Aclaris Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides a Corporate Update

February 27, 2025

- Rich Catalyst Calendar Expected in 2025 Including Phase 2 Data in Multiple Immuno-Inflammatory Disease Indications -

- Data from CTTQ's Phase 2 Studies of Bosakitug (ATI-045) in Chinese Patients with Severe Asthma and Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Expected in the First Half of 2025 to Inform Internal Development Programs -

- Initiation of Enrollment in Phase 2b Trial for Bosakitug in Atopic Dermatitis (AD) on Track for the First Half of 2025 -

- Cash Runway Expected into 2028 -

WAYNE, Pa., Feb. 27, 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 fourth quarter and full year ended 2024 and provided a corporate update.

"2024 was a transformative year that has positioned Aclaris with multiple clinical catalysts expected in 2025 across our expanded pipeline," stated Dr. Neal Walker, Chief Executive Officer and Chair of the Board of Directors of Aclaris. "We are particularly excited about the upcoming Phase 2 data for bosakitug in both severe asthma and chronic rhinosinusitis with nasal polyps anticipated from our partner CTTQ, which we expect will provide important insights into our future development of bosakitug in respiratory diseases. We also anticipate top-line data from our Phase 2a trial of ATI-2138 in atopic dermatitis in the first half of 2025. With multiple clinical catalysts expected throughout 2025 across our pipeline of differentiated assets with mechanisms shown to have proven activity in the diseases we are addressing, we look to drive continued innovation for the patients we seek to treat."

Fourth Quarter 2024 Highlights and Recent Updates

Pipeline:

- **Announced Exclusive, Global License Agreement with Biosion, Inc., Adding Potential Best-in-Class Biologic Assets to Pipeline:** Aclaris acquired worldwide rights (excluding Greater China) to bosakitug (ATI-045), a potential best-in-class, clinical-stage, novel anti-TSLP monoclonal antibody, and ATI-052, a potential best-in-class, pre-clinical stage, novel bispecific antibody that is directed against both TSLP and IL4R. As a result of this license agreement, the Company recorded a one-time $86.9 million in-process research and development charge. (press release here)
- **Confirmed Expectation of Phase 2 Data in the First Half of 2025 for Bosakitug in Chinese Patients with Certain Pulmonary Disorders:** Aclaris' regional partner, Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (CTTQ), is conducting concurrent Phase 2 studies in China for patients with severe asthma, CRSwNP, and chronic obstructive pulmonary disease. Data from trials in severe asthma and CRSwNP expected in first half of 2025 to inform internal development programs.
- **Initiated Clinical Trial Activities for a Phase 2b Trial of Bosakitug in Atopic Dermatitis (AD); Enrollment Expected to Begin in the First Half of 2025:** This trial will investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of bosakitug in patients with moderate to severe AD.
- **Confirmed Expectation of Top Line Results in the First Half of 2025 for Phase 2a Trial in AD of ATI-2138, an Investigational Oral Covalent ITK/JAK3 Inhibitor:** This ongoing Phase 2a open-label trial is being conducted to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 in patients with moderate to severe AD.
- **Announced Plan to File an Investigational New Drug (IND) Application for ATI-052 in the First Quarter of 2025:** Following allowance of the IND, Aclaris expects to initiate a Phase 1 clinical trial evaluating single ascending doses and multiple ascending doses of ATI-052.
- **Announced New Publication Highlighting the Unique Properties of ATI-2138:** New publication provides important clinical and non-clinical evidence of the potential for ATI-2138 to be a best-in-class inhibitor of key signal transduction kinases due to its unique mechanism of action. (press release here)

Corporate:

- **Completed $80 Million Private Placement in November 2024 to Bolster Cash Runway:** Aclaris' cash runway expected

into 2028. (press release here)

- **Provided Update on Senior Leadership:**
  - Dr. Neal Walker, formerly interim Chief Executive Officer, has been named Chief Executive Officer. Dr. Walker is a co-founder of Aclaris and has served as a member of the Board of Directors since its inception. He previously served as Aclaris' Chief Executive Officer until 2022 before being appointed as interim Chief Executive Officer in January 2024. Dr. Walker serves as Chair of the Board of Directors of Aclaris.
  - Hugh Davis, Ph.D. joined Aclaris as President and Chief Operating Officer. Dr. Davis brings over 35 years of experience in biologics development, clinical pharmacology, and business development to Aclaris. He most recently served as Biosion's Chief Business & Development Officer and President.
  - William Roberts has been appointed as Senior Vice President, Corporate Communications and Investor Relations. Mr. Roberts brings 30 years of corporate communications, investor relations, and scientific experience in the biotech/biopharma industry to the Company. He most recently served as the Communications Officer of G1 Therapeutics, which was recently acquired by Pharmacosmos Group.

Fourth Quarter and Full Year 2024 Financial Results

As of December 31, 2024, Aclaris had aggregate cash, cash equivalents and marketable securities of $203.9 million compared to $181.9 million as of December 31, 2023. The Company believes that its cash, cash equivalents and marketable securities as of December 31, 2024 will be sufficient to fund its operations into 2028, without giving effect to any potential business development transactions or financing activities.

Net loss was $96.6 million for the fourth quarter of 2024 compared to $1.5 million for the fourth quarter of 2023. Net loss was $132.1 million for the year ended December 31, 2024 compared to $88.5 million for the year ended December 31, 2023.

Total revenue was $9.2 million for the fourth quarter of 2024 compared to $17.6 million for the fourth quarter of 2023. The decrease was primarily driven by a one-time upfront payment under the license agreement with Sun Pharmaceutical Industries, Inc. received in the fourth quarter of 2023, offset 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 $18.7 million for the year ended December 31, 2024 compared to $31.2 million for the year ended December 31, 2023.

Research and development (R&D) expenses were $9.0 million for the quarter ended December 31, 2024 compared to $26.6 million for the prior year period. The $17.6 million decrease was primarily the result of lower zunsemetinib development expenses, lepzacitinib preclinical and clinical development activities, and compensation-related expenses. For the year ended December 31, 2024, R&D expenses were $33.6 million compared to $98.4 million for the year ended December 31, 2023.

General and administrative (G&A) expenses were $5.0 million for the quarter ended December 31, 2024 compared to $8.2 million for the corresponding prior year period. The decrease was primarily due to a reduction in personnel and stock-based compensation expenses. For the year ended December 31, 2024, G&A expenses were $22.2 compared to $32.4 million for the year ended December 31, 2023, primarily due to lower compensation-related costs.

Licensing expenses were $8.6 million for the quarter ended December 31, 2024 compared to $5.7 million for the prior year period. The increase was primarily attributable 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, 2024, licensing expenses were $12.7 million compared to $14.7 million for the year ended December 31, 2023.

Revaluation of contingent consideration resulted in a $1.3 million gain for the quarter ended December 31, 2024 compared to a $26.3 million gain for the prior year period. For the year ended December 31, 2024, revaluation of contingent consideration resulted in a charge of $2.5 million compared to a $26.9 million gain for the year ended December 31, 2023.

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. During the quarter ended December 31, 2023, the Company recorded an intangible asset impairment charge of $6.6 million representing the full balance of its in-process research and development intangible asset.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug 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, the clinical development of its product candidates, including enrolling trials, the timing of data from trials and the timing of submitting an IND for ATI-052, and the sufficiency of its cash, cash equivalents and marketable securities to fund its operations into 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenues:				
Contract research	$ 615	$ 566	$ 2,541	$ 3,035
Licensing	8,596	17,004	16,179	28,214
Total revenue	9,211	17,570	18,720	31,249
Costs and expenses:				
Cost of revenue (1)	705	725	2,792	3,423
Research and development (1)	9,026	26,646	33,586	98,384
General and administrative (1)	4,954	8,214	22,203	32,412
Licensing	8,596	5,703	12,666	14,658
Revaluation of contingent consideration	(1,300)	(26,300)	2,500	(26,900)
In-process research and development	86,905	6,629	86,905	6,629
Total costs and expenses	108,886	21,617	160,652	128,606
Loss from operations	(99,675)	(4,047)	(141,932)	(97,357)
Other income:				
Interest income	2,103	2,189	7,953	8,509
Non-cash royalty income	1,020	—	1,914	—
Total other income	3,123	2,189	9,867	8,509
Loss before income taxes	(96,552)	(1,858)	(132,065)	(88,848)
Income tax benefit	—	(367)	—	(367)
Net loss	$ (96,552)	$ (1,491)	$ (132,065)	$ (88,481)
Net loss per share, basic and diluted	$ (1.01)	$ (0.02)	$ (1.71)	$ (1.27)
Weighted average common shares outstanding, basic and diluted	95,305,768	70,866,315	77,296,665	69,808,855
(1) *Amounts include stock-based compensation expense as follows:*				
Cost of revenue	$ 231	$ 337	$ 938	$ 1,456
Research and development	943	(2,367)	3,135	6,801
General and administrative	1,686	3,296	6,783	12,285
Total stock-based compensation expense	$ 2,860	$ 1,266	$ 10,856	$ 20,542

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 203,896	$ 181,877
Total assets	$ 220,327	$ 197,405

Total current liabilities	$ 31,596	$ 30,952
Total liabilities	$ 64,773	$ 40,226
Total stockholders' equity	$ 155,554	$ 157,179
Common stock outstanding	107,850,124	70,894,889

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

	Year Ended December 31, 2024	Year Ended December 31, 2023
Net loss	$ (132,065)	$ (88,481)
Depreciation and amortization	807	863
Stock-based compensation expense	10,856	20,542
Revaluation of contingent consideration	2,500	(26,900)
In-process research and development expense	86,905	6,629
Deferred taxes	—	(367)
Changes in operating assets and liabilities	10,922	9,389
Net cash used in operating activities	$ (20,075)	$ (78,325)

Source: Aclaris Therapeutics, Inc.