

**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): September 3, 2019

Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37581
(Commission File Number)

46-0571712
(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 2.05 Costs Associated with Exit or Disposal Activities.

On September 5, 2019, Aclaris Therapeutics, Inc. (the “Company”) announced the completion of a strategic review of its business, as a result of which the Company will refocus its resources on its immuno-inflammatory development programs and actively seek commercialization partners for its commercial products business. In order to streamline operations and reduce costs, the Company also announced a plan to reduce its workforce by terminating 86 employees, which the Company expects to be completed over the next six months. On September 3, 2019, the Company’s Board of Directors approved these actions, which were effective immediately. As a result, the Company expects to incur a one-time charge totaling approximately \$2.0 million in connection with one-time employee termination costs, including severance and other benefits. This charge is expected to be incurred during the quarter ending September 30, 2019. In addition, an estimated charge between \$1.0 million and \$1.5 million is expected to be incurred for retention benefits and other related charges over the next six months. In total, this restructuring plan is estimated to cost between \$3.0 million and \$3.5 million over the next six months, excluding non-cash charges, with related cash payments expected to be substantially paid out by March 31, 2020.

The estimates of costs that the Company expects to incur and the timing thereof are subject to a number of assumptions and actual results may differ.

Item 7.01 Regulation FD Disclosure.

The Company issued a press release on September 5, 2019 announcing the Company’s new strategic direction, a copy of which is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 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 Company’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.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press Release, dated September 5, 2019.

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.

Date: September 5, 2019

By: /s/ Frank Ruffo

Frank Ruffo
Chief Financial Officer

ACLARIS THERAPEUTICS ANNOUNCES NEW STRATEGIC DIRECTION

- **Completion of Strategic Review and Refocusing of Resources on Immuno-Inflammatory Development Pipeline**
- **Actively Seeking a Commercialization Partner for RHOFADE® (oxymetazoline hydrochloride) cream, 1%**
- **Actively Exploring Strategic Alternatives for Commercial Assets, Alopecia and Wart Development Assets**

Wayne, PA – September 5, 2019 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced the completion of a strategic review of its business, as a result of which the Company will refocus its resources on its immuno-inflammatory development programs and actively seek commercialization partners for its commercial products business.

This review of the Company’s overall business strategy is intended to streamline operations and reduce costs, to position the Company for long-term growth and maximize shareholder value. “Our goal when we commenced this review was to find an effective way to refocus our resources on our novel drug candidates for immuno-inflammatory diseases,” said Dr. Neal Walker, President and Chief Executive Officer.

This new strategic direction includes the following actions:

- 1) Aclaris is actively seeking partners for its commercial products business. For its remaining marketed product, RHOFADE® (oxymetazoline hydrochloride) cream, 1%, Aclaris will no longer utilize a sales force to promote the product. In the interim, Aclaris will continue to sell and distribute RHOFADE in the United States. In addition, Aclaris will also seek strategic partners for ESKATA® (hydrogen peroxide) topical solution, 40% (w/w).
- 2) Aclaris is actively seeking a strategic partner to commercialize its drug candidate A-101 45% Topical Solution, an investigational compound being developed as a potential treatment for verruca vulgaris (common warts). The Company’s two ongoing Phase 3 pivotal clinical trials, THWART-1 and THWART-2, in which A-101 45% Topical Solution is being evaluated as a potential treatment for common warts, are progressing as planned. Aclaris has completed enrollment of more than 1,000 patients across these two trials, and data from both trials are expected in the second half of 2019.
- 3) Aclaris is actively seeking a development and commercialization partner for its drug candidates, ATI-501 (oral) and ATI-502 (topical), which are investigational Janus Kinase (JAK) 1/3 inhibitor compounds for the potential treatment of alopecia.

In addition, Aclaris plans to focus on its portfolio of novel kinase inhibitors and its proprietary kinase discovery platform. To that end, Aclaris will continue the development of its drug candidate, ATI-450, an internally developed, investigational oral MK2 inhibitor, which is currently in a Phase 1 clinical trial for development as a potential treatment for rheumatoid arthritis. Aclaris also plans further investment in its drug candidate, ATI-1777 and other preclinical drug candidates, utilizing its robust drug discovery technology and scientific expertise, to develop treatments that may benefit patients suffering from immuno-inflammatory diseases.

“We believe this change in strategy will benefit Aclaris in the near term by lowering expenses and eliminating the inherent risks and investment related to maintaining a commercial infrastructure. By actively seeking a commercialization partner for our commercial products business and refocusing our resources with a view to optimizing our immuno-inflammatory development portfolio, we believe we can significantly reduce our costs,

strengthen the organization, and extend our cash runway,” said Dr. Walker. “Our resources can now be dedicated to prudently advancing our pipeline of novel drug candidates for immuno-inflammatory diseases.”

“As part of our new business strategy, we have approved a plan to significantly reduce our workforce. We expect to complete this reduction over the course of the next six months. This decision was extremely difficult but necessary.

I would like to personally thank all of the affected employees for their contributions over the past years,” said Dr. Walker.

Aclaris’ restructuring plan includes the termination of 86 employees across the organization, actively seeking commercialization partners for its commercial products business, and the elimination of various development programs. During the time Aclaris is seeking a commercialization partner for RHOFADÉ, Aclaris will continue to incur certain expenses related to the sale and distribution of RHOFADÉ in the United States.

This restructuring plan is estimated to cost between \$3.0 million and \$3.5 million in total over the next 6 months, excluding non-cash charges, with the related cash payments to be substantially complete by March 31, 2020. Aclaris anticipates that its current cash and cash equivalents will be sufficient to fund its operations into the third quarter of 2021, without giving effect to any potential new business development transactions or financing activities. The estimates of costs that Aclaris expects to incur and the timing thereof are subject to a number of assumptions and actual results may differ.

Additional financial guidance will be provided when Aclaris announces its third quarter operating results.

Aclaris also announced today that it will host an R&D Investor Event focused on our pipeline of novel drug candidates for immuno-inflammatory diseases on September 27, 2019 in New York, New York.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory diseases who lack satisfactory treatment options. The company’s diverse portfolio includes one late-stage investigational medicine and a pipeline powered by a robust R&D engine exploring protein kinase regulation. Aclaris Therapeutics’ active development programs focus on areas where significant treatment gaps exist. 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", "may", "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include statements about changes in Aclaris' future corporate focus and strategy, development plans with respect to its preclinical and clinical drug candidates, anticipated cost savings as a result of the restructuring actions, the duration of time that Aclaris' cash and cash equivalents will be able to fund its operations and anticipated costs of the restructuring. 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 and in commercialization of products, Aclaris' reliance on third parties over which it may not always have full control, 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, 2018, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 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 Contact

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