Aclaris Therapeutics Reports First Quarter 2021 Financial Results and Provides a Corporate Update

May 7, 2021

- ***Data from Phase 2a Trial of ATI-1777 for Moderate to Severe Atopic Dermatitis Expected in Second Quarter of 2021***
- ***Advancing ATI-450 with Planned Initiation of Phase 2b Trial for Moderate to Severe Rheumatoid Arthritis in Second Half of 2021***
- ***Advancing ATI-450 into Two Additional Indications: Hidradenitis Suppurativa and Psoriatic Arthritis***
- ***Expands Scientific Advisory Board***

WAYNE, Pa., May 07, 2021 (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 2021 and provided a corporate update.

"We're very pleased with the progress of our novel immuno-inflammatory drug development pipeline and look forward to reporting data from our Phase 2a trial of ATI-1777 in the second quarter of 2021," said Dr. Neal Walker, President & CEO of Aclaris. "ATI-1777 is our second development program generated by KINect, our proprietary drug discovery platform. After generating proof of mechanism in inhibiting TNFα, IL1β and IL6 in our Phase 2a trial of ATI-450 in moderate to severe rheumatoid arthritis, we are planning to move ATI-450 forward with a Phase 2b trial in moderate to severe rheumatoid arthritis in the second half of 2021 and planning to initiate two additional trials of ATI-450 in hidradenitis suppurativa and psoriatic arthritis."

Research and Development Highlights:

The global COVID-19 pandemic continues to rapidly evolve and has caused and may continue to cause Aclaris to experience disruptions that could impact the timing of its research and development and regulatory activities listed below.

- **ATI-450**, an investigational oral small molecule MK2 inhibitor compound:
  - **ATI-450-RA-201**: A Phase 2a, multicenter, randomized, investigator and patient-blind, sponsor-unblinded, parallel group, placebo-controlled clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in 19 subjects with moderate to severe rheumatoid arthritis. The trial consisted of a 12-week treatment period and a 4-week follow-up period. Two subjects withdrew from the trial during the treatment period, one in the treatment arm and one in the placebo arm.
    - Final per-protocol analysis, which consisted of 17 subjects who completed the treatment period (15 in the treatment arm and two in the placebo arm), confirmed that ATI-450 demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of ACR20/50/70 responses over 12 weeks.
    - Overall, ATI-450 was generally well tolerated. There were no treatment-related serious adverse events and all adverse events were mild to moderate. There was one non-treatment-related serious adverse event (COVID-19) reported in the 4-week follow-up period of the trial in a subject who was no longer receiving treatment. The subject withdrew during the 4-week follow-up period of the trial.
  - Aclaris intends to progress ATI-450 into a Phase 2b trial in moderate to severe rheumatoid arthritis in the second half of 2021.
  - As part of its planned expansion of its Phase 2 immuno-inflammatory clinical development programs, Aclaris also plans to progress ATI-450 into Phase 2 trials in hidradenitis suppurativa and psoriatic arthritis.

- **ATI-1777**, an investigational topical "soft" Janus Kinase (JAK) 1/3 inhibitor compound:
  - **ATI-1777-AD-201**: An ongoing Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to investigate the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in 50 subjects with moderate to severe atopic dermatitis. The primary endpoint is the percentage change from baseline in the Eczema Area and Severity Index (EASI) score at week 4.
    - Enrollment in this trial was completed in March 2021.
    - Data from this trial are now expected in the second quarter of 2021.

- **ATI-2138**, an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound:
  - Currently being developed as a potential treatment for T-cell mediated diseases such as psoriasis and/or inflammatory bowel disease.

- Submission of Investigational New Drug Application is expected in the second half of 2021.

Aclaris is also expanding its Scientific Advisory Board with the addition of Dr. Philip Mease. Dr. Mease, a rheumatologist, currently serves as a Director of the Division of Rheumatology Clinical Research at the Swedish Medical Center/Providence St. Joseph Health and is a Clinical Professor at the University of Washington in Seattle. His major clinical and research focus is psoriatic arthritis and axial spondyloarthritis.

Financial Highlights:

Liquidity and Capital Resources

As of March 31, 2021, Aclaris had aggregate cash, cash equivalents and marketable securities of $142.7 million compared to $54.1 million as of December 31, 2020. The primary factors for the change in cash, cash equivalents and marketable securities during the three months ended March 31, 2021 included:

- Net proceeds of $103.3 million from a public offering in January 2021 in which Aclaris sold 6.3 million shares of common stock.

- Net cash used in operating activities of $12.2 million resulting from net loss of $28.8 million and changes in operating assets and liabilities of $2.9 million, partially offset by non-cash adjustments of $19.4 million which was primarily related to a $16.4 million charge for the revaluation of contingent consideration.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of March 31, 2021 will be sufficient to fund its operations through the end of 2023, including estimated costs for the Phase 2b trial of ATI-450 for moderate to severe rheumatoid arthritis and the planned expansion of its Phase 2 immuno-inflammatory clinical development programs for hidradenitis suppurativa and psoriatic arthritis, without giving effect to any potential business development transactions or financing activities.

Financial Results

First Quarter 2021

- Net loss was $28.8 million for the first quarter of 2021 compared to $15.6 million for the first quarter of 2020.

- Total revenue was $1.8 million for the first quarter of 2021 compared to $1.4 million for the first quarter of 2020.

- Research and development (R&D) expenses were $7.8 million for the quarter ended March 31, 2021 compared to $7.7 million for the prior year period.
  - The quarter-over-quarter increase of $0.1 million was primarily the result of continued investment in the further development of Aclaris' immuno-inflammatory drug development pipeline, including ATI-450, ATI-1777 and ATI-2138, partially offset by a reduction in spend for legacy dermatology assets and personnel costs.

- General and administrative (G&A) expenses were $4.8 million for the quarter ended March 31, 2021 compared to $6.2 million for the prior year period.
  - The quarter-over-quarter decrease of $1.4 million was primarily the result of lower personnel and non-cash stock-based compensation expenses.

- Revaluation of contingent consideration charges related to the Confluence acquisition was $16.4 million for the quarter ended March 31, 2021 compared to $1.8 million for the prior year period.
  - The quarter-over-quarter increase in contingent consideration of $14.7 million primarily resulted from updates to probability of success and estimated future sales level assumptions following the completion of a Phase 2a clinical trial of ATI-450 in subjects with moderate to severe rheumatoid arthritis.

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 clinical development of Aclaris' drug candidates, including the availability of data from its clinical trials and timing for 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 2023. 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 COVID-19 pandemic 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, 2020, 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,	
	2021	**2020**
Revenues:		
Contract research	$ 1,535	$ 1,189
Other revenue	242	218
Total revenue	1,777	1,407
Costs and expenses:		
Cost of revenue (1)	1,202	1,269
Research and development (1)	7,838	7,677
General and administrative (1)	4,827	6,200
Revaluation of contingent consideration	16,439	1,767
Total costs and expenses	30,306	16,913
Loss from operations	(28,529)	(15,506)
Other income (expense), net	(225)	178
Loss from continuing operations	(28,754)	(15,328)
Loss from discontinued operations	—	(258)
Net loss	$ (28,754)	$ (15,586)
Net loss per share, basic and diluted	$ (0.57)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	50,337,807	41,618,429

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

Cost of revenue	$ 247	$ 260
Research and development	876	816
General and administrative	1,552	2,377
Total stock-based compensation expense	$ 2,675	$ 3,453

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

	March 31, 2021	**December 31, 2020**
Cash, cash equivalents and marketable securities	$ 142,657	$ 54,131
Total assets	$ 161,399	$ 70,784
Total current liabilities	$ 14,505	$ 14,874
Total liabilities	$ 49,105	$ 33,134
Total stockholders' equity	$ 112,294	$ 37,650
Common stock outstanding	52,081,729	45,109,314

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Source: Aclaris Therapeutics, Inc.