Aclaris Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides a Corporate Update

February 24, 2022

WAYNE, Pa., Feb. 24, 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 fourth quarter and full year of 2021 and provided a corporate update.

“2021 was a tremendous year for the progression of our drug development pipeline, and I’m very proud of what our team has accomplished,” said Dr. Neal Walker, President & CEO of Aclaris. “We reported positive data for our Phase 2a trials of zunsemetinib in subjects with moderate to severe rheumatoid arthritis (RA) and ATI-1777 in subjects with moderate to severe atopic dermatitis (AD), and strengthened our balance sheet to continue this momentum in 2022. Moving forward, we are progressing zunsemetinib in three immuno-inflammatory indications, moving ATI-1777 forward in moderate to severe AD, and progressing ATI-2138 in SAD/MAD studies. Our KINect® drug discovery platform continues to be productive and we now have three clinical-stage compounds as well as an early-stage immuno-inflammatory and oncology pipeline. We have the privilege of working toward the goal of helping address the needs of patients with immuno-inflammatory diseases as well as cancer and look forward to progressing our assets to achieve this goal.”

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

- **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 RA is ongoing.
    - Aclaris anticipates increasing the size of the patient population from approximately 195 to approximately 240 subjects and 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 HS is ongoing.
    - Aclaris expects topline data in the first half of 2023.
  - **ATI-450-PsA-201**: Aclaris plans to progress zunsemetinib (50 mg twice daily) into a Phase 2a trial in subjects with moderate to severe psoriatic arthritis in the first half of 2022.
- **ATI-1777**, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor:
  Currently being developing as a potential treatment for moderate to severe AD
  - Aclaris plans to progress ATI-1777 into a Phase 2b trial in subjects with moderate to severe AD 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, in patients 12 years and older.
- **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:

- James Loerop appointed as Chief Business Officer in January 2022.
- Aclaris plans to hire additional key leadership positions over the coming months to support its operational plans and strategic direction.

Financial Highlights:

Liquidity and Capital Resources

As of December 31, 2021, Aclaris had aggregate cash, cash equivalents and marketable securities of $225.7 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 year ended December 31, 2021 included:

- Net cash used in operating activities of $52.1 million. This amount was comprised of the following:
    - $90.9 million net loss
    - $1.3 million cash used from changes in operating assets and liabilities
    - $24.3 million of non-cash charges for the revaluation of contingent consideration
    - $14.1 million of non-cash stock-based compensation expense
    - $1.7 million of other non-cash charges
- Net cash used to repay outstanding debt and fees of $11.5 million in July 2021.
- Aggregate net proceeds of $238.2 million from public offerings in January 2021 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 December 31, 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

Fourth Quarter 2021

- Net loss was $22.8 million for the fourth quarter of 2021 compared to $13.2 million for the fourth quarter of 2020.
- Total revenue was $1.5 million for the fourth quarter of 2021 compared to $1.6 million for the fourth quarter of 2020.
- Research and development (R&D) expenses were $14.1 million for the quarter ended December 31, 2021 compared to $9.0 million for the prior year period.
    - The $5.1 million increase was the result of additional zunsemetinib expenses, including costs associated with clinical development activities for a Phase 2b trial for moderate to severe RA and a Phase 2 trial for moderate to severe HS and preclinical development activities related to ATI-2231.
- General and administrative (G&A) expenses were $6.9 million for the quarter ended December 31, 2021 compared to $4.9 million for the prior year period.
    - The $2.0 million increase was primarily the result of higher compensation-related costs, including stock-based compensation, as well as higher accounting, compliance and professional fees. Severance payments relating to the retirement of our former Chief Legal Officer also contributed to the increase.
- Revaluation of contingent consideration charges related to the Confluence acquisition was $2.2 million for the quarter ended December 31, 2021 compared to $0 for the prior year period.

Full Year 2021

- Net loss was $90.9 million for the year ended December 31, 2021 compared to $51.0 million for the year ended December 31, 2020.
- Total revenue was $6.8 million for the year ended December 31, 2021 compared to $6.5 million for the year ended December 31, 2020.
- R&D expenses were $43.8 million for the year ended December 31, 2021 compared to $29.3 million for the prior year period.
    - The $14.5 million increase was primarily the result of additional zunsemetinib expenses, including costs associated

with drug candidate development and clinical development activities for a Phase 2b trial for moderate to severe RA and a Phase 2a trial for moderate to severe HS. Continued investment in the further development of Aclaris' immuno-inflammatory drug development pipeline also contributed to the increase as Aclaris progressed toward the October 2021 IND submission for ATI-2138 and began pre-clinical development activities on ATI-2231.

- G&A expenses were $23.6 million for the year ended December 31, 2021 compared to $20.5 million for the prior year period.
  - The $3.1 million increase was primarily the result of higher stock-based compensation costs as well as higher accounting, compliance and professional fees. Severance payments relating to the retirement of our former Chief Legal Officer also contributed to the increase.
- Revaluation of contingent consideration charges related to the Confluence acquisition was $24.3 million for the year ended December 31, 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, 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Contract research	$ 1,274	$ 1,413	$ 5,830	$ 5,786
Other revenue	227	167	931	696
Total revenue	1,501	1,580	6,761	6,482
Costs and expenses:				
Cost of revenue [1]	1,149	1,286	4,713	5,133
Research and development [1]	14,102	8,956	43,813	29,338
General and administrative [1]	6,943	4,898	23,619	20,530
Revaluation of contingent consideration	2,200	—	24,339	2,393
Total costs and expenses	24,394	15,140	96,484	57,394
Loss from operations	(22,893)	(13,560)	(89,723)	(50,912)
Other income (expense), net	89	(219)	(1,142)	(424)
Loss from continuing operations before income taxes	(22,804)	(13,779)	(90,865)	(51,336)
Income tax benefit	—	(182)	—	(182)
Loss from continuing operations	(22,804)	(13,597)	(90,865)	(51,154)
Income from discontinued operations	—	424	—	139
Net loss	$ (22,804)	$ (13,173)	$ (90,865)	$ (51,015)
Net loss per share, basic and diluted	$ (0.37)	$ (0.30)	$ (1.60)	$ (1.20)
Weighted average common shares outstanding, basic and diluted	61,227,800	43,588,095	56,730,583	42,539,293

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

Cost of revenue	$ 194	$ 218	$ 981	$ 946
Research and development	897	727	3,866	2,919
General and administrative	2,760	1,559	9,213	7,342
Total stock-based compensation expense	$ 3,851	$ 2,504	$ 14,060	$ 11,207

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 225,656	$ 54,131
Total assets	$ 251,211	$ 70,784
Total current liabilities	$ 22,931	$ 14,874
Total liabilities	$ 53,870	$ 33,134
Total stockholders' equity	$ 197,341	$ 37,650
Common stock outstanding	61,228,446	45,109,314

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Source: Aclaris Therapeutics, Inc.