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

May 8, 2023

- Management to Host Conference Call at 8:00 AM ET Today –

WAYNE, Pa., May 08, 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 first quarter of 2023 and provided a corporate update.

“The first quarter of 2023 represented another period of continued progress advancing our clinical stage development programs toward important data milestones,” stated Doug Manion, M.D., Chief Executive Officer of Aclaris. “As we continue to move toward data catalysts for zunsemetinib in rheumatoid arthritis and psoriatic arthritis as well as ATI-1777 in atopic dermatitis, we also are making positive progress towards bringing our next potentially broadly applicable candidate, ATI-2138, into its first proof of concept trial in ulcerative colitis.”

Continued Dr. Manion, “Regarding our proof-of-concept trial of zunsemetinib in hidradenitis suppurativa, which we reported in March, while we did not see positive efficacy results in this particularly challenging disease, we were able to strengthen our safety database and demonstrate mechanistically that our potentially first-in-class MK2 inhibitor performed as expected.”

Research and Development Highlights:

Clinical Development Programs:

- **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 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 subjects with moderate to severe rheumatoid arthritis (RA) is ongoing. Based on the continued positive enrollment momentum, Aclaris is narrowing its timing guidance for topline data to the fourth quarter of 2023.
  - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (PsA) is ongoing. Based on a slower than anticipated study start up in Europe, the trial enrollment has taken longer than expected. Based on current enrollment trends and momentum, particularly in Poland, Aclaris now expects topline data in the first half of 2024, rather than year end 2023.
- **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor:
  Currently being developing as a potential treatment for mild to severe atopic dermatitis (AD)
  - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b trial to determine the efficacy, safety, tolerability, and PK of multiple doses and application regimens of ATI-1777 in subjects with mild to severe AD is ongoing. In April 2023, Aclaris modified the protocol to expand the inclusion criteria for the trial to enroll patients with milder disease to broaden the drug’s target indication potential and to further aide enrollment which was challenged by an unexpected milder winter season. As a result, Aclaris currently projects topline data in the second half of 2023, rather than mid-year 2023.
- **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor:
  Currently being developed as a potential treatment for T cell-mediated autoimmune diseases
  - Aclaris has selected ulcerative colitis as the intended first clinical development target for ATI-2138. Aclaris is also exploring additional indications that are relevant to the mechanism of action.
  - **Healthy Volunteers (ATI-2138-PKPD-102)**: This Phase 1 MAD (multiple ascending dose) trial to investigate the safety, tolerability, PK and PD of ATI-2138 in healthy volunteers is ongoing. Aclaris continues to expect topline data in the second half of 2023.

Preclinical Development Program

- **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
    - Second MK2 inhibitor generated from Aclaris' proprietary KINect® drug discovery platform and designed to have a long plasma half-life.
    - Aclaris expects clinical development activities to be initiated in 2023, which is expected to advance as a collaboration with an academic third party.

Financial Highlights:

Liquidity and Capital Resources

As of March 31, 2023, Aclaris had aggregate cash, cash equivalents and marketable securities of $204.4 million compared to $229.8 million as of December 31, 2022.

Additionally, in March 2023, Aclaris issued a placement notice to sell approximately 3.4 million shares under its ATM facility for aggregate net proceeds of $26.7 million. This transaction closed in April 2023.

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of March 31, 2023 in combination with the $26.7 million in net proceeds from sales under the ATM facility subsequent to quarter end, will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or additional financing activities.

Financial Results

First Quarter 2023

- Net loss was $28.2 million for the first quarter of 2023 compared to $18.8 million for the first quarter of 2022.
- Total revenue was $2.5 million for the first quarter of 2023 compared to $1.5 million for the first quarter of 2022. The increase was driven by higher licensing revenue primarily from royalties earned on out-licensed intellectual property in the first quarter of 2023.
- Research and development (R&D) expenses were $22.6 million for the quarter ended March 31, 2023 compared to $14.3 million for the prior year period.
    - The $8.3 million increase was primarily the result of higher:
        - Zunsemetinib development expenses related to drug candidate manufacturing and costs associated with clinical activities for a Phase 2b trial for RA.
        - ATI-1777 development expenses related to costs associated with 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 an increase in headcount.
- General and administrative (G&A) expenses were $8.8 million for the quarter ended March 31, 2023 compared to $6.1 million for the prior year period. The increase was primarily due to an increase in compensation-related expenses due to an increase in headcount.
- Licensing expenses were $1.1 million for the quarter ended March 31, 2023 resulting from separate third-party contractual obligations related to the non-exclusive patent license agreement with Lilly. There were no licensing expenses for the quarter ended March 31, 2022.
- Revaluation of contingent consideration resulted in a $0.8 million credit for the quarter ended March 31, 2023 compared to a credit of $1.2 million for the prior year period.

Conference Call and Webcast

As previously disclosed on May 2, 2023, management will host a conference call and webcast, with an accompanying slide presentation, at 8:00 AM 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 “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 March 31,	
	2023	**2022**
Revenues:		
Contract research	$ 889	$ 1,221
Licensing	1,639	202
Other	—	30
Total revenue	2,528	1,453
Costs and expenses:		
Cost of revenue (1)	808	1,155
Research and development (1)	22,587	14,306
General and administrative (1)	8,790	6,099
Licensing	1,061	—
Revaluation of contingent consideration	(800)	(1,200)
Total costs and expenses	32,446	20,360
Loss from operations	(29,918)	(18,907)
Other income, net	1,758	118
Net loss	$ (28,160)	$ (18,789)
Net loss per share, basic and diluted	$ (0.42)	$ (0.31)
Weighted average common shares outstanding, basic and diluted	66,872,778	61,431,026

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

Cost of revenue	$ 299	$ 228
Research and development	2,602	(113)
General and administrative	3,905	2,231
Total stock-based compensation expense	$ 6,806	$ 2,346

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

	March 31, 2023	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 204,405	$ 229,813
Total assets	$ 229,705	$ 254,596
Total current liabilities	$ 18,258	$ 21,938

Total liabilities	$ 52,895	$ 56,975
Total stockholders' equity	$ 176,810	$ 197,621
Common stock outstanding	67,206,025	66,688,647

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Net loss	$ (28,160)	$ (18,789)
Depreciation and amortization	198	208
Stock-based compensation expense	6,806	2,346
Revaluation of contingent consideration	(800)	(1,200)
Changes in operating assets and liabilities	(4,397)	(3,534)
Net cash used in operating activities	$ (26,353)	$ (20,969)

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