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

November 2, 2021

- ***Investigational New Drug Application for ATI-2138 for the Treatment of Psoriasis Submitted in October 2021***
- ***Planning to Initiate Phase 2b Trial of Zunsemetinib (ATI-450) in Moderate to Severe Rheumatoid Arthritis in the Fourth Quarter of 2021***

WAYNE, Pa., Nov. 02, 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 third quarter of 2021 and provided a corporate update.

"This quarter we are pleased to announce the submission of an investigational new drug application for ATI-2138, our investigational oral ITK/TXK/JAK3 inhibitor, the third novel clinical candidate generated by our proprietary KINect® drug discovery platform," said Dr. Neal Walker, President & CEO of Aclaris. "If allowed, we plan to progress ATI-2138 into a Phase 1 trial. We also continue to make progress toward initiating a Phase 2b trial of zunsemetinib (ATI-450) in moderate to severe rheumatoid arthritis and Phase 2 trials of zunsemetinib in psoriatic arthritis and moderate to severe hidradenitis suppurativa, as well as our Phase 2b trial of ATI-1777 in moderate to severe atopic dermatitis."

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.

- **Clinical Programs**
  - MK2 Inhibitor Asset
    - **Zunsemetinib (ATI-450)**, an investigational oral small molecule MK2 inhibitor compound:
      - Zunsemetinib has been adopted as the nonproprietary name for ATI-450.
      - Aclaris plans to progress zunsemetinib into a Phase 2b trial in moderate to severe rheumatoid arthritis in the fourth quarter of 2021.
      - Aclaris also plans to progress zunsemetinib into Phase 2 trials in psoriatic arthritis and moderate to severe hidradenitis suppurativa.
      - In pre-clinical studies, positive effects on MK2 inhibition have been observed for breast cancer metastasis and cancer-associated bone loss.
  - "Soft" JAK Inhibitor Asset
    - **ATI-1777**, an investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor compound:
      - Aclaris plans to progress ATI-1777 into a Phase 2b trial in moderate to severe atopic dermatitis in the first half of 2022. In this trial, Aclaris plans to explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777.
- **Preclinical Programs**
  - **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.
    - Aclaris submitted an Investigational New Drug Application (IND) for ATI-2138 for the treatment of psoriasis in October 2021 and, if allowed, Aclaris plans to progress to a first-in-human Phase 1 single ascending dose trial of ATI-2138 in healthy volunteers.
  - **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 pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer.
    - IND-enabling studies are underway.
- **Discovery Programs**
  - Currently developing oral gut-restricted JAK inhibitors with limited systemic exposure as potential treatments for

inflammatory bowel disease.
    - Central nervous system (CNS) kinase inhibitor targets
        - Currently engaged in research to identify brain penetrant kinase inhibitor candidates and assess their impact on neuronal pro-inflammatory cytokine production, microglia growth and survival, and neurodegeneration.

- **Planned Retirement**
    - Kamil Ali-Jackson, Co-Founder, Chief Legal Officer, Chief Compliance Officer and Corporate Secretary has announced her retirement, effective January 3, 2022. “Kamil was one of the co-founders of Aclaris in 2012 and on behalf of the entire Aclaris team and our Board of Directors, I thank Kamil for her hard work and dedication to the company,” said Dr. Walker. “During her tenure, Kamil has been responsible for building and overseeing Aclaris’ Legal, Compliance, Corporate Communications, Human Resources, and Quality functions and her significant contributions have contributed to the success of the company. We wish Kamil the very best in her retirement.”

Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2021, Aclaris had aggregate cash, cash equivalents and marketable securities of $243.6 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 nine months ended September 30, 2021 included:

- Net cash used in operating activities of $35.1 million. This amount was comprised of the following:
    - $68.1 million net loss
    - $0.8 million cash used from changes in operating assets and liabilities
    - $22.1 million of non-cash charges for the revaluation of contingent consideration
    - $10.2 million of non-cash stock-based compensation expense
    - $1.5 million of other non-cash charges
- Net cash used to repay outstanding debt and fees of $11.5 million in July 2021.
- Net proceeds of $238.2 million from public offerings in January and June 2021 in which Aclaris sold a total of 14.4 million shares of common stock.

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

Third Quarter 2021

- Net loss was $21.1 million for the third quarter of 2021 compared to $10.7 million for the third quarter of 2020.
- Total revenue was $1.7 million for the third quarter of 2021 compared to $1.4 million for the third quarter of 2020.
- Research and development (R&D) expenses were $14.0 million for the quarter ended September 30, 2021 compared to $6.2 million for the prior year period.
    - The $7.7 million increase was primarily the result of additional zunsemetinib expenses, including costs associated with drug product manufacturing and clinical development activities for a Phase 2b trial for moderate to severe rheumatoid arthritis and a Phase 2 trial for moderate to severe hidradenitis suppurativa.
- General and administrative (G&A) expenses were $6.0 million for the quarter ended September 30, 2021 compared to $3.9 million for the prior year period.
    - The $2.1 million increase was primarily the result of higher compensation-related costs, including stock-based compensation as well as higher accounting, compliance and professional fees.
- Revaluation of contingent consideration charges related to the Confluence acquisition was $0.9 million for the quarter ended September 30, 2021 compared to $0.6 million for the prior year period.

Year-to-date 2021

- Net loss was $68.1 million for the nine months ended September 30, 2021 compared to $37.8 million for the nine months ended September 30, 2020.
- Total revenue was $5.3 million for the nine months ended September 30, 2021 compared to $4.9 million for the nine months ended September 30, 2020.

- R&D expenses were $29.7 million for the nine months ended September 30, 2021 compared to $20.4 million for the prior year period.
    - The $9.3 million increase was primarily the result of additional zunsemetinib expenses, including costs associated with drug product manufacturing and clinical development activities for a Phase 2b trial for moderate to severe rheumatoid arthritis and a Phase 2 trial for moderate to severe hidradenitis suppurativa. Continued investment in the further development of Aclaris' immuno-inflammatory drug development pipeline also contributed to the increase as Aclaris progressed towards an IND submission for ATI-2138.

- G&A expenses were $16.7 million for the nine months ended September 30, 2021 compared to $15.6 million for the prior year period.
    - The $1.0 million increase was primarily the result of higher accounting, compliance and professional fees.

- Revaluation of contingent consideration charges related to the Confluence acquisition was $22.1 million for the nine months ended September 30, 2021 compared to $2.4 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Contract research	$ 1,415	$ 1,331	$ 4,556	$ 4,373
Other revenue	244	118	704	529
Total revenue	1,659	1,449	5,260	4,902
Costs and expenses:				
Cost of revenue [1]	1,099	1,189	3,564	3,847
Research and development [1]	13,976	6,240	29,711	20,382
General and administrative [1]	5,979	3,859	16,676	15,632
Revaluation of contingent consideration	900	626	22,139	2,393
Total costs and expenses	21,954	11,914	72,090	42,254
Loss from operations	(20,295)	(10,465)	(66,830)	(37,352)
Other expense, net	(851)	(194)	(1,231)	(205)
Loss from continuing operations	(21,146)	(10,659)	(68,061)	(37,557)
Loss from discontinued operations	—	—	—	(285)
Net loss	$ (21,146)	$ (10,659)	$ (68,061)	$ (37,842)
Net loss per share, basic and diluted	$ (0.35)	$ (0.25)	$ (1.23)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	61,219,321	42,802,582	55,215,037	42,187,140

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

Cost of revenue	$ 206	$ 216	$ 787	$ 728
Research and development	939	437	2,969	2,192
General and administrative	2,557	1,288	6,453	5,783
Total stock-based compensation expense	$ 3,702	$ 1,941	$ 10,209	$ 8,703

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 243,617	$ 54,131
Total assets	$ 263,494	$ 70,784
Total current liabilities	$ 17,839	$ 14,874
Total liabilities	$ 46,913	$ 33,134
Total stockholders' equity	$ 216,581	$ 37,650
Common stock outstanding	61,226,750	45,109,314

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Source: Aclaris Therapeutics, Inc.