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

August 5, 2021

- ***Public Offering with Net Proceeds of $134.9 Million in June Strengthens Balance Sheet and Extends Cash Runway Through the End of 2024***
- ***Positive Preliminary Topline Data for Phase 2a Trial of ATI-1777 in Moderate to Severe Atopic Dermatitis Announced in June***
- ***Advancing ATI-450 with Planned Initiation of Phase 2b Trial for Moderate to Severe Rheumatoid Arthritis in Fourth Quarter of 2021***

WAYNE, Pa., Aug. 05, 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 second quarter of 2021 and provided a corporate update.

“We’re very pleased with the preliminary topline data from our Phase 2a trial of our “soft” topical JAK1/3 inhibitor, ATI-1777, that we announced during the quarter,” said Dr. Neal Walker, President & CEO of Aclaris. “Our recent clinical trial successes with ATI-450 and ATI-1777 demonstrate the value and productivity of our proprietary KINect® drug discovery platform. With our financing in June, we are well positioned to advance our clinical trial programs for ATI-450 and ATI-1777 and develop compounds from our early stage pipeline.”

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.

- **MK2 Inhibitor Assets**
  - **ATI-450**, an investigational oral small molecule MK2 inhibitor compound:
    - Aclaris plans to progress ATI-450 into a Phase 2b trial in moderate to severe rheumatoid arthritis in the fourth quarter of 2021.
    - Aclaris also plans to progress ATI-450 into Phase 2 trials in hidradenitis suppurativa and psoriatic arthritis.
    - In pre-clinical studies, positive effects on MK2 inhibition have been observed for breast cancer metastasis and cancer-associated bone loss.

  - **ATI-2231**, an investigational oral MK2 inhibitor compound:
    - Second MK2 inhibitor generated from Aclaris’ proprietary KINect ® drug discovery platform and designed to have a long half-life.
    - Currently being explored as a potential treatment for metastatic breast cancer and pancreatic cancer as well as use in preventing bone loss in this patient population.
    - IND-enabling studies are underway.

- **“Soft” JAK Inhibitor Asset**
  - **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor compound:
    - **ATI-1777-AD-201**: A Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to evaluate the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in 50 subjects with moderate to severe atopic dermatitis (AD). The trial consisted of a 4-week treatment period and a 2-week follow-up period during which no treatment was given.
      - As announced in June 2021, the trial achieved its primary endpoint, the percent change from baseline in the modified Eczema Area and Severity Index (mEASI) score at week 4, with a high degree of statistical significance ($p<0.001$) (one-sided p-value), which corresponded to a 74.4% reduction in mEASI score from baseline at week 4 in subjects applying ATI-1777 compared to a 41.4% reduction in subjects applying vehicle. The preliminary topline data was based on the full analysis set (FAS), which was comprised of 48 subjects randomized and documented to have received at least one dose of trial medication.
      - Positive trends in favor of ATI-1777 were observed in key secondary efficacy endpoints, such as improvement in itch, percent of mEASI-50 responders, investigator’s global assessment responder

analysis, and reduction in body surface area impacted by disease. In addition, the FAS analysis also showed positive trends in favor of ATI-1777 in percent of mEASI-75 responders (65.2% for ATI-1777 compared to 24.0% for vehicle) and mEASI-90 responders (30.4% for ATI-1777 compared to 20.0% for vehicle). These secondary efficacy endpoints were not powered for statistical significance.
- Based on an analysis of pharmacokinetic plasma samples in the ATI-1777 arm at multiple timepoints, minimal systemic exposure was observed which supports a “soft” topical JAK inhibitor approach.
- ATI-1777 was generally well tolerated. No serious adverse events were reported. The most common adverse events (AEs) (reported in ≥2 subjects in the trial) were increased blood creatinine phosphokinase levels and headache in subjects in the ATI-1777 arm and urinary tract infection (one in each of the ATI-1777 and the vehicle arm); none of these AEs in the ATI-1777 arm were determined by the clinical trial investigators to be related to ATI-1777. One treatment-related AE, application site pruritus, was reported in one subject in the ATI-1777 arm.
- Aclaris plans to progress ATI-1777 into a Phase 2b trial in moderate to severe atopic dermatitis.

- **Preclinical Asset**
  - **ATI-2138**, an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound:
    - Currently being developed as a potential treatment for psoriasis and/or inflammatory bowel disease.
    - Submission of Investigational New Drug Application (IND) is expected in the second half of 2021.

- **Discovery Assets**
  - Currently developing oral gut-restricted JAK inhibitors with limited systemic exposure as potential treatments for inflammatory bowel disease.
    - Identification of a lead development candidate is expected by the end of 2021.
  - Central nervous system (CNS) kinase inhibitor targets
    - Currently engaged in research to identify brain penetrant kinase inhibitor candidates and their impact on neuronal pro-inflammatory cytokine production, microglia growth and survival, and neurodegeneration.

Financial Highlights:

Liquidity and Capital Resources

As of June 30, 2021, Aclaris had aggregate cash, cash equivalents and marketable securities of $266.2 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 six months ended June 30, 2021 included:

- Net proceeds of $134.9 million from a public offering in June 2021 in which Aclaris sold 8.1 million shares of common stock.

- 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 $24.5 million. This amount was comprised of a net loss of $46.9 million and changes in operating assets and liabilities of $5.8 million, partially offset by non-cash charges of $21.2 million for the revaluation of contingent consideration and $6.5 million for stock-based compensation.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 2021 will be sufficient to fund its operations through the end of 2024, without giving effect to any potential business development transactions or financing activities.

Financial Results

Second Quarter 2021

- Net loss was $18.2 million for the second quarter of 2021 compared to $11.6 million for the second quarter of 2020.

- Total revenue was $1.8 million for the second quarter of 2021 compared to $2.0 million for the second quarter of 2020.

- Research and development (R&D) expenses were $7.9 million for the quarter ended June 30, 2021 compared to $6.5 million for the prior year period.

  - The quarter-over-quarter increase of $1.4 million was primarily the result of continued investment in the further development of Aclaris’ immuno-inflammatory drug development pipeline, including ATI-450 and ATI-2138, partially offset by lower quarter-over-quarter development costs for ATI-1777.

- General and administrative (G&A) expenses were $5.9 million for the quarter ended June 30, 2021 compared to $5.6 million for the prior year period.
    - The quarter-over-quarter increase of $0.3 million was primarily the result of higher legal and compliance costs, partially offset by lower compensation expenses.
- Revaluation of contingent consideration charges related to the Confluence acquisition was $4.8 million for the quarter ended June 30, 2021 compared to $0 for the prior year period.

Year-to-date 2021

- Net loss was $46.9 million for the six months ended June 30, 2021 compared to $27.2 million for the six months ended June 30, 2020.
- Total revenue was $3.6 million for the six months ended June 30, 2021 compared to $3.5 million for the six months ended June 30, 2020.
- R&D expenses were $15.7 million for the six months ended June 30, 2021 compared to $14.1 million for the prior year period.
    - The quarter-over-quarter increase of $1.6 million was primarily the result of continued investment in the further development of Aclaris' immuno-inflammatory drug development pipeline, including ATI-450 and ATI-2138, partially offset by lower quarter-over-quarter development costs for ATI-1777 and compensation expenses.
- G&A expenses were $10.7 million for the six months ended June 30, 2021 compared to $11.8 million for the prior year period.
    - The quarter-over-quarter decrease of $1.1 million was primarily the result of lower compensation expenses, partially offset by higher legal and compliance costs.
- Revaluation of contingent consideration charges related to the Confluence acquisition was $21.2 million for the six months ended June 30, 2021 compared to $1.8 million for the 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 "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 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 2024. 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Contract research	$ 1,606	$ 1,853	$ 3,141	$ 3,042

Other revenue	218	193	460	411
Total revenues	1,824	2,046	3,601	3,453
Costs and expenses:				
Cost of revenue (1)	1,263	1,389	2,465	2,658
Research and development (1)	7,897	6,466	15,735	14,142
General and administrative (1)	5,870	5,572	10,697	11,773
Revaluation of contingent consideration	4,800	—	21,239	1,767
Total costs and expenses	19,830	13,427	50,136	30,340
Loss from operations	(18,006)	(11,381)	(46,535)	(26,887)
Other expense, net	(155)	(189)	(380)	(11)
Loss from continuing operations	(18,161)	(11,570)	(46,915)	(26,898)
Loss from discontinued operations	—	(27)	—	(285)
Net loss	$ (18,161)	$ (11,597)	$ (46,915)	$ (27,183)
Net loss per share, basic and diluted	$ (0.34)	$ (0.28)	$ (0.90)	$ (0.65)
Weighted average common shares outstanding, basic and diluted	53,968,405	42,133,646	52,163,136	41,876,037

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

Cost of revenue	$ 335	$ 252	$ 582	$ 512
Research and development	1,154	939	2,030	1,755
General and administrative	2,343	2,118	3,895	4,495
Total stock-based compensation expense	$ 3,832	$ 3,309	$ 6,507	$ 6,762

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 266,177	$ 54,131
Total assets	$ 288,046	$ 70,784
Total current liabilities	$ 14,916	$ 14,874
Total liabilities	$ 54,231	$ 33,134
Total stockholders' equity	$ 233,815	$ 37,650
Common stock outstanding	61,204,987	45,109,314

Aclaris Contact

investors@aclaristx.com

Source: Aclaris Therapeutics, Inc.