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): August 7, 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.)

640 Lee Road, Suite 200
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 2.02 Results of Operations and Financial Condition.

On August 7, 2023, Aclaris Therapeutics, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter and six months ended June 30, 2023. 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 (the "***Securities Act***"), 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 August 7, 2023.
104	The cover page from Aclaris Therapeutics, Inc.'s Form 8-K filed on August 7, 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
President and Chief Executive Officer

Date: August 7, 2023

Exhibit 99.1

Aclaris Therapeutics Reports Second Quarter 2023 Financial Results and Provides a Corporate Update

- Completion of Enrollment in Zunsemetinib Phase 2b Trial in Rheumatoid Arthritis As Previously Announced; Data Expected in Q4 2023 –

WAYNE, Pa., Aug. 07, 2023 (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 second quarter of 2023 and provided a corporate update.

“During the second quarter of this year, we continued to make positive strides across our clinical development pipeline, most notably through the completion of enrollment in our Phase 2b trial of zunsemetinib in patients with rheumatoid arthritis, which positions that trial to be our next Phase 2 data read-out,” stated Doug Manion, M.D., Chief Executive Officer of Aclaris. “The next several quarters are lining up well with data read-outs for each of our clinical stage development therapeutics, all created by our KINect® drug discovery platform.”

Research and Development Highlights:

- **Zunsemetinib**, an investigational oral small molecule MK2 inhibitor:
  Currently being developed as a potential treatment for immuno-inflammatory diseases
    - **Rheumatoid Arthritis (ATI-450-RA-202)**: This Phase 2b placebo-controlled dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (RA) completed enrollment in June 2023. Aclaris continues to expect topline data in the fourth quarter of 2023.
    - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a placebo-controlled trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (PsA) is ongoing. Aclaris continues to expect topline data in the first half of 2024.
- **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor:
  Currently being developed as a potential treatment for mild to severe atopic dermatitis (AD)
    - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b vehicle-controlled trial to determine the efficacy, safety, tolerability, and PK of multiple doses and application regimens of ATI-1777 in subjects with mild to severe AD is ongoing. Aclaris continues to expect topline data in the second half of 2023.

- **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor:
  Currently being developed as a potential treatment for ulcerative colitis; Aclaris is also exploring additional indications for other T cell-mediated autoimmune diseases

    - **Healthy Volunteers (ATI-2138-PKPD-102)**: This two-week Phase 1 MAD (multiple ascending dose) trial to investigate the safety, tolerability, PK and PD of ATI-2138 in healthy volunteers has been completed. Based on a preliminary analysis of the PK, PD and safety, Aclaris believes the data support the progression of ATI-2138 into Phase 2 clinical development in ulcerative colitis. Aclaris expects to report the data in September 2023.

- **ATI-2231**, an investigational oral MK2 inhibitor compound:
  Currently being explored as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer

    - This is the second MK2 inhibitor generated from Aclaris' proprietary KINect® drug discovery platform and is designed to have a long plasma half-life.

    - Aclaris is supporting Washington University in a first-in-human investigator-initiated Phase 1a trial of ATI-2231 in patients with advanced solid tumor malignancies. Aclaris expects clinical development activities to be initiated in the second half of 2023.

Financial Highlights:

Liquidity and Capital Resources

As of June 30, 2023, Aclaris had aggregate cash, cash equivalents and marketable securities of $210.8 million compared to $229.8 million as of December 31, 2022. Aggregate cash, cash equivalents and marketable securities as of June 30, 2023 included $26.7 million of net proceeds from the sale of 3.4 million shares under its ATM facility in April 2023.

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or additional financing activities.

Financial Results

Second Quarter 2023

- Net loss was $29.6 million for the second quarter of 2023 compared to $20.5 million for the second quarter of 2022.

- Total revenue was $1.9 million for the second quarter of 2023 compared to $1.5 million for the second quarter of 2022. The increase was driven by higher licensing revenue primarily from royalties earned on out-licensed intellectual property.

- Research and development (R&D) expenses were $25.3 million for the quarter ended June 30, 2023 compared to $18.8 million for the prior year period.

    - The $6.5 million increase was primarily the result of higher:

        - Zunsemetinib development expenses related to drug candidate manufacturing and costs associated with clinical activities for a Phase 2b trial for RA.
        - ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial and other preclinical activities.
        - Compensation-related expenses due to an increase in headcount.

- General and administrative (G&A) expenses were $8.3 million for the quarter ended June 30, 2023 compared to $6.1 million for the prior year period. The increase was primarily due to bad debt expense recorded from Aclaris' determination that collection of amounts due from EPI Health are uncertain as a result of their filing for Chapter 11 bankruptcy protection. Compensation-related expenses also increased due to an increase in headcount.

- Licensing expenses were $0.6 million for the quarter ended June 30, 2023 resulting from separate third-party contractual obligations related to the non-exclusive patent license agreement with Lilly. There were no licensing expenses for the quarter ended June 30, 2022.

- Revaluation of contingent consideration resulted in a $1.5 million gain for the quarter ended June 30, 2023 compared to a gain of $3.4 million for the prior year period.

Year-to-date 2023

- Net loss was $57.7 million for the six months ended June 30, 2023 compared to $39.3 million for the six months ended June 30, 2022.

- Total revenue was $4.4 million for the six months ended June 30, 2023 compared to $3.0 million for the six months ended June 30, 2022.

- R&D expenses were $47.9 million for the six months ended June 30, 2023 compared to $33.1 million for the prior year period.
    - The $14.8 million increase was primarily the result of higher:
        - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA and a Phase 2a trial for PsA.
        - ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial and other preclinical activities.
        - Compensation-related expenses due to an increase in headcount.

- G&A expenses were $17.1 million for the six months ended June 30, 2023 compared to $12.2 million for the prior year period.
    - The $4.9 million increase was primarily the result of higher compensation-related costs, including stock-based compensation, due to increased headcount and the impact of equity awards granted during the six months ended June 30, 2023. Bad debt expense recorded from

Aclaris' determination that collection of amounts due from EPI Health are uncertain as a result of their filing for Chapter 11 bankruptcy protection also contributed to the increase.

- Revaluation of contingent consideration resulted in a $2.3 million gain for the six months ended June 30, 2023 compared to a gain of $4.6 million for the 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 "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 the development of Aclaris' drug candidates, including the timing of its clinical trials, availability of data from those trials, and regulatory filings, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations through the end of 2025. 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, 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.

Aclaris Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Contract research	$ 875	$ 1,218	$ 1,764	$ 2,439
Licensing	994	280	2,633	481
Other	-	30	-	61
Total revenue	1,869	1,528	4,397	2,981
Costs and expenses:				
Cost of revenue (1)	1,042	1,068	1,850	2,223
Research and development (1)	25,275	18,779	47,862	33,085
General and administrative (1)	8,317	6,075	17,107	12,174
Licensing	550	-	1,611	-
Revaluation of contingent consideration	(1,500)	(3,400)	(2,300)	(4,600)
Total costs and expenses	33,684	22,522	66,130	42,882
Loss from operations	(31,815)	(20,994)	(61,733)	(39,901)
Other income, net	2,246	462	4,004	580
Net loss	$ (29,569)	$ (20,532)	$ (57,729)	$ (39,321)
Net loss per share, basic and diluted	$ (0.42)	$ (0.31)	$ (0.84)	$ (0.62)
Weighted average common shares outstanding, basic and diluted	70,633,528	65,990,031	68,763,542	63,723,123

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

Cost of revenue	$ 473	$ 302	$ 772	$ 530
Research and development	3,494	941	6,096	828
General and administrative	2,555	2,449	6,460	4,680
Total stock-based compensation expense	$ 6,522	$ 3,692	$ 13,328	$ 6,038

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(unaudited, in thousands, except share data)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 210,767	$ 229,813
Total assets	$ 235,649	$ 254,596
Total current liabilities	$ 22,829	$ 21,938
Total liabilities	$ 55,899	$ 56,975
Total stockholders' equity	$ 179,750	$ 197,621
Common stock outstanding	70,769,702	66,688,647

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

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Net loss	$ (57,729)	$ (39,321)
Depreciation and amortization	416	414
Stock-based compensation expense	13,328	6,038
Revaluation of contingent consideration	(2,300)	(4,600)
Changes in operating assets and liabilities	(722)	(3,166)
Net cash used in operating activities	$ (47,007)	$ (40,635)

Aclaris Therapeutics Contact:

Robert A. Doody Jr.
Vice President, Investor Relations
484-639-7235
rdoody@aclaristx.com