Aclaris Therapeutics Reports First Quarter 2022 Financial Results and Provides a Corporate Update

May 10, 2022

- ***Clinical Sites Activated for Phase 2b Trial of ATI-1777***
- ***April Capital Raise Extends Cash Runway Through End of 2025***

WAYNE, Pa., May 10, 2022 (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 2022 and provided a corporate update.

“We have continued to progress our clinical programs, including activating multiple clinical sites in our Phase 2b trial of ATI-1777 in subjects with moderate to severe atopic dermatitis,” said Dr. Neal Walker, President and CEO of Aclaris. “We look forward to advancing all of our clinical and preclinical programs.”

Research and Development Highlights:

Clinical Programs

- **Zunsemetinib,** an investigational oral small molecule MK2 inhibitor:
  Currently being developed as a potential treatment for immuno-inflammatory diseases
  - **ATI-450-RA-202**: This Phase 2b dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (RA) is ongoing.
    - Aclaris expects topline data in 2023.
  - **ATI-450-HS-201**: This Phase 2a trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe hidradenitis suppurativa (HS) is ongoing.
    - Aclaris expects topline data in the first half of 2023.
  - **ATI-450-PsA-201**: Aclaris expects to activate clinical sites in the coming weeks in this Phase 2a trial of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis.
- **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor:
  Currently being developing as a potential treatment for moderate to severe atopic dermatitis (AD)
  - **ATI-1777-AD-202**: Aclaris activated multiple clinical sites in May 2022 in this Phase 2b trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe AD. In this trial, Aclaris will explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777, in patients 12 years and older.
    - Aclaris expects topline data in the first half of 2023.
- **ATI-2138**, an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor:
  Currently being developed as a potential treatment for T cell-mediated autoimmune diseases
  - **ATI-2138-PKPD-101**: This Phase 1 single ascending dose (SAD) trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-2138 in healthy subjects is ongoing.
    - Aclaris expects topline data in 2022.
  - If the Phase 1 SAD trial is successful, Aclaris currently plans to initiate a two-week Phase 1 multiple ascending dose trial of ATI-2138 in subjects with psoriasis in 2022. Aclaris is also currently exploring alternative indications to the planned indication that are relevant to the mechanism of action.

Preclinical Programs

- **ATI-2231**, an investigational oral MK2 inhibitor compound:
  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

    - Second MK2 inhibitor generated from Aclaris' proprietary KINect® drug discovery platform and designed to have a long half-life.

    - IND-enabling studies are underway, and Aclaris expects to submit an IND by the end of 2022.

Discovery Programs

- Currently developing oral gut-biased 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.

Other Highlights

Aclaris continues to expand its senior R&D team and recently appointed Ian Anderson, Ph.D., as Executive Vice President, Translational Research & Development, and Rob Ortmann, M.D., as Vice President, Clinical Development. Dr. Anderson brings more than 30 years of immunology research experience in drug development, from discovery through Phase 2. He previously held senior scientific leadership roles at Flame Biosciences, Janssen Pharmaceutical, MedImmune and Cambridge Antibody Technology. Dr. Ortmann is a board-certified rheumatologist with more than 10 years of clinical research experience in autoimmune-related therapeutic areas. He previously held clinical development positions at Horizon Therapeutics and Eli Lilly and Company.

Financial Highlights:

Liquidity and Capital Resources

As of March 31, 2022, Aclaris had aggregate cash, cash equivalents and marketable securities of $204 million compared to $226 million as of December 31, 2021. Additionally, in April 2022, Aclaris sold approximately 4.8 million shares under its ATM facility for aggregate net proceeds of $73 million.

Aclaris now anticipates that its cash, cash equivalents and marketable securities as of March 31, 2022 in combination with the $73 million in net proceeds from the April 2022 ATM sale will be sufficient to fund its operations through the end of 2025, without giving effect to any additional potential business development transactions or financing activities.

Financial Results

First Quarter 2022

- Net loss was $18.8 million for the first quarter of 2022 compared to $28.8 million for the first quarter of 2021.

- Total revenue was $1.5 million for the first quarter of 2022 compared to $1.8 million for the first quarter of 2021.

- Research and development (R&D) expenses were $14.3 million for the quarter ended March 31, 2022 compared to $7.8 million for the prior year period.
    - The $6.5 million increase was primarily the result of:
        - Higher zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA and a Phase 2a trial for HS.
        - Higher ATI-1777 development expenses related to drug candidate manufacturing and other preclinical activities and start-up costs associated with a Phase 2b clinical trial.
        - Higher preclinical development activities related to ATI-2231.

- General and administrative (G&A) expenses were $6.1 million for the quarter ended March 31, 2022 compared to $4.8 million for the prior year period.
    - The $1.3 million increase was primarily the result of higher compensation-related costs, including stock-based compensation, due to increased headcount and the impact of new equity awards granted during the first quarter of 2022.

- Revaluation of contingent consideration resulted in a $1.2 million credit for the quarter ended March 31, 2022 compared to a contingent consideration charge of $16.4 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 2025. 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, 2021, 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,	
	2022	**2021**
Revenues:		
Contract research	$ 1,221	$ 1,535
Other revenue	232	242
Total revenue	1,453	1,777
Costs and expenses:		
Cost of revenue[(1)]	1,155	1,202
Research and development[(1)]	14,306	7,838
General and administrative[(1)]	6,099	4,827
Revaluation of contingent consideration	(1,200)	16,439
Total costs and expenses	20,360	30,306
Loss from operations	(18,907)	(28,529)
Other income (expense), net	118	(225)
Net loss	$ (18,789)	$ (28,754)
Net loss per share, basic and diluted	$ (0.31)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	61,431,026	50,337,807

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

Cost of revenue	$ 228	$ 247
Research and development	(113)	876
General and administrative	2,231	1,552
Total stock-based compensation expense	$ 2,346	$ 2,675

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

	March 31, 2022	**December 31, 2021**
Cash, cash equivalents and marketable securities	$ 203,577	$ 225,656
Total assets	$ 226,527	$ 251,211

Total current liabilities	$	16,726	$	22,931
Total liabilities	$	46,328	$	53,870
Total stockholders' equity	$	180,199	$	197,341
Common stock outstanding		61,737,483		61,228,446

Aclaris Therapeutics, Inc.
Selected Consolidated Cash Flow Data
(unaudited, in thousands)

		March 31, 2022		March 31, 2021
Net loss	$	(18,789)	$	(28,754)
Depreciation and amortization		208		288
Stock-based compensation expense		2,346		2,675
Revaluation of contingent consideration		(1,200)		16,439
Changes in operating assets and liabilities		(3,534)		(2,880)
Net cash used in operating activities	$	(20,969)	$	(12,232)

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Source: Aclaris Therapeutics, Inc.