UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **February 6, 2023**

Aceragen, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-31918**	**04-3072298**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

505 Eagleview Blvd., Suite 212 Exton, Pennsylvania	**19341**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(484) 348-1600**

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, par value $0.001 per share	ACGN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01. Other Events.

As previously disclosed in the Current Report on Form 8-K/A filed by Aceragen, Inc. (formerly known as Idera Pharmaceuticals, Inc.) (the "Company") with the Securities and Exchange Commission on December 9, 2022, the Company is conducting the TERRA study (NCT05105035), a phase 2 randomized, double-blind, placebo-controlled study for the treatment of melioidosis in hospitalized patients with melioidosis (the "TERRA Study"). The Company previously disclosed that the independent data monitoring committee ("iDMC"), which has responsibility for overseeing safety and efficacy data from the TERRA Study, was expected to convene in the first quarter of 2023 to provide recommendations for potential changes in eligibility criteria based on its assessment of safety and aggregate clinical event rates observed in the TERRA Study. On February 6, 2023, the Company issued a press release announcing that the iDMC for the TERRA Study met and recommended that the TERRA Study continue without modification. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

See the Exhibit Index below, which is incorporated by reference herein.

Exhibit No.	**Description**
99.1	Press Release, dated February 6, 2023.
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.

ACERAGEN, INC.

By: /s/ Bryant D. Lim
Bryant D. Lim
Chief Business Officer and General Counsel

Dated: February 6, 2023

Exhibit 99.1

ACERAGEN ANNOUNCES RECOMMENDATION OF DATA MONITORING COMMITTEE IN *TERRA* STUDY

DURHAM, N.C. and EXTON, Pa., Feb. 6, 2023 (GLOBE NEWSWIRE) -- Aceragen, Inc. (Nasdaq: ACGN) a clinical-stage biopharmaceutical company committed to transforming the care of people living with rare pulmonary and rheumatic diseases, today announced the recommendation of its independent Data Monitoring Committee (DMC) in regard to the on-going TERRA Phase 2 study of ACG-701 in patients with melioidosis. The DMC is responsible for providing oversight of safety and efficacy for this study and has recommended the TERRA study continue without modification.

The DMC review was a planned meeting held in order to monitor the safety of the seriously ill subjects participating in the TERRA study.

“This safety review represents an important milestone for ACG-701, as it allows the TERRA study to continue to evaluate ACG-701 in these hospitalized melioidosis patients. We are very pleased that the DMC recommended that the trial continue. We look forward to delivering the data from the study later this year,” stated Carl Kraus, M.D., Aceragen’s Chief Medical Officer.

ACG-701 for Melioidosis

Aceragen has executed an ~$50 million development partnership with the Department of Defense’s Defense Threat Reduction Agency (“DTRA”) to investigate ACG-701 as a potential medical countermeasure for melioidosis, a life-threatening infection caused by the *B. pseudomallei* pathogen. This program is centered around a Phase 2 trial, the TERRA study (NCT05105035), which is a randomized double-blind, placebo-controlled trial conducted in hospitalized melioidosis patients. TERRA was initiated in May 2022 and continues to actively enroll patients with a data read-out expected in the fourth quarter of 2023.

About Aceragen, Inc.

Aceragen is a clinical-stage biopharmaceutical company committed to transforming the care of people living with rare pulmonary and rheumatic diseases. Our lead product candidate, ACG-701, is an oral, loading dose formulation of sodium fusidate that is in development for the treatment of melioidosis and acute pulmonary exacerbations associated with cystic fibrosis. ACG-701 has received Fast Track Designation, Orphan Drug Designation, and Qualified Infectious Disease Product (QIDP) from the FDA in acute exacerbations with cystic fibrosis. Aceragen is also developing ACG-801, recombinant human acid ceramidase, as an enzyme replacement therapy for an untreated lysosomal storage disorder called Farber disease. To learn more about us and our programs, please visit Aceragen.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including, without limitation, statements regarding the Company's new development opportunities, clinical trials and studies, product designation and/or status, financial position, funding for continued operations, cash reserves, projected costs, prospects, clinical trials, plans, expectations, strategies, projections and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," “schedule,” and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on our current expectations and projections about future events and various assumptions. We cannot guarantee that we will achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond our control, and which may cause our actual results, performance, or achievements to differ materially from future results, performance, or achievements expressed or implied by such forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by its forward-looking statements including, without limitation: whether we will be able to successfully integrate the acquired operations; whether our cash resources will be sufficient to fund continuing operations; and newly acquired operations; whether our products will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether our products receive approval, they will be successfully distributed and marketed; and whether our collaborations will be successful. All forward-looking statements included in this press release are made as of the date hereof and are expressly qualified in their entirety by this cautionary notice, including, without limitation, those risks and uncertainties described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, and otherwise in the Company’s subsequent filings and reports filed with Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as may be required by law.

Please direct questions to:

John Kirby
Chief Financial Officer
Aceragen, Inc.
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