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

August 3, 2022

- ***Appointed Douglas Manion, M.D., FRCP (C), as President and COO***
- ***Initiated Phase 2a Study Activities for Psoriatic Arthritis***

WAYNE, Pa., Aug. 03, 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 second quarter of 2022 and provided a corporate update.

“It has been a busy first half of the year as we continue in our pursuit of becoming a leading development-stage immunology company,” said Dr. Neal Walker, Chief Executive Officer of Aclaris. “We have strengthened our senior leadership team this year with the addition of a number of accomplished leaders, including James Loerop, Chief Business Officer, Gail Cawkwell, MD, PhD, Chief Medical Officer, and most recently, Doug Manion, MD, President and Chief Operating Officer. During the second quarter we also were able to raise additional capital, which extended our expected cash runway to the end of 2025. We look forward to continuing to advance our clinical and pre-clinical programs as we move through the second half of the year.”

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
  - **Rheumatoid Arthritis (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 continues to expect topline data in 2023.
  - **Hidradenitis Suppurativa (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 continues to expect topline data in the first half of 2023.
  - **Psoriatic Arthritis (ATI-450-PsA-201)**: Aclaris initiated study activities in the second quarter in 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 psoriatic arthritis (PsA). Aclaris continues to expect topline data in the first half of 2023.
- **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)
  - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe AD is ongoing. 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 continues to expect 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 continues to expect topline data in 2022.
  - If the Phase 1 SAD trial is successful, Aclaris currently plans to initiate a Phase 1 multiple ascending dose (MAD) trial of ATI-2138 in subjects with psoriasis in 2022. Aclaris is also currently exploring alternative indications 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.

Financial Highlights:

Liquidity and Capital Resources

As of June 30, 2022, Aclaris had aggregate cash, cash equivalents and marketable securities of $256 million compared to $226 million as of December 31, 2021. Aggregate cash, cash equivalents and marketable securities as of June 30, 2022 included $73 million of net proceeds from the sale of 4.8 million shares under its ATM facility in April 2022.

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of June 30, 2022 will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or additional financing activities.

Financial Results

Second Quarter 2022

- Net loss was $20.5 million for the second quarter of 2022 compared to $18.2 million for the second quarter of 2021.
- Total revenue was $1.5 million for the second quarter of 2022 compared to $1.8 million for the second quarter of 2021.
- Research and development (R&D) expenses were $18.8 million for the quarter ended June 30, 2022 compared to $7.9 million for the prior year period.
  - The $10.9 million increase was primarily the result of higher:
    - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA, a Phase 2a trial for HS and a Phase 2a trial for PsA.
    - ATI-1777 development expenses related to drug candidate manufacturing and other preclinical activities and start-up costs associated with a Phase 2b clinical trial.
    - Preclinical development activities related to ATI-2231.
    - Compensation-related expenses due to an increase in headcount.
- General and administrative (G&A) expenses were $6.1 million for the quarter ended June 30, 2022 compared to $5.9 million for the prior year period.
- Revaluation of contingent consideration resulted in a $3.4 million reduction of expense for the quarter ended June 30, 2022 mainly due to higher discount rates, compared to a revaluation of contingent consideration expense of $4.8 million for the prior year period.

Year-to-date 2022

- Net loss was $39.3 million for the six months ended June 30, 2022 compared to $46.9 million for the six months ended June 30, 2021.
- Total revenue was $3.0 million for the six months ended June 30, 2022 compared to $3.6 million for the six months ended June 30, 2021.
- R&D expenses were $33.1 million for the six months ended June 30, 2022 compared to $15.7 million for the prior year period.
  - The $17.4 million increase was primarily the result of higher:
    - Zunsemetinib development expenses, including costs associated with clinical activities for a Phase 2b trial for RA, a Phase 2a trial for HS and a Phase 2a trial for PsA.
    - ATI-1777 development expenses related to drug candidate manufacturing and other preclinical activities and start-up costs associated with a Phase 2b clinical trial.
    - Preclinical development activities related to ATI-2231.
    - Compensation-related expenses due to an increase in headcount.
- G&A expenses were $12.2 million for the six months ended June 30, 2022 compared to $10.7 million for the prior year period.
  - The $1.5 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 six months ended June 30, 2022.
- Revaluation of contingent consideration resulted in a $4.6 million reduction of expense for the six months ended June 30, 2022 mainly due to higher discount rates, compared to a revaluation of contingent consideration expense of $21.2 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Contract research	$ 1,218	$ 1,606	$ 2,439	$ 3,141
Other revenue	310	218	542	460
Total revenue	1,528	1,824	2,981	3,601
Costs and expenses:				
Cost of revenue (1)	1,068	1,263	2,223	2,465
Research and development (1)	18,779	7,897	33,085	15,735
General and administrative (1)	6,075	5,870	12,174	10,697
Revaluation of contingent consideration	(3,400)	4,800	(4,600)	21,239
Total costs and expenses	22,522	19,830	42,882	50,136
Loss from operations	(20,994)	(18,006)	(39,901)	(46,535)
Other income (expense), net	462	(155)	580	(380)
Net loss	$ (20,532)	$ (18,161)	$ (39,321)	$ (46,915)
Net loss per share, basic and diluted	$ (0.31)	$ (0.34)	$ (0.62)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	65,990,031	53,968,405	63,723,123	52,163,136

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

Cost of revenue	$ 302	$ 335	$ 530	$ 582
Research and development	941	1,154	828	2,030
General and administrative	2,449	2,343	4,680	3,895
Total stock-based compensation expense	$ 3,692	$ 3,832	$ 6,038	$ 6,507

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 255,824	$ 225,656
Total assets	$ 277,976	$ 251,211
Total current liabilities	$ 16,217	$ 22,931
Total liabilities	$ 42,224	$ 53,870
Total stockholders' equity	$ 235,752	$ 197,341
Common stock outstanding	66,667,580	61,228,446

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

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Net loss	$ (39,321)	$ (46,915)
Depreciation and amortization	414	535
Stock-based compensation expense	6,038	6,507
Revaluation of contingent consideration	(4,600)	21,239
Changes in operating assets and liabilities	(3,166)	(5,819)
Net cash used in operating activities	$ (40,635)	$ (24,453)

Aclaris Contact

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Source: Aclaris Therapeutics, Inc.