
**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 18, 2020**

IVERIC bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36080
(Commission
File Number)

20-8185347
(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**

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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))

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

Any statements in this Current Report on Form 8-K and Exhibit 99.1 attached hereto about IVERIC bio, Inc.'s (the "Company") 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 Current Report on Form 8-K and Exhibit 99.1 attached hereto, the Company's forward looking statements include statements about its expectations to initiate enrollment in its second pivotal trial of Zimura in geographic atrophy secondary to dry AMD and 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 and the potential utility of its product candidates. 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 third parties, establishment of manufacturing capabilities, expectations for regulatory matters, need for additional financing 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 Current Report on 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 8.01 Other Events

Update for Second Zimura Pivotal Clinical Trial

The Company today announced that due to the threat of the coronavirus (COVID-19) global pandemic, the Company has decided to delay the initiation of enrollment of patients in the second pivotal clinical trial (the "ISEE2008 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).

A press release announcing this event is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference.

Projected Cash Runway and 2020 Year End Cash and Cash Equivalents

Accounting for the announced delay of the initiation of enrollment in the ISEE2008 trial, the Company continues to believe 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 continues to estimate that its year-end 2020 cash and cash equivalents will range between \$60 million and \$70 million. These estimates are provided as of the date of this Current Report and are based on the Company's current business plan, including the continuation of its current research and development programs and the delayed initiation of patient enrollment for the ISEE2008 trial. The Company will continue to monitor the evolving COVID-19 situation. These estimates also 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

The following Exhibit 99.1 to this Current Report on Form 8-K is incorporated by reference herein.

[99.1 IVERIC bio, Inc. Press Release, dated March 18, 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: March 18, 2020

By: /s/ David F. Carroll

David F. Carroll

Senior Vice President, Chief Financial Officer and Treasurer



IVERIC bio Provides Update on the Initiation of the Second Pivotal Clinical Trial Enrollment for Zimura® in Patients with Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration

NEW YORK, March 18, 2020 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced that due to the threat of the coronavirus (COVID-19) global pandemic, the Company has decided to delay the initiation of enrollment of patients in 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).

“In light of the COVID-19 pandemic and out of an abundance of caution for the safety and well-being of our elderly patients and participating physicians and their staffs, we have decided to delay the initiation of enrollment in our second pivotal trial of Zimura in geographic atrophy secondary to dry AMD, the ISEE2008 trial, which was on track to begin this month,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. “It is critically important that we heed the warnings from the U.S. Centers for Disease Control, World Health Organization and national, state and local governments during this time of uncertainty. We will continue to closely monitor the situation in the United States and abroad to determine when enrollment should begin.”

“Our first priority is to ensure the best interest of our patients, caregivers, and physicians,” stated Kourous A. Rezaei, M.D., Chief Medical Officer of IVERIC bio. “We want to thank clinical investigators and their teams for their enthusiasm and support in completing the activities necessary to begin enrolling patients at a number of clinical sites, including identification of potential patients for this trial. We will continue our efforts to prepare additional clinical sites, so that we can begin enrolling patients expeditiously, once the COVID-19 threat dissipates.”

Zimura Pivotal Program

The Company plans to enroll approximately 400 patients in the ISEE2008 trial, which is an international, multicenter, double masked, sham controlled clinical trial. Patients will be randomized to receive either monthly administration of Zimura 2 mg or sham during the first 12 months of the trial, at which time the primary efficacy analysis of the mean rate of change of GA growth at 12 months will be performed. If the 12 month results are positive, the Company plans to file an application with the U.S. Food and Drug Administration and the European Medicines Agency for marketing approval of Zimura for GA following receipt of that data. 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. All the patients who were initially randomized to the sham control arm will continue with monthly administration of sham. The final evaluation will take place at month 24.

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, referred to as the OPH2003 trial. 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 Annual Report on Form 10-K filed on February 27, 2020.

Dry AMD / Geographic Atrophy

Dry AMD is a significant cause of moderate and severe loss of central vision in older adults, affecting both eyes in the majority of patients. Although dry AMD is the most common form of AMD, there are no U.S. Food and Drug Administration or European Medicines Agency approved therapies to treat this condition. In dry AMD, thinning of the retinal pigment epithelial (RPE) cells in the central portion of the retina, or the macula, develops, along with other age-related changes to the adjacent retinal and choroidal tissue layers. Geographic atrophy, the advanced stage of dry AMD, is a disease characterized by degeneration of retinal tissue leading to further loss of vision.

About 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 RPE cells providing the potential therapeutic rationale in GA secondary to dry AMD.

About 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

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 to initiate enrollment in its second pivotal trial of Zimura in geographic atrophy secondary to dry AMD and 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 and the potential utility of its product candidates. 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 third parties, establishment of manufacturing capabilities, expectations for regulatory matters, need for additional financing 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 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.

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