Aclaris Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate and Clinical Update

November 5, 2026

- Initiation of Phase 2b Trial of Modzatinib (ATI-2138) in Lichen Planus Expected in Fourth Quarter of 2026 -

- Timeline Reaffirmed for Top Line Results from Phase 2 ADMIRATION Trial of Bosakitug (ATI-045) in Atopic Dermatitis (AD) -

- Positive Primary Analysis Results Announced from Phase 1b Proof-of-Concept (POC) Trials of ATI-052 in AD and Asthma -

- Strong Cash Runway Expected to Enable Development of Pipeline Through the First Half of 2029 -

WAYNE, Pa., Nov. 05, 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 third quarter of 2026 and provided a corporate and clinical update.

“Aclaris is developing unique product candidates designed to provide improved therapeutic options across a variety of inflammatory disorders with the goal of raising the efficacy ceiling, and our recent progress reflects continued execution toward that objective,” stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. “We recently announced strongly positive primary analysis results from our Phase 1b POC trials with ATI-052 in AD and asthma; we look forward to starting a Phase 2b trial in eosinophilic esophagitis early next year. Beyond that, we have a series of expected clinical and regulatory milestones throughout the rest of 2026 and 2027, including Phase 2 results in AD from bosakitug and the start of the Phase 2b trial of our oral ITK/JAK3 inhibitor modzatinib in lichen planus, both in the coming few weeks.”

Third Quarter 2026 Highlights, Recent Updates and Upcoming Catalysts

Pipeline:

Biologics: Antibody Franchise

- **Positive Primary Analysis Results Demonstrated Rapid Improvement in Skin and Itch in Phase 1b POC Trial of Investigational Bispecific Anti-TSLP/IL-4Rα Antibody ATI-052 in Severe AD:** Patients treated with ATI-052 experienced a 45% placebo-adjusted mean change in EASI score from baseline at week 8 with durable responses for the subset of patients with available data observed through week 16 (follow up ongoing) and a 78% placebo-adjusted EASI-50 at week 8. Patients who received ATI-052 experienced a 43% placebo-adjusted mean improvement in itch (PP-NRS) at week 8. ATI-052 was well tolerated and demonstrated a favorable safety profile. No conjunctivitis was observed. (press release here)
- **Normalization of Lesional Skin Toward Baseline with ATI-052 Observed in Pharmacodynamic Results in AD:** Marked normalization observed in the lesional skin proteome at week 8 in patients receiving ATI-052, with immune protein expression resembling that of non-lesional skin. ATI-052 induced a broad pathway downregulation, with modulation across multiple inflammatory pathways, Th1, Th2 and Th17/Th22, fibrosis/ECM remodeling, and itch-associated molecular pathways. (press release here)
- **Positive Primary Analysis Results Showed Rapid Improvement in Airway Inflammation and Lung Function in Phase 1b POC Trials of ATI-052 in Asthma:** Following a single dose of ATI-052, patients experienced a rapid 59% mean absolute reduction in fractional exhaled nitric oxide (FeNO) (45 ppb) only 15 days after administration and a 40% reduction at day 29. Patients receiving ATI-052 experienced a placebo adjusted and absolute 200 ml improvement in Forced Expiratory Volume in 1 Second (FEV1) at day 15. Safety and tolerability were consistent with that of the Phase 1b AD POC trial, including no observations of conjunctivitis. (press release here)
- **Aclaris to Prioritize Development of ATI-052 in Eosinophilic Esophagitis (EoE):** Consistent with its development strategy and capital management discipline, Aclaris intends to prioritize Phase 2b development of ATI-052 initially in EoE, where the Company believes ATI-052 is mechanistically well-matched. The Company expects to complete its assessment of an additional Phase 2b indication shortly, likely either AD or asthma.
- **Readout of Top Line Results from Phase 2 Trial of Investigational Anti-TSLP Monoclonal Antibody Bosakitug Expected in the Fourth Quarter 2026:** The randomized, double-blind, placebo-controlled Phase 2 ADMIRATION trial is evaluating the efficacy and safety of bosakitug in 109 patients with moderate-to-severe atopic dermatitis.

Kinase Inhibitors: ITK Franchise

- **Initiation of Phase 2b Clinical Trial in Lichen Planus for Investigational Oral ITK/JAK3 Inhibitor Modzatinib**

Expected in the Fourth Quarter of 2026: Startup activities are ongoing with first site activation expected in November 2026 for this Phase 2b trial in lichen planus, an unaddressed chronic, inflammatory, CD8-driven interface dermatitis. There are currently no approved therapies in this indication.

- **Filing of Investigational New Drug (IND) Application for Investigational Dual Inhibitor of ITK and TXK ATI-9494 On Track for Fourth Quarter 2026:** 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 administration across a broad range of disease indications.

Financial Results

Liquidity and Capital Resources

As of September 30, 2026, Aclaris had cash, cash equivalents and marketable securities of $204.6 million compared to $151.4 million as of December 31, 2025. During October 2026, the Company sold 7.8 million shares of its common stock and issued pre-funded warrants to purchase 6.5 million shares of common stock for aggregate gross proceeds of $50.0 million, pursuant to the Company's underwriting agreement with Leerink Partners LLC, Piper Sandler & Co. and Cantor Fitzgerald & Co.

Taking into account the net proceeds from the October offering, the Company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operations through the first half of 2029, without giving effect to any potential business development transactions or additional financing activities.

Third Quarter 2026 and Year-to-Date 2026

Net loss was $18.5 million for the third quarter of 2026 compared to $14.6 million for the third quarter of 2025. Net loss was $59.8 million for the nine months ended September 30, 2026 compared to $45.1 million for the nine months ended September 30, 2025.

Total revenue was $1.5 million for the third quarter of 2026 compared to $3.3 million for the third quarter of 2025. Total revenue was $5.1 million for the nine months ended September 30, 2026 compared to $6.5 million for the nine months ended September 30, 2025. The decreases were primarily driven by a sales milestone achieved under the Sun Pharma license agreement during the quarter and nine months ended September 30, 2025.

Research and development (R&D) expenses were $16.1 million and $49.8 million for the quarter and nine months ended September 30, 2026, respectively, compared to $13.0 million and $36.1 million for the corresponding prior year periods. The increases were primarily driven by expenses related to ATI-052, including product candidate manufacturing costs and clinical development expenses associated with Phase 1b programs in AD and asthma, as well as product candidate manufacturing costs and preclinical development expenses for ATI-9494.

General and administrative (G&A) expenses were $6.0 million and $18.8 million for the quarter and nine months ended September 30, 2026, respectively, compared to $4.9 million and $16.4 million for the prior year periods. The increases were primarily due to an increase in professional and legal expenses as well as personnel and stock-based compensation expenses.

Revaluation of contingent consideration resulted in a $0.6 million gain for the quarter ended September 30, 2026 compared to a $0.1 million charge for the prior year period, primarily due to higher discount rates and changes in estimated sales levels during the quarter ended September 30, 2026. For the nine months ended September 30, 2026, revaluation of contingent consideration resulted in a $0.3 million gain compared to a $1.9 million charge for the prior year period, primarily due to changes to the probability of success for certain product candidates during the nine months ended September 30, 2025.

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-045), ATI-052, modzatinib (ATI-2138), and ATI-9494, including the timing of reporting top line results from its Phase 2 trial of bosakitug in AD, the clinical development plans for ATI-052 including its intention to prioritize EoE and the timing to initiate a Phase 2b trial in EoE, and the timing to initiate a Phase 2b trial in lichen planus with modzatinib, the timing to file an IND for ATI-9494, the potential of ATI-9494 to enable low drug burden, dosing flexibility, and once daily administration across a broad range of disease indications, the therapeutic potential of its product candidates including 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 through the first half of 2029. 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 preclinical and clinical studies, risks associated with interim, top line and preliminary data, 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.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenues:				
Contract research	$ 300	$ 485	$ 1,193	$ 1,372
Licensing	1,181	2,814	3,913	5,159
Total revenue	1,481	3,299	5,106	6,531
Costs and expenses:				
Cost of revenue[(1)]	189	538	802	1,559
Research and development[(1)]	16,066	13,028	49,789	36,061
General and administrative[(1)]	6,038	4,871	18,829	16,396
Licensing	1,132	1,911	3,760	4,256
Revaluation of contingent consideration	(600)	100	(300)	1,900
Total costs and expenses	22,825	20,448	72,880	60,172
Loss from operations	(21,344)	(17,149)	(67,774)	(53,641)
Other income:				
Interest income	1,849	1,819	5,124	6,003
Non-cash royalty income	985	716	2,811	2,510
Total other income	2,834	2,535	7,935	8,513
Net loss	$ (18,510)	$ (14,614)	$ (59,839)	$ (45,128)
Net loss per share, basic and diluted	$ (0.12)	$ (0.12)	$ (0.43)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	149,449,067	122,619,311	140,407,589	122,531,032
(1) Amounts include stock-based compensation expense as follows:				
Cost of revenue	$ 4	$ 191	$ 19	$ 600
Research and development	979	964	2,925	3,255
General and administrative	2,036	1,705	5,945	5,603
Total stock-based compensation expense	$ 3,019	$ 2,860	$ 8,889	$ 9,458

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

	September 30, 2026	**December 31, 2025**
Cash, cash equivalents and marketable securities	$ 204,607	$ 151,363
Total assets	$ 216,157	$ 160,460
Total current liabilities	$ 24,222	$ 28,645
Total liabilities	$ 49,358	$ 57,378
Total stockholders' equity	$ 166,799	$ 103,082
Common stock outstanding	150,825,196	120,499,433

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

	Nine Months Ended September 30,	
	2026	**2025**
Net loss	$ (59,839)	$ (45,128)
Depreciation and amortization	309	352
Stock-based compensation expense	8,889	9,458
Revaluation of contingent consideration	(300)	1,900
Changes in operating assets and liabilities	(11,135)	(564)
Net cash used in operating activities	$ (62,076)	$ (33,982)

Source: Aclaris Therapeutics, Inc.