Aclaris Therapeutics Reports Second Quarter 2020 Financial Results and Provides R&D and Business Highlights

August 7, 2020

- ***First Subject Dosed in Phase 2a Trial of ATI-450, an Investigational Oral MK2 Inhibitor, as a Potential Treatment for Moderate to Severe Rheumatoid Arthritis***
- ***First Subject Dosed in Phase 2a Trial of ATI-450 for Cytokine Release Syndrome in Hospitalized Patients with COVID-19***
- ***Clinical Trial of ATI-1777, an Investigational "Soft" Topical JAK 1/3 Inhibitor, to Proceed in Patients with Moderate to Severe Atopic Dermatitis***

WAYNE, Pa., Aug. 07, 2020 (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 second quarter of 2020 and provided research and development (R&D) and business highlights.

"As the pandemic evolves, our team has continued to work hard to make the appropriate business adjustments, advance our pipeline and execute through these uncertain times," said Dr. Neal Walker, President and CEO of Aclaris. "In the second quarter, we dosed the first subject in our Phase 2a trial of ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis. We are also proud to be participating in the effort to find effective therapeutics for COVID-19 by supporting an investigator-initiated clinical trial of ATI-450 for cytokine release syndrome in hospitalized patients with COVID-19 and the first subject has been dosed in this trial. In addition, we are progressing with the first-in-human trial of ATI-1777 in patients with moderate to severe atopic dermatitis. We look forward to continuing to execute on our clinical development plans."

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

- **ATI-450**, an investigational oral small molecule MK2 inhibitor compound:
  - **ATI-450-RA-201**: An ongoing Phase 2a trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis.
    - This trial was initiated in March 2020. Due to the COVID-19 pandemic, Aclaris temporarily paused enrollment. Aclaris resumed enrolling subjects, and the first subject was dosed, in May 2020. At this time, Aclaris is actively recruiting for this trial. Given the continuing evolution of the COVID-19 pandemic, Aclaris now anticipates reporting data from this trial in the first half of 2021.
  - **ATI-450-CAPS-201**: Aclaris expects to initiate a Phase 2a clinical trial of ATI-450 in cryopyrin-associated periodic syndrome (CAPS), an IL1β-driven disease, in the second half of 2020.
  - **IIT-2020-ATI-450-COVID-19**: An ongoing investigator-initiated Phase 2a, randomized, double-blind, placebo-controlled clinical trial to investigate the safety and efficacy of ATI-450, when used in addition to standard of care therapy, as a potential treatment for cytokine release syndrome in 36 hospitalized patients with COVID-19. Aclaris is providing funding and clinical drug supply to the University of Kansas Medical Center (KUMC), the sponsor of the trial. The primary endpoint in this trial is the proportion of subjects who are free from respiratory failure by day 14.
    - The first subject was dosed in August 2020.

- **ATI-1777**, an investigational topical "soft" Janus Kinase (JAK) 1/3 inhibitor compound:
  - Aclaris submitted an Investigational New Drug (IND) Application for ATI-1777 for the treatment of moderate to severe atopic dermatitis (AD) in June 2020 and now plans to progress to the first-in-human trial of ATI-1777 in subjects with moderate to severe AD.
  - **ATI-1777-AD-201**: Aclaris expects to initiate a Phase 1/2a multicenter, randomized, double-blind, vehicle-controlled trial to investigate the safety, tolerability, pharmacokinetics and efficacy of topically applied ATI-1777 in subjects with moderate to severe AD in the second half of 2020. The primary endpoint will assess efficacy at four weeks.

- **ATI-2138**, an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound:
  - Aclaris is developing ATI-2138 as a potential treatment for psoriasis and/or inflammatory bowel disease and expects to submit an IND for ATI-2138 in 2021.

Business Development Highlights:

- Aclaris continues to pursue strategic alternatives, including seeking partners for:
  - **A-101 45% Topical Solution**: to obtain regulatory approval and commercialize A-101 45% Topical Solution, an investigational compound, as a potential treatment for common warts (verruca vulgaris);
  - **ATI-501 & ATI-502**: to further develop, obtain regulatory approval and commercialize ATI-501 (oral) and ATI-502

(topical), investigational JAK 1/3 inhibitor compounds, as potential treatments for alopecia; and
- **ESKATA**: to commercialize ESKATA® (hydrogen peroxide) topical solution, 40% (w/w).

Financial Highlights:

Liquidity and Capital Resources

As of June 30, 2020, Aclaris had aggregate cash, cash equivalents and marketable securities of $68.1 million compared to $75.0 million as of December 31, 2019. For the quarter and six months ended June 30, 2020, net cash used in operating activities was $10.8 million and $17.6 million, respectively. As of June 30, 2020, Aclaris had approximately 42.7 million shares of common stock outstanding.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 2020 will be sufficient to fund its operations through the first quarter of 2022, without giving effect to any potential business development transactions or financing activities.

Second Quarter 2020 and Year-to-Date Financial Results

- The accompanying consolidated statements of operations and selected consolidated balance sheet data have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to Aclaris' commercial products as discontinued operations.

- Net loss was $11.6 million for the second quarter of 2020, compared to $49.9 million for the second quarter of 2019, and was $27.2 million for the six months ended June 30, 2020, compared to $87.4 million for the six months ended June 30, 2019.

- Total costs and expenses from continuing operations for the second quarter of 2020 were $13.4 million, compared to $44.5 million for the second quarter of 2019, and were $30.3 million for the six months ended June 30, 2020, compared to $72.8 million for the six months ended June 30, 2019.
    - Total costs and expenses in the second quarter of 2020 included non-cash stock-based compensation expense of $3.3 million, compared to $4.6 million in the prior year period.
    - Total costs and expenses for the six months ended June 30, 2020 included non-cash stock-based compensation expense of $6.8 million, compared to $8.9 million in the prior year period.
    - Recorded a non-cash goodwill impairment charge of $18.5 million for the quarter and six months ended June 30, 2019. There were no impairment charges in either period in 2020.

- R&D expenses were $6.5 million and $15.9 million for the quarter and six months ended June 30, 2020, respectively, compared to $17.5 million and $37.2 million for the quarter and six months ended June 30, 2019, respectively.
    - The quarter-over-quarter decrease of $11.1 million was primarily the result of the substantial completion of Aclaris' various Phase 2 clinical trials of ATI-501 and ATI-502 and two pivotal Phase 3 clinical trials of A-101 45% Topical Solution in 2019, and the corresponding reduction in personnel costs to support these programs.

- General and administrative expenses were $5.6 million and $11.8 million for the quarter and six months ended June 30, 2020, respectively, compared to $7.5 million and $14.9 million for the quarter and six months ended June 30, 2019, respectively.
    - The quarter-over-quarter decrease of $1.9 million was primarily the result of lower personnel costs resulting from the Company's decision to discontinue commercial operations in September 2019.

- Loss from continuing operations was $11.6 million and $26.9 million for the quarter and six months ended June 30, 2020, respectively, compared to $43.7 million and $71.0 million for the quarter and six months ended June 30, 2019, respectively. Loss from discontinued operations was $27,000 and $0.3 million for the quarter and six months ended June 30, 2020, respectively, compared to $6.2 million and $16.5 million for the quarter and six months ended June 30, 2019, respectively.

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 and follow Aclaris on LinkedIn or Twitter @aclaristx.

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, timing for initiation of clinical trials and timing for regulatory filings, its plan to pursue strategic alternatives for its drug candidates and ESKATA, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations through the first quarter of 2022. 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, 2019, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 30, 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Contract research	$ 1,853	$ 886	$ 3,042	$ 2,149
Other revenue	193	—	411	—
Total revenues	2,046	886	3,453	2,149
Costs and expenses:				
Cost of revenue (1)	1,389	994	2,658	2,201
Research and development (1)	6,466	17,519	15,909	37,161
General and administrative (1)	5,572	7,469	11,773	14,926
Goodwill impairment	—	18,504	—	18,504
Total costs and expenses	13,427	44,486	30,340	72,792
Loss from operations	(11,381)	(43,600)	(26,887)	(70,643)
Other expense, net	(189)	(85)	(11)	(315)
Loss from continuing operations	(11,570)	(43,685)	(26,898)	(70,958)
Loss from discontinued operations (1)	(27)	(6,191)	(285)	(16,483)
Net loss	$ (11,597)	$ (49,876)	$ (27,183)	$ (87,441)
Net loss per share, basic and diluted	$ (0.28)	$ (1.21)	$ (0.65)	$ (2.12)
Weighted average common shares outstanding, basic and diluted	42,133,646	41,274,808	41,876,037	41,261,808

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

Cost of revenue	$ 252	$ 223	$ 512	$ 429
Research and development	939	1,721	1,755	3,315
General and administrative	2,118	2,654	4,495	5,126
Loss from discontinued operations	—	216	—	806
Total stock-based compensation expense	$ 3,309	$ 4,814	$ 6,762	$ 9,676

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

	June 30, 2020	**December 31, 2019**
Cash, cash equivalents, and marketable securities	$ 68,115	$ 75,015
Total assets	84,999	98,297
Total current liabilities	17,745	22,432
Total liabilities	35,633	28,385
Total stockholders' equity	49,366	69,912

Aclaris Contact
investors@aclaristx.com

Source: Aclaris Therapeutics, Inc.