Aclaris Therapeutics Reports Third Quarter 2024 Financial Results and Provides a Corporate Update

November 6, 2024

– First Patient Dosed in ATI-2138 Phase 2a Trial in Atopic Dermatitis As Previously Announced;
Top-line Data Anticipated in First Half of 2025 –

WAYNE, Pa., Nov. 06, 2024 (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 third quarter of 2024 and provided a corporate update.

"The third quarter of 2024 marked an important milestone for Aclaris with the dosing of our first patient in the Phase 2a trial of ATI-2138 for moderate to severe atopic dermatitis," said Dr. Neal Walker, Interim President & CEO and Chair of the Board of Directors of Aclaris. "This milestone, combined with our robust financial position, underscores our commitment to executing a capital-efficient development strategy."

Research and Development Highlights:

- **ITK Inhibitor Programs**
  - **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor
    - **Atopic Dermatitis (ATI-2138-AD-201)**: This Phase 2a open-label trial to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 in patients with moderate to severe atopic dermatitis (AD) is ongoing. Aclaris continues to expect top-line data in the first half of 2025.
  - **ITK Selective Compound**
    - Aclaris is progressing a second generation ITK selective inhibitor to development candidate selection for autoimmune indications.
- **Lepzacitinib (ATI-1777)**, an investigational topical “soft” JAK 1/3 inhibitor
  - In January 2024, Aclaris reported positive top-line results from its Phase 2b trial of lepzacitinib in AD.
  - Aclaris is currently seeking a global development and commercialization partner for this program (excluding Greater China). As previously announced, in 2022 Aclaris granted Pediatrix Therapeutics exclusive rights to develop and commercialize lepzacitinib in Greater China.
- **Zunsemetinib (ATI-450)**, an investigational oral small molecule MK2 inhibitor
  - Aclaris plans to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib as a potential treatment for pancreatic cancer and metastatic breast cancer. Aclaris expects these trials to be primarily funded by grants awarded to Washington University.

Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2024, Aclaris had aggregate cash, cash equivalents and marketable securities of $173.4 million compared to $181.9 million as of December 31, 2023.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of September 30, 2024 will be sufficient to fund its operations into 2028, without giving effect to any potential business development transactions, financing activities or the outcome of its strategic review.

Financial Results

Third Quarter 2024

- Net loss was $7.6 million for the third quarter of 2024 compared to $29.3 million for the third quarter of 2023.
- Total revenue was $4.3 million for the third quarter of 2024 compared to $9.3 million for the third quarter of 2023. The decrease was primarily driven by higher milestones earned during the prior year period compared to the current year period.
- Research and development (R&D) expenses were $6.0 million for the quarter ended September 30, 2024 compared to $23.9 million for the prior year period.
  - The $17.9 million decrease was primarily the result of:
    - Zunsemetinib development expenses associated with clinical trials in 2023, and drug candidate manufacturing costs;
    - Costs associated with lepzacitinib preclinical development activities and a Phase 2b clinical trial for AD

which was completed in January 2024;
    - ATI-2138 development expenses, including costs associated with a Phase 1 multiple ascending dose (MAD) trial which was completed in September 2023 and other preclinical activities, which were partially offset by clinical development expenses associated with a Phase 2a clinical trial which commenced in August 2024; and
    - Lower compensation-related expenses due to a decrease in headcount and higher forfeiture credits.
- General and administrative (G&A) expenses were $5.7 million for the quarter ended September 30, 2024 compared to $7.1 million for the corresponding prior year period. The decrease was primarily due to a reduction in compensation-related expenses due to lower headcount and higher forfeiture credits.
- Licensing expenses were $1.8 million for the quarter ended September 30, 2024 compared to $7.3 million for the corresponding prior year period. The decrease was primarily due to higher milestones earned during the prior year period compared to the current year period.
- Revaluation of contingent consideration resulted in a $0.8 million loss for the quarter ended September 30, 2024 compared to a loss of $1.7 million for the prior year period.

Year-to-date 2024

- Net loss was $35.5 million for the nine months ended September 30, 2024 compared to $87.0 million for the nine months ended September 30, 2023.
- Total revenue was $9.5 million for the nine months ended September 30, 2024 compared to $13.7 million for the nine months ended September 30, 2023. The decrease was primarily driven by higher milestones earned during the prior year period compared to the current year period.
- R&D expenses were $24.6 million for the nine months ended September 30, 2024 compared to $71.7 million for the corresponding prior year period.
    - The $47.1 million decrease was primarily the result of:
        - Zunsemetinib development expenses associated with clinical trials in 2023, and drug candidate manufacturing costs;
        - Costs associated with lepzacitinib preclinical development activities and a Phase 2b clinical trial for AD which was completed in January 2024;
        - ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial which was completed in September 2023 and other preclinical activities, which were partially offset by clinical development expenses associated with a Phase 2a clinical trial which commenced in August 2024; and
        - Lower compensation-related expenses due to a decrease in headcount and higher forfeiture credits.
- G&A expenses were $17.2 million for the nine months ended September 30, 2024 compared to $24.2 million for the prior year period. The decrease was primarily due to a reduction in compensation-related expenses due to lower headcount and higher forfeiture credits and the recognition of bad debt expense recorded in the prior year period from Aclaris' determination that collection of amounts due from EPI Health are uncertain as a result of their filing for Chapter 11 bankruptcy protection.
- Licensing expenses were $4.1 million for the nine months ended September 30, 2024 compared to $9.0 million for the prior year period. The decrease was primarily due to higher milestones earned during the prior year period compared to the current year period.
- Revaluation of contingent consideration resulted in a $3.8 million loss for the nine months ended September 30, 2024 compared to a gain of $0.6 million for the corresponding prior year period.

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 exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

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, including its plans to seek a development and commercialization partner for lepzacitinib, the clinical development of ATI-2138, including the timing of top-line data, its plan to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib, the sufficiency of its cash, cash equivalents and marketable securities to fund its operations into 2028, as well as its strategic review. 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, 2023, 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, 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,	
	2024	2023	2024	2023
Revenues:				
Contract research	$ 645	$ 705	$ 1,926	$ 2,469
Licensing	3,701	8,577	7,583	11,210
Total revenue	4,346	9,282	9,509	13,679
Costs and expenses:				
Cost of revenue [1]	654	848	2,087	2,698
Research and development [1]	5,956	23,876	24,560	71,738
General and administrative [1]	5,653	7,091	17,249	24,198
Licensing	1,754	7,344	4,070	8,955
Revaluation of contingent consideration	800	1,700	3,800	(600)
Total costs and expenses	14,817	40,859	51,766	106,989
Loss from operations	(10,471)	(31,577)	(42,257)	(93,310)
Other income:				
Interest income	1,991	2,316	5,850	6,320
Non-cash royalty income	894	—	894	—
Total other income	2,885	2,316	6,744	6,320
Net loss	$ (7,586)	$ (29,261)	$ (35,513)	$ (86,990)
Net loss per share, basic and diluted	$ (0.11)	$ (0.41)	$ (0.50)	$ (1.25)
Weighted average common shares outstanding, basic and diluted	71,381,731	70,807,934	71,249,813	69,452,495

(1) *Amounts include stock-based compensation expense as follows:*

Cost of revenue	$ 232	$ 347	$ 707	$ 1,119
Research and development	1,124	3,072	2,192	9,168
General and administrative	1,648	2,529	5,097	8,989
Total stock-based compensation expense	$ 3,004	$ 5,948	$ 7,996	$ 19,276

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 173,436	$ 181,877
Total assets	$ 182,394	$ 197,405
Total current liabilities	$ 18,816	$ 30,952
Total liabilities	$ 52,243	$ 40,226
Total stockholders' equity	$ 130,151	$ 157,179
Common stock outstanding	71,417,513	70,894,889

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

Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023

Net loss	$ (35,513)	$ (86,990)
Depreciation and amortization	664	635
Stock-based compensation expense	7,996	19,276
Revaluation of contingent consideration	3,800	(600)
Changes in operating assets and liabilities	11,916	(3,885)
Net cash used in operating activities	$ (11,137)	$ (71,564)

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Source: Aclaris Therapeutics, Inc.