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): December 19, 2023

Aclaris Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37581**	**46-0571712**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

701 Lee Road, Suite 103
Wayne, PA 19087
(Address of principal executive offices, including zip code)

(484) 324-7933
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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:

☐ 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, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

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 2.05 Costs Associated with Exit or Disposal Activities.

On December 19, 2023, Aclaris Therapeutics, Inc. (the "***Company***") announced a reduction of its workforce by approximately 46%, which the Company expects to be substantially completed by June 30, 2024, and fully completed by December 31, 2024. The Board of Directors approved these actions on December 18, 2023 in light of the Company's revised operating plans, in order to streamline operations, reduce costs and preserve capital.

As a result of the reduction in force, the Company expects to incur a one-time charge totaling approximately $3.1 million in connection with one-time employee termination costs, including severance and other benefits. This charge is expected to be incurred during the quarter ending December 31, 2023. In addition, an estimated charge between $1.9 million and $2.2 million is expected to be incurred for additional termination costs, including severance and other benefits, over the next twelve months. In total, this plan is estimated to cost between $5.0 million and $5.3 million over the next twelve months, excluding non-cash charges, with related cash payments expected to be substantially paid out by September 30, 2024.

The estimates of costs that the Company expects to incur and the timing thereof are subject to a number of assumptions and actual results may differ.

Cautionary Note Regarding Forward-Looking Statements

This Current Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the scope, timing and impacts of the reduction in force and the expected costs related to the reduction in force, which are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, the Company's reliance on third parties over which it may not always have full control, the Company's ability to enter into strategic partnerships on commercially reasonable terms and other risks and uncertainties that are described in the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and other filings the Company makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC Filings" page of the "Investors" section of the Company's website at www.aclaristx.com. Any forward-looking statements speak only as of the date of this Form 8-K and are based on information available to the Company as of the date of this Form 8-K, and the Company assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 7.01 Regulation FD Disclosure.

The Company issued a press release on December 19, 2023 announcing a corporate update, a copy of which is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto 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 that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated December 19, 2023.
104	The cover page from Aclaris Therapeutics, Inc.'s Form 8-K filed on December 19, 2023, formatted in Inline XBRL.

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.

ACLARIS THERAPEUTICS, INC.

By: /s/ Douglas Manion
Douglas Manion
Chief Executive Officer and President

Date: December 19, 2023

Aclaris Therapeutics Provides Corporate Update

- ATI-1777 Phase 2a Trial Results Published in *JID Innovations* -
- ATI-1777 Phase 2b Trial Topline Data Anticipated in January 2024 -
- Aclaris Announces Reduction in Workforce -

WAYNE, Pa., Dec. 19, 2023 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drugs for immuno-inflammatory diseases, today announced several corporate updates.

First, Aclaris announced the publication of the Phase 2a trial results of ATI-1777 in moderate to severe atopic dermatitis (AD) in the peer-reviewed journal *JID Innovations* on November 27, 2023. ATI-1777 is Aclaris' investigational topical "soft" JAK 1/3 inhibitor being developed as a potential treatment for mild to severe AD that was generated from its proprietary KINect® drug discovery platform.

The article, entitled "ATI-1777 a topical JAK 1/3 inhibitor may benefit atopic dermatitis without systemic drug exposure, results from preclinical development and Phase 2a randomized-controlled study ATI-1777-AD-201," presents the results from both preclinical development studies and the Phase 2a study of ATI-1777 in moderate to severe AD, and is available here.

In the Phase 2a study, ATI-1777 demonstrated meaningful improvement in the modified Eczema Area and Severity Index (EASI) over 4 weeks of treatment and minimal measurable systemic exposure with a 2% formulation applied twice daily.

Based on these results, Aclaris progressed ATI-1777 into a Phase 2b trial in patients with mild to severe AD. The Phase 2b vehicle-controlled trial is designed to further explore the concentration range (0.5%, 1%, and 2%) of ATI-1777, as well as a once-daily regimen using the 2% formulation. The trial enrolled 250 patients, including adults and children as young as 12 years old, across 34 clinical trial sites in the United States. The primary efficacy endpoint is the percent change in EASI over a period of 4 weeks. Secondary measures of efficacy, as well as safety and pharmacokinetics, will also be assessed. Aclaris now expects to report top-line results from this trial in January 2024.

"We are excited by the recent publication of our ATI-1777 Phase 2a trial in *JID Innovations*, particularly with our top-line results from the Phase 2b trial expected early next year," stated Douglas Manion, M.D., Aclaris' Chief Executive Officer. "If the results of the Phase 2b trial are positive, we intend to seek a commercialization partner for the asset."

Aclaris also announced the following corporate updates:

- Aclaris now plans to explore the use of zunsemetinib (ATI-450), its investigational lead oral small molecule MK2 inhibitor, as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer. Aclaris plans to use ATI-450

instead of ATI-2231, its second MK2 inhibitor, due to ATI-450's more advanced clinical development package. Aclaris plans to continue the development in collaboration with Washington University.
- Aclaris is reassessing the most effective pathway for ATI-2138, its investigational oral covalent ITK/JAK3 inhibitor, including the indication selection due to the evolving competitive landscape within ulcerative colitis. Aclaris plans to provide further guidance in early 2024.
- Aclaris intends to accelerate the advancement of several of its discovery programs emerging from the KINect drug discovery platform, with the goal of generating investigational new drug applications from these programs in the near term.

In addition, Aclaris has approved a plan to reduce its workforce by approximately 46%. Aclaris anticipates this reduction will begin immediately and will be substantially complete by June 30, 2024.

Continued Manion, "With the discontinuation of development of ATI-450 for immuno-inflammatory disease indications, we are taking steps to reduce our spending and streamline our organization which we expect to meaningfully preserve capital. I would like to offer my deepest appreciation to all of our employees for their passion, professionalism and dedication they have put forth every day."

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe," "expect," "intend," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include statements concerning or implying the therapeutic potential of Aclaris' drug candidates, Aclaris' expectations regarding the availability of data and timing of reporting results from its ATI-1777 Phase 2b trial and the development strategy for ATI-1777, including intentions to seek a commercialization partner for the asset, the development plans for its other drug candidates, including zunsemetinib, Aclaris' plans regarding the timing of additional guidance on its ATI-2138 program, Aclaris' intentions to accelerate the advancement of its discovery programs, and statements regarding Aclaris' planned reduction in force, including the expected timing and Aclaris' ability to achieve the expected benefits thereof. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, Aclaris' ability to enter into strategic partnerships on commercially reasonable terms and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2022 and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC Filings" page of the "Investors" section of Aclaris' website at www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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