Iveric Bio Reports First Quarter 2019 Financial and Operating Results

May 8, 2019

- Conference Call and Webcast Today, May 8, 2019, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--May 8, 2019-- IVERIC bio (Nasdaq: ISEE) today announced financial and operating results for the first quarter ended March 31, 2019 and provided a business update.

“2019 is a transformational year for the Company,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. “Our recent re-branding and corporate name change reflects our commitment to develop gene therapy treatments for patients with orphan inherited retinal diseases. We believe this is an important time for the Company as we advance our diversified pipeline with multiple IRD gene therapy programs, including programs for rhodopsin-mediated autosomal dominant retinitis pigmentosa, BEST1 related retinal diseases, Leber congenital amaurosis type 10 (LCA10) and Stargardt disease. We expect to enter into the clinic with IC-100, our RHO-adRP product candidate, in 2020. Our therapeutics programs continue to remain on track with clinical data for Zimura expected in the fourth quarter of 2019 and the second half of 2020. We look forward to the exciting opportunities that lie ahead to generate value for our shareholders.”

First Quarter/Recent 2019 Highlights

- As part of the Company’s transformation strategy to focus on discovering and developing novel gene therapy solutions to treat orphan inherited retinal diseases (IRDs) with significant unmet medical needs, the Company rebranded to IVERIC bio, Inc. In conjunction with the corporate rebrand, the Company began trading on the Nasdaq Global Select Market under the new ticker symbol “ISEE” on April 17, 2019.
- A natural history study and IND enabling activities for IC-100 are ongoing. The Company expects to initiate a Phase 1/2 clinical trial in rhodopsin mediated adRP in 2020.
- In April 2019, the Company entered into an exclusive global license agreement with the University of Pennsylvania (Penn) and the University of Florida Research Foundation for rights to develop and commercialize novel adeno-associated virus gene therapy product candidates for the treatment of BEST1 related retinal diseases, including Best vitelliform macular dystrophy, also known as Best disease. Natural history studies for BEST1 related retinal diseases and IND enabling activities for IC-200, the product candidate for this program, are ongoing. The Company expects to initiate a Phase 1/2 clinical trial with IC-200 in the first half of 2021.
- The Company’s sponsored research programs to evaluate a minigene strategy for both LCA10, caused by mutations in the CEP290 gene, and autosomal recessive Stargardt disease, caused by mutations in the ABCA4 gene, are ongoing. The Company expects to receive research results for the LCA10 program during this year and expects to receive research results for the Stargardt minigene ABCA4 program during 2020.
- Initial top-line data for the Company’s ongoing Phase 2b clinical trial of Zimura® (avacincaptad pegol sodium), which is a C5 complement inhibitor, for the treatment of geographic atrophy secondary to dry age-related macular degeneration remains on track for data to be available in the fourth quarter of 2019. In February 2019, the Company completed patient enrollment in its Phase 2b clinical trial assessing the efficacy and safety of Zimura monotherapy in patients with autosomal recessive Stargardt disease. Initial top-line data is expected to be available in the second half of 2020.
- Effective January 1, 2019, Calvin W. Roberts, M.D., Senior Vice President and Chief Medical Officer, Eye Care at Bausch Health Companies and Clinical Professor of Ophthalmology at Weill Medical College of Cornell University, was elected to IVERIC bio’s Board of Directors.

2019 Operational Update

As of March 31, 2019, the Company had $116.6 million in cash and cash equivalents. The Company estimates its year end 2019 cash and cash equivalents will range between $80 million and $85 million based on its current 2019 business plan, including the continued preclinical development of IC-100 and IC-200, the continuation of its ongoing collaborative gene therapy sponsored research programs, the continued clinical development of Zimura and the continued preclinical development of its HtrA1 inhibitor program. This estimate does not reflect any expenditures resulting from additional sponsored research agreements the Company may enter into or the potential in-licensing or acquisition of additional product candidates or technologies or any associated development that the Company may pursue.

2019 Financial Highlights

- **R&D Expenses**: Research and development expenses were $7.7 million for the quarter ended March 31, 2019, unchanged from the same period in 2018 as increases in costs associated with the Company's gene therapy programs were offset by decreases in costs associated with the Company's Zimura programs.
- **G&A Expenses**: General and administrative expenses were $5.5 million for the quarter ended March 31, 2019, compared to $5.6 million for the same period in 2018. General and administrative expenses decreased primarily due to decreases in costs to support the Company's operations and infrastructure.
- **Net Income**: The Company reported a net loss for the quarter ended March 31, 2019 of $12.5 million, or ($0.30) per diluted share, compared to net loss of $13.1 million, or ($0.36) per diluted share, for the same period in 2018.

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 May 8, 2019 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 888-224-1005 (USA) or 323-794-2551 (International), passcode 9765307. A live, listen-only audio webcast of the conference call can be accessed on the Investor Relations 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 888-203-1112 (USA Toll Free), passcode 9765307.

About IVERIC bio

IVERIC bio is a biotechnology company with a focus on the discovery and development of novel gene therapy solutions to treat orphan inherited retinal diseases with unmet medical needs. Vision is Our Mission. For more information on the Company's gene therapy and other programs, 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," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, the Company's forward looking statements include statements about the implementation of its strategic plan, including its transition to a gene therapy focused company, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities, the potential utility of its product candidates, and the potential for its business development strategy, including any potential in-license or acquisition opportunities. 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 conduct and design of research programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, 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 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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IVERIC bio
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2019	**2018**
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 7,685	$ 7,686
General and administrative	5,481	5,645
Total operating expenses	13,166	13,331
Loss from operations	(13,166)	(13,331)
Interest income	670	473
Other expense	-	(16)
Loss before income tax provision	(12,496)	(12,874)
Income tax provision	5	199
Net loss	$ (12,501)	$ (13,073)
Net loss per common share:		
Basic and diluted	$ (0.30)	$ (0.36)

Weighted average common shares outstanding:		
Basic and diluted	41,427	36,153

	March 31, 2019	December 31, 2018
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 116,639	$ 131,201
Total assets	124,096	137,165
Total liabilities	10,127	13,206
Additional paid-in capital	548,096	545,585
Accumulated deficit	(434,168)	(421,667)
Total stockholders' equity	$ 113,969	$ 123,959

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