rights to IC-100, the Company's former preclinical product candidate for Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa, and IC-200, the Company's former preclinical product candidate for BEST1-Related IRDs.

Corporate Update

- In December 2022, the Company raised approximately $324.3 million in net proceeds in an underwritten public offering of common stock.

- In late December 2022, the Company's Board of Directors (the Board) elected Pravin U. Dugel, MD, President of Iveric Bio, to the Board, effective as of January 1, 2023. Dr. Dugel has been instrumental in helping to shape the Company's business strategy and in overseeing the development and regulatory strategy for ACP since he joined the Company in 2020.

Fourth Quarter and Year Ended 2022 Financial Results

- As of December 31, 2022, the Company had approximately $646.8 million in cash, cash equivalents and available-for-sale securities. The Company estimates that its cash, cash equivalents, available-for-sale securities and committed loan facilities will be sufficient to fund its planned capital expenditure requirements, debt service obligations and operating expenses for at least the next 12 months. This estimate does not include any potential new borrowings under its term loan facility with Hercules Capital and Silicon Valley Bank, beyond the $25.0 million that the Company plans to borrow during 2023 based on its achievement of the performance milestone related to the FDA's acceptance of its NDA for filing.

2022 Q4 Financial Highlights

- **R&D Expenses**: Research and development expenses were $35.8 million for the quarter ended December 31, 2022, compared to $25.1 million for the same period in 2021. For the year ended December 31, 2022, research and development expenses were $117.0 million compared to $85.1 million for the same period in 2021. Research and development expenses increased primarily due to the continued progress of the Company's GATHER2 trial, increased manufacturing activities for ACP, and increases in personnel costs associated with additional research and development staffing, including share-based compensation, offset by decreases in costs associated with the Company's gene therapy programs.

- **G&A Expenses**: General and administrative expenses were $27.1 million for the quarter ended December 31, 2022 compared to $8.0 million for the same period in 2021. For the year ended December 31, 2022, general and administrative expenses were $72.9 million, compared to $29.7 million for the same period in 2021. General and administrative expenses increased year over year primarily due to increases in commercial preparation expenses for ACP and costs associated with additional staffing for commercial preparation, including share-based compensation.

- **Net Loss**: The Company reported a net loss for the quarter ended December 31, 2022, of $59.1 million, or ($0.47) per diluted share, compared to a net loss of $33.0 million, or ($0.29) per diluted share, for the same period in 2021. For the year ended December 31, 2022, the Company reported a net loss of $185.2 million or ($1.53) per diluted share, compared to a net loss of $114.5 million or ($1.12) for the same period in 2021.

Conference Call/Webcast 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 March 1, 2023, 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 1375589. 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 4132187.

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.

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 regulatory pathway for and potential approval of ACP for the treatment of GA secondary to AMD, including its plans to submit MAAs to the European Medicines Agency and the UK Medicines and Healthcare Products Agency, statements regarding the Company's commercial plans and strategy for ACP, the clinical relevance of the clinical data from its GATHER1 and GATHER2 trials of ACP in GA, including from post-hoc analyses that it conducted, its development and regulatory strategy for ACP and its other product candidates, including its plans for the use of ACP in treating patients with intermediate AMD, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, the potential safety and efficacy and commercial potential of its product candidates, its projected use of cash, cash equivalents, marketable securities

and its committed loan facilities and the sufficiency of its cash resources, and statements regarding the Company's business development and hiring plans. 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, expectations for regulatory matters, interpretation of clinical trial results by the scientific and medical community, the initiation, progress and success of research and development programs and clinical trials, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, developments from the Company's competitors and the marketplace for the Company's products, need for and availability of additional financing, negotiation and consummation of business development transactions, the hiring of personnel 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 December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 35,841	$ 25,096	$ 117,012	$ 85,068
General and administrative	27,130	8,001	72,894	29,689
Total operating expenses	62,971	33,097	189,906	114,757
Loss from operations	(62,971)	(33,097)	(189,906)	(114,757)
Interest income, net	1,449	61	2,264	245
Gain on sale of IC100 & IC200	2,369	—	2,369	—
Other income (expense), net	92	3	62	(10)
Loss before income tax benefit	(59,061)	(33,033)	(185,211)	(114,522)
Income tax benefit	—	—	—	—
Net loss	$ (59,061)	$ (33,033)	$ (185,211)	$ (114,522)
Net loss per common share:				
Basic and diluted	$ (0.47)	$ (0.29)	$ (1.53)	$ (1.12)
Weighted average common shares outstanding:				
Basic and diluted	125,367	115,073	121,037	101,866

	December 31, 2022	December 31, 2021
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 646,835	$ 381,749
Total assets	$ 666,823	$ 389,358
Term loan, net	$ 96,568	$ —
Total liabilities	$ 132,166	$ 28,830
Additional paid-in capital	$ 1,399,555	$ 1,040,098
Accumulated deficit	$ (864,806)	$ (679,595)
Total stockholders' equity	$ 534,657	$ 360,528