UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 25, 2021

Aclaris Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37581**	**46-0571712**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

640 Lee Road, Suite 200
Wayne, PA 19087
(Address of principal executive offices, including zip code)

(484) 324-7933
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 25, 2021, Aclaris Therapeutics, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter and year ended December 31, 2020. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated February 25, 2021.
104	The cover page from Aclaris Therapeutics, Inc.'s Form 8-K filed on February 25, 2021, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ACLARIS THERAPEUTICS, INC.

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer

Date: February 25, 2021

EXHIBIT 99.1

Aclaris Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides a Corporate Update

- ***Positive Preliminary Topline Data for ATI-450, an Investigational Oral MK2 Inhibitor, in Moderate to Severe Rheumatoid Arthritis Announced in January 2021***
- ***ATI-450 Data Support New Oral Approach for the Potential Treatment of Immuno-inflammatory Diseases, such as Rheumatoid Arthritis***
- ***Public Offering of $103.5M in January 2021 Strengthens Balance Sheet***

WAYNE, Pa., February 25, 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 fourth quarter and full year of 2020 and provided a corporate update.

"As we reflect on 2020, we are proud of how we have progressed our immuno-inflammatory development programs," said Dr. Neal Walker, President & CEO of Aclaris. "We are very excited about the platform potential of ATI-450, an oral MK2 inhibitor which we have shown to inhibit TNFα, IL1β, and IL6. Given its novel mechanism, there are several immuno-inflammatory indications that ATI-450 may potentially address. We are also excited about the potential of our pipeline which is internally generated from KINect®, our proprietary drug discovery platform, for various immuno-inflammatory indications. We look forward to building on this momentum in 2021."

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.

- **ATI-450**, an investigational oral small molecule MK2 inhibitor compound:
  - **ATI-450-RA-201**: A Phase 2a, multicenter, randomized, investigator and patient-blind, sponsor-unblinded, parallel group, placebo-controlled clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis.
    - Positive preliminary topline data announced in January 2021. In this trial, ATI-450 demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of ACR20/50/70 responses over 12 weeks. This clinical activity was further supported by pharmacodynamic analyses showing a marked and durable inhibition of TNFα, IL1β, IL6, and IL8 in ex vivo stimulated samples as well as an endogenous inflammation biomarker analysis which also demonstrated a marked and sustained inhibition of median concentrations of hsCRP, TNFα, IL6, IL8, and MIP1β in the treatment arm over the 12 week period.
    - ATI-450 was generally well tolerated. The most common adverse events (AE) (each reported in 2 subjects) were urinary tract infection (UTI), elevated lipids and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. There was one non-treatment-related serious adverse event (COVID-19) reported in

the four-week safety follow-up phase of the trial in a subject who was no longer receiving treatment.
        - Aclaris intends to progress ATI-450 into a Phase 2b trial in moderate to severe rheumatoid arthritis in the second half of 2021.
        - Aclaris is currently evaluating additional potential indications driven by TNFα, IL1β and IL6 as part of its planned expansion of its Phase 2 immuno-inflammatory clinical development programs.

    - **ATI-450-PKPD-102**: A Phase 1, placebo-controlled, randomized, observer-blind clinical trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ATI-450 at 80 mg and 120mg twice daily in health subjects.
        - Positive preliminary topline data announced in January 2021. Pharmacodynamic analysis demonstrated incremental cytokine suppression at these higher doses. ATI-450 was generally well tolerated. The most common AEs (reported by 2 or more subjects who received ATI-450) were headache, dizziness, nausea, parasthesia and, in the post-dosing safety follow-up phase of the trial, dry skin. These AEs were all mild in severity.
        - A final analysis of this trial is underway.

    - **ATI-450-CAPS-201**: A Phase 2a, multicenter, open-label, single-arm clinical trial to investigate the safety, tolerability, efficacy and pharmacodynamics of ATI-450 for the maintenance of remission in subjects with cryopyrin-associated periodic syndrome (CAPS) previously managed with anti-IL1 therapy. Due to the COVID-19 pandemic, subject enrollment in this trial was paused. As a result of the ongoing pandemic and given the positive preliminary topline data from the ATI-450-RA-201 trial, Aclaris has decided to focus its efforts and resources on other immuno-inflammatory diseases.

- **ATI-1777**, an investigational topical “soft” Janus Kinase (JAK) 1/3 inhibitor compound:
    - **ATI-1777-AD-201**: An ongoing Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to investigate the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis. The primary endpoint is the percentage change from baseline in the Eczema Area and Severity Index (EASI) score at week 4. Data from this trial are expected mid-year 2021.

- **ATI-2138**, an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound:
    - Aclaris is developing ATI-2138 as a potential treatment for T-cell mediated diseases such as psoriasis and/or inflammatory bowel disease and expects to submit an Investigational New Drug Application for ATI-2138 in the second half of 2021.

Financial Highlights:

Liquidity and Capital Resources

As of December 31, 2020, Aclaris had aggregate cash, cash equivalents, restricted cash and marketable securities of $54.1 million compared to $75.0 million as of December 31, 2019. The changes in cash and cash equivalents and marketable securities during the year included:

- Net cash used in operating activities was $38.6 million resulting from net loss of $51.0 million and changes in operating assets and liabilities of $2.4 million, partially offset by non-cash adjustments of $14.7 million.

- Net borrowings of $10.9 million pursuant to a Loan and Security Agreement.

- Net proceeds of $7.7 million from the sale of 2.1 million shares of common stock under an equity line of credit agreement.

In January 2021, Aclaris closed a public offering in which it sold approximately 6.3 million shares of common stock. Proceeds from the offering were $103.5 million, net of underwriting discounts, commissions and offering expenses. Aclaris anticipates that its cash, cash equivalents and marketable securities as of December 31, 2020 in combination with the proceeds from the January 2021 public offering will be sufficient to fund its operations through the end of 2023, without giving effect to any potential business development transactions or financing activities.

Financial Results

Fourth Quarter 2020

- Net loss was $13.2 million for the fourth quarter of 2020 compared to $18.6 million for the fourth quarter of 2019. Loss from continuing operations was $13.6 million for the quarter ended December 31, 2020 compared to $19.2 million for the prior year period.

- Total revenue was $1.6 million for the fourth quarter of 2020 compared to $1.1 million for the fourth quarter of 2019.

- Research and development (R&D) expenses were $9.0 million for the quarter ended December 31, 2020 compared to $11.5 million for the prior year period.
    - The quarter-over-quarter decrease of $2.6 million was primarily the result of expenses related to Aclaris' legacy JAK inhibitors ATI-501 and ATI-502, including the substantial completion of Aclaris' various Phase 2 clinical trials, and the substantial completion of two pivotal Phase 3 clinical trials of A-101 45% Topical Solution in 2019.

- General and administrative (G&A) expenses were $4.9 million for the quarter ended December 31, 2020 compared to $5.8 million for the prior year period.
    - The quarter-over-quarter decrease of $0.9 million was primarily the result of lower non-cash stock-based compensation expense resulting from headcount reductions. Stock-based compensation expense was $1.6 million compared to $2.6 million in the prior year period.

Full Year 2020

- Net loss was $51.0 million for the year ended December 31, 2020 compared to $161.4 million for the year ended December 31, 2019. Loss from continuing operations was $51.2 million for the year ended December 31, 2020 compared to $113.5 million for the prior year period. Income from discontinued operations was $0.1 million for the year ended December 31, 2020 compared to a loss from discontinued operations of $47.8 million for the year ended December 31, 2019.

- Total revenue was $6.5 million for the year ended December 31, 2020 compared to $4.2 million for the year ended December 31, 2019.

- R&D expenses were $31.7 million for the year ended December 31, 2020 compared to $64.9 million for the prior year period.
    - The decrease of $33.2 million was primarily the result of expenses related to ATI-501 and ATI-502, including the substantial completion of Aclaris' various Phase 2 clinical trials, and the substantial completion of two pivotal Phase 3 clinical trials of A-101 45% Topical Solution in 2019.
    - R&D expenses in 2020 included non-cash stock-based compensation expense of $2.9 million compared to $5.1 million in the prior year period.
- G&A expenses were $20.5 million for the year ended December 31, 2020 compared to $27.8 million for the prior year period.
    - The decrease of $7.3 million was primarily the result of lower personnel and non-cash stock-based compensation resulting from headcount reductions.
    - G&A expenses in 2020 included non-cash stock-based compensation expense of $7.3 million compared to $10.3 million in the prior year period.
- For the year ended December 31, 2019, there was also a $18.5 million non-cash charge for the impairment of goodwill.

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 clinical development of Aclaris' drug candidates, including the availability of data from its clinical trials and timing for 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 2023. 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.

Consolidated Statements of Operations

(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Contract research	$ 1,413	$ 1,095	$ 5,786	$ 4,227
Other revenue	167	—	696	—
Total revenue	1,580	1,095	6,482	4,227
Costs and expenses:				
Cost of revenue (1)	1,286	1,028	5,133	4,055
Research and development (1)	8,956	11,540	31,731	64,899
General and administrative (1)	4,898	5,809	20,530	27,827
Goodwill impairment	—	—	—	18,504
Total costs and expenses	15,140	18,377	57,394	115,285
Loss from operations	(13,560)	(17,282)	(50,912)	(111,058)
Other expense, net	(219)	(1,895)	(424)	(2,484)
Loss from continuing operations before income taxes	(13,779)	(19,177)	(51,336)	(113,542)
Income tax benefit	(182)	—	(182)	—
Loss from continuing operations	(13,597)	(19,177)	(51,154)	(113,542)
Income (loss) from discontinued operations, net of tax (1)	424	583	139	(47,812)
Net loss	$ (13,173)	$ (18,594)	$ (51,015)	$ (161,354)
Net loss per share, basic and diluted	$ (0.30)	$ (0.45)	$ (1.20)	$ (3.90)
Weighted average common shares outstanding, basic and diluted	43,588,095	41,405,657	42,539,293	41,323,921
(1) *Amounts include stock-based compensation expense as follows:*				
Cost of revenue	$ 218	$ 249	$ 946	$ 703
Research and development	727	358	2,919	5,091
General and administrative	1,559	2,581	7,342	10,288
Income (loss) from discontinued operations, net of tax	—	(7)	—	95
Total stock-based compensation expense	$ 2,504	$ 3,181	$ 11,207	$ 16,177

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(unaudited, in thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents, restricted cash and marketable securities	$ 54,131	$ 75,015
Total assets	70,784	98,297
Total current liabilities	14,874	22,432
Total liabilities	33,134	28,385
Total stockholders' equity	37,650	69,912

Aclaris Contact

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