
**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): November 6, 2024

Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-37581
(Commission File Number)

46-0571712
(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)

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 2.02 Results of Operations and Financial Condition.

On November 6, 2024, Aclaris Therapeutics, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 2024. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02 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 Registrant’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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release, dated November 6, 2024.
104	The cover page from Aclaris Therapeutics, Inc.’s Form 8-K filed on November 6, 2024, 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.

Date: November 6, 2024

By: /s/ Kevin Balthaser
Kevin Balthaser
Chief Financial Officer

Aclaris Therapeutics Reports Third Quarter 2024 Financial Results and Provides a Corporate Update

- First Patient Dosed in ATI-2138 Phase 2a Trial in Atopic Dermatitis As Previously Announced; Top-line Data Anticipated in First Half of 2025 –

WAYNE, Pa., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced its financial results for the third quarter of 2024 and provided a corporate update.

"The third quarter of 2024 marked an important milestone for Aclaris with the dosing of our first patient in the Phase 2a trial of ATI-2138 for moderate to severe atopic dermatitis," said Dr. Neal Walker, Interim President & CEO and Chair of the Board of Directors of Aclaris. "This milestone, combined with our robust financial position, underscores our commitment to executing a capital-efficient development strategy."

Research and Development Highlights:

- **ITK Inhibitor Programs**
 - **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor
 - **Atopic Dermatitis (ATI-2138-AD-201)**: This Phase 2a open-label trial to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 in patients with moderate to severe atopic dermatitis (AD) is ongoing. Aclaris continues to expect top-line data in the first half of 2025.
 - **ITK Selective Compound**
 - Aclaris is progressing a second generation ITK selective inhibitor to development candidate selection for autoimmune indications.
 - **Lepzacinib (ATI-1777)**, an investigational topical "soft" JAK 1/3 inhibitor
 - In January 2024, Aclaris reported positive top-line results from its Phase 2b trial of lepzacinib in AD.
 - Aclaris is currently seeking a global development and commercialization partner for this program (excluding Greater China). As previously announced, in 2022 Aclaris granted Pediatrix Therapeutics exclusive rights to develop and commercialize lepzacinib in Greater China.
 - **Zunsemetinib (ATI-450)**, an investigational oral small molecule MK2 inhibitor
 - Aclaris plans to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib as a potential treatment for pancreatic cancer and metastatic breast cancer. Aclaris expects these trials to be primarily funded by grants awarded to Washington University.
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Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2024, Aclaris had aggregate cash, cash equivalents and marketable securities of \$173.4 million compared to \$181.9 million as of December 31, 2023.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of September 30, 2024 will be sufficient to fund its operations into 2028, without giving effect to any potential business development transactions, financing activities or the outcome of its strategic review.

Financial Results

Third Quarter 2024

- Net loss was \$7.6 million for the third quarter of 2024 compared to \$29.3 million for the third quarter of 2023.
- Total revenue was \$4.3 million for the third quarter of 2024 compared to \$9.3 million for the third quarter of 2023. The decrease was primarily driven by higher milestones earned during the prior year period compared to the current year period.
- Research and development (R&D) expenses were \$6.0 million for the quarter ended September 30, 2024 compared to \$23.9 million for the prior year period.
 - The \$17.9 million decrease was primarily the result of:
 - Zunsemetinib development expenses associated with clinical trials in 2023, and drug candidate manufacturing costs;
 - Costs associated with lepzacitinib preclinical development activities and a Phase 2b clinical trial for AD which was completed in January 2024;
 - ATI-2138 development expenses, including costs associated with a Phase 1 multiple ascending dose (MAD) trial which was completed in September 2023 and other preclinical activities, which were partially offset by clinical development expenses associated with a Phase 2a clinical trial which commenced in August 2024; and
 - Lower compensation-related expenses due to a decrease in headcount and higher forfeiture credits.
- General and administrative (G&A) expenses were \$5.7 million for the quarter ended September 30, 2024 compared to \$7.1 million for the corresponding prior year period. The decrease was primarily due to a reduction in compensation-related expenses due to lower headcount and higher forfeiture credits.
- Licensing expenses were \$1.8 million for the quarter ended September 30, 2024 compared to \$7.3 million for the corresponding prior year period. The decrease was primarily due to higher milestones earned during the prior year period compared to the current year period.
- Revaluation of contingent consideration resulted in a \$0.8 million loss for the quarter ended September 30, 2024 compared to a loss of \$1.7 million for the prior year period.

Year-to-date 2024

- Net loss was \$35.5 million for the nine months ended September 30, 2024 compared to \$87.0 million for the nine months ended September 30, 2023.
 - Total revenue was \$9.5 million for the nine months ended September 30, 2024 compared to \$13.7 million for the nine months ended September 30, 2023. The decrease was primarily driven by higher milestones earned during the prior year period compared to the current year period.
 - R&D expenses were \$24.6 million for the nine months ended September 30, 2024 compared to \$71.7 million for the corresponding prior year period.
 - The \$47.1 million decrease was primarily the result of:
 - Zunsemetinib development expenses associated with clinical trials in 2023, and drug candidate manufacturing costs;
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- Costs associated with lepzacitinib preclinical development activities and a Phase 2b clinical trial for AD which was completed in January 2024;
 - ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial which was completed in September 2023 and other preclinical activities, which were partially offset by clinical development expenses associated with a Phase 2a clinical trial which commenced in August 2024; and
 - Lower compensation-related expenses due to a decrease in headcount and higher forfeiture credits.
- G&A expenses were \$17.2 million for the nine months ended September 30, 2024 compared to \$24.2 million for the prior year period. The decrease was primarily due to a reduction in compensation-related expenses due to lower headcount and higher forfeiture credits and the recognition of bad debt expense recorded in the prior year period from Aclaris' determination that collection of amounts due from EPI Health are uncertain as a result of their filing for Chapter 11 bankruptcy protection.
 - Licensing expenses were \$4.1 million for the nine months ended September 30, 2024 compared to \$9.0 million for the prior year period. The decrease was primarily due to higher milestones earned during the prior year period compared to the current year period.
 - Revaluation of contingent consideration resulted in a \$3.8 million loss for the nine months ended September 30, 2024 compared to a gain of \$0.6 million for the corresponding prior year period.

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 "anticipate," "believe," "expect," "intend," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding its plans for its development programs, including its plans to seek a development and commercialization partner for lepzacitinib, the clinical development of ATI-2138, including the timing of top-line data, its plan to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib, the sufficiency of its cash, cash equivalents and marketable securities to fund its operations into 2028, as well as its strategic review. 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, the uncertainty regarding the macroeconomic environment 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, 2023, 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.

Aclaris Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Contract research	\$ 645	\$ 705	\$ 1,926	\$ 2,469
Licensing	3,701	8,577	7,583	11,210
Total revenue	<u>4,346</u>	<u>9,282</u>	<u>9,509</u>	<u>13,679</u>
Costs and expenses:				
Cost of revenue (1)	654	848	2,087	2,698
Research and development (1)	5,956	23,876	24,560	71,738
General and administrative (1)	5,653	7,091	17,249	24,198
Licensing	1,754	7,344	4,070	8,955
Revaluation of contingent consideration	800	1,700	3,800	(600)
Total costs and expenses	<u>14,817</u>	<u>40,859</u>	<u>51,766</u>	<u>106,989</u>
Loss from operations	<u>(10,471)</u>	<u>(31,577)</u>	<u>(42,257)</u>	<u>(93,310)</u>
Other income:				
Interest income	1,991	2,316	5,850	6,320
Non-cash royalty income	894	—	894	—
Total other income	<u>2,885</u>	<u>2,316</u>	<u>6,744</u>	<u>6,320</u>
Net loss	<u>\$ (7,586)</u>	<u>\$ (29,261)</u>	<u>\$ (35,513)</u>	<u>\$ (86,990)</u>
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.41)</u>	<u>\$ (0.50)</u>	<u>\$ (1.25)</u>
Weighted average common shares outstanding, basic and diluted	71,381,731	70,807,934	71,249,813	69,452,495

(1) Amounts include stock-based compensation expense as follows:

Cost of revenue	\$ 232	\$ 347	\$ 707	\$ 1,119
Research and development	1,124	3,072	2,192	9,168
General and administrative	1,648	2,529	5,097	8,989
Total stock-based compensation expense	<u>\$ 3,004</u>	<u>\$ 5,948</u>	<u>\$ 7,996</u>	<u>\$ 19,276</u>

Aclaris Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited, in thousands, except share data)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 173,436	\$ 181,877
Total assets	\$ 182,394	\$ 197,405
Total current liabilities	\$ 18,816	\$ 30,952
Total liabilities	\$ 52,243	\$ 40,226
Total stockholders' equity	\$ 130,151	\$ 157,179
Common stock outstanding	71,417,513	70,894,889

Aclaris Therapeutics, Inc.
Selected Consolidated Cash Flow Data
(unaudited, in thousands)

	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Net loss	\$ (35,513)	\$ (86,990)
Depreciation and amortization	664	635
Stock-based compensation expense	7,996	19,276
Revaluation of contingent consideration	3,800	(600)
Changes in operating assets and liabilities	11,916	(3,885)
Net cash used in operating activities	<u>\$ (11,137)</u>	<u>\$ (71,564)</u>

Aclaris Therapeutics Contact:

investors@aclaristx.com

