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 26, 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 1.01 Entry into a Material Definitive Agreement.

On July 26, 2022 (the "Closing Date"), IVERIC bio, Inc. (the "Company") and certain of its subsidiaries (the "Subsidiary Borrowers) entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules"), in its capacity as administrative agent and collateral agent (the "Agent") and as a lender, Silicon Valley Bank ("SVB") and certain other financial institutions that from time to time become parties to the Loan Agreement as lenders (collectively, the "Lenders"). The Loan Agreement provides for term loans in an aggregate principal amount of up to $250.0 million under multiple tranches (the "2022 Term Loan Facility"), available as follows: (i) a term loan advance in the amount of $50.0 million on the Closing Date; (ii) subject to the Company's announcement that GATHER2, the Company's Phase 3 clinical trial evaluating the safety and efficacy of Zimura® (avacincaptad pegol) for the treatment of Geographic Atrophy ("GA") secondary to age-related macular degeneration, has achieved its protocol-specified primary endpoint and that the Company has a sufficient clinical data package to support the submission of a new drug application ("NDA") to the United States Food and Drug Administration (the "FDA") for Zimura in GA ("Milestone 1"), a second tranche consisting of term loan advances in the aggregate principal amount of $50.0 million available at the Company's option beginning on the date that Milestone 1 is achieved through December 15, 2022; (iii) subject to the Company's submission of an NDA to the FDA for Zimura in GA and the FDA accepting such NDA for review ("Milestone 2"), a third tranche consisting of term loan advances in the aggregate principal amount of $25.0 million available at the Company's option beginning on the date that Milestone 2 is achieved through September 30, 2023; (iv) subject to FDA approval of Zimura in GA with a label generally consistent with that sought in the Company's NDA ("Milestone 3"), a fourth tranche consisting of term loan advances in the aggregate principal amount of $75.0 million available at the Company's option beginning on the date that Milestone 3 is achieved and continuing through the earlier of (x) September 30, 2024 and (y) the date that is ninety (90) days after the date that Milestone 3 is achieved; and (v) subject to approval by the Lenders' investment committee in its discretion, a fifth tranche of additional term loans in an aggregate principal amount of up to $50.0 million available on or before the Amortization Date (as defined below). With the exception of the first $50.0 million tranche available on the Closing Date, each of the tranches may be drawn down in $5.0 million increments at the Company's election. The Company has agreed to use the proceeds of the 2022 Term Loan Facility for working capital and general corporate purposes.

Notwithstanding limitations and restrictions imposed by covenants in the Loan Agreement, the Company is permitted to engage in certain specified transactions. For example, the terms of the Loan Agreement provide that the Company may issue convertible notes in an aggregate principal amount of not more than $400.0 million, provided that such notes are unsecured, have a maturity date no earlier than six months following the Maturity Date (as defined below), and meet certain other conditions. The Loan Agreement also provides that the Company may enter into royalty interest financing transactions that are subordinated to the 2022 Term Loan Facility, have a maturity date no earlier than six months following the Maturity Date, and meet certain other conditions. Following the achievement of Milestone 3, the Loan Agreement also provides for a possible additional revolving credit facility of up to $50.0 million, which will be formula-based and backed by the Company's accounts receivables. This potential revolving credit facility is not an existing facility under the Loan Agreement, is not committed, and is subject to agreement among the Company and the Lenders. The Company may enter into non-exclusive and certain specified exclusive licensing arrangements with respect to core intellectual property and non-exclusive and exclusive licensing arrangements or otherwise transfer non-core intellectual property without the consent of the Lenders. The Company may also enter into certain permitted acquisitions, subject to a limit on total cash consideration for acquisitions consummated during specified periods. Additionally, the Company must provide the Lenders the opportunity to invest up to $10.0 million in any equity financing, subject to certain exclusions, that is broadly marketed to multiple investors and in which the Company receives net cash proceeds of $75.0 million or more in any one or series of related financings (or in the case of any such equity financing that is a registered offering, use its commercially reasonable efforts to provide such opportunity to the Lenders).

The 2022 Term Loan Facility will mature on August 1, 2027 (the "Maturity Date"). The outstanding principal balance of the 2022 Term Loan Facility bears interest at a floating interest rate per annum equal to the greater of either (i) (x) the lesser of the Wall Street Journal prime rate and 6.25% plus (y) 4.00% or (ii) 8.75%. The per annum interest rate is capped at 10.25%. Accrued interest is payable monthly following the funding of each term loan. The Company may make payments of interest only, without any loan amortization payments, for a period of forty-two (42) months following the Closing Date, which period may be extended to the Maturity Date if (i) Milestone 3 has been achieved and (ii) no default or event of default exists under the Loan Agreement. At the end of the interest only period (the "Amortization Date"), the Company is required to begin repayment of the outstanding principal of the 2022 Term Loan Facility in equal monthly installments.

As collateral for the obligations under the 2022 Term Loan Facility, the Company has granted to the Agent for the benefit of the Lenders a senior security interest in substantially all of its and each Subsidiary Borrower's property, inclusive of intellectual property, with certain limited exceptions set forth in the Loan Agreement.

The Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of

default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favor of the Agent (the "Qualified Cash") during the period commencing on May 15, 2023 through August 14, 2024. Commencing on August 15, 2024, the Company will also be required to maintain a certain minimum amount of trailing six-month net product revenue from the sale of Zimura, tested on a quarterly basis. The revenue covenant will be waived at any time at which the Company (x) (i) maintains a market capitalization in excess of $600.0 million and (ii) maintains Qualified Cash in an amount greater than or equal to fifty percent (50%) of the outstanding 2022 Term Loan Facility at such time or (y) maintains Qualified Cash in an amount greater than or equal to ninety percent (90%) of the outstanding 2022 Term Loan Facility at such time. Upon the occurrence of an event of default, including a material adverse effect, subject to certain exceptions, on the business, operations, properties, assets or financial condition of the Company and the Subsidiary Borrowers taken as a whole, and subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by the Lenders. As of the Closing Date, the Company was in compliance with all applicable covenants under the Loan Agreement.

In addition, the Company is required to make a final payment fee (the "End of Term Charge") upon the earlier of (i) the Maturity Date or (ii) the date it prepays, in full or in part, the outstanding principal balance of the 2022 Term Loan Facility. The End of Term Charge is 4.25% of the aggregate original principal amount of the term loans repaid or prepaid under the Loan Agreement.

The Company may, at its option, prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.0% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the Closing Date, (ii) 1.5% of the principal amount prepaid if the prepayment occurs on or after the first anniversary and prior to the second anniversary of the Closing Date, and (iii) 0.75% of the principal amount prepaid if the prepayment occurs on or after the second anniversary and prior to the third anniversary of the Closing Date.

IVERIC plans to file the Loan Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended on June 30, 2022, and intends to seek confidential treatment for the Loan Agreement. The foregoing description of the Loan Agreement is qualified in its entirety by reference to the complete text of the Loan Agreement when filed.

Item 2.02. Results of Operations and Financial Condition.

On July 26, 2022, the Company announced its financial results and results of operations for the three and six months ended June 30, 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), but not the information in Items 1.01 and 2.03 of this Form 8-K, 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 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth in Item 1.01 above is incorporated herein by reference.

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 July 26, 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: July 26, 2022

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

Iveric Bio Reports Second Quarter 2022 Operational Highlights and Financial Results

- Zimura® GATHER2 Topline Data Expected in September of this Year-

- GATHER2 Patient Retention Continues to Exceed Expectations with a 12-Month Injection Fidelity Rate of 92.5% –

- Agreement for up to $250 Million in Non-dilutive Debt Financing Secured -

- Exclusive License Entered into for Sustained Release Delivery Technology for Zimura® -

- Conference Call and Webcast Today, July 26, 2022, at 8:00 a.m. ET –

PARSIPPANY, N.J. – July 26, 2022 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the second quarter ended June 30, 2022 and provided a general business update.
"We are excited to share that today marks one year since we completed patient enrollment of GATHER2, our second Phase 3 clinical trial for Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, for the treatment of geographic atrophy (GA)," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "Our team executed well all year as we exceeded our expectations for patient retention and injection fidelity, which we believe further de-risks GATHER2 and is an integral part of the clinical trial outcome. We look forward to reporting the topline data of GATHER2 in September of this year."

Mr. Sblendorio added, "In our topline data announcement, we intend to provide the primary efficacy endpoint analysis as well as a safety analysis, including the inflammation and endophthalmitis rates, if any, as well as rates of conversion to wet age-related macular degeneration (AMD), both using the traditional definition of a choroidal neovascular membrane (CNVM) as well as using the newer definitions of exudative versus non-exudative macular neovascularization (MNV), as defined in our Form 8-K filed on April 4, 2022."

"If the results from GATHER2 are positive, our key objective and plan is to make Zimura commercially available to physicians and their patients with GA as quickly as possible, assuming regulatory approval," stated Pravin U. Dugel, MD, President of Iveric Bio. "Over the past several months, exploratory post-hoc analyses from GATHER1, our first pivotal clinical trial for Zimura in GA, were presented at major medical conferences. We believe these analyses further support the consistency of the positive data previously reported for GATHER1 and inform future potential development opportunities for Zimura in earlier indications. We continue to invest in lifecycle initiatives such as sustained release delivery technologies for Zimura."

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

The Company expects topline data from the GATHER2 clinical trial to be available in September 2022. Following the Company's topline announcement, the American Academy of Ophthalmology has

reserved timeslots at its Annual Meeting on Friday, September 30th for presentations of the topline efficacy and safety results from GATHER2.

Patient retention for the GATHER2 clinical trial, as measured by the injection fidelity rate, continues to exceed the Company's expectations. The Company achieved an injection fidelity rate for GATHER2, as measured through month 12, of 92.5%. As a comparison, the 12-month injection fidelity rate for its GATHER1 clinical trial, in which it observed a statistically significant reduction in GA progression at 12 months, was 87%. Injection fidelity is calculated by dividing the total number of actual injections (drug and sham) for all patients by the total number of expected injections (drug and sham) based on the total number of patients enrolled in the trial. 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.

In June 2022, the Company entered into a license agreement with DelSiTech Ltd. providing the Company with a worldwide, exclusive license to develop and commercialize new formulations of Zimura using DelSiTech's silica-based sustained release technology.

The Company plans to initiate a clinical trial studying Zimura in patients with intermediate AMD in the fourth quarter of 2022, following planned interactions with the U.S. Food and Drug Administration (FDA) and other regulatory authorities. The Company's development strategy in this indication is subject to regulatory feedback.

In July 2022, a post-hoc analysis from the Zimura GATHER1 clinical trial was presented at the Annual Meeting of the American Society of Retina Specialists. Results of the post hoc analysis showed that Zimura reduced GA lesion growth compared to sham across all distances from the foveal center point. In this trial, 84.4% of GA lesions were within 500 microns of the foveal center at baseline and 28.3% were within 100 microns of the foveal center at baseline. These results were generally well balanced across all treatment arms and their corresponding sham control groups.

In June 2022, a post-hoc analysis from the Zimura GATHER1 clinical trial was presented at the Macula Society Meeting. Results of the post-hoc analysis showed that optical coherence tomography (OCT)-measured GA area strongly correlated with fundus autofluorescence (FAF)-measured GA area, with minimal average differences in GA area between modalities. As typically used in GA clinical trials, FAF was utilized to measure GA in the GATHER1 clinical trial and is currently being used in the GATHER2 clinical trial. In GATHER1, a 30% reduction was observed in OCT-measured GA growth with Zimura at 12 months, which is consistent with findings using FAF-measured GA growth. The post-hoc analysis illustrates the potential for eye care providers to accurately diagnose and monitor patients with GA with OCT alone, without additional equipment required.

In May 2022, a post-hoc analysis from the Zimura GATHER1 clinical trial was presented at the Retinal World Congress. The post-hoc analysis evaluated the reduction in GA lesion growth observed for patients receiving Zimura as compared to patients receiving sham in a subset of patients based on the distance of a patient's GA lesion from the foveal center at baseline. Consistent with previously reported GATHER1 results, the results of this post-hoc analysis showed that Zimura reduced GA lesion growth compared to sham across all baseline distances from the foveal center, and that early administration with Zimura when the GA lesion is still farther away from the foveal center and is growing the fastest, may be most beneficial.

Patient enrollment in STAR, the Company's Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease (STGD1), is ongoing. The results of this clinical trial are expected after the topline results of GATHER2.

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

The Company is planning for IND-enabling toxicology studies for IC-500. The Company expects to submit an investigational new drug application (IND) to the FDA for IC-500 during mid-2023.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

As the Company focuses its efforts and resources on the development and potential commercialization of Zimura, the Company is currently seeking potential collaborations for the future development and potential commercialization of IC-100, the Company's product candidate for Rhodopsin-Mediated

Autosomal Dominant Retinitis Pigmentosa (RHO-adRP) and IC-200, the Company's product candidate for BEST1-Related IRDs.

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

Corporate Update

In July 2022, the Company entered into a term loan debt financing facility with Hercules Capital, Inc. (Hercules) and Silicon Valley Bank (SVB) providing the Company with total borrowing capacity of up to $250 million in non-dilutive debt financing. The Company is borrowing $50 million under this facility in July 2022, with an additional $150 million in the aggregate being available subject to the Company's achievement of specified performance milestones relating to development and regulatory events for Zimura and an additional $50 million being available subject to the lenders' approval.

Second Quarter Financial Results and 2022 Cash Guidance

As of June 30, 2022, the Company had $312 million in cash, cash equivalents and available for sale securities.

Today, the Company is borrowing $50 million under its term loan facility with Hercules and SVB. Including the proceeds of this borrowing, the Company estimates its year-end 2022 cash, cash equivalents and available for sale securities to range between $260 and $270 million.

The Company plans to provide additional information regarding its financing strategy following the GATHER2 topline data announcement.

2022 Q2 Financial Highlights

R&D Expenses: Research and development expenses were $33.6 million for the quarter ended June 30, 2022, compared to $23.5 million for the same period in 2021. For the six months ended June 30, 2022, research and development expenses were $56.2 million compared to $42.0 million for the same period in 2021. Research and development expenses increased primarily due to the continued progress of the GATHER2 trial, increased manufacturing activities for Zimura, and increases in personnel costs, including share-based compensation associated with additional research and development staffing, offset by decreases in costs associated with IC-100 and IC-200.

G&A Expenses: General and administrative expenses were $16.1 million for the quarter ended June 30, 2022, compared to $6.7 million for the same period in 2021. For the six months ended June 30, 2022, general and administration expenses were $28.2 million compared to $15.0 million for the same period in 2021. General and administrative expenses increased primarily due increases in personnel costs, including share-based compensation associated with staffing for commercial preparation.

Net Loss: The Company reported a net loss for the quarter ended June 30, 2022, of $49.3 million, or ($0.41) per diluted share, compared to a net loss of $30.1 million, or $(0.32) per diluted share, for the same period in 2021. For the six months ended June 30, 2022, the Company reported a net loss of $83.8 million or ($0.70) per diluted share, compared to a net loss of $56.9 million or ($0.61) for the same period in 2021.

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 July 26, 2022, 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 0932671. 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 6585313.

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.

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 clinical 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 clinical 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 initiating a clinical trial studying Zimura in patients with intermediate AMD, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, including the submission of an investigational new drug application for IC-500, the potential utility of its product candidates and sustained release delivery technologies for Zimura, the clinical meaningfulness of clinical trial results and data, including the post-hoc analyses that the Company performed on data from GATHER1, 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 strategy. 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 other macroeconomic events 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, progress and success of research and development programs and clinical trials, including enrollment and retention in clinical trials and 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, the scientific and medical community and the marketplace for the Company's products, human capital matters, need for and availability of 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 33,647	$ 23,488	$ 56,204	$ 42,037
General and administrative	16,106	6,718	28,219	15,040
Total operating expenses	49,753	30,206	84,423	57,077
Loss from operations	(49,753)	(30,206)	(84,423)	(57,077)
Interest income	482	65	615	142
Other income (expense), net	8	(2)	9	(3)
Loss before income tax benefit	(49,263)	(30,143)	(83,799)	(56,938)
Income tax benefit	-	-	-	-
Net loss	$ (49,263)	$ (30,143)	$ (83,799)	$ (56,938)
Net loss per common share:				
Basic and diluted	$ (0.41)	$ (0.32)	$ (0.70)	$ (0.61)
Weighted average common shares outstanding:				
Basic and diluted	119,687	93,409	119,223	93,382

	June 30, 2022	**December 31, 2021**
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 311,963	$ 381,749
Total assets	$ 319,756	$ 389,358
Total liabilities	$ 26,810	$ 28,830
Additional paid-in capital	$ 1,056,751	$ 1,040,098
Accumulated deficit	$ (763,394)	$ (679,595)
Total stockholders' equity	$ 292,946	$ 360,528