Aclaris Therapeutics Reports Third Quarter 2023 Financial Results and Provides a Corporate Update

November 6, 2023

- Topline Data from Zunsemetinib Phase 2b Trial in Rheumatoid Arthritis Expected this Month –

- Completion of Enrollment in ATI-1777 Phase 2b Trial in Atopic Dermatitis As Previously Announced; Topline Data Anticipated Around Year-End 2023 -

WAYNE, Pa., Nov. 06, 2023 (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 2023 and provided a corporate update.

“Throughout the first three quarters of this year, I believe our company has performed remarkably well in terms of executing across our clinical development programs,” stated Doug Manion, M.D., Chief Executive Officer of Aclaris. “Most importantly, we are rapidly approaching the topline data read-outs for our two most advanced clinical programs, zunsemetinib in rheumatoid arthritis this month and ATI-1777 in atopic dermatitis around the end of this year. This level of high-quality execution is further exemplified as we advance ATI-2138 in patients with ulcerative colitis, and we’re pleased to collaborate with Washington University as they advance ATI-2231 in patients with advanced solid tumor malignancies.”

Research and Development Highlights:

- **Zunsemetinib**, an investigational oral small molecule MK2 inhibitor:
  Currently being developed as a potential treatment for immuno-inflammatory diseases
  - **Rheumatoid Arthritis (ATI-450-RA-202)**: This Phase 2b placebo-controlled dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in patients with moderate to severe rheumatoid arthritis (RA) completed enrollment in June 2023. Aclaris continues to expect topline data this month.
  - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a placebo-controlled trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in patients with moderate to severe psoriatic arthritis (PsA) is ongoing. Aclaris continues to expect topline data in the first half of 2024.
- **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor:
  Currently being developed as a potential treatment for mild to severe atopic dermatitis (AD)
  - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b vehicle-controlled trial to determine the efficacy, safety, tolerability, and PK of multiple doses and application regimens of ATI-1777 in patients with mild to severe AD completed enrollment in September 2023. Aclaris continues to expect topline data around the end of 2023.
- **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor:
  Currently being developed as a potential treatment for ulcerative colitis; Aclaris is also exploring additional indications for other T cell-mediated autoimmune diseases
  - **Healthy Volunteers (ATI-2138-PKPD-102)**: This two-week Phase 1 MAD (multiple ascending dose) trial to investigate the safety, tolerability, PK and PD of ATI-2138 in healthy volunteers has been completed. Based on analysis of the PK, PD and safety, Aclaris is progressing ATI-2138 into Phase 2a clinical development in ulcerative colitis, which it expects to initiate in early 2024. Aclaris reported the data in September 2023.
  - Preliminary data from the MAD trial demonstrated:
    - ATI-2138 was generally well tolerated at all doses tested in the trial;
    - ATI-2138 had dose proportional PK; and
    - a dose-dependent inhibition of both ITK and JAK3 exploratory PD biomarkers, with near maximal inhibition achieved at the 30 mg total daily dose.
- **ATI-2231**, an investigational oral MK2 inhibitor compound:
  Currently being explored as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer. Aclaris is also currently exploring options to use ATI-2231 as a potential treatment for immuno-inflammatory diseases.
  - This is the second MK2 inhibitor generated from Aclaris’ proprietary KINect® drug discovery platform and is designed to have a long plasma half-life.
  - Aclaris is supporting Washington University in a first-in-human investigator-initiated Phase 1a trial of ATI-2231 in patients with advanced solid tumor malignancies. Aclaris expects clinical development activities to be initiated in the second half of 2023.

Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2023, Aclaris had aggregate cash, cash equivalents and marketable securities of $187.0 million compared to $229.8 million as of December 31, 2022.

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of September 30, 2023 will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or financing activities.

Financial Results

Third Quarter 2023

- Net loss was $29.3 million for the third quarter of 2023 compared to $20.0 million for the third quarter of 2022.
- Total revenue was $9.3 million for the third quarter of 2023 compared to $19.0 million for the third quarter of 2022. The decrease was primarily driven by a one-time upfront payment under the non-exclusive patent license agreement with Eli Lilly and Company (Lilly) received in the third quarter of 2022.
- Research and development (R&D) expenses were $23.9 million for the quarter ended September 30, 2023 compared to $23.7 million for the prior year period.
    - The $0.2 million increase was primarily the result of:
        - An increase in ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial and other preclinical activities; and
        - An increase in compensation-related expenses due to an increase in headcount.
        - The increases were partially offset by a decrease in zunsemetinib costs associated with the completion of the Phase 2a trial in patients with hidradenitis suppurativa.
- General and administrative (G&A) expenses were $7.1 million for the quarter ended September 30, 2023 compared to $5.8 million for the corresponding prior year period. The increase was primarily due to increased compensation-related expenses due to an increase in headcount.
- Licensing expenses were $7.3 million for each of the quarters ended September 30, 2023 and September 30, 2022, resulting from separate third-party contractual obligations related to the non-exclusive patent license agreement with Lilly.
- Revaluation of contingent consideration resulted in a $1.7 million charge for the quarter ended September 30, 2023 compared to a charge of $2.2 million for the prior year period.

Year-to-date 2023

- Net loss was $87.0 million for the nine months ended September 30, 2023 compared to $59.3 million for the nine months ended September 30, 2022.
- Total revenue was $13.7 million for the nine months ended September 30, 2023 compared to $22.0 million for the nine months ended September 30, 2022. The decrease was primarily driven by a one-time upfront payment under the non-exclusive patent license agreement with Lilly received in the nine months ended September 30, 2022.
- R&D expenses were $71.7 million for the nine months ended September 30, 2023 compared to $56.7 million for the corresponding prior year period.
    - The $15.0 million increase was primarily the result of higher:
        - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA and a Phase 2a trial for PsA;
        - ATI-2138 development expenses, including costs associated with a Phase 1 MAD trial and other preclinical activities; and
        - Compensation-related expenses due to an increase in headcount.
- G&A expenses were $24.2 million for the nine months ended September 30, 2023 compared to $18.0 million for the prior year period.
    - The $6.2 million increase was primarily the result of higher compensation-related costs, including stock-based compensation, due to increased headcount and the impact of equity awards granted during the nine months ended September 30, 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 $0.6 million gain for the nine months ended September 30, 2023 compared to a gain of $2.4 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 the development of Aclaris’ drug candidates, including the timing of its clinical trials, availability of data from those trials, and regulatory filings, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations through the end of 2025. 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, 2022, 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,	
	2023	2022	2023	2022
Revenues:				
Contract research	$ 705	$ 1,090	$ 2,469	$ 3,529
Licensing	8,577	17,898	11,210	18,378
Other	-	30	-	92
Total revenue	9,282	19,018	13,679	21,999
Costs and expenses:				
Cost of revenue[(1)]	848	923	2,698	3,146
Research and development[(1)]	23,876	23,656	71,738	56,741
General and administrative[(1)]	7,091	5,813	24,198	17,987
Licensing	7,344	7,300	8,955	7,300
Revaluation of contingent consideration	1,700	2,200	(600)	(2,400)
Total costs and expenses	40,859	39,892	106,989	82,774
Loss from operations	(31,577)	(20,874)	(93,310)	(60,775)
Other income, net	2,316	922	6,320	1,502
Net loss	$ (29,261)	$ (19,952)	$ (86,990)	$ (59,273)
Net loss per share, basic and diluted	$ (0.41)	$ (0.30)	$ (1.25)	$ (0.92)
Weighted average common shares outstanding, basic and diluted	70,807,934	66,675,337	69,452,495	64,718,008

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

Cost of revenue	$ 347	$ 307	$ 1,119	$ 837
Research and development	3,072	1,400	9,168	2,228
General and administrative	2,529	2,481	8,989	7,161
Total stock-based compensation expense	$ 5,948	$ 4,188	$ 19,276	$ 10,226

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 186,996	$ 229,813
Total assets	$ 218,354	$ 254,596
Total current liabilities	$ 27,320	$ 21,938

Total liabilities	$ 62,021	$ 56,975
Total stockholders' equity	$ 156,333	$ 197,621
Common stock outstanding	70,818,954	66,688,647

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net loss	$ (86,990)	$ (59,273)
Depreciation and amortization	635	607
Stock-based compensation expense	19,276	10,226
Revaluation of contingent consideration	(600)	(2,400)
Changes in operating assets and liabilities	(3,885)	2,388
Net cash used in operating activities	$ (71,564)	$ (48,452)

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Source: Aclaris Therapeutics, Inc.