



Iveric Bio Reports Second Quarter 2022 Operational Highlights and Financial Results

July 26, 2022

- *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.--(BUSINESS WIRE)--Jul. 26, 2022-- [IVERIC bio, Inc.](https://www.ivericbio.com) (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 DeSiTech Ltd. providing the Company with a worldwide, exclusive license to develop and commercialize new formulations of Zimura using DeSiTech'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.

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

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