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

May 7, 2026

- Full Top Line Results from Phase 1a SAD/MAD Trial of ATI-052 Exceed Aclaris' Target Profile, Validating Potential Best-in-Class Potency Advantage and Opportunity for Extended Dosing -

- Unique Dual Mechanism of ATI-2138 Supports Planned Phase 2b Clinical Trial in Lichen Planus -

- Strong Cash Runway Expected to Enable Development of Pipeline Through 2028 -

WAYNE, Pa., May 07, 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 first quarter of 2026 and provided a corporate and clinical update.

"Since the start of 2026, we have made great progress toward our goal of developing best-in-class compounds to address a variety of immuno-inflammatory diseases," stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. "Most recently, the positive results from our Phase 1a SAD/MAD trial of our bispecific antibody ATI-052 confirmed its potential as having a best-in-class PK/PD profile with an extended dosing schedule of up to every three months. We look forward to an exciting rest of the year with expected milestones including delivery of placebo-controlled top line results from our Phase 1b proof-of-concept trials of ATI-052 in both asthma and atopic dermatitis and the Phase 2 trial of our anti-TSLP monoclonal antibody bosakitug in atopic dermatitis."

First Quarter 2026 Highlights and Recent Updates

Pipeline:

Biologics: Antibody Franchise

- **Provided Positive Full Top Line Results of Phase 1a Single (SAD) and Multiple Ascending Dose (MAD) Trial of Investigational Bispecific Anti-TSLP/IL-4Rα Antibody ATI-052 Confirming Potency and Potential for Extended Dosing**: ATI-052 exhibited a potential best-in-class pharmacokinetic (PK) profile, including an estimated half-life of approximately 45 days. The pharmacodynamic (PD) results validate the potency of ATI-052, including robust target engagement demonstrated by complete and sustained inhibition through at least week 20 of ex vivo TSLP stimulated CCL17 (TARC) and at least week 12 of ex vivo IL-4 stimulated CCL17 in the 480 mg MAD cohort. The combination of the strong and sustained PK duration and PD effect supports the potential for up to every three-month dosing. ATI-052 was well tolerated and demonstrated a favorable safety profile. (press release here)
- **Confirmed Expectation of Top Line Results in the Second Half of 2026 from Two Ongoing Phase 1b Proof-of-Concept (POC) Trials of ATI-052:** In January, the Company announced initiation of a POC trial in patients with atopic dermatitis (AD). In February, Aclaris initiated a POC trial in patients with asthma. Dosing is ongoing in both trials, and top line results from both are expected in the second half of 2026. (press releases here and here)
- **Announced Phase 2b Program for ATI-052:** Given the data developed to date and its unique mechanism of action, the Company announced its intent to initiate a Phase 2b program with ATI-052, initially targeting asthma, in the fourth quarter of 2026.
- **Completed Enrollment in Phase 2 Trial of Investigational Anti-TSLP Monoclonal Antibody Bosakitug; Confirmed Expectation of Top Line Results in the Fourth Quarter of 2026:** Enrollment is complete in this randomized, double-blind, placebo-controlled Phase 2 trial designed to evaluate bosakitug in 109 patients with AD. The Company expects to provide top line results in the fourth quarter of 2026. (press release here)

Oral Inhibitors: ITK Franchise

- **Announced Lichen Planus Development Strategy for ATI-2138, a Potent and Selective Investigational Inhibitor of ITK and JAK3:** Aclaris intends to initiate a phased Phase 2b basket study of ATI-2138 comprising the three most common subtypes of lichen planus (LP), an unaddressed chronic, inflammatory, CD8-driven interface dermatitis: erosive mucosal, cutaneous, and lichen planopilaris, a rare form of LP that causes permanent hair loss. There are currently no approved therapies. Aclaris expects to initiate Part A (erosive mucosal; cutaneous) of this trial in the second half of 2026 and intends to move into Part B (LPP) soon thereafter. (press release here)
- **Presented Additional Phase 2a Results at 2026 American Academy of Dermatology (AAD) Annual Meeting**

Providing Additional Support for the Therapeutic Potential of ATI-2138: Additional week 12 results included a 70% improvement in the affected percentage of Body Surface Area (BSA) score, a 50% improvement in worst itch intensity as measured by Peak Pruritus Numerical Rating Scale (PP-NRS), a 55% improvement in AD severity over the past week as measured by patient-oriented eczema measure (POEM), and a 65% improvement in quality of life as measured by the Dermatology Life Quality Index (DLQI). (press release here)

- **Confirmed Intent to File Investigational New Drug (IND) Application for Lead ITK Inhibitor ATI-9494 in the Second Half of 2026:** Aclaris' lead preclinical 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.

Financial Results

Liquidity and Capital Resources

In March 2026, the Company sold 18.4 million shares of its common stock for aggregate gross proceeds of $59.8 million, pursuant to the Company's amended and restated sales agreement with Leerink Partners LLC and Cantor Fitzgerald & Co., as sales agents.

As of March 31, 2026, Aclaris had cash, cash equivalents and marketable securities of $190.8 million compared to $151.4 million as of December 31, 2025. The Company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operations through the end of 2028, without giving effect to any potential business development transactions or financing activities.

First quarter 2026

Net loss was $19.8 million for the first quarter of 2026 compared to $15.1 million for the first quarter of 2025.

Total revenue was $2.0 million for the first quarter of 2026 compared to $1.5 million for the first quarter of 2025. The increase was primarily driven by higher royalties earned under the Lilly and Sun Pharma license agreements.

Research and development (R&D) expenses were $15.7 million for the quarter ended March 31, 2026 compared to $11.6 million for the prior year period. The increase was primarily driven by expenses related to ATI-052, including clinical development expenses associated with a Phase 1a program and Phase 1b programs in AD and asthma, as well as product candidate manufacturing costs for ATI-9494. The increase was partially offset by a reduction in preclinical and clinical development expenses for ATI-2138.

General and administrative (G&A) expenses were $6.7 million for the quarter ended March 31, 2026 compared to $6.1 million for the prior year period. The increase was primarily due to an increase in professional and legal expenses as well as personnel expenses.

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 top line results from its Phase 2 trial of bosakitug in AD and its Phase 1b trials of ATI-052 in asthma and AD, the timing of initiating a Phase 2b program for ATI-052, the timing of initiating a Phase 2b trial in lichen planus with ATI-2138, the timing to file an IND for ATI-9494, the potential for ATI-052 to have extended 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 through the end 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.

Aclaris Therapeutics Contacts:

Kevin Balthaser
Chief Financial Officer
(484) 329-2178
kbalthaser@aclaristx.com

Will Roberts
Senior Vice President
Corporate Communications and Investor Relations

(484) 329-2125
wroberts@aclaristx.com

Aclaris Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2026	**2025**
Revenues:		
Contract research	$ 537	$ 445
Licensing	1,459	1,010
Total revenue	1,996	1,455
Costs and expenses:		
Cost of revenue[(1)]	395	506
Research and development[(1)]	15,657	11,584
General and administrative[(1)]	6,743	6,139
Licensing	1,393	1,010
Revaluation of contingent consideration	—	300
Total costs and expenses	24,188	19,539
Loss from operations	(22,192)	(18,084)
Other income:		
Interest income	1,514	2,166
Non-cash royalty income	854	833
Total other income	2,368	2,999
Net loss	$ (19,824)	$ (15,085)
Net loss per share, basic and diluted	$ (0.15)	$ (0.12)
Weighted average common shares outstanding, basic and diluted	128,810,050	122,390,303
(1) Amounts include stock-based compensation expense as follows:		
Cost of revenue	$ 28	$ 219
Research and development	1,162	1,185
General and administrative	2,008	2,131
Total stock-based compensation expense	$ 3,198	$ 3,535

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

	March 31, 2026	**December 31, 2025**
Cash, cash equivalents and marketable securities	$ 190,788	$ 151,363
Total assets	$ 198,720	$ 160,460
Total current liabilities	$ 27,370	$ 28,645
Total liabilities	$ 55,071	$ 57,378
Total stockholders' equity	$ 143,649	$ 103,082
Common stock outstanding	139,652,849	120,499,433

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

	Three Months Ended March 31,	
	2026	2025
Net loss	$ (19,824)	$ (15,085)
Depreciation and amortization	102	128
Stock-based compensation expense	3,198	3,535
Revaluation of contingent consideration	—	300
Changes in operating assets and liabilities	(1,625)	(1,935)
Net cash used in operating activities	$ (18,149)	$ (13,057)

Source: Aclaris Therapeutics, Inc.