

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 22, 2019**

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))

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.

Exclusive License Agreement

On July 22, 2019, IVERIC bio, Inc. (“IVERIC”) entered into an Exclusive License Agreement (the “License Agreement”) with the University of Massachusetts (“UMass”). IVERIC entered into the License Agreement by exercising its exclusive option rights under an option agreement and a sponsored research agreement that IVERIC previously entered into with UMass in February 2018. Under the License Agreement, UMass granted IVERIC a worldwide, exclusive license under specified patent rights and specified biological materials and a non-exclusive license under specified know-how to make, have made, use, offer to sell, sell, have sold and import products for the treatment of diseases associated with mutations in the *CEP290* gene, including Leber congenital amaurosis type 10. IVERIC may grant sublicenses of the licensed patent rights and know-how without the consent of UMass.

IVERIC has agreed to use diligent efforts to develop licensed products and to introduce such licensed products into the commercial market. Subject to obtaining marketing approval, IVERIC agreed to make any approved licensed product reasonably available to the public. In addition, IVERIC has agreed to meet specified development and regulatory milestones with respect to a licensed product by specified dates, as the same may be extended under the terms of the License Agreement.

Financial Terms

IVERIC has agreed to pay UMass a \$400,000 upfront license fee upon execution of the License Agreement. In addition, IVERIC has agreed to issue to UMass 75,000 shares of common stock of IVERIC, par value \$0.001 per share (“Common Stock”), promptly following execution of the License Agreement pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended.

IVERIC has also agreed to pay UMass an annual license maintenance fee in the low double-digit thousands of dollars, which fee will be payable on an annual basis until the expiration of the royalty term for the licensed products. Furthermore, IVERIC has agreed to reimburse UMass for the costs and expenses of patent prosecution and maintenance related to the licensed patent rights.

IVERIC has further agreed to pay UMass up to an aggregate of \$14.75 million in cash and issue up to 75,000 shares of Common Stock if IVERIC achieves specified clinical and regulatory milestones with respect to a licensed product. In addition, IVERIC has agreed to pay UMass up to an aggregate of \$48.0 million if IVERIC achieves specified commercial sales milestones with respect to a licensed product.

IVERIC is also obligated to pay UMass royalties at a low single-digit percentage of net sales of licensed products. IVERIC’s obligation to pay royalties under the License Agreement will continue on a licensed product-by-licensed product and country-by-country basis until the later of: (a) the expiration of the last-to-expire licensed patent rights covering the sale of the applicable licensed product in the country of sale, or (b) 10 years from the first commercial sale of the applicable licensed product in the country of sale. Beginning with the calendar year following receipt of marketing approval for a licensed product, IVERIC is also obligated to pay certain minimum royalties, not to exceed an amount in the mid-double-digit thousands of dollars on an annual basis, which minimum royalties are creditable against IVERIC’s royalty obligation with respect to net sales of licensed products due in the year the minimum royalty is paid.

If IVERIC or any of its affiliates sublicenses any of the licensed patent rights or know-how to a third party, IVERIC will be obligated to pay UMass a high single-digit to a mid-tens percentage of the consideration received in exchange for such sublicense, with the applicable percentage based upon the stage of development of the licensed products at the time IVERIC or the applicable affiliate enters into the sublicense.

If IVERIC receives a rare pediatric disease priority review voucher (a “priority review voucher”) from the U.S. Food and Drug Administration in connection with obtaining marketing approval for a licensed product, and IVERIC subsequently uses such priority review voucher in connection with a different product candidate outside the scope of the License Agreement, IVERIC will be obligated to pay UMass a low-tens percentage of the fair market value of the priority review voucher at the time of approval of such product candidate and a low-twenties percentage of the fair market value of the priority review voucher at the time of achievement of a specified commercial sales milestone for such other product candidate. In addition, if IVERIC sells such a priority review voucher to a third party, IVERIC will be obligated to pay UMass a low-thirties percentage of any consideration received from such third party in connection with such sale.

Term and Termination

The License Agreement, unless earlier terminated by IVERIC or UMass, will expire upon the expiration of IVERIC's obligation to pay royalties to UMass on net sales of licensed products. IVERIC may terminate the License Agreement at any time for any reason upon prior written notice to UMass. IVERIC may also terminate the License Agreement if UMass materially breaches the License Agreement and does not cure such breach within a specified cure period.

UMass may terminate the License Agreement if IVERIC materially breaches the License Agreement and does not cure such breach within a specified cure period.

Following any termination of the License Agreement prior to expiration of the term of the License Agreement, all rights to the licensed patent rights and know-how that UMass granted to IVERIC will revert to UMass.

Incorporation by Reference

IVERIC expects to file the License Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2019, and intends to seek confidential treatment for certain terms and provisions of the License Agreement. The foregoing descriptions of the License Agreement are qualified in their entirety by reference to the complete text of the License Agreement when filed.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 8-K contains forward-looking statements of IVERIC that involve substantial risks and uncertainties. Any statements in this Form 8-K about IVERIC'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 IVERIC's strategy, future operations and future expectations and plans and prospects for IVERIC, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this Form 8-K, IVERIC's forward looking statements include statements about the potential future performance under the License Agreement and potential payments thereunder, the implementation of its strategic plan, IVERIC's projected use of cash and cash balances, and the timing, progress and results of IVERIC's research and development activities. Such forward-looking statements involve substantial risks and uncertainties that could cause IVERIC's preclinical and clinical 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 conduct and design of research and development programs, 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 in-license and/or acquisition transactions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that IVERIC files with the Securities and Exchange Commission. Any forward-looking statements represent IVERIC's views only as of the date of this Form 8-K. IVERIC anticipates that subsequent events and developments will cause its views to change. While IVERIC may elect to update these forward-looking statements at some point in the future, IVERIC specifically disclaims any obligation to do so except as required by law.

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 23, 2019

By: /s/ David F. Carroll

David F. Carroll

Senior Vice President, Chief Financial Officer and Treasurer