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): **January 13, 2020**

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.)

One Penn Plaza, 35th Floor
New York, NY 10119
(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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 o

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. o

Forward-Looking Statements

This Form 8-K and Exhibit 99.1 attached hereto contain forward-looking statements of Iveric bio, Inc. (the "Company") that involve substantial risks and uncertainties. Any statements in this Form 8-K and Exhibit 99.1 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 Form 8-K and Exhibit 99.1, the Company's forward looking statements include statements about its expectations to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy as a pivotal trial, its development strategy for Zimura, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities, the potential utility of its product candidates, estimates regarding the number of patients affected by the diseases and indications the Company's product candidates are intended to treat and the potential for its 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 initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory 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 Form 8-K. The Company anticipates that subsequent events and developments will 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 2.02 Results of Operations and Financial Condition

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2019, the Company will announce during the 38th Annual J.P. Morgan Healthcare Conference, which begins on January 13, 2020, that it expects to report that it had approximately $126 million in cash and cash equivalents as of December 31, 2019.

The information contained in this Item 2.02 of Form 8-K is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2019 and its results of operations for the three months and year ended December 31, 2019. The audit of the Company's financial statements for the year ended December 31, 2019 is ongoing and could result in changes to the information set forth above. The Company anticipates making a public announcement of its results of operations for the fourth quarter and fiscal year ended December 31, 2019 on or about February 27, 2020.

Item 8.01 Other Events

2019 Year End Cash and Cash Equivalents

The information in Item 2.02 of this Form 8-K is incorporated by reference.

Second Zimura Pivotal Clinical Trial Design

On January 13, 2020, the Company issued a press release announcing the design of its second pivotal clinical trial of Zimura® (avacincaptad pegol), the Company's complement factor C5 inhibitor, in geographic atrophy ("GA") secondary to dry age-related macular degeneration ("AMD" and such clinical trial, the "ISEE2008 trial"). A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The ISEE2008 trial will be an international, multicenter, double masked, sham controlled clinical trial. The Company plans to enroll approximately 400 patients to be randomized to receive monthly administration of Zimura 2 mg or sham during the first 12 months of the trial. The prespecified primary endpoint, mean rate of change in GA growth over 12 months, will be measured by fundus autofluorescence ("FAF") based on readings at three time points (baseline, month 6, and month 12). At month 12, the Company plans to re-randomize patients in the Zimura 2 mg arm to receive either monthly or every other month administration of Zimura 2 mg. The final evaluation will take place at month 24.

Key ophthalmic inclusion criteria for the ISEE2008 trial include:

- non-foveal GA secondary to dry AMD;
- total GA area between 2.5mm^2 and 17.5mm^2, inclusive;
- if GA is multifocal, at least one focal lesion should measure 1.25mm^2 or greater;
- GA in part within 1500 microns from the foveal center; and
- Snellen equivalent best corrected visual acuity (BCVA) in the study eye between 20/25 and 20/320, inclusive.

Instead of removing patients who develop choroidal neovascularization ("CNV") in the study eye from further treatments and assessments, as was done in the Company's OPH2003 trial for which it announced positive results in October 2019, the protocol for the ISEE2008 trial will provide that patients who develop CNV in the study eye will remain in the trial, receiving either Zimura 2 mg or sham, together with standard of care anti-vascular endothelial growth factor (anti-VEGF) treatment at the investigator's discretion. Measurements of these patients' GA will be included in the primary efficacy analysis if their FAF images can be reliably assessed by the masked reading center.

Projected External Costs Associated with ISEE2008 Trial

The Company currently estimates that the aggregate external costs of the ISEE2008 trial will range between $30 million and $40 million, and that the aggregate external costs associated with manufacturing process scale-up and validation for Zimura in preparation for a potential application for regulatory approval will range between $10 million and $20 million. These costs do not include employee-related expenses for employees dedicated to Zimura clinical development and manufacturing activities, including salaries, benefits and share-based compensation expense. The Company's estimates could change in the event that it modifies the design of the ISEE2008 trial, if the Company decides or is required to conduct one or more additional clinical trials of Zimura in GA beyond the ISEE2008 trial in order to obtain data sufficient to seek regulatory approval in GA or for other reasons, if the Company encounters difficulties in Zimura manufacturing scale-up and process validation, or if the Company encounters delays or other unforeseen events.

Projected Cash Runway and 2020 Year End Cash and Cash Equivalents

The Company believes that its cash and cash equivalents will be sufficient to fund its operations and capital expenditure requirements as currently planned into the beginning of 2022. In addition, the Company estimates that its year-end 2020 cash and cash equivalents will range between $60 million and $70 million. These estimates are based on the Company's current business plan, including the continuation of its current research and development programs including the ISEE2008 trial. These estimates do not reflect any additional expenditures, including associated development costs, in the event the Company in-licenses or acquires any new product candidates or commences any new research or development programs. The Company has based these estimates on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated January 13, 2020

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: January 13, 2020

By: /s/ David F. Carroll

David F. Carroll

Senior Vice President, Chief Financial Officer and Treasurer

IVERIC bio Announces Design for Second Pivotal Clinical Trial of Zimura® in Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration

- On-Track for First Patient Enrollment in 1Q 2020 -

- Company to Host R&D Symposium for Investors/Analysts on Tuesday January 14, 2020 in San Francisco, CA from 6:30 to 8:00 am (Pacific Time) -

NEW YORK, January 13, 2020 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced the design of the second pivotal clinical trial for Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, in development for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD). This second pivotal trial will be an international, multicenter, double masked, sham controlled clinical trial. The Company plans to enroll approximately 400 patients to be randomized to receive monthly administration of Zimura 2 mg or sham during the first 12 months of the trial. The prespecified primary endpoint, mean rate of change in GA growth over 12 months, will be measured by fundus autofluorescence (FAF) based on readings at three time points (baseline, month 6, and month 12) consistent with the previous Zimura pivotal clinical trial design. At month 12, the Company plans to re-randomize patients in the Zimura 2 mg arm to receive either monthly or every other month administration of Zimura 2 mg. The final evaluation will take place at month 24.

“This trial is our top priority and we are working to address this major unmet medical need where there are no approved treatment options available for the approximately 1.5 million patients living with geographic atrophy in the US alone,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio.

“Based on the positive 12-month results from our first pivotal trial for Zimura in GA we are looking forward to enrolling our first patient in our second pivotal clinical trial,” stated Kourous A. Rezaei, M.D., Chief Medical Officer of IVERIC bio. “In the first trial, both the Zimura 2 mg and Zimura 4 mg doses met the primary efficacy endpoint at month 12 with statistical significance and similar efficacy as compared to sham. Since Zimura 2 mg is administered as a single intravitreal injection, as compared to two intravitreal injections for Zimura 4 mg, the upcoming trial will compare the safety and efficacy of the Zimura 2 mg dose to sham control in patients with GA. Our goal is to enroll the first patient in the first quarter of 2020.”

On October 28, 2019, the Company announced that Zimura met its pre-specified primary efficacy endpoint and reached statistical significance in an international, multicenter, randomized, double masked, sham-controlled clinical trial in GA secondary to dry AMD. Zimura was generally well tolerated after 12 months of administration. IVERIC bio provided further details supporting the positive results from this trial, which the Company plans to use as a pivotal trial, in its Quarterly Report on Form 10-Q filed on November 12, 2019.

R&D Symposium for Investors/Analysts
The Company will host an R&D Symposium for Investors/Analysts on Tuesday, January 14, 2020 from 6:30a.m. to 8:00a.m. Pacific Time in San Francisco, CA. The event will feature a presentation on the Zimura pivotal program in GA secondary to dry AMD with details on the design followed by additional presentations on statistical analysis and the primary endpoint for the program.

The event will be accessible via webcast on the IVERIC bio website at www.ivericbio.com. For more information, please contact Kathy Galante at kathy.galante@ivericbio.com or 212-845-8231.

Geographic Atrophy
Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in aging adults, affecting both eyes in the majority of patients. The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of retinal cells and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue. Geographic atrophy, the advanced stage of AMD, leads to further irreversible loss of vision in these patients. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy.

Zimura
Complement factor C5 is a central component of the complement cascade and is believed to be involved in the development and progression of dry AMD. Zimura is designed to target and inhibit complement factor C5. Zimura binds to C5 and inhibits its cleavage into the terminal fragments, C5a and C5b. By inhibiting the formation of complement system terminal fragments, Zimura may decrease the activation of inflammasomes and the formation of membrane attack complex (MAC), which occur at the end of the complement cascade. This mechanism of action could potentially prevent or slow down the degeneration of retinal pigment epithelial (RPE) cells providing the potential therapeutic rationale in GA secondary to dry AMD.

IVERIC bio
IVERIC bio is a biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. Vision is Our Mission. For more information on the Company please visit www.ivericbio.com.

Forward-looking Statements
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