UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): May 7, 2020

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 May 7, 2020, Aclaris Therapeutics, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended March 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 May 7, 2020.

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: May 7, 2020

EXHIBIT 99.1

Aclaris Therapeutics Reports First Quarter 2020 Financial Results and Provides R&D and Business Highlights

- ***Projected Cash Runway into the First Quarter of 2022***
- ***Borrowed $11 Million from Term Loan Facility***

Wayne, PA – May 7, 2020 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, today announced its financial results for the first quarter of 2020 and provided research and development (R&D) and business highlights.

"In the first quarter, we borrowed $11 million from Silicon Valley Bank enabling us to extend our cash runway, and started enrolling subjects with moderate-to-severe rheumatoid arthritis in our Phase 2a trial of ATI-450. As a result of the COVID-19 pandemic and as a precautionary measure, we temporarily paused subject enrollment in this trial. At this time, we have decided to resume enrollment at one clinical trial site. We will continue to monitor the COVID-19 pandemic and engage additional clinical trial sites, as appropriate, based on our assessment of the impact on our trial. I'm proud of our team's focus, dedication and resilience while navigating through the unique challenges that the COVID-19 pandemic has created," said Dr. Neal Walker, President and CEO of Aclaris.

R&D Highlights:

The global outbreak of COVID-19 continues to rapidly evolve and has caused and may continue to cause Aclaris to experience disruptions that could impact the timing of its regulatory and research and development activities listed below.

- **ATI-450**:
  - ATI-450 is an investigational oral small molecule MK2 inhibitor.
  - **ATI-450-RA-201**: A Phase 2a trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ATI-450 in subjects with moderate-to-severe rheumatoid arthritis.
    - Aclaris started subject enrollment in the first quarter of 2020. Due to the COVID-19 pandemic, Aclaris temporarily paused enrollment of subjects in the trial. At this time, Aclaris has decided to resume enrolling subjects at one clinical trial site. The initiation of additional clinical trial sites will be determined on an ongoing basis as the COVID-19 pandemic evolves.

        - Aclaris previously anticipated reporting data from this trial in the second half of 2020; however, Aclaris expects that the data may be delayed and will provide an update, at a later date, regarding the timing of reporting data from this trial.
    - **ATI-450-PKPD-101:** This Phase 1 single and multiple ascending dose (SAD/MAD) trial evaluated the safety, tolerability, pharmacokinetics, and pharmacodynamics of orally administered ATI-450 in 77 healthy subjects.
        - Final data from this trial demonstrated that ATI-450:
            - resulted in marked inhibition of TNFα, IL1β, IL8, and IL6;
            - was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received ATI-450) observed during the trial were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain, and nausea;
            - had dose-proportional pharmacokinetics (PK) with a terminal half-life of 9-12 hours in the MAD cohort; and
            - had no meaningful food effect or drug-drug interaction with methotrexate.
    - Aclaris is also planning to initiate a Phase 2a clinical trial of ATI-450 in an additional immuno-inflammatory indication.

- **ATI-1777:**
    - ATI-1777 is an investigational topical soft-Janus Kinase (JAK) inhibitor compound.
    - Aclaris expects to submit an IND for ATI-1777 for the treatment of atopic dermatitis in mid-2020.
    - If the IND is allowed, Aclaris expects to initiate a Phase 1/2 clinical trial in subjects with atopic dermatitis in the second half of 2020 evaluating ATI-1777 as a potential topical treatment for moderate-to-severe atopic dermatitis.

- **ATI-2138:**
    - ATI-2138 is an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound that Aclaris is developing as a potential treatment for psoriasis and/or inflammatory bowel disease.
    - Aclaris expects to submit an IND for ATI-2138 in the fourth quarter of 2020 or the first quarter of 2021.

Business Development Highlights:

- Aclaris continues to pursue strategic alternatives, including seeking partners for:
  - **A-101 45% Topical Solution**: to obtain regulatory approval and commercialize A-101 45% Topical Solution, an investigational compound, as a potential treatment for common warts (verruca vulgaris);
  - **ATI-501 & ATI-502:** to further develop, obtain regulatory approval and commercialize ATI-501 (oral) and ATI-502 (topical), investigational JAK 1/3 inhibitor compounds, as potential treatments for alopecia; and
  - **ESKATA:** to commercialize ESKATA® (hydrogen peroxide) topical solution, 40% (w/w).

Financial Highlights:

Liquidity and Capital Resources

As of March 31, 2020, Aclaris had aggregate cash, cash equivalents and restricted cash and marketable securities of $79.0 million compared to $75.0 million as of December 31, 2019. For the quarter ended March 31, 2020, net cash used in operating activities was $6.8 million, which includes $5.2 million received from Allergan Sales, LLC on behalf of EPI Health, LLC for sales of RHOFADE (oxymetazoline hydrochloride) cream, 1%. On March 30, 2020, Aclaris entered into a loan and security agreement with Silicon Valley Bank pursuant to which Aclaris borrowed $11.0 million. As of March 31, 2020, Aclaris had approximately 41.8 million shares of common stock outstanding.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of March 31, 2020, will be sufficient to fund its operations into the first quarter of 2022, without giving effect to any potential business development transactions or financing activities.

First Quarter 2020 Financial Results

- The accompanying consolidated statements of operations and selected consolidated balance sheet data have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to Aclaris' commercial products as discontinued operations. The accompanying financial statement data are generally presented in conformity with Aclaris' historical format. Aclaris believes this format provides comparability with its previously filed financial statements.

- Net loss was $15.6 million for the first quarter of 2020, compared to $37.6 million for the first quarter of 2019. Total costs and expenses from continuing operations for the first quarter of 2020 were $16.9 million, compared to $28.3 million for the first quarter of 2019.
    - Total costs and expenses in the first quarter of 2020 included non-cash stock-based compensation expense of $3.5 million, compared to $4.3 million in the prior year period.
- R&D expenses were $9.4 million for the quarter ended March 31, 2020, compared to $19.6 million for the prior year period.
    - The quarter-over-quarter decrease of $10.2 million was primarily the result of the substantial completion of Aclaris' various Phase 2 clinical trials of ATI-501 and ATI-502 and two pivotal Phase 3 clinical trials of A-101 45% Topical Solution in 2019, and the corresponding reduction in personnel costs to support these programs.
    - These reductions were offset by a $1.8 million non-cash charge for the change in the fair value of contingent consideration that was recorded in the first quarter of 2020.
- General and administrative expenses were $6.2 million for the first quarter of 2020, compared to $7.5 million for the first quarter of 2019. The decrease was primarily the result of lower personnel and stock-based compensation related costs due to lower headcount.
- Loss from continuing operations was $15.3 million for the first quarter of 2020 compared to $27.3 million for the first quarter of 2019, while our loss from discontinued operations was $0.3 million for the first quarter of 2020 compared to $10.3 million for the first quarter of 2019.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing 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 and follow Aclaris on LinkedIn or Twitter @aclaristx.

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, timing for initiation of clinical trials and timing for regulatory filings, its plan to pursue strategic alternatives for its drug candidates and ESKATA, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the first quarter of 2022. 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, 2019, Aclaris’ Quarterly Report on Form 10-Q for the quarter ended March 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” section of the Investors page of Aclaris' website at http://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 March 31,	
	2020	**2019**
Revenues:		
Contract research	$ 1,189	$ 1,263
Other revenue	218	—
Total revenue	1,407	1,263
Costs and expenses:		
Cost of revenue (1)	1,269	1,207
Research and development (1)	9,444	19,643
General and administrative (1)	6,200	7,464
Total costs and expenses	16,913	28,314
Loss from operations	(15,506)	(27,051)
Other income (expense), net	178	(230)
Loss from continuing operations	(15,328)	(27,281)
Loss from discontinued operations (1)	(258)	(10,284)
Net loss	$ (15,586)	$ (37,565)
Net loss per share, basic and diluted	$ (0.37)	$ (0.91)
Weighted average common shares outstanding, basic and diluted	41,618,429	41,248,663

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

Cost of revenue	$ 260	$ 206
Research and development	816	1,594
General and administrative	2,377	2,472
Loss from discontinued operations	—	590
Total stock-based compensation expense	$ 3,453	$ 4,862

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents and restricted cash and marketable securities	$ 79,005	$ 75,015
Total assets	96,812	98,297
Total current liabilities	20,603	22,432
Total liabilities	38,637	28,385
Total stockholders' equity	58,175	69,912

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