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

May 7, 2024

- Progressing ATI-2138 into Atopic Dermatitis -
- Management to Host Conference Call at 5:00 PM ET Today -

WAYNE, Pa., May 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 first quarter of 2024 and provided a corporate update.

"We are pleased to announce that following a review of the potential development pathways for ATI-2138, our investigational ITK/JAK3 compound with best-in-class potential, we have decided to progress ATI-2138 into a proof-of-concept Phase 2a trial in patients with moderate to severe atopic dermatitis," stated Dr. Neal Walker, co-founder and Interim Chief Executive Officer & President of Aclaris. "Across all of our programs, we remain focused on executing a capital efficient strategy to advance novel immuno-inflammatory therapies."

Research and Development Highlights:

- **ITK Inhibitor Programs**
  - **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor
    - Aclaris plans to progress ATI-2138 into a Phase 2a trial in subjects with moderate to severe atopic dermatitis.
    - In September 2023, Aclaris reported positive results from its Phase 1 multiple ascending dose (MAD) trial of ATI-2138.
  - **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 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 March 31, 2024, Aclaris had aggregate cash, cash equivalents and marketable securities of $161.4 million compared to $181.9 million as of December 31, 2023. A majority of cash expenditures in the first quarter of 2024 were related to payments associated with exit activities, including the wind down of discontinued R&D programs and the previously announced reduction in force. Aclaris anticipates payments associated with these activities to be substantially completed by the second quarter of 2024. As a result, Aclaris expects significantly lower quarterly cash expenditures in future quarters, without giving effect to any potential business development activities resulting from its ongoing strategic review of its business.

Financial Results

First Quarter 2024

- Net loss was $16.9 million for the first quarter of 2024 compared to $28.2 million for the first quarter of 2023.
- Total revenue was $2.4 million for the first quarter of 2024 compared to $2.5 million for the first quarter of 2023. The decrease was primarily driven by lower contract research revenue during the three months ended March 31, 2024.
- Research and development (R&D) expenses were $9.8 million for the quarter ended March 31, 2024 compared to $22.6 million for the prior year period.

  - The $12.8 million decrease was primarily the result of lower:

- Zunsemetinib development expenses associated with clinical activities for a Phase 2a trial for hidradenitis suppurativa, a Phase 2b trial for rheumatoid arthritis, and drug candidate manufacturing costs.
- Costs associated with lepzacitinib preclinical development activities and a Phase 2b clinical trial for AD.
- ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial and other preclinical activities.
- Compensation-related expenses due to a decrease in headcount and higher forfeiture credits.

- General and administrative (G&A) expenses were $6.8 million for the quarter ended March 31, 2024 compared to $8.8 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.
- Licensing expenses were $1.0 million for the quarter ended March 31, 2024 compared to $1.1 million for the prior year period. The decrease was due to the achievement of a commercial milestone during the three months ended March 31, 2023, offset by an increase in royalties earned under the Lilly license agreement.
- Revaluation of contingent consideration resulted in a $2.8 million loss for the quarter ended March 31, 2024 compared to a gain of $0.8 million for the prior year period.

Conference Call and Webcast

As previously disclosed on April 30, 2024, management will host a conference call and webcast, with an accompanying slide presentation, at 5:00 PM ET today to provide a corporate update. To access the live webcast of the call and the accompanying slide presentation, please visit the “Events” page of the “Investors” section of Aclaris’ website, www.aclaristx.com. The webcast will be archived for at least 30 days on the Aclaris website.

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, and its plan to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib, as well as Aclaris’ expectations regarding the wind down of discontinued R&D programs and costs associated with its recent reduction in force and the associated impact on anticipated cash burn, and its strategic review of its business. 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 March 31,	
	2024	**2023**
Revenues:		
Contract research	$ 657	$ 889
Licensing	1,741	1,639
Total revenue	2,398	2,528
Costs and expenses:		
Cost of revenue [1]	809	808
Research and development [1]	9,845	22,587
General and administrative [1]	6,844	8,790
Licensing	1,031	1,061
Revaluation of contingent consideration	2,800	(800)
Total costs and expenses	21,329	32,446
Loss from operations	(18,931)	(29,918)

Other income, net	1,990	1,758
Net loss	$ (16,941)	$ (28,160)
Net loss per share, basic and diluted	$ (0.24)	$ (0.42)
Weighted average common shares outstanding, basic and diluted	71,074,858	66,872,778

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

Cost of revenue	$ 252	$ 299
Research and development	(29)	2,602
General and administrative	1,866	3,905
Total stock-based compensation expense	$ 2,089	$ 6,806

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 161,365	$ 181,877
Total assets	$ 174,065	$ 197,405
Total current liabilities	$ 20,080	$ 30,952
Total liabilities	$ 32,051	$ 40,226
Total stockholders' equity	$ 142,014	$ 157,179
Common stock outstanding	71,248,017	70,894,889

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

	March 31, 2024	March 31, 2023
Net loss	$ (16,941)	$ (28,160)
Depreciation and amortization	243	198
Stock-based compensation expense	2,089	6,806
Revaluation of contingent consideration	2,800	(800)
Changes in operating assets and liabilities	(9,006)	(4,397)
Net cash used in operating activities	$ (20,815)	$ (26,353)

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Source: Aclaris Therapeutics, Inc.