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): September 28, 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 7.01. Regulation FD.
On September 29, 2022, Dr. Dhaval Desai, Pharm.D., IVERIC bio, Inc. (the "Company")'s Chief Development Officer, will present supplemental data from the Company's GATHER2 Phase 3 clinical trial of avacincaptad pegol (also known as Zimura®), the Company's complement protein C5 inhibitor, in patients with geographic atrophy ("GA") at Eyecelerator, a meeting to be held adjacent to the 2022 American Academy of Ophthalmology Annual Meeting in Chicago, Illinois. The presentation slides are furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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:

99.1 Desai Eyecelerator presentation

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: September 28, 2022

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


IVERIC
BIO
GATHER CLINICAL PROGRAM OVERVIEW
AVACINCAPTAD PEGOL IN GEOGRAPHIC ATROPHY
DHAVAL DESAI
SVP & CHIEF DEVELOPMENT OFFICER
Avacincaptad Pegol is an investigational product that has not been evaluated for safety and efficacy by the FDA

FORWARD-LOOKING STATEMENTS

Any statements in this presentation about IVERIC bio (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 statements about the strategy, 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 presentation, the Company's forward-looking statements include statements about the significance and implications of the Company's GATHER1 and GATHER2 clinical trials evaluating avacincaptad pegol (ACP or Zimura) for the treatment of geographic atrophy, and the potential utility of ACP. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's research and 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, the progress and results of clinical trials and other research and development programs, developments from the scientific and medical community and from the Company's competitors, 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 presentation. 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.

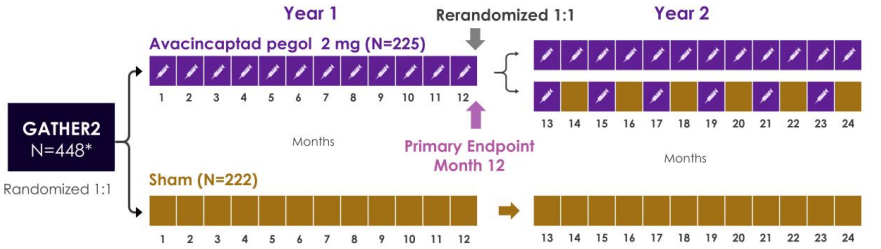
Avacincaptad Pegol is an investigational product that has not been evaluated for safety and efficacy by the FDA

GATHER clinical program evaluated avacincaptad pegol vs. sham in identical GA patient populations

GATHER2
Geographic Atrophy Therapy Trial

Phase 3, international, multicenter, prospective, randomized, double-masked, sham-controlled study

(NCT04435366)



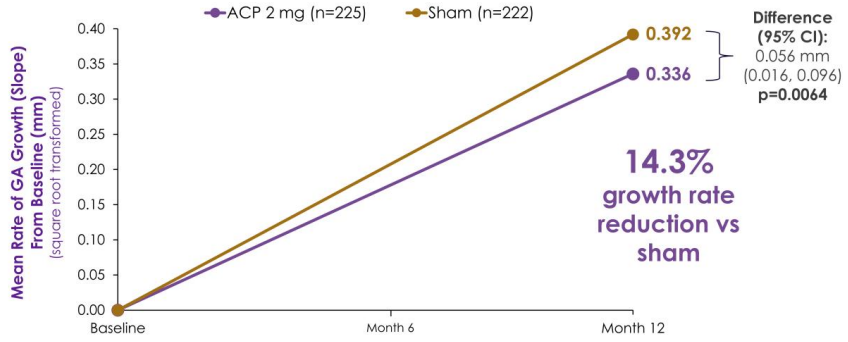
Primary Endpoint

Mean rate of in geographic atrophy growth (slope) from baseline to month 12 (square root transformation)

*448 randomized, with 447 treated (one patient in sham not receiving treatment after randomization).

GATHER2
Geographic Atrophy Therapy Trial

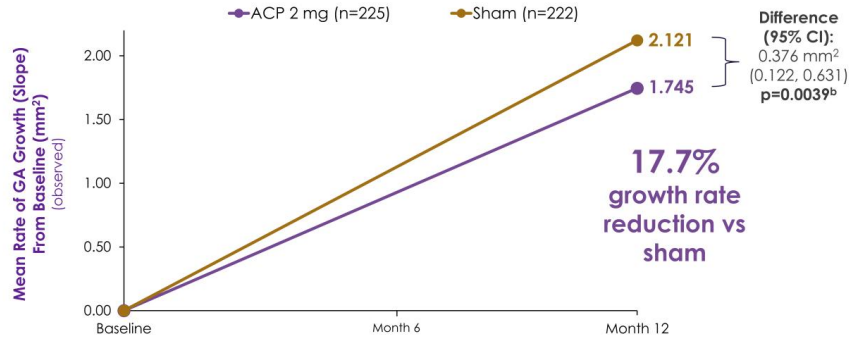
Primary endpoint (slope analysis) achieved at year one with a high degree of statistical significance



ACP, avacincaptad pegol; CI, confidence interval; GA, geographic atrophy.

GATHER2
Geographic Atrophy Therapy Trial

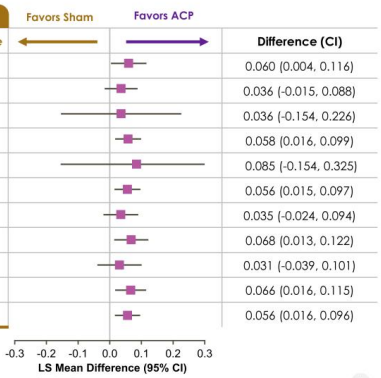
Prespecified (slope) analysis utilizing observed data[a] was consistent with primary analysis



[a]non-square root transformation; [b]Descriptive p-value
ACP, avacincaptad pegol; CI, confidence interval; GA, geographic atrophy.

Prespecified subgroup analysis shows benefit of avacincaptad pegol in all prespecified subgroups

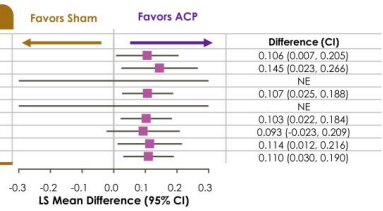
	ACP 2 mg		Sham		
Subgroup	**n**	**Growth Rate**	**n**	**Growth Rate**	**Difference (CI)**
Baseline GA <4 disc area	142	0.34	139	0.40	0.060 (0.004, 0.116)
Baseline GA ≥4 disc area	83	0.55	83	0.58	0.036 (-0.015, 0.088)
Baseline VA <50 Letters	15	0.32	13	0.36	0.036 (-0.154, 0.226)
Baseline VA ≥50 Letters	210	0.32	209	0.37	0.058 (0.016, 0.099)
FAF pattern: None/Focal	12	0.26	9	0.34	0.085 (-0.154, 0.325)
FAF pattern: Banded/Diffuse	213	0.39	213	0.45	0.056 (0.015, 0.097)
<75 years old	91	0.32	85	0.35	0.035 (-0.024, 0.094)
≥75 years old	134	0.35	137	0.42	0.068 (0.013, 0.122)
Male	71	0.27	66	0.30	0.031 (-0.039, 0.101)
Female	154	0.35	156	0.42	0.066 (0.016, 0.115)
Overall	225	0.34	222	0.39	0.056 (0.016, 0.096)



ACP, avacincaptad pegol; CI, confidence interval; FAF, Fundus Autofluorescence; GA, geographic atrophy; LS, least squares; VA, visual acuity.

Benefit across subgroups is consistent among the pivotal GATHER1 and GATHER2 studies

12 Month	ACP 2 mg		Sham		Difference (CI)
Subgroup	**n**	**LS Mean**	**n**	**LS Mean**	
Baseline GA <4 disc area	48	0.33	70	0.43	0.106 (0.007, 0.205)
Baseline GA ≥4 disc area	11	0.29	29	0.43	0.145 (0.023, 0.266)
Baseline VA <50 Letters	1	NE	4	NE	NE
Baseline VA ≥50 Letters	58	0.27	95	0.37	0.107 (0.025, 0.188)
FAF pattern: None/Focal		NE	1	NE	NE
FAF pattern: Banded/Diffuse	54	0.37	87	0.47	0.103 (0.022, 0.184)
Part 1	22	0.33	20	0.42	0.093 (-0.023, 0.209)
Part 2	37	0.31	79	0.42	0.114 (0.012, 0.216)
Overall	59	0.29	99	0.40	0.110 (0.030, 0.190)



ACP, avacincaptad pegol; CI, confidence interval; FAF, Fundus Autofluorescence; GA, geographic atrophy; LS, least squares; NE, not estimated; VA visual acuity.

Benefit across subgroups seen in GATHER1 increases with duration of therapy

12 Month	ACP 2 mg		Sham		Difference (CI)
Subgroup	**n**	**LS Mean**	**n**	**LS Mean**	
Baseline GA <4 disc area	48	0.33	70	0.43	0.106 (0.007, 0.205)
Baseline GA ≥4 disc area	11	0.29	29	0.43	0.145 (0.023, 0.266)
Baseline VA <50 Letters	1	NE	4	NE	NE
Baseline VA ≥50 Letters	58	0.27	95	0.37	0.107 (0.025, 0.188)
FAF pattern: None/Focal		NE	1	NE	NE
FAF pattern: Banded/Diffuse	54	0.37	87	0.47	0.103 (0.022, 0.184)
Part 1	22	0.33	20	0.42	0.093 (-0.023, 0.209)
Part 2	37	0.31	79	0.42	0.114 (0.012, 0.216)
Overall	59	0.29	99	0.40	0.110 (0.030, 0.190)

18 Month	ACP 2 mg		Sham		Difference (CI)
Subgroup	**n**	**LS Mean**	**n**	**LS Mean**	
Baseline GA <4 disc area	48	0.52	70	0.66	0.146 (0.022, 0.269)
Baseline GA ≥4 disc area	11	0.27	30	0.57	0.295 (0.104, 0.486)
Baseline VA <50 Letters	1	NE	5	NE	NE
Baseline VA ≥50 Letters	58	0.36	95	0.53	0.167 (0.062, 0.272)
FAF pattern: None/Focal		NE	1	NE	NE
FAF pattern: Banded/Diffuse	54	0.50	88	0.67	0.170 (0.063, 0.278)
Part 1	22	0.46	20	0.63	0.170 (0.007, 0.334)
Part 2	37	0.44	80	0.61	0.168 (0.043, 0.294)
Overall	59	0.43	100	0.60	0.168 (0.066, 0.271)

ACP, avacincaptad pegol; CI, confidence interval; FAF, Fundus Autofluorescence; GA, geographic atrophy; LS, least squares; NE, not estimated; VA visual acuity.

GATHER2
Geographic Atrophy Therapy Trial

Study eye cases of intraocular inflammation, endophthalmitis, or ischemic optic neuropathy

	ACP 2 mg (N=225)	Sham (N=222)
Intraocular inflammation, n	0	0
Endophthalmitis, n	0	0
Ischemic optic neuropathy, n	0	0

ACP, avacincaptad pegol.

Comprehensive CNV surveillance program

	ACP 2 mg (N=225)	Sham (N=222)
Total CNV, n (%)	15 (6.7)	9 (4.1)

- Suspected development of CNV in the study eye by the principal investigator triggered full imaging workup assessed with FP, FA and OCT and confirmed by the Duke Reading Center within 1 hour of submission
- If the diagnosis was confirmed, the patient continued receiving the study treatment in the trial, and study eye was also treated with study-supplied ranibizumab or aflibercept according to the country label
  - No patients in GATHER2 received anti-VEGF therapy without a Duke-confirmed CNV diagnosis
- All Month 12 imaging (FP, FA, and OCT) was evaluated by the Duke Reading Center for CNV, irrespective of suspicion by principal investigator or visual acuity

ACP, avacincaptad pegol; CNV, choroidal neovascularization; FA, Fluorescein angiography; FP, fundus photography; OCT, optical coherence tomography.

Exudative MNV in the study eye

	ACP 2 mg (N=225)	Sham (N=222)
Total CNV, n (%)	**15 (6.7)**	**9 (4.1)**
eMNV, n (%)	11 (4.9)	7 (3.2)
neMNV, n (%)	1 (0.4)	0
Peripapillary NV, n (%)	3 (1.3)	2 (0.9)

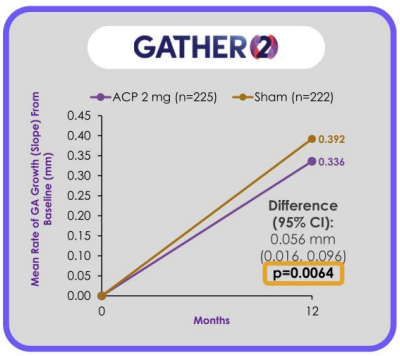
- Exudation status was read by the CORE Reading Center at Cole Eye Institute of the Cleveland Clinic
- OCT images were read to determine the number of CNV cases that were (1) macular neovascularization (MNV), versus peripapillary neovascularization and (2) exudative vs. non-exudative

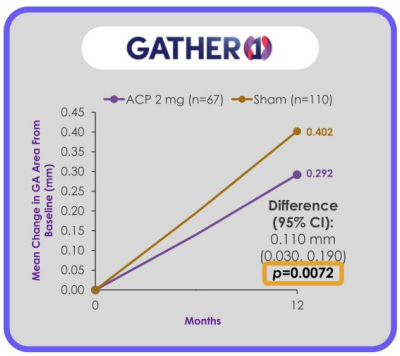
The Reading Center classifies cases of MNV as exudative or non-exudative based on the following OCT criteria:

- **"eMNV"** is MNV that presents with new onset fluid in either the subretinal space or the intraretinal space
- **"neMNV"** is MVV which does not present with new onset fluid in the subretinal or intraretinal spaces. In some cases, isolated fluid may be present in the sub-RPE space. A case is considered to be neMNV when the MNV may not be visible but both a double-layer sign and sub-RPE fluid are present

ACP, avacincaptad pegol; CNV, choroidal neovascularization; CORE, Center for Ocular Research and Evaluation; eMNV, exudative MNV; OCT, optical coherence tomography; MNV, macular neovascularization; neMNV, non-exudative MNV; RPE, retinal pigment epithelium.

Avancincaptad pegol is the first investigational therapy in GA to achieve the 12-month prespecified, primary endpoint, in two pivotal, phase 3 studies





ACP, avacincaptad pegol; CI, confidence interval; GA, geographic atrophy.


Thank you to the GATHER program
investigators, research staff, and patients
GATHER1
GATHER2