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): June 30, 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.

License Agreement

On June 30, 2022, IVERIC bio, Inc. ("IVERIC" or the "Company") entered into a License Agreement (the "License Agreement") with DelSiTech Ltd. ("DelSiTech"). Under the License Agreement, DelSiTech granted IVERIC a worldwide, exclusive license under specified patent rights and know-how to develop, have developed, make, have made, use, offer to sell, sell, have sold, otherwise commercialize, export and import Zimura® (avacincaptad pegol) using DelSiTech's silica-based sustained release technology for the treatment of diseases of the eye in humans (the "Licensed Product"). IVERIC may grant sublicenses of the licensed patent rights and know-how without DelSiTech's consent.

As a condition to the ongoing effectiveness of DelSiTech's grant of exclusive rights, (a) IVERIC would use commercially reasonable efforts to develop the Licensed Product and to seek regulatory approval for the Licensed Product in either the United States or the European Union and (b) IVERIC would use commercially reasonable efforts to commercialize the Licensed Product following receipt of regulatory approval in the United States, France, Germany, Italy, Spain or the United Kingdom, as applicable. IVERIC has sole discretion as to the use of commercially reasonable efforts for the above, and in the event that IVERIC chooses not to or fails to use commercially reasonable efforts to develop or commercialize the Licensed Product, DelSiTech's sole remedy for such failure is to convert the licenses granted to IVERIC under the License Agreement from exclusive to non-exclusive.

IVERIC has agreed to pay DelSiTech a €1.25 million upfront license fee within 60 days after execution of the License Agreement. IVERIC has further agreed to pay DelSiTech up to an aggregate of €35.0 million if IVERIC achieves specified clinical and development milestones with respect to the Licensed Product. In addition, IVERIC has agreed to pay DelSiTech up to an aggregate of €60.0 million if IVERIC achieves specified commercial sales milestones with respect to worldwide net sales of the Licensed Product.

IVERIC is also obligated to pay DelSiTech royalties at a low single-digit percentage of net sales of the Licensed Product. The royalties payable by IVERIC are subject to reduction under specified circumstances. IVERIC's obligation to pay royalties under the License Agreement will continue on a country-by-country basis until the later of: (a) the expiration of the last-to-expire licensed patent rights covering the Licensed Product in the country of sale, or (b) expiration of all regulatory exclusivity for the Licensed Product in the country of sale.

The License Agreement also contains representations and warranties, covenants, indemnification and other negotiated provisions, including confidentiality obligations, customary for transactions of this nature. Unless earlier terminated by IVERIC or DelSiTech, the License Agreement will expire on a country-by-country basis upon the expiration of IVERIC's obligation to pay royalties to DelSiTech on net sales of the Licensed Product. Upon expiration of the License Agreement, the licenses granted by DelSiTech to IVERIC will become fully paid up and irrevocable. IVERIC may terminate the License Agreement at any time for any reason upon 60 days' prior written notice to DelSiTech. Either party may also terminate the License Agreement if the other party 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 DelSiTech granted to IVERIC will revert to DelSiTech, subject to IVERIC's right to sell off any Licensed Product in IVERIC's inventory as of the effectiveness of such termination.

IVERIC expects to file the License 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 certain terms and provisions of the License Agreement. The foregoing description of the License Agreement is qualified in its entirety by reference to the complete text of the License Agreement when filed.

Item 7.01. Regulation FD.

On July 5, 2022, the Company issued a press release announcing the License Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 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. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1 Press Release dated July 5, 2022
104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 5, 2022

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

Iveric Bio and DelSiTech Enter Exclusive Agreement for Development of Sustained Release Zimura®

Parsippany, N.J. and Turku, Finland – July 5, 2022 – IVERIC bio, Inc. (Nasdaq: ISEE) and DelSiTech Ltd, announced today an exclusive global license agreement providing Iveric Bio with the right to develop and commercialize new formulations of Zimura® (avacincaptad pegol) using DelSiTech's silica-based sustained release technology. As part of Iveric Bio's lifecycle expansion plan for Zimura, the Company is committed to developing sustained release technologies for the treatment of age-related macular degeneration (AMD). These technologies potentially could address patients being treated for geographic atrophy (GA) and intermediate AMD.

"We are thrilled to collaborate with the DelSiTech team on investigating additional sustained release formulations for Zimura with their drug delivery expertise and advanced technology and look forward to evaluating a sustained release formulation in GA and potentially earlier stages of AMD," stated Pravin U. Dugel, MD, President of Iveric Bio. "Previously reported post-hoc analyses from GATHER1 suggest that Zimura may have the potential to impact AMD in early stages before atrophy occurs in patients. We believe Zimura, which is a chemically synthesized RNA aptamer, is amenable to injectable sustained release formulations."

"As a leading developer of long-acting controlled release formulations for small molecules and biological entities, we are excited about collaborating with Iveric Bio on bringing innovative solutions to patients living with AMD," stated Lasse Leino, PhD, Chief Executive Officer of DelSiTech. "We are inspired by the opportunity to leverage our drug delivery technology to potentially help AMD patients early and improve their treatment experience."

"This agreement underscores our commitment to invest in lifecycle initiatives for Zimura," said Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We are excited about the possibilities to expand Zimura into earlier stages of AMD and potentially allow for a next-generation treatment to help patients with GA."

"We are proud to bring our competencies into this promising alliance and contribute to Iveric Bio's mission to address unmet needs for patients," said Dr. Frederic Dargelas, Head of Business Development and Alliance Management for DelSiTech.

Under the terms of the license agreement, Iveric Bio will pay DelSiTech an upfront payment of €1,250,000, as well as development and commercial milestones and royalties on net sales of licensed products.

In addition to working with DelSiTech, Iveric Bio plans to explore the potential for Zimura in earlier stages of AMD by initiating a clinical trial studying the current formulation of Zimura in patients with intermediate AMD in the fourth quarter of 2022. The development strategy in this indication is subject to global regulatory feedback from the U.S. Food and Drug Administration (FDA) and other regulatory authorities, which Iveric Bio plans to obtain before initiating this trial.

About Zimura GATHER1 and GATHER2 Clinical Trials
Iveric Bio previously announced that GATHER1, the Company's first Phase 3 clinical trial for Zimura (avacincaptad pegol) for GA, met its pre-specified primary efficacy endpoint with statistical significance. The most frequently reported ocular adverse events in this trial were related to the injection procedure. The Company expects topline data for GATHER2, the Company's second Phase 3 clinical trial for Zimura for GA, to be available in the third quarter of 2022, approximately one year after the enrollment of the last patient in the trial plus the time needed for database lock and analysis. If 12-month results from GATHER2 are positive, the Company plans to submit applications with the FDA and the European Medicines Agency (EMA) for marketing approval of Zimura for GA. There are no FDA or EMA approved treatments available for patients with GA.

About Zimura
Zimura (avacincaptad pegol) is an investigational drug product and has not been approved for use anywhere globally. Zimura is designed to target and inhibit the cleavage of complement protein C5 and the formation of its downstream fragments, C5a and C5b. By inhibiting the formation of these fragments, Zimura is believed to decrease or slow the chronic inflammation and cell death associated with the retinal aging process by decreasing the formation of membrane attack complex (MAC) and inflammasome activity, thereby potentially avoiding or slowing the degeneration of retinal pigment epithelial cells. This potential mechanism is the rationale for Zimura as a potential therapy for GA and earlier stages of AMD.

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.

About DelSiTech
DelSiTech Ltd., located in Turku, Finland, is the leading technology specialist in biodegradable silica-based controlled release of small molecule drugs, biologics, and viral vectors. It develops and commercializes its proprietary, drug delivery technology in collaboration with a number of pharma and biotech companies to turn their ideas into novel drug products. For more information, see www.delsitech.com.

Iveric Bio Forward-looking Statements

Any statements in this press release about Iveric Bio'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 its development and regulatory strategy for Zimura, including the timing of receipt of topline data from the GATHER2 clinical trial, its ability to use its completed GATHER1 trial as a Phase 3 trial for purposes of seeking regulatory approval, its plans to file for marketing approval for geographic atrophy (GA) if the results of GATHER2 are positive, its plans for initiating a clinical trial studying Zimura in patients with intermediate AMD, the potential utility of Zimura, the Company's hypotheses regarding the role of complement inhibition in potentially treating AMD, the clinical meaningfulness of clinical trial results and data, including from post-hoc analyses of the GATHER1 clinical trial, and its business development and lifecycle management strategies. 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 progress and success of research and development programs and clinical trials, developments from the scientific and medical community, expectations for regulatory matters, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, establishment of manufacturing capabilities, need for additional financing, 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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