Aclaris Therapeutics Reports Third Quarter 2020 Financial Results and Provides a Corporate Update

November 4, 2020

- **First Subject Dosed in Phase 2a Trial of ATI-1777, an Investigational Topical "Soft" JAK 1/3 Inhibitor, for the Treatment of Moderate to Severe Atopic Dermatitis**

- **Initiated Phase 2a Trial of ATI-450, an Investigational Oral MK2 Inhibitor, for the Treatment of Cryopyrin-Associated Periodic Syndrome (CAPS)**

WAYNE, Pa., Nov. 04, 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 third quarter of 2020 and provided a corporate update.

"We have continued to meet our milestones and meaningfully advance our pipeline," said Dr. Neal Walker, President & CEO of Aclaris. "We recently announced that we dosed our first subject in our Phase 2a trial of ATI-1777 for the treatment of moderate to severe atopic dermatitis. In addition, we initiated our Phase 2a trial of ATI-450 as a potential treatment for cryopyrin-associated periodic syndrome, an orphan immuno-inflammatory indication. We look forward to progressing these trials as well as our ongoing trial of ATI-450 for rheumatoid arthritis."

Research and Development 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 research and development and regulatory activities listed below.

- **ATI-450**, an investigational oral small molecule MK2 inhibitor compound:
  - **ATI-450-RA-201**: An ongoing Phase 2a clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis. Aclaris' planned enrollment for this trial is up to 25 subjects.
    - Aclaris anticipates reporting data from this trial in the first half of 2021.
  - **ATI-450-CAPS-201**: An ongoing Phase 2a open-label, single-arm clinical trial to investigate the safety, tolerability, efficacy and pharmacodynamics of ATI-450 for the maintenance of remission in subjects with cryopyrin-associated periodic syndrome (CAPS) previously managed with anti-IL1 therapy. Aclaris' planned enrollment for this trial is up to 10 subjects. The primary endpoint of the trial is an assessment of safety and tolerability. The key secondary efficacy endpoint of the trial is the proportion of subjects who maintain disease remission.
    - Aclaris initiated this trial and filed for orphan drug designation for the indication in November 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 approximately 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.

- **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 subjects with moderate or severe atopic dermatitis. Aclaris' planned enrollment for this trial is approximately 42 subjects. The primary endpoint is the percentage change from baseline in the Eczema Area and Severity Index (EASI) score at week 4.
    - The first subject was dosed in October 2020.

- **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 Investigational New Drug (IND) Application 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 September 30, 2020, Aclaris had aggregate cash, cash equivalents, restricted cash and marketable securities of $55.2 million compared to $75.0 million as of December 31, 2019. For the three and nine months ended September 30, 2020, net cash used in operating activities was $12.2 million and $29.8 million, respectively. As of September 30, 2020, Aclaris had approximately 42.9 million shares of common stock outstanding.

In August 2020, Aclaris entered into an equity purchase agreement with Lincoln Park Capital Fund, LLC (Lincoln Park). The agreement allows Aclaris to sell, at its discretion, up to $15.0 million of its common stock to Lincoln Park.

Aclaris anticipates that its cash, cash equivalents, restricted cash and marketable securities as of September 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.

Third Quarter 2020 and Year-to-Date Financial Results

- The accompanying condensed 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 $10.7 million for the third quarter of 2020 compared to $55.3 million for the third quarter of 2019, and was $37.8 million for the nine months ended September 30, 2020 compared to $142.8 million for the nine months ended September 30, 2019.
- Total revenue was $1.4 million for the third quarter of 2020 compared to $1.0 million for the third quarter of 2019, and was $4.9 million for the nine months ended September 30, 2020 compared to $3.1 million for the nine months ended September 30, 2019.
- Research and development (R&D) expenses were $6.9 million for the quarter ended September 30, 2020 compared to $16.2 million for the prior year period, and were $22.8 million for the nine months ended September 30, 2020 compared to $53.3 million for the prior year period.
    - The quarter-over-quarter decrease of $9.3 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. Additionally, Aclaris made a $4.0 million milestone payment for the achievement of a development milestone in the third quarter of 2019 which also contributed to the decrease quarter-over-quarter.
    - R&D expenses in the third quarter of 2020 included non-cash stock-based compensation expense of $0.4 million compared to $1.4 million in the prior year period.
- General and administrative (G&A) expenses were $3.9 million for the quarter ended September 30, 2020 compared to $6.8 million for the prior year period, and were $15.6 million for the nine months ended September 30, 2020 compared to $21.8 million for the prior year period.
    - The quarter-over-quarter decrease of $3.0 million was primarily the result of lower personnel costs resulting from Aclaris' decision to discontinue commercial operations in September 2019.
    - G&A expenses in the third quarter of 2020 included non-cash stock-based compensation expense of $1.3 million compared to $2.6 million in the prior year period.
- Loss from continuing operations was $10.7 million for the quarter ended September 30, 2020 compared to $23.1 million for the prior year period, and was $37.6 million for the nine months ended September 30, 2020 compared to $94.1 million for the prior year period. Loss from discontinued operations was $0 for the third quarter of 2020 compared to $32.2 million for the third quarter of 2019, and was $0.3 million for the nine months ended September 30, 2020 compared to $48.7 million for the nine months ended September 30, 2019.

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, its plan to pursue strategic alternatives for its drug candidates and ESKATA, and its belief that its existing cash, cash equivalents, restricted cash 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 September 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 http://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,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Contract research	$ 1,331	$ 983	$ 4,373	$ 3,132
Other revenue	118	—	529	—
Total revenue	1,449	983	4,902	3,132
Costs and expenses:				
Cost of revenue [1]	1,189	826	3,847	3,028
Research and development [1]	6,866	16,183	22,775	53,334
General and administrative [1]	3,859	6,838	15,632	21,771
Goodwill impairment	—	—	—	18,504
Total costs and expenses	11,914	23,847	42,254	96,637
Loss from operations	(10,465)	(22,864)	(37,352)	(93,505)
Other expense, net	(194)	(274)	(205)	(589)
Loss from continuing operations	(10,659)	(23,138)	(37,557)	(94,094)
Loss from discontinued operations [1]	—	(32,181)	(285)	(48,666)
Net loss	$ (10,659)	$ (55,319)	$ (37,842)	$ (142,760)
Net loss per share, basic and diluted	$ (0.25)	$ (1.34)	$ (0.90)	$ (3.46)
Weighted average common shares outstanding, basic and diluted	42,802,582	41,364,387	42,187,140	41,296,377

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

Cost of revenue	$ 216	$ 25	$ 728	$ 454
Research and development	437	1,418	2,192	4,733
General and administrative	1,288	2,581	5,783	7,707
Loss from discontinued operations	—	(704)	—	102
Total stock-based compensation expense	$ 1,941	$ 3,320	$ 8,703	$ 12,996

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

	September 30, 2020	**December 31, 2019**
Cash, cash equivalents, restricted cash and marketable securities	$ 55,230	$ 75,015
Total assets	71,902	98,297
Total current liabilities	12,788	22,432
Total liabilities	31,145	28,385
Total stockholders' equity	40,757	69,912

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Source: Aclaris Therapeutics, Inc.