Aclaris Therapeutics Reports Second Quarter 2025 Financial Results and Provides Corporate Update

August 7, 2025

- Positive Clinical Results from Phase 2a Trial of ITK/JAK3 Inhibitor ATI-2138 Confirm Tolerability Profile, Show Strong Efficacy Signal, and Validate ITK as Therapeutic Target -

- Advanced Anti-TSLP Monoclonal Antibody Bosakitug (ATI-045) into Phase 2 Trial in Atopic Dermatitis (AD); Patient Dosing Underway -

- Initiated Dosing in Phase 1a/1b Clinical Program for Anti-TSLP/IL-4R Bispecific Antibody ATI-052 -

- Strong Cash Runway Expected to Fund Operations into the Second Half of 2028 -

WAYNE, Pa., Aug. 07, 2025 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel product candidates for immuno-inflammatory diseases, today announced its financial results for the second quarter of 2025 and provided a corporate update.

“Aclaris is in a period of strong execution throughout the business as we advance our innovative therapies toward our goal of improving therapeutic options for patients with certain I&I diseases,” stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. “For example, the results from the single arm Phase 2a clinical trial of our ITK/JAK3 inhibitor ATI-2138 represent a significant achievement for our ITK franchise by both confirming the strong tolerability profile and mechanism of ATI-2138 in AD ahead of our planned alopecia areata clinical trial and validating ITK as an important therapeutic target. Importantly, with an expected cash runway that funds our operations into the second half of 2028, we have sufficient capital to execute our strategic plan. We are also exploring additional non-dilutive opportunities to extend our cash runway even further.”

Second Quarter 2025 Highlights and Recent Updates

Pipeline:

- **Achieved Primary and Key Secondary Endpoints in Phase 2a Trial of ATI-2138, a Potent and Selective Investigational Inhibitor of ITK and JAK3:** Positive results from this open-label, single arm trial further confirmed the favorable tolerability profile of ATI-2138, demonstrated clinically meaningful improvements from baseline in assessments of disease severity in patients with moderate-to-severe AD receiving low doses of ATI-2138, and validated ITK as a therapeutic target. Overall, these results provide evidence that the contribution of ITK may enable ATI-2138, even at low doses, to achieve efficacy results comparable to approved JAK inhibitors in moderate-to-severe AD, but with improved tolerability and without the significant safety risks typically associated with JAK inhibition. (press release here)
- **Initiated Dosing in Phase 2 Trial of Potential Best-in-Class Investigational Anti-TSLP Monoclonal Antibody Bosakitug:** Patient dosing is ongoing in the randomized, double-blind, placebo-controlled global Phase 2 trial designed to evaluate bosakitug in approximately ninety (90) patients with moderate-to-severe AD. The Company expects to provide top line results in the second half of 2026. (press release here)
- **Initiated Dosing in Phase 1a/1b Program for Potential Best-in-Class Investigational Bispecific Anti-TSLP/IL-4R Antibody ATI-052:** Dosing is ongoing in the randomized, blinded, placebo-controlled Phase 1a portion, designed to evaluate single and multiple ascending doses of ATI-052 in healthy adults. The Phase 1b proof-of-concept portion in up to two indications is expected to follow the Phase 1a portion. Aclaris expects to complete the Phase 1a portion by year-end 2025 and provide top line results in early 2026, followed by top line results from the Phase 1b portion in the second half of 2026. (press release here)

Corporate:

- **Strong Cash Runway Funds the Company’s Planned Operations into the Second Half of 2028:** The Company is assessing potential non-dilutive opportunities to extend the cash runway further.
- **Provided Update on Senior Leadership:** Roland Kolbeck, Ph.D. has been appointed as Chief Scientific Officer, replacing Joe Monahan, Ph.D. who will remain with the Company as Special Scientific Advisor to the Chief Executive Officer through the first quarter of 2026 as part of his planned retirement. (press release here)

Financial Results

Liquidity and Capital Resources

As of June 30, 2025, Aclaris had cash, cash equivalents and marketable securities of $180.9 million compared to $203.9 million as of December 31, 2024. The Company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second half of 2028, without giving effect to any potential business development transactions or financing activities.

Second Quarter 2025 and Year-to-Date 2025

Net loss was $15.4 million for the second quarter of 2025 compared to $11.0 million for the second quarter of 2024. Net loss was $30.5 million for the six months ended June 30, 2025 compared to $27.9 million for the six months ended June 30, 2024.

Total revenue was $1.8 million for the second quarter of 2025 compared to $2.8 million for the second quarter of 2024. Total revenue was $3.2 million for the six months ended June 30, 2025 compared to $5.2 million for the six months ended June 30, 2024. The decrease for both comparison periods was primarily driven by the sale of a portion of royalty payments under the Company's agreement with Eli Lilly and Company to OCM IP Healthcare Portfolio IP, an investment vehicle for Ontario Municipal Employees Retirement System (OMERS), in July 2024.

Research and development (R&D) expenses were $11.4 million and $23.0 million for the quarter and six months ended June 30, 2025, respectively, compared to $8.8 million and $18.6 million for the corresponding prior year periods. The increases were primarily driven by product candidate manufacturing costs, preclinical development activities, and clinical development expenses associated with the Phase 2 trial in AD for bosakitug and the Phase 1a/1b program for ATI-052. For the six-month comparison period, clinical development expenses associated with the Phase 2a trial in AD for ATI-2138 also contributed to the increase. The increases were partially offset by a reduction in development expenses for zunsemetinib for both comparison periods.

General and administrative (G&A) expenses were $5.4 million for the quarter ended June 30, 2025 compared to $4.8 million for the corresponding prior year period. The increase was primarily driven by higher personnel expenses as a result of higher headcount. G&A expenses were $11.5 million for the six months ended June 30, 2025 compared to $11.6 million for the six months ended June 30, 2024. The decrease was primarily driven by lower personnel expenses as a result of lower termination benefits.

Revaluation of contingent consideration resulted in a $1.5 million charge for the quarter ended June 30, 2025 compared to a $0.2 million charge for the prior year period. The increase was primarily due to changes to the probability of success for certain product candidates and lower discount rates resulting from changes in credit spreads being applied to potential payments during the quarter ended June 30, 2025. For the six months ended June 30, 2025, revaluation of contingent consideration resulted in a charge of $1.8 million compared to $3.0 million for the prior year period. The decrease was primarily due to changes in estimated sales levels and changes to the probability of success for certain product candidates during the six months ended June 30, 2024.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel product candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of product candidates powered by a robust R&D engine. For additional information, please visit www.aclaristx.com and follow Aclaris on X (formerly Twitter) at @AclarisTx and on LinkedIn.

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 for bosakitug, ATI-2138 and ATI-052, including the anticipated timing of reporting results from its Phase 2 trial of bosakitug in AD and its Phase 1a/1b program of ATI-052, the potential to evaluate ATI-052 in up to two undisclosed indications in a Phase 1b program, the development of ATI-2138 in AA and additional indications, the sufficiency of its cash, cash equivalents and marketable securities to fund its operations into the second half of 2028, and the Company's plans to pursue non-dilutive financing opportunities. 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, 2024, 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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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,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Contract research	$ 442	$ 625	$ 887	$ 1,281
Licensing	1,335	2,141	2,345	3,882
Total revenue	1,777	2,766	3,232	5,163
Costs and expenses:				
Cost of revenue[(1)]	515	624	1,021	1,433
Research and development[(1)]	11,449	8,759	23,033	18,604
General and administrative[(1)]	5,386	4,752	11,525	11,596
Licensing	1,335	1,285	2,345	2,316
Revaluation of contingent consideration	1,500	200	1,800	3,000
Total costs and expenses	20,185	15,620	39,724	36,949
Loss from operations	(18,408)	(12,854)	(36,492)	(31,786)
Other income:				
Interest income	2,018	1,868	4,184	3,859
Non-cash royalty income	961	—	1,794	—
Total other income	2,979	1,868	5,978	3,859
Net loss	$ (15,429)	$ (10,986)	$ (30,514)	$ (27,927)
Net loss per share, basic and diluted	$ (0.13)	$ (0.15)	$ (0.25)	$ (0.39)
Weighted average common shares outstanding, basic and diluted	122,580,967	71,291,400	122,486,162	71,183,129
(1) Amounts include stock-based compensation expense as follows:				
Cost of revenue	$ 190	$ 223	$ 409	$ 475
Research and development	1,106	1,097	2,291	1,068
General and administrative	1,767	1,583	3,898	3,449
Total stock-based compensation expense	$ 3,063	$ 2,903	$ 6,598	$ 4,992

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

	June 30, 2025	**December 31, 2024**
Cash, cash equivalents and marketable securities	$ 180,890	$ 203,896
Total assets	$ 189,147	$ 220,327
Total current liabilities	$ 26,839	$ 31,596
Total liabilities	$ 57,408	$ 64,773
Total stockholders' equity	$ 131,739	$ 155,554
Common stock outstanding	108,328,794	107,850,124

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

	Six Months Ended June 30,	
	2025	**2024**

Net loss	$ (30,514)	$ (27,927)
Depreciation and amortization	242	485
Stock-based compensation expense	6,598	4,992
Revaluation of contingent consideration	1,800	3,000
Changes in operating assets and liabilities	(1,176)	(13,687)
Net cash used in operating activities	$ (23,050)	$ (33,137)

Source: Aclaris Therapeutics, Inc.