



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

November 6, 2025

- Positive Results from Phase 2a Trial of ITK/JAK3 Inhibitor ATI-2138 Presented at the 2025 European Academy of Dermatology and Venereology (EADV) Congress, Further Validating ITK as Therapeutic Target; Initiation of Phase 2 Trial in an Additional Indication Expected in the First Half of 2026

- Timelines Reiterated for Top Line Clinical Results from Ongoing Trials of Investigational Anti-TSLP Monoclonal Antibody Bosakitug (ATI-045) and Anti-TSLP/IL-4R Bispecific Antibody ATI-052 -

- Initiation of Phase 1b Proof-of-Concept Trials of ATI-052 in Asthma and Atopic Dermatitis (AD) Expected in the First Half of 2026 -

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

WAYNE, Pa., Nov. 06, 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 third quarter of 2025 and provided a corporate update.

"Aclaris is advancing a diversified pipeline of product candidates designed to overcome the limitations of existing therapies for certain immuno-inflammatory disorders, and the third quarter was a period of continued execution in that regard," said Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. "The strong top line results from our Phase 2a trial of ATI-2138 in atopic dermatitis are emblematic of our execution during the quarter. As we described during our October R&D Day, our progress is tangible and significant. We have two immune franchise areas in oral kinase inhibitors and biologics which we expect to drive four clinical stage product candidates in 2026, addressing validated and therapeutically relevant immune targets. We have an expected cash runway that provides nearly three years of capital with opportunities to expand it further without dilution and look forward to a rich calendar of anticipated clinical milestones and data events throughout 2026 and 2027."

Third Quarter 2025 Highlights and Recent Updates

Pipeline:

Oral Inhibitors: ITK Franchise

- **Announced Anticipated Phase 2 Trial of ATI-2138, a Potent and Selective Investigational Inhibitor of ITK and JAK3, in an Additional Indication:** Aclaris expects to further assess ATI-2138 in additional unaddressed chronic, inflammatory, immune-mediated disorders, such as Lichen planus, scarring alopecias, and alopecia areata. The Company intends to initiate a Phase 2 trial in the first half of 2026.
- **Achieved Primary and Key Secondary Endpoints in Phase 2a Trial of ATI-2138:** Positive top line 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 atopic dermatitis receiving low doses of ATI-2138, and validated ITK as a therapeutic target. (press release [here](#))
- **Additional Results on Robust Clinical Activity and Reductions in Fibrosis and Systemic Inflammation from ATI-2138 Phase 2a Trial Provided in Oral Presentation During the 2025 European Academy of Dermatology and Venereology (EADV) Congress:** Additional results included week 4 decreases (n=9) of 77% in Eczema Area and Severity Index (EASI) score (p<0.001), a 64% in Body Surface Area (BSA) score (p<0.001), and 45% in Peak Pruritus Numerical Rating Scale (PP-NRS) (p<0.01). These changes were maintained through end of treatment. Transcriptomic and proteomic analyses showed significant downregulation of the Th1, Th2 and Th17 markers along with downregulation of fibrosis. The observed reductions in inflammatory and fibrosis biomarkers in skin positively and strongly correlated with improvements in clinical scores.
- **Announced Intent to File Initial Investigational New Drug (IND) Application for Next-Generation JAK-Sparing ITK Inhibitor in the Second Half of 2026:** Aclaris' next-generation ITK-selective inhibitors have extended half-lives and show complete ITK occupancy at very low doses. These compounds are significantly more efficient inactivators of ITK as compared to other ITK inhibitors in development and potently block Th2 function and differentially modulate Th1 activation.

Biologics: Antibody Franchise

- **Top Line Results Expected in Early 2026 from Phase 1a Single Ascending Dose (SAD) and Multiple Ascending**

Dose (MAD) Portion of Ongoing Phase 1a/1b Program of Investigational Bispecific Anti-TSLP/IL-4R Antibody

ATI-052: Dosing is complete in the Phase 1a SAD portion and ongoing in the Phase 1a MAD portion of the randomized, blinded, placebo-controlled Phase 1a/1b program. Aclaris expects to complete the Phase 1a portion by year-end 2025 and provide top line results in early 2026.

- **Announced Intent to Conduct Phase 1b Proof-of-Concept (POC) Trials of ATI-052 in Asthma and Atopic Dermatitis:** Following completion of the Phase 1a SAD/MAD portion, the Company expects to initiate these Phase 1b POC studies in the first half of 2026, with top line results expected in the second half of 2026.
- **Top Line Results Expected in the Second Half of 2026 from Phase 2 Trial of Investigational Anti-TSLP Monoclonal Antibody Bosakitug:** Patient enrollment is ongoing in the randomized, double-blind, placebo-controlled 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.

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 Corporate Update During the Company's October 14, 2025, R&D Day event: Patient Focused Innovation: Addressing Gaps in Immuno-Inflammatory Markets:** Aclaris hosted an R&D Day in New York City that highlighted recent progress and expected milestones across the Company's pipeline, including those related to its preclinical next generation ITK inhibitor program and multispecific antibodies and its ongoing clinical programs. The event featured members of Aclaris' executive team and leading experts in the fields of pulmonology and dermatology. A replay of the event is available on the Events page of the Aclaris corporate website [here](#).

Financial Results

Liquidity and Capital Resources

As of September 30, 2025, Aclaris had cash, cash equivalents and marketable securities of \$167.2 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.

Third Quarter 2025 and Year-to-Date 2025

Net loss was \$14.6 million for the third quarter of 2025 compared to \$7.6 million for the third quarter of 2024. Net loss was \$45.1 million for the nine months ended September 30, 2025 compared to \$35.5 million for the nine months ended September 30, 2024.

Total revenue was \$3.3 million for the third quarter of 2025 compared to \$4.3 million for the third quarter of 2024. Total revenue was \$6.5 million for the nine months ended September 30, 2025 compared to \$9.5 million for the nine months ended September 30, 2024. The decreases for both comparison periods were primarily due to larger milestones achieved under the Sun Pharma license agreement during the quarter and nine months ended September 30, 2024, and for the nine-month period, higher licensing revenue under the Eli Lilly license agreement. The Company sold a portion of its Eli Lilly royalties 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 \$13.0 million and \$36.1 million for the quarter and nine months ended September 30, 2025, respectively, compared to \$6.0 million and \$24.6 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 as well as preclinical development activities associated with toxicity studies for ATI-2138, and for the nine-month comparison period, clinical development expenses associated with the Phase 2a trial in AD for ATI-2138. The increases were partially offset by a reduction in development expenses for former development assets.

General and administrative (G&A) expenses were \$4.9 million and \$16.4 million for the quarter and nine months ended September 30, 2025, respectively, compared to \$5.7 million and \$17.2 million for the corresponding prior year periods. The decreases were primarily driven by business development expenses incurred in connection with the royalty purchase agreement with OMERS during the quarter and nine months ended September 30, 2024.

Revaluation of contingent consideration resulted in a \$0.1 million charge for the quarter ended September 30, 2025 compared to a \$0.8 million charge for the prior year period. The decrease was primarily due to higher discount rates resulting from changes in credit spreads being applied to potential payments during the quarter ended September 30, 2025. For the nine months ended September 30, 2025, revaluation of contingent consideration resulted in a charge of \$1.9 million compared to a \$3.8 million charge 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 nine months ended September 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, ATI-052, and its next generation ITK inhibitors, including the timing of reporting results from its Phase 2 trial of bosakitug in AD and its Phase 1a assessment of ATI-052, the timing to initiate and report results from Phase 1b trials of ATI-052 in asthma and atopic dermatitis, the potential to evaluate and the timing to initiate a Phase 2 trial of ATI-2138 in additional indications, the timing to file an IND for its next-generation ITK inhibitor program, 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		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Revenues:				
Contract research	\$ 485	\$ 645	\$ 1,372	\$ 1,926
Licensing	2,814	3,701	5,159	7,583
Total revenue	3,299	4,346	6,531	9,509
Costs and expenses:				
Cost of revenue ⁽¹⁾	538	654	1,559	2,087
Research and development ⁽¹⁾	13,028	5,956	36,061	24,560
General and administrative ⁽¹⁾	4,871	5,653	16,396	17,249
Licensing	1,911	1,754	4,256	4,070
Revaluation of contingent consideration	100	800	1,900	3,800
Total costs and expenses	20,448	14,817	60,172	51,766
Loss from operations	(17,149)	(10,471)	(53,641)	(42,257)
Other income:				
Interest income	1,819	1,991	6,003	5,850
Non-cash royalty income	716	894	2,510	894
Total other income	2,535	2,885	8,513	6,744
Net loss	\$ (14,614)	\$ (7,586)	\$ (45,128)	\$ (35,513)
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.11)	\$ (0.37)	\$ (0.50)
Weighted average common shares outstanding, basic and diluted	122,619,311	71,381,731	122,531,032	71,249,813

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

Cost of revenue	\$	191	\$	232	\$	600	\$	707
Research and development		964		1,124		3,255		2,192
General and administrative		1,705		1,648		5,603		5,097
Total stock-based compensation expense	\$	<u>2,860</u>	\$	<u>3,004</u>	\$	<u>9,458</u>	\$	<u>7,996</u>

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data
(unaudited, in thousands, except share data)

		September 30,		December 31,
		2025		2024
Cash, cash equivalents and marketable securities	\$	167,209	\$	203,896
Total assets	\$	175,534	\$	220,327
Total current liabilities	\$	25,631	\$	31,596
Total liabilities	\$	55,434	\$	64,773
Total stockholders' equity	\$	120,100	\$	155,554
Common stock outstanding		108,342,592		107,850,124

Aclaris Therapeutics, Inc.

Selected Consolidated Cash Flow Data
(unaudited, in thousands)

		Nine Months Ended	
		September 30,	
		2025	2024
Net loss	\$	(45,128)	\$ (35,513)
Depreciation and amortization		352	664
Stock-based compensation expense		9,458	7,996
Revaluation of contingent consideration		1,900	3,800
Changes in operating assets and liabilities		(564)	11,916
Net cash used in operating activities	\$	<u>(33,982)</u>	\$ <u>(11,137)</u>



Source: Aclaris Therapeutics, Inc.