Aclaris Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides a Corporate Update

February 27, 2024

WAYNE, Pa., Feb. 27, 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 fourth quarter and full year of 2023 and provided a corporate update.

“As we enter 2024, we are financially strong, focused and motivated,” stated Dr. Neal Walker, co-founder and Interim Chief Executive Officer & President of Aclaris. “Returning to the CEO role, I look forward to building on our strong foundation and deep expertise in kinase discovery and development as we look to shape the future of Aclaris.”

Research and Development Highlights:

- **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, and is currently seeking a development and commercialization partner for this program.
- **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor
  - Aclaris is assessing the most effective development pathway, including the lead indication, for ATI-2138. Aclaris reported positive results from its Phase 1 MAD trial of ATI-2138 in September 2023.
- **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.
  - ATI-2231, Aclaris’ second MK2 inhibitor, was previously being developed for oncology and Aclaris was supporting Washington University in an investigator-initiated Phase 1a trial of ATI-2231 in patients with advanced solid tumor malignancies. However, Aclaris and Washington University agreed to instead study zunsemetinib in oncology in order to expedite the development timeline by eliminating the need to conduct the Phase 1a trial due to zunsemetinib’s more advanced clinical package.
- **Discovery**
  - Aclaris plans to continue to advance discovery programs through KINect®, its proprietary drug discovery platform.

Financial Highlights:

Liquidity and Capital Resources

As of December 31, 2023, Aclaris had aggregate cash, cash equivalents and marketable securities of $181.9 million compared to $229.8 million as of December 31, 2022.

Financial Results

Fourth Quarter 2023

- Net loss was $1.5 million for the fourth quarter of 2023 compared to $27.6 million for the fourth quarter of 2022.
- Total revenue was $17.6 million for the fourth quarter of 2023 compared to $7.8 million for the fourth quarter of 2022. The increase was primarily driven by a one-time upfront payment under the license agreement with Sun Pharmaceutical Industries, Inc. (Sun Pharma) received in the fourth quarter of 2023.
- Research and development (R&D) expenses were $26.6 million for the quarter ended December 31, 2023 compared to $21.1 million for the prior year period. The $5.5 million increase was primarily the result of an increase in expenses associated with drug candidate manufacturing for zunsemetinib.

- General and administrative (G&A) expenses were $8.2 million for the quarter ended December 31, 2023 compared to $7.1 million for the corresponding prior year period. The increase was primarily due to an increase in personnel and stock-based compensation expenses.

- Licensing expenses were $5.7 million for the quarter ended December 31, 2023 compared to $0.6 million for the prior year period. The increase was primarily attributable to amounts payable to third parties in connection with amounts earned under the Sun Pharma license agreement.

- Revaluation of contingent consideration resulted in a $26.3 million gain for the quarter ended December 31, 2023 compared to a charge of $7.1 million for the prior year period.

- Intangible asset impairment charges were $6.6 million for the quarter ended December 31, 2023, representing the full balance of the in-process research and development (IPR&D) intangible asset. The impairment charge resulted from Aclaris' decision to discontinue further development of the drug candidate for immuno-inflammatory diseases.

Full Year 2023

- Net loss was $88.5 million for the year ended December 31, 2023 compared to $86.9 million for the year ended December 31, 2022.

- Total revenue was $31.2 million for the year ended December 31, 2023 compared to $29.8 million for the year ended December 31, 2022. The increase was primarily driven by a one-time upfront payment under the license agreement with Sun Pharma received in the year ended December 31, 2023. The increase was partially offset by both a one-time upfront payment received under a license agreement with Eli Lilly and Company and a one-time upfront payment received under a license agreement with Pediatrix Therapeutics, Inc. in the year ended December 31, 2022.

- R&D expenses were $98.4 million for the year ended December 31, 2023 compared to $77.8 million for the prior year period.

    - The $20.6 million increase was primarily the result of higher:
        - Zunsemetinib development expenses, including costs associated with clinical activities for the Phase 2b trial for rheumatoid arthritis and drug candidate manufacturing costs;
        - ATI-2138 development expenses, including costs associated with the Phase 1 MAD trial and other preclinical activities; and
        - Compensation-related expenses due to an increase in headcount.

- G&A expenses were $32.4 million for the year ended December 31, 2023 compared to $25.1 million for the prior year period.

    - The $7.3 million increase was primarily the result of higher compensation-related costs due to increased headcount and the impact of equity awards granted during the year ended December 31, 2023.
    - Bad debt expense recorded from Aclaris' determination that collection of amounts due from EPI Health are uncertain as a result of their filing for Chapter 11 bankruptcy protection also contributed to the increase.

- Revaluation of contingent consideration resulted in a $26.9 million gain for the year ended December 31, 2023 compared to a charge of $4.7 million for the corresponding prior year period.

- Intangible asset impairment charges were $6.6 million for the year ended December 31, 2023, representing the full balance of the IPR&D intangible asset. The impairment charge resulted from Aclaris' decision to discontinue further development of the drug candidate for immuno-inflammatory diseases.

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 development plans for its development programs, including its plans to seek a development and commercialization

partner for ATI-1777 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues:				
Contract research	$ 566	$ 866	$ 3,035	$ 4,395
Licensing	17,004	6,722	28,214	25,100
Other	—	165	—	257
Total revenue	17,570	7,753	31,249	29,752
Costs and expenses:				
Cost of revenue [1]	725	877	3,423	4,023
Research and development [1]	26,646	21,072	98,384	77,813
General and administrative [1]	8,214	7,146	32,412	25,133
Licensing	5,703	637	14,658	7,937
Revaluation of contingent consideration	(26,300)	7,100	(26,900)	4,700
Intangible asset impairment	6,629	—	6,629	—
Total costs and expenses	21,617	36,832	128,606	119,606
Loss from operations	(4,047)	(29,079)	(97,357)	(89,854)
Other income, net	2,189	1,444	8,509	2,946
Loss before income taxes	(1,858)	(27,635)	(88,848)	(86,908)
Income tax benefit	(367)	—	(367)	—
Net loss	$ (1,491)	$ (27,635)	$ (88,481)	$ (86,908)
Net loss per share, basic and diluted	$ (0.02)	$ (0.41)	$ (1.27)	$ (1.33)
Weighted average common shares outstanding, basic and diluted	70,866,315	66,685,580	69,808,855	65,213,944

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

Cost of revenue	$ 337	$ 314	$ 1,456	$ 1,151
Research and development	(2,367)	1,517	6,801	3,745
General and administrative	3,296	2,982	12,285	10,143
Total stock-based compensation expense	$ 1,266	$ 4,813	$ 20,542	$ 15,039

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 181,877	$ 229,813
Total assets	$ 197,405	$ 254,596
Total current liabilities	$ 30,952	$ 21,938
Total liabilities	$ 40,226	$ 56,975
Total stockholders' equity	$ 157,179	$ 197,621
Common stock outstanding	70,894,889	66,688,647

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
Net loss	$ (88,481)	$ (86,908)
Depreciation and amortization	863	797
Stock-based compensation expense	20,542	15,039
Revaluation of contingent consideration	(26,900)	4,700
Intangible asset impairment charge	6,629	—
Deferred taxes	(367)	—
Changes in operating assets and liabilities	9,389	(1,195)
Net cash used in operating activities	$ (78,325)	$ (67,567)

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Source: Aclaris Therapeutics, Inc.