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

May 8, 2025

- Multiple Catalysts in Immuno-Inflammatory Indications Anticipated in 2025 and 2026 -

- Expected Cash Runway Extended Through the First Half of 2028 -

- Phase 2 Results Received to Date from Chinese Partner CTTQ Provide Clinical Evidence of Enhanced Potency of Bosakitug (ATI-045) and Opportunity for Development Partnerships -

- Investigational New Drug (IND) Application for Bispecific Antibody ATI-052 Cleared by U.S. Food and Drug Administration -

WAYNE, Pa., May 08, 2025 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced its financial results for the first quarter of 2025 and provided a corporate update.

“We are entering into a potentially transformative multi-year period for Aclaris, with important milestones throughout our business that we believe will position us for future growth,” stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. “Ensuring successful and timely execution of our clinical programs is our priority, and given the realities of today’s financial market environment, it’s imperative that we continue to do so in a manner that efficiently utilizes our capital. As such, we’ve announced that further global development of bosakitug - our uniquely potent anti-TSLP monoclonal antibody - in respiratory indications will be dependent on partnerships. Regarding our internal programs, we expect to initiate new clinical trials with bosakitug; ATI-2138, our highly selective oral ITK/JAK3 inhibitor; and ATI-052, our potential best-in-class bispecific anti-TSLP/IL-4R antibody, for which we recently received IND clearance from the FDA. Work is also ongoing toward next-generation small molecule kinase inhibitors and biologic antagonists of immuno-inflammatory pathways to further expand our pipeline and continue our innovative work in I&I.”

“Importantly, we have the cash we believe we need to execute our plan,” continued Dr. Walker. “Our expected cash runway now extends through the first half of 2028, and we will continue to practice rigorous financial stewardship with a goal of extending our runway further by exploring additional non-dilutive opportunities.”

First Quarter 2025 Highlights and Recent Updates

Pipeline:

Bosakitug (ATI-045): Investigational Anti-TSLP monoclonal antibody

- **Aclaris Expects to Initiate Enrollment in Placebo-Controlled Two-Arm Phase 2 Trial in Atopic Dermatitis (AD) in the Second Quarter of 2025:** Based on the potency of bosakitug observed in preclinical and clinical studies to date, including the compelling results of the Phase 2a single arm trial in AD, Aclaris intends to initiate a two-arm placebo-controlled Phase 2 trial of bosakitug in approximately 90 patients with moderate-to-severe AD in the second quarter of 2025. This trial is designed to evaluate the Company’s anti-TSLP therapeutic in a placebo-controlled setting in a time- and cost-efficient manner.
- **Results from CTTQ’s Phase 2 Trials in Respiratory Indications Support Further Development:** The totality of the results received to date from Aclaris’ regional partner, Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (CTTQ) from their Phase 2 trials of bosakitug in Chinese patients with chronic rhinosinusitis with nasal polyps (CRSwNP) and severe asthma provide additional clinical evidence of the enhanced potency of bosakitug. CTTQ has announced that they are conducting Phase 3 clinical trials of bosakitug in both indications and are currently conducting a Phase 2 trial in chronic obstructive pulmonary disease (COPD). CTTQ is responsible for the disclosure and presentation of the results of their clinical trials.
- **Aclaris Intends to Seek Partners to Develop Bosakitug in Respiratory Indications:** Aclaris’ clinical focus for bosakitug will remain on dermatological immuno-inflammatory indications. Further global (excluding China) development in respiratory indications is dependent on entering into potential partnerships.

ATI-2138: Investigational oral covalent ITK/JAK3 inhibitor

- **Top Line Results from Phase 2a Trial in AD Expected in June 2025:** Dosing is complete in the single arm Phase 2a open-label trial of ATI-2138 designed to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 in patients with moderate-to-severe AD. The Company expects to report top line results in June 2025. Potential target indications under consideration include alopecia areata (AA) and vitiligo.

ATI-052: Investigational bispecific anti-TSLP/IL4R monoclonal antibody

- **Announced Clearance of ATI-052 Investigational New Drug (IND) Application and Plan to Initiate Phase 1 Trial:** Aclaris announced that the U.S. Food and Drug Administration cleared its IND application for ATI-052 in April 2025. The Company expects to initiate the placebo-controlled Phase 1a/1b trial evaluating single and multiple ascending doses of ATI-052, followed by a proof-of-concept portion in an undisclosed indication, in the second quarter of 2025. (press release here)

Next Generation Kinase and Cytokine Signaling Pathway Inhibitor Development:

- **Confirmed Plan for Next IND Submission:** Preclinical work is ongoing to develop next-generation ITK inhibitors, which the Company expects to provide the basis for new INDs starting in 2026.
- **Development of Novel Bispecific Antibodies Targeting Certain Cytokine Pathways Underway:** Preclinical work is ongoing to develop next-generation bispecific antibodies utilizing the bosakitug anti-TSLP binding region paired with binding fragments targeting other undisclosed cytokine signaling pathways.

Corporate:

- **Expected Cash Runway Extends Through the First Half of 2028 and Fully Funds Preclinical and Clinical Development Plans:** During the first quarter of 2025, Aclaris took certain steps to focus its pipeline investments while extending its cash runway further. In doing so, the Company continues to prioritize clinical execution and achievement of development milestones, all of which Aclaris expects to be funded by the Company's current cash runway. Aclaris ended the first quarter of 2025 with $190.5 million in cash, cash equivalents, and marketable securities providing balance sheet strength to execute on its development plan. Aclaris' cash management policy is focused on capital preservation and holding a portfolio of securities with short-term maturities. The investment portfolio is composed of fixed income securities, primarily high-credit quality corporate debt and U.S. government securities.
- **Injunction Against Sun Pharmaceuticals Lifted, Providing Aclaris with a Potential Additional Opportunity for Non-Dilutive Financing:** In 2023, Aclaris granted Sun Pharma exclusive rights under certain patents for, among other things, the use of deuruxolitinib, Sun Pharma's JAK inhibitor, to treat AA. The agreement included an upfront payment of $15.0 million, regulatory and commercial milestones, and royalties. In 2024, Incyte Corporation was granted a preliminary injunction against Sun Pharma, blocking Sun Pharma from launching its product LEQSELVI®. In April 2025, a U.S. Appeals Court lifted the injunction. As Aclaris has successfully executed similar financings in the past, the Company may seek to monetize this financial asset to provide additional non-dilutive financing.
- **Provided Update on Senior Leadership:** Jesse W. Hall, M.D. has been appointed as Chief Medical Officer. Dr. Hall brings decades of experience in all phases of drug development, from early development through global regulatory filings and approvals, Phase IV post-marketing surveillance obligations, and commercial launch support to Aclaris. He most recently served as Chief Medical Officer for AltruBio where he was responsible for leadership of all clinical and medical functions. (press release here)

First Quarter 2025 Financial Results

As of March 31, 2025, Aclaris had cash, cash equivalents and marketable securities of $190.5 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 through the first half of 2028, without giving effect to any potential business development transactions or financing activities.

Net loss was $15.1 million for the first quarter of 2025 compared to $16.9 million for the first quarter of 2024.
Total revenue was $1.5 million for the first quarter of 2025 compared to $2.4 million for the first quarter of 2024. The decrease 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 $11.6 million for the quarter ended March 31, 2025 compared to $9.8 million for the prior year period. The increase was primarily driven by expenses related to the Company's bosakitug program, specifically preclinical and clinical development expenses associated with startup activities for a Phase 2 trial in AD. The increase was partially offset by a reduction in development expenses for zunsemetinib and lepzacitinib and lower compensation-related expenses.

General and administrative (G&A) expenses were $6.1 million for the quarter ended March 31, 2025 compared to $6.8 million for the corresponding prior year period. The decrease was primarily due to a reduction in personnel expenses as a result of lower headcount and lower termination benefits.

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 for the initiation of its Phase 2 trial of bosakitug in AD and its Phase 1 trial of ATI-052, the timing for reporting the results of its Phase 2a trial of ATI-2138 in AD, and its plans to explore additional future indications for ATI-2138 including AA and vitiligo, its plans for its preclinical development programs and timing of IND submissions, its plans to monetize the Sun Pharma financial asset, and the sufficiency of its cash, cash equivalents and marketable securities to fund its operations through the first 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, 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 March 31,	
	2025	**2024**
Revenues:		
Contract research	$ 445	$ 657
Licensing	1,010	1,741
Total revenue	1,455	2,398
Costs and expenses:		
Cost of revenue(1)	506	809
Research and development(1)	11,584	9,845
General and administrative(1)	6,139	6,844
Licensing	1,010	1,031
Revaluation of contingent consideration	300	2,800
Total costs and expenses	19,539	21,329
Loss from operations	(18,084)	(18,931)
Other income:		
Interest income	2,166	1,990
Non-cash royalty income	833	—
Total other income	2,999	1,990
Net loss	$ (15,085)	$ (16,941)
Net loss per share, basic and diluted	$ (0.12)	$ (0.24)
Weighted average common shares outstanding, basic and diluted	122,390,303	71,074,858
(1) Amounts include stock-based compensation expense as follows:		
Cost of revenue	$ 219	$ 252

Research and development	1,185	(29)
General and administrative	2,131	1,866
Total stock-based compensation expense	$ 3,535	$ 2,089

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 190,525	$ 203,896
Total assets	$ 198,094	$ 220,327
Total current liabilities	$ 21,514	$ 31,596
Total liabilities	$ 54,028	$ 64,773
Total stockholders' equity	$ 144,066	$ 155,554
Common stock outstanding	108,265,529	107,850,124

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

	Three Months Ended March 31,	
	2025	2024
Net loss	$ (15,085)	$ (16,941)
Depreciation and amortization	128	243
Stock-based compensation expense	3,535	2,089
Revaluation of contingent consideration	300	2,800
Changes in operating assets and liabilities	(1,935)	(9,006)
Net cash used in operating activities	$ (13,057)	$ (20,815)

Source: Aclaris Therapeutics, Inc.