Aclaris Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides a Corporate Update

February 23, 2023

WAYNE, Pa., Feb. 23, 2023 (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 fourth quarter and full year of 2022 and provided a corporate update.

“The past year for Aclaris was marked by tremendous execution across our organization notably highlighted by our clinical development programs and our proprietary kinase-focused drug discovery platform,” stated Doug Manion, M.D., Chief Executive Officer of Aclaris. “We enter 2023 well positioned to capitalize on that momentum with multiple data read-outs expected, beginning with top line data from the Phase 2a trial of zunsemetinib in hidradenitis suppurativa next month.”

Continued Dr. Manion, “In addition to the enthusiasm related to our upcoming development-stage milestones, we also continue to benefit from the output of our KINect® discovery engine, and the ability to identify novel development candidates, which we believe will not only position us to continue to build long-term shareholder value, but also enable us to further fulfill our mission of delivering new therapeutic options for patients.”

Research and Development Highlights:

Clinical Development 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 (PK) and pharmacodynamics (PD) 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 the second half of 2023.
  - **Hidradenitis Suppurativa (ATI-450-HS-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) over 12 weeks in subjects with moderate to severe hidradenitis suppurativa (HS) has completed enrollment with 95 patients randomized and is ongoing. Aclaris expects topline data in March of 2023.
  - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (PsA) is ongoing. Aclaris expects topline data by year end 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 PK of multiple doses and application regimens of ATI-1777 in subjects with moderate to severe AD is ongoing. Aclaris expects topline data mid-year 2023.

- **ATI-2138** , an investigational oral covalent ITK/JAK3 inhibitor:
  Currently being developed as a potential treatment for T cell-mediated autoimmune diseases
  - Aclaris has selected ulcerative colitis as the intended first clinical development target for ATI-2138. Aclaris is also exploring additional indications that are relevant to the mechanism of action.
  - Aclaris initiated a Phase 1 MAD (multiple ascending dose) trial of ATI-2138 in healthy volunteers in December of 2022. Aclaris expects topline data from the MAD trial in the second half of 2023.

Preclinical Development Program

- **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 plasma half-life.

- Aclaris expects clinical development activities to be initiated in 2023, which is expected to advance as a collaboration with an academic third party.

Financial Highlights:

Liquidity and Capital Resources

As of December 31, 2022, Aclaris had aggregate cash, cash equivalents and marketable securities of $229.8 million compared to $225.7 million as of December 31, 2021. Aggregate cash, cash equivalents and marketable securities as of December 31, 2022 included proceeds received during the fourth quarter under a license agreement with Pediatrix Therapeutics, Inc. (Pediatrix).

Aclaris continues to anticipate that its cash, cash equivalents and marketable securities as of December 31, 2022 will be sufficient to fund its operations through the end of 2025, without giving effect to any potential business development transactions or financing activities.

Financial Results

Fourth Quarter 2022

- Net loss was $27.6 million for the fourth quarter of 2022 compared to $22.8 million for the fourth quarter of 2021.

- Total revenue was $7.8 million for the fourth quarter of 2022 compared to $1.5 million for the fourth quarter of 2021. The increase was driven by $6.7 million of licensing revenue in the quarter, including $5 million from the license agreement with Pediatrix.

- Research and development (R&D) expenses were $21.1 million for the quarter ended December 31, 2022 compared to $14.1 million for the prior year period.
    - The $7.0 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 costs associated with a Phase 2b clinical trial for AD.
        - ATI-2138 development expenses, including costs associated with a Phase 1 SAD trial, a Phase 1 MAD trial, and other preclinical activities.
        - Compensation-related expenses due to an increase in headcount.

- General and administrative (G&A) expenses were $7.1 million for the quarter ended December 31, 2022 compared to $6.9 million for the prior year period.

- Licensing expenses were $0.6 million for the quarter ended December 31, 2022 resulting primarily from obligations to the former Confluence equity holders from revenue generated from the Pediatrix license agreement. There were no licensing expenses for the quarter ended December 31, 2021.

- Revaluation of contingent consideration was $7.1 million for the quarter ended December 31, 2022, compared to a revaluation of contingent consideration expense of $2.2 million for the prior year period.

Full Year 2022

- Net loss was $86.9 million for the year ended December 31, 2022 compared to $90.9 million for the year ended December 31, 2021.

- Total revenue was $29.8 million for the year ended December 31, 2022 compared to $6.8 million for the year ended December 31, 2021.
    - The $23.0 million increase was driven by a $24.3 million increase in licensing revenue during 2022, which included $17.6 million of upfront and milestone payments received under the non-exclusive patent license agreement with Eli Lilly and a $5.0 million upfront payment received under the Pediatrix license agreement. The increase in licensing revenue was offset by a decrease in contract research revenues.

- R&D expenses were $77.8 million for the year ended December 31, 2022 compared to $43.8 million for the prior year period.
    - The $34.0 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 costs associated with a Phase 2b clinical trial for AD.
- ATI-2138 development expenses, including costs associated with a Phase 1 SAD trial, a Phase 1 MAD trial, and other preclinical activities.
- ATI-2231 preclinical development expenses associated with preclinical activities and IND-enabling studies.
- Compensation-related expenses due to an increase in headcount.

- Licensing expenses were $7.9 million for the year ended December 31, 2022 resulting from separate third-party contractual obligations primarily related to the non-exclusive patent license agreement with Eli Lilly. There were no licensing expenses for the year ended December 31, 2021.

- G&A expenses were $25.1 million for the year ended December 31, 2022 compared to $23.6 million for the prior year period.
  - The $1.5 million increase was primarily the result of higher stock-based compensation and personnel costs due to an increase in headcount.

- Revaluation of contingent consideration charges related to the Confluence acquisition was $4.7 million for the year ended December 31, 2022 compared to $24.3 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, availability of data from those trials, and regulatory filings, the identification of novel development candidates through Aclaris' KINect discovery engine, 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 macroeconomic environment and 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, 2022, 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Contract research	$ 866	$ 1,274	$ 4,395	$ 5,830
Licensing	6,722	197	25,100	809
Other	165	30	257	122
Total revenue	7,753	1,501	29,752	6,761
Costs and expenses:				
Cost of revenue [1]	877	1,149	4,023	4,713
Research and development [1]	21,072	14,102	77,813	43,813
General and administrative [1]	7,146	6,943	25,133	23,619
Licensing	637	—	7,937	—
Revaluation of contingent consideration	7,100	2,200	4,700	24,339
Total costs and expenses	36,832	24,394	119,606	96,484
Loss from operations	(29,079)	(22,893)	(89,854)	(89,723)

Other income (expense), net	1,444	89	2,946	(1,142)
Net loss	$ (27,635)	$ (22,804)	$ (86,908)	$ (90,865)
Net loss per share, basic and diluted	$ (0.41)	$ (0.37)	$ (1.33)	$ (1.60)
Weighted average common shares outstanding, basic and diluted	66,685,580	61,227,800	65,213,944	56,730,583

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

Cost of revenue	$ 314	$ 194	$ 1,151	$ 981
Research and development	1,517	897	3,745	3,866
General and administrative	2,982	2,760	10,143	9,213
Total stock-based compensation expense	$ 4,813	$ 3,851	$ 15,039	$ 14,060

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 229,813	$ 225,656
Total assets	$ 254,596	$ 251,211
Total current liabilities	$ 21,938	$ 22,931
Total liabilities	$ 56,975	$ 53,870
Total stockholders' equity	$ 197,621	$ 197,341
Common stock outstanding	66,688,647	61,228,446

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net loss	$ (86,908)	$ (90,865)
Depreciation and amortization	797	923
Stock-based compensation expense	15,039	14,060
Revaluation of contingent consideration	4,700	24,339
Loss on extinguishment of debt	—	752
Changes in operating assets and liabilities	(1,195)	(1,343)
Net cash used in operating activities	$ (67,567)	$ (52,134)

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