Aclaris Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Update

February 26, 2026

- Positive Interim Results of Phase 1a Single (SAD) and Multiple Ascending Dose (MAD) Trial of Anti-TSLP/IL-4Rα Bispecific Antibody ATI-052 Support Rapid Clinical Advancement; Complete Top Line Results Expected in the Second Quarter of 2026 -

- Phase 1b Proof-of-Concept Trials of ATI-052 in Atopic Dermatitis (AD) and Asthma Underway; Top Line Results from Both Trials Anticipated in the Second Half of 2026 -

- Investigational New Drug (IND) Application for Lead ITK Inhibitor Candidate ATI-9494 Expected in the Second Half of 2026 -

- ATI-2138, Aclaris' Investigational Inhibitor of ITK and JAK3, Demonstrated Potential Best-in-Class Hair Regrowth in Murine Alopecia Model -

WAYNE, Pa., Feb. 26, 2026 (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 fourth quarter and full year ended 2025 and provided a corporate update.

"2025 was a year of strong business execution and continued momentum in each of our potential best-in-class programs and positioned us for an exciting 2026 with important milestones and data readouts expected from each program," stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. "2026 started with derisking events for two of our key programs, ITK and ATI-052; this included compelling ATI-052 interim Phase 1a SAD/MAD results showing strong safety and tolerability profiles, robust target engagement reinforcing the potency of the compound even at very low doses, and the opportunity for extended dosing supported by dose proportional pharmacokinetic and pharmacodynamic profiles. Since then, we have initiated two Phase 1b POC trials with ATI-052, with top line results expected from both trials in the second half of this year. With a strong cash position and several meaningful catalysts across our biologics and ITK pipeline expected this year, including top line results from the Phase 2 trial of our anti-TSLP monoclonal antibody bosakitug in AD, we are looking forward to an exciting and productive year."

Fourth Quarter 2025 Highlights and Recent Updates

Pipeline:

Biologics: Antibody Franchise

- **Provided Positive Interim Results of Phase 1a Single (SAD) and Multiple Ascending Dose (MAD) Trial of Investigational Bispecific Anti-TSLP/IL-4Rα Antibody ATI-052; Complete Top Line Results from SAD and MAD Cohorts Expected in the Second Quarter of 2026:** ATI-052 was well tolerated and demonstrated a favorable safety profile across all single and multiple ascending dose cohorts in this Phase 1a trial. Interim results included a dose proportional pharmacokinetic (PK) profile and concentration-dependent pharmacodynamics (PD) validating the potency and specificity of the compound, including robust target engagement and near complete target occupancy even at very low doses. These results support the potential for up to every three months dosing. Additional SAD and MAD results from this trial are expected in the second quarter of 2026. (press release here)

- **Announced Initiation of Two Phase 1b Proof-of-Concept (POC) Trials of ATI-052:** Following positive interim Phase 1a SAD/MAD results, the Company has initiated Phase 1b POC studies in AD and asthma. Top line results from both trials are expected in the second half of 2026. (press releases here and here)

- **Planning Underway for Phase 2b Program for ATI-052:** Planning is ongoing for a Phase 2b program encompassing asthma and AD as potential first indications. The Company expects to initiate this program in the second half of 2026.

- **Confirmed Expectation of Top Line Results in the Second Half of 2026 from Ongoing Phase 2 Trial of Investigational Anti-TSLP Monoclonal Antibody Bosakitug:** This randomized, double-blind, placebo-controlled Phase 2 trial is designed to evaluate bosakitug in approximately 96 patients with moderate-to-severe AD.

Oral Inhibitors: ITK Franchise

- **Aclaris' Lead ITK Inhibitor ATI-9494 Advancing Toward Expected Investigational New Drug (IND) Application in the Second Half of 2026:** Aclaris' lead ITK inhibitor candidate ATI-9494 has demonstrated potent blockade of Th1 and Th2

responses, a prolonged half-life, and high potency against ITK, potentially enabling low drug burden, dosing flexibility, and once daily (QD) administration across a broad range of disease indications. Aclaris intends to file an IND for ATI-9494 in the second half of 2026.

- **ATI-2138, a Potent and Selective Investigational Inhibitor of ITK and JAK3, Demonstrated Rapid and Sustained Hair Regrowth in Validated Murine Model of Severe Alopecia Areata (AA), Further Validating Best-in-Class Potential:** ATI-2138 and ritlecitinib were assessed compared to control in a reversal model of murine alopecia universalis, the most severe AA phenotype. ATI-2138 demonstrated potential best-in-class results including rapid, near complete, and sustained hair regrowth compared to control and ritlecitinib including mean hair regrowth of 93% for ATI-2138 at week 6 (end of study) compared to 78% for the same dose of ritlecitinib. Mice receiving control showed no improvement in hair regrowth. The Company is completing the assessment of additional indications that are relevant to the dual pharmacology and mechanism of action, including certain alopecias and other inflammatory disorders. (press release here)

Financial Results

Liquidity and Capital Resources

As of December 31, 2025, Aclaris had cash, cash equivalents and marketable securities of $151.4 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, or trial execution costs associated with its planned Phase 2b program for ATI-052.

Fourth Quarter and Full Year 2025

Net loss was $19.8 million for the fourth quarter of 2025 compared to $96.6 million for the fourth quarter of 2024. Net loss was $64.9 million for the year ended December 31, 2025 compared to $132.1 million for the year ended December 31, 2024.

Total revenue was $1.3 million for the fourth quarter of 2025 compared to $9.2 million for the fourth quarter of 2024. The decrease was primarily driven by the achievement of a commercial milestone under the license agreement with Eli Lilly and Company in the fourth quarter of 2024. Total revenue was $7.8 million for the year ended December 31, 2025 compared to $18.7 million for the year ended December 31, 2024.

Research and development (R&D) expenses were $16.6 million for the quarter ended December 31, 2025 compared to $9.0 million for the prior year period. The increase was primarily due to higher product candidate manufacturing costs and preclinical and clinical development expenses for bosakitug and ATI-052, and preclinical development expenses for ATI-9494. For the year ended December 31, 2025, R&D expenses were $52.6 million compared to $33.6 million for the year ended December 31, 2024.

General and administrative (G&A) expenses were $5.6 million for the quarter ended December 31, 2025 compared to $5.0 million for the prior year period. The increase was primarily due to higher compensation-related expenses and legal expenses. For the year ended December 31, 2025, G&A expenses were $22.0 million compared to $22.2 million for the year ended December 31, 2024.

Licensing expenses were $0.9 million for the quarter ended December 31, 2025 compared to $8.6 million for the prior year period. The decrease was primarily due to a milestone achieved during the fourth quarter of 2024, the entirety of which was payable to a third party. For the year ended December 31, 2025, licensing expenses were $5.2 million compared to $12.7 million for the year ended December 31, 2024.

Revaluation of contingent consideration resulted in a $0.4 million charge for the quarter ended December 31, 2025 compared to a $1.3 million gain for the prior year period. For the year ended December 31, 2025, revaluation of contingent consideration resulted in a charge of $2.3 million compared to a $2.5 million charge for the year ended December 31, 2024.

During the quarter and year ended December 31, 2024, the Company recorded $86.9 million of in-process research and development expenses, representing the fair value of consideration expensed in connection with the in-license of bosakitug (ATI-045) and ATI-052, as well as transaction costs incurred.

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 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-052, ATI-2138 and ATI-9494, including the timing of reporting complete results from its Phase 1a SAD/MAD trial, results from its Phase 2 trial of bosakitug in AD, and results from its Phase 1b trials of ATI-052 in asthma and AD, the timing of initiating a Phase 2b program for ATI-052 and the timing to file an IND for ATI-9494 and its dosing potential, the potential for ATI-052 to have up to every three-month dosing, the therapeutic potential of its product candidates and the potential for such candidates to be best-in-class, and the sufficiency of its cash, cash equivalents and marketable securities to fund its operations into the second half of 2028. 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, 2025, 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Contract research	$ 500	$ 615	$ 1,872	$ 2,541
Licensing	795	8,596	5,954	16,179
Total revenue	1,295	9,211	7,826	18,720
Costs and expenses:				
Cost of revenue[(1)]	532	705	2,091	2,792
Research and development[(1)]	16,584	9,026	52,645	33,586
General and administrative[(1)]	5,576	4,954	21,972	22,203
Licensing	937	8,596	5,193	12,666
Revaluation of contingent consideration	400	(1,300)	2,300	2,500
In-process research and development	—	86,905	—	86,905
Total costs and expenses	24,029	108,886	84,201	160,652
Loss from operations	(22,734)	(99,675)	(76,375)	(141,932)
Other income:				
Interest income	1,634	2,103	7,637	7,953
Non-cash royalty income	1,305	1,020	3,815	1,914
Total other income	2,939	3,123	11,452	9,867
Net loss	$ (19,795)	$ (96,552)	$ (64,923)	$ (132,065)
Net loss per share, basic and diluted	$ (0.16)	$ (1.01)	$ (0.53)	$ (1.71)
Weighted average common shares outstanding, basic and diluted	122,664,768	95,305,768	122,564,741	77,296,665
(1) Amounts include stock-based compensation expense as follows:				
Cost of revenue	$ 188	$ 231	$ 788	$ 938
Research and development	1,003	943	4,258	3,135
General and administrative	1,735	1,686	7,338	6,783
Total stock-based compensation expense	$ 2,926	$ 2,860	$ 12,384	$ 10,856

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

	December 31, 2025	December 31, 2024

Cash, cash equivalents and marketable securities	$ 151,363	$ 203,896
Total assets	$ 160,460	$ 220,327
Total current liabilities	$ 28,645	$ 31,596
Total liabilities	$ 57,378	$ 64,773
Total stockholders' equity	$ 103,082	$ 155,554
Common stock outstanding	120,499,433	107,850,124

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

	Year Ended December 31,	
	2025	**2024**
Net loss	$ (64,923)	$ (132,065)
Depreciation and amortization	454	807
Stock-based compensation expense	12,384	10,856
Revaluation of contingent consideration	2,300	2,500
In-process research and development expense	—	86,905
Changes in operating assets and liabilities	2,672	10,922
Net cash used in operating activities	$ (47,113)	$ (20,075)

Source: Aclaris Therapeutics, Inc.