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): **November 14, 2022**

Idera Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in 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 Exchange Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	IDRA	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 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Idera Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's financial results for the third quarter ended September 30, 2022. As set forth below, the Company is furnishing the press release as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K, including the accompanying 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 liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit No.	**Financial Statements and Exhibits.**
99.1	Press Release by the Company, dated November 14, 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.

IDERA PHARMACEUTICALS, INC.

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

Dated: November 14, 2022

Exhibit 99.1

Idera Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Closing of Aceragen acquisition positions combined company for success with late-stage rare disease portfolio

EXTON, PA & DURHAM, NC, November 14, 2022 — Idera Pharmaceuticals, Inc. ("Idera," the "Company," "we," "us," or "our") (Nasdaq: IDRA) today reported its consolidated financial and operational results for the third quarter ended September 30, 2022.

"We are pleased to have completed the merger of Idera and Aceragen at the end of the third quarter, better enabling us to deliver important therapies for people living with rare diseases," stated John Taylor, Idera's Chief Executive Officer. "Our resulting cash position is expected to provide runway into Q3 2023 and fund the advancement of our pipeline, including ACG-701 and ACG-801, through important anticipated 2023 clinical milestones. Our team continues to execute on the integration effort and diligently progress toward our near-term clinical milestones, which include initiation of our cystic fibrosis (CF) and Farber disease clinical trials and anticipated data from our melioidosis study."

Clinical Development Updates

REPRIEVE Study in Cystic Fibrosis: Randomized, double-blind, placebo-controlled Phase 2 study evaluating treatment with ACG-701, a proprietary oral formulation of sodium fusidate, in newly diagnosed pulmonary exacerbations in CF patients.

- The REPRIEVE study is on track for initiation by the end of 2022, with data anticipated in Q3 2023

TERRA Study for Melioidosis: Randomized, double-blind, placebo-controlled Phase 2 study evaluating ACG-701 in hospitalized melioidosis patients.

- The independent Data Monitoring Committee (DMC) for the TERRA Study is expected to meet by the end of 2022 to recommend whether the study should continue as planned or, if efficacy and safety data are compelling, to be immediately unblinded for full analysis. This DMC assessment is intended to be in lieu of the interim analysis originally anticipated in Q1 2023.

ADVANCE Study for Farber Disease: Randomized, double-blind, placebo-controlled, first-in-human, Phase 2 study of ACG-801 in patients with Farber disease.

- The ADVANCE study is on track for initiation in the second half of 2023.

Corporate Updates

Since June 30, 2022, the following corporate updates were announced:

- As previously disclosed, on September 28, 2022, the Company announced its acquisition, via a stock-for-stock transaction, of Aceragen, Inc., a private biotechnology company addressing severe, rare pulmonary and rheumatic diseases for which there is significant medical need and limited or no available treatments.
    - The combined cash of the two companies is expected to provide runway into Q3 2023, funding the advancement of ACG-701 and ACG-801 through important 2023 clinical milestones.
- In connection with the acquisition, the Company announced several leadership and Board changes:
    - John Taylor, the former Chief Executive Officer of Aceragen, was named Chief Executive Officer of the Company. Additional management team members are Carl Kraus, Aceragen's former Chief Medical Officer, who now serves in that role for Idera; Bryant Lim, who continues in his role as Idera's Chief Business Officer and General Counsel; Daniel Salain, Aceragen's former Chief Operating Officer, who serves in that role for Idera; Andy Jordan, Aceragen's former Chief Financial Officer, who was appointed Chief Strategy Officer for Idera; and John Kirby, who continues in his role as Idera's Chief Financial Officer.
    - Vincent Milano, Idera's former Chief Executive Officer, was named Chair of the Board of Directors for the Company. Idera Board members Cristina Csimma, Pharm. D., M.H.P., James Geraghty, Maxine Gowen, Ph.D., and Michael Dougherty continue in their positions and are joined by John Taylor and Ron Wooten, Senior Founding Partner, NovaQuest Capital Management LLC. Mr. Taylor and Mr. Wooten previously served on Aceragen's board.

Third Quarter Financial Results

The Company's pro forma cash position as of September 30, 2022 was approximately $27 million. Research and development expenses for the three months ended September 30, 2022 totaled $1.5 million, compared to $3.5 million for the same period in 2021. General and administrative expenses for the three months ended September 30, 2022 totaled $2.3 million, compared to $2.3 million for the same period in 2021. Restructuring costs for the three months ended September 30, 2022 totaled approximately $2.8 million, compared to $0.1 million for the same period in 2021, and relate to a reduction in force due to our acquisition of Aceragen. Merger related costs for the three months ended September 30, 2022 totaled $2.8 million. The Company recorded an income tax benefit of $6.0 million in the three months ended September 30, 2022.

As a result of the factors above, net loss applicable to common stockholders for the three months ended September 30, 2022 was $3.1 million or $0.06 per basic and diluted share compared to net loss applicable to common stockholders of $6.0 million or $0.11 per basic and diluted share for the same period in 2021.

About Idera Pharmaceuticals

Idera is a clinical-stage biopharmaceutical company committed to transforming the care of people living with rare pulmonary and rheumatic diseases. Our portfolio includes late-stage programs that we are developing to be innovative therapeutics capable of addressing the unmet medical needs of these individuals. To learn more about Idera, visit IderaPharma.com.

About ACG-701 for Acute Pulmonary Exacerbations

ACG-701 is a proprietary oral formulation of sodium fusidate being developed as a potential treatment for acute pulmonary exacerbations ("PEx") associated with cystic fibrosis ("CF") and for melioidosis, a life-threatening infection caused by the *B. pseudomallei* pathogen.

The Phase 2 trial of ACG-701 in CF PEx (the REPRIEVE study) is expected to initiate during Q4 2022 at clinical sites in the United States in collaboration with the CF Foundation's Therapeutic Development Network (TDN). The CF Foundation has also graciously provided a funding award in support of the study. If approved, ACG-701 would represent the first product in the United States indicated for the treatment of CF PEx, a major factor driving lung function decline in people living with CF. Initial data from the REPRIEVE study is expected in Q3 2023. The active component of ACG-701, sodium fusidate, has the opportunity for new chemical entity (NCE) status in the US, as sodium fusidate has not been previously approved by the FDA. Despite this, the compound has an established clinical efficacy and safety profile from more than 50 years of use in other countries, including as part of CF PEx treatment guidelines in the United Kingdom and Australia. The FDA has assigned Orphan, Fast Track, and Qualified Infectious Disease Product status to ACG-701 for CF PEx.

The melioidosis clinical program for ACG-701 is supported by funding up to $49.7 million, of which $13.2 million has been received by the Company, from the Defense Threat Reduction Agency ("DTRA") to investigate our product as a potential medical countermeasure for this disease. This trial, the TERRA study (NCT05105035), is currently enrolling, targeting review by a independent DMC during Q4 2022. This clinical study is distinct as it is the first randomized double-blinded, placebo-controlled trial to ever be run for melioidosis. Complete Phase 2 data are expected by Q2 2023.

About ACG-801 for Farber Disease

ACG-801, recombinant human acid ceramidase, is an investigational biologic under development to be the first-ever enzyme replacement therapy for the treatment of acid ceramidase deficiency, also called Farber disease, a progressive, severe and life-threatening lysosomal storage disorder. The condition is hallmarked by loss of acid ceramidase enzyme activity leading to abnormal accumulation of ceramide, profound macrophage-driven inflammation and multi-organ disease affecting bone and joints, cartilage, the immune system, central nervous system, and the lungs. Many of these patients die from complications of the disease, with the most severely affected patients dying in the first years of life. There are no Farber disease-specific medications currently available that can alter the natural history of the disease.

The Company expects to initiate the ADVANCE clinical study for ACG-801 in Farber disease in 2H 2023 with data expected in Q1 2024. Due to the ultra-rare nature of Farber disease, this study has the potential to be registrational. The FDA has granted Orphan, Fast Track, and Rare Pediatric Disease designations for ACG-801, which may be eligible for a priority review voucher (PRV) upon approval by FDA.

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 the Company's current expectations and projections about future events and various assumptions. Idera cannot guarantee that it will achieve the plans, intentions, or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company 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 Idera's actual results to differ materially from those indicated or implied by its forward-looking statements including, without limitation: whether the Company will be able to successfully integrate the Aceragen operations; whether the Company's stockholders approve the conversion of the Series Z Preferred Stock; whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the newly acquired Aceragen operations, including the liabilities of Aceragen incurred in connection with the completion of the transactions; whether the Company's 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, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and whether the Company will be able to comply with the continued listing requirements of the Nasdaq Capital Market. 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 filings and reports filed with Securities and Exchange Commission. While Idera may elect to do so at some point in the future, 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.

Idera Pharmaceuticals, Inc.
Statements of Operations
(In thousands, except per share data)

	Three Months Ended September 30		Nine Months Ended September 30	
	2022	**2021**	**2022**	**2021**
Government contracts revenue	$ 49	$ -	$ 49	$ -
Operating expenses:				
Research and development	1,470	3,507	5,960	14,271
General and administrative	2,268	2,331	7,325	7,959
Acquisition-related costs	2,836	-	2,836	
Restructuring and other costs	2,802	130	2,802	1,322
Total operating expenses	9,376	5,968	18,923	23,552
Loss from operations	(9,327)	(5,968)	(18,874)	(23,552)
Other income (expense)				
Warrant revaluation gain	116	-	116	6,983
Future tranche right revaluation gain	-	-	-	118,803
Other income (expense), net	73	3	135	(24)
(Loss) income before income tax benefit	$ (9,138)	$ (5,965)	$ (18,623)	$ 102,210
Income tax benefit	6,039	-	6,039	-
Net (loss) income	$ (3,099)	$ (5,965)	$ (12,584)	$ 102,210
Undistributed earnings to preferred stockholders	-	-	-	-
Net income (loss) applicable to common stockholders	$ (3,099)	$ (5,965)	$ (12,584)	$ 102,210
Net income (loss) applicable to common stockholders				
— Basic	$ (3,099)	$ (5,965)	$ (12,584)	$ 100,574
— Diluted	$ (3,099)	$ (5,965)	$ (12,584)	$ (23,576)
Net income (loss) per share applicable to common stockholders				
— Basic	$ (0.06)	$ (0.11)	$ (0.24)	$ 2.10
— Diluted	$ (0.06)	$ (0.11)	$ (0.24)	$ (0.46)
Weighted-average number of common shares used in computing net income (loss) per share applicable to common stockholders				
— Basic	53,286	52,740	53,052	47,990
— Diluted	53,286	52,740	53,052	51,613

Idera Pharmaceuticals, Inc.
Balance Sheet Data
(In thousands)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 26,795	$ 32,545
Other assets	76,887	2,319
Total assets	$ 103,682	$ 34,864
Total Redeemable	$ 29,175	$ -
Total liabilities	53,739	5,411
Total stockholders' equity (deficit)	20,768	29,453
Total liabilities, convertible redeemable preferred stock and stockholders' equity (deficit)	$ 103,682	$ 34,864

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