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

August 7, 2024

-Initiated Phase 2a Study Activities for ATI-2138 in Atopic Dermatitis-
-Strengthened Balance Sheet Through Sale of Future OLUMIANT® Royalties for Proceeds of up to $31.5 Million-

WAYNE, Pa., Aug. 07, 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 second quarter of 2024 and provided a corporate update.

"With study activities underway for our ATI-2138 Phase 2a trial in moderate to severe atopic dermatitis and the strengthening of our balance sheet through the completion of our royalty purchase agreement with OMERS, we're well-positioned to drive our strategic initiatives forward," said Dr. Neal Walker, Interim President & CEO and Chair of the Board of Directors of Aclaris. "Our focus remains on leveraging our resources to maximize the potential of our innovative drug candidates, pursue available opportunities, and create long-term value for patients and shareholders alike."

Research and Development Highlights:

- **ITK Inhibitor Programs**
  - **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor
    - **ATI-2138-AD-201:** Aclaris is activating clinical sites and expects to enroll patients in the coming weeks in this Phase 2a open-label trial to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 in subjects with moderate to severe atopic dermatitis (AD).
  - **ITK Selective Compound**
    - Aclaris is progressing to development candidate selection a second generation ITK selective inhibitor 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 atopic dermatitis (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 June 30, 2024, Aclaris had aggregate cash, cash equivalents and marketable securities of $149.9 million compared to $181.9 million as of December 31, 2023. In July 2024, Aclaris received an upfront payment of $26.5 million and is eligible to receive up to an additional $5.0 million upon the achievement of certain sales milestones in connection with the sale of OLUMIANT® royalties and milestones to OMERS Life Sciences.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 2024 in combination with the $26.5 million from the sale of OLUMIANT® royalties and milestones will be sufficient to fund its operations into 2028, without giving effect to any potential new business development transactions, additional financing activities or the outcome of its strategic review.

Financial Results

Second Quarter 2024

- Net loss was $11.0 million for the second quarter of 2024 compared to $29.6 million for the second quarter of 2023.

- Total revenue was $2.8 million for the second quarter of 2024 compared to $1.9 million for the second quarter of 2023. The increase was primarily driven by an increase in royalties under the Lilly license agreement during the three months ended

June 30, 2024.

- Research and development (R&D) expenses were $8.8 million for the quarter ended June 30, 2024 compared to $25.3 million for the prior year period.
    - The $16.5 million decrease was primarily the result of lower:
        - Zunsemetinib development expenses associated with clinical activities for a Phase 2a trial for hidradenitis suppurativa which was completed in March 2023, a Phase 2b trial for rheumatoid arthritis which was completed in November 2023, a Phase 2b trial for psoriatic arthritis which was discontinued in December 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; and
        - Compensation-related expenses due to a decrease in headcount and higher forfeiture credits.

- General and administrative (G&A) expenses were $4.8 million for the quarter ended June 30, 2024 compared to $8.3 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, along with 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 $1.3 million for the quarter ended June 30, 2024 compared to $0.6 million for the prior year period. The increase was due to an increase in royalties earned under the Lilly license agreement.

- Revaluation of contingent consideration resulted in a $0.2 million loss for the quarter ended June 30, 2024 compared to a gain of $1.5 million for the prior year period.

Year-to-date 2024

- Net loss was $27.9 million for the six months ended June 30, 2024 compared to $57.7 million for the six months ended June 30, 2023.

- Total revenue was $5.2 million for the six months ended June 30, 2024 compared to $4.4 million for the six months ended June 30, 2023. The increase was primarily driven by an increase in royalties under the Lilly license agreement during the six months ended June 30, 2024.

- R&D expenses were $18.6 million for the six months ended June 30, 2024 compared to $47.9 million for the prior year period.
    - The $29.3 million decrease was primarily the result of lower:
        - Zunsemetinib development expenses associated with clinical activities for a Phase 2a trial for hidradenitis suppurativa which was completed in March 2023, a Phase 2b trial for rheumatoid arthritis which was completed in November 2023, a Phase 2b trial for psoriatic arthritis which was discontinued in December 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; and
        - Compensation-related expenses due to a decrease in headcount and higher forfeiture credits.

- G&A expenses were $11.6 million for the six months ended June 30, 2024 compared to $17.1 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, a decrease in patent, legal and accounting related expenses, 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 $2.3 million for the six months ended June 30, 2024 compared to $1.6 million for the prior year period. The increase was due to an increase in royalties earned under the Lilly license agreement.

- Revaluation of contingent consideration resulted in a $3.0 million loss for the six months ended June 30, 2024 compared to a gain of $2.3 million for the prior year period.

OLUMIANT® is a registered trademark of Eli Lilly and Company.

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, 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 plans and 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Contract research	$ 625	$ 875	$ 1,281	$ 1,764
Licensing	2,141	994	3,882	2,633
Total revenue	2,766	1,869	5,163	4,397
Costs and expenses:				
Cost of revenue (1)	624	1,042	1,433	1,850
Research and development (1)	8,759	25,275	18,604	47,862
General and administrative (1)	4,752	8,317	11,596	17,107
Licensing	1,285	550	2,316	1,611
Revaluation of contingent consideration	200	(1,500)	3,000	(2,300)
Total costs and expenses	15,620	33,684	36,949	66,130
Loss from operations	(12,854)	(31,815)	(31,786)	(61,733)
Other income, net	1,868	2,246	3,859	4,004
Net loss	$ (10,986)	$ (29,569)	$ (27,927)	$ (57,729)
Net loss per share, basic and diluted	$ (0.15)	$ (0.42)	$ (0.39)	$ (0.84)
Weighted average common shares outstanding, basic and diluted	71,291,400	70,633,528	71,183,129	68,763,542
(1) *Amounts include stock-based compensation expense as follows:*				
Cost of revenue	$ 223	$ 473	$ 475	$ 772
Research and development	1,097	3,494	1,068	6,096
General and administrative	1,583	2,555	3,449	6,460
Total stock-based compensation expense	$ 2,903	$ 6,522	$ 4,992	$ 13,328

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

	June 30, 2024	December 31, 2023

Cash, cash equivalents and marketable securities	$ 149,871	$ 181,877
Total assets	$ 161,071	$ 197,405
Total current liabilities	$ 15,682	$ 30,952
Total liabilities	$ 27,249	$ 40,226
Total stockholders' equity	$ 133,822	$ 157,179
Common stock outstanding	71,332,825	70,894,889

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

	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Net loss	$ (27,927)	$ (57,729)
Depreciation and amortization	485	416
Stock-based compensation expense	4,992	13,328
Revaluation of contingent consideration	3,000	(2,300)
Changes in operating assets and liabilities	(13,687)	(722)
Net cash used in operating activities	$ (33,137)	$ (47,007)

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Source: Aclaris Therapeutics, Inc.