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): November 7, 2019

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 November 7, 2019, Aclaris Therapeutics, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter and nine months ended September 30, 2019, as well as information regarding a conference call to discuss these financial results and business updates. 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 November 7, 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.

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

Date: November 7, 2019

Exhibit 99.1

Aclaris Therapeutics Reports Third Quarter 2019 Financial Results and Provides Business Highlights and an Update on R&D Programs

- ***Completed Strategic Review and Announced Refocusing of Resources on Immuno-inflammatory Development Pipeline***
- ***Divested RHOFADE® (oxymetazoline hydrochloride) cream, 1%***
- ***Repaid $30 Million Term Loan***
- ***Successful Pivotal Phase 3 Clinical Trials of A-101 45% Topical Solution as a Potential Treatment for Common Warts (THWART-1 and THWART-2)***
- ***Management to Host Conference Call at 5:00 PM ET today***

Wayne, PA – November 7, 2019 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, today announced its financial results for the third quarter of 2019 and provided business highlights and an update on its research and development programs.

Business Highlights:

- Announced the completion of the strategic review of its business in September 2019, as a result of which Aclaris is refocusing its resources on its immuno-inflammatory development programs and is actively seeking partners for its commercial products and certain clinical development assets.
  - Divested RHOFADE® (oxymetazoline hydrochloride) cream, 1% (RHOFADE) to EPI Health, LLC in October 2019 for up to $55.0 million, consisting of:
    - Upfront payment of $35.0 million; and
    - Potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the agreement; as well as
    - A high single-digit royalty on net sales, on a product-by-product and country-by-country basis; and
    - 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health from a licensee or sublicensee in any territory outside of the United States, subject to specified exceptions.

- Seeking partners to:
  - Commercialize A-101 45% Topical Solution, an investigational compound being developed as a potential treatment for common warts (verruca vulgaris);
  - Further develop and commercialize ATI-501 (oral) and ATI-502 (topical), which are investigational Janus Kinase (JAK) 1/3 inhibitor compounds, as potential treatments for alopecia; and
  - Commercialize ESKATA® (hydrogen peroxide) topical solution, 40% (w/w).

R&D Program Updates:

- Recently announced positive results from THWART-1 (WART-301) and THWART-2 (WART-302), Aclaris' two pivotal Phase 3 clinical trials of A-101 45% Topical Solution as a potential treatment for common warts.
- Announced in August that the first subject in its Phase 1 clinical trial of ATI-450, an investigational oral MK2 inhibitor compound, has been dosed. ATI-450 is Aclaris' first internally developed novel compound to enter the clinical phase of development.

"We are excited with the progress we have made toward executing on our new business strategy, with our first step being the divestiture of RHOFADE," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. "With the success of our two pivotal Phase 3 trials for A-101 45% Topical Solution, which has the potential to be the first FDA-approved prescription treatment for common warts, we believe this program will be of interest to potential commercial partners. In September, we presented our new focus on immuno-inflammatory diseases at our R&D day. We look forward to reporting the results of our Phase 1 trial for ATI-450 by the end of the first quarter of 2020 and providing further updates on the execution of our new strategy," said Dr. Walker.

Clinical Pipeline Update:

- **A-101 45% Topical Solution:**
  - A-101 45% Topical Solution met the primary and all secondary efficacy endpoints in both THWART-1 and THWART-2, Aclaris' pivotal Phase 3 clinical trials for the treatment of common warts.
  - The majority of adverse events (AEs) in THWART-1 and THWART-2 were application site reactions, which were predominantly mild or moderate. No treatment-related serious adverse

events were observed in the trials. Only one subject in the Phase 3 program had an AE that led to treatment discontinuation. The most common AEs occurring in more than 5% of subjects in the A-101 45% Topical Solution group were AEs at the application site such as pain, scabbing, erythema, pruritus, pallor and erosion.

- An open-label safety extension Phase 3 clinical trial (WART-303) evaluating the long-term safety of A-101 45% Topical Solution as a potential treatment for common warts, has completed enrollment of 425 patients. Aclaris expects WART-303 to be completed in the first half of 2020.

- **ATI-450:**
  - **ATI-450-PKPD-101** - This is an ongoing Single Ascending Dose / Multiple Ascending Dose (SAD/MAD) safety, pharmacokinetic and pharmacodynamic Phase 1 clinical trial of approximately 60-80 subjects. If successfully completed, Aclaris expects to initiate a Phase 2 clinical trial for ATI-450 in subjects with rheumatoid arthritis in the first half of 2020. Aclaris is also considering developing ATI-450 for an additional inflammatory indication.

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

Financial Highlights:

Liquidity and Capital Resources

As of September 30, 2019, Aclaris had aggregate cash, cash equivalents and marketable securities of $91.4 million compared to $168.0 million as of December 31, 2018. For the quarter and nine months ended September 30, 2019, net cash used in operating activities was $23.4 million and $76.1 million, respectively. As of September 30, 2019, Aclaris had approximately 41.4 million shares of common stock outstanding.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of September 30, 2019, after giving effect to both the upfront payment from the sale of RHOFADE and the full repayment of the loan facility with Oxford Finance LLC, 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.

Third Quarter 2019 and Year-to-Date Financial Results

- As described above, on September 5, 2019, Aclaris announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to actively seek partners for its commercial products. The accompanying condensed consolidated statements of operations and selected condensed 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.
- Contract research revenues decreased to $1.0 million and $3.1 million for the quarter and nine months ended September 30, 2019, compared to $1.1 million and $3.4 million for the quarter and nine months ended September 30, 2018. Cost of revenue was $0.8 million and $3.0 million for the quarter and nine months ended September 30, 2019, compared to $1.1 million and $3.1 million for the quarter and nine months ended September 30, 2018. These amounts included non-cash stock-based compensation, and amortization and depreciation expenses, of $0.2 million and $0.8 million for the quarter and nine months ended September 30, 2019, respectively, and $0.3 million and $0.8 million for the quarter and nine months ended September 30, 2018, respectively.
- Research and development expenses were $16.2 million and $53.3 million for the quarter and nine months ended September 30, 2019, respectively, compared to $15.2 million and $41.5 million for the quarter and nine months ended September 30, 2018, respectively. The increases were mainly the result of a $4.0 million milestone payment made by Aclaris to Rigel Pharmaceuticals, Inc. for the achievement of a specified development milestone, and activities associated with preclinical development and the recently initiated Phase 1 clinical trial for ATI-450. These increases were offset in part by decreases in expenses for several Phase 2 clinical trials of ATI-501 and ATI-502 and two Phase 3 clinical trials of A-101 45% Topical Solution, which reached or neared completion in the third quarter of 2019.
- General and administrative expenses were $6.7 million and $21.1 million for the quarter and nine months ended September 30, 2019, respectively, compared to $6.1 million and $20.5 million for the quarter and nine months ended September 30, 2018, respectively.

- Total costs and expenses from continuing operations for the third quarter of 2019 were $23.8 million, compared to $22.5 million for the third quarter of 2018. For the nine months ended September 30, 2019, total costs and expenses were $96.6 million, compared to $65.1 million for the same period in 2018. These amounts included non-cash stock-based compensation expenses of $4.0 million and $12.9 million for the quarter and nine months ended September 30, 2019, respectively, compared to $4.0 million and $12.4 million for the prior year periods, respectively. For the nine months ended September 30, 2019, there was also an $18.5 million non-cash charge for the impairment of goodwill. There was no such charge in the prior year.
- Loss from continuing operations was $23.1 million for the third quarter of 2019, compared to $20.6 million for the third quarter of 2018. Loss from continuing operations was $94.1 million for the nine months ended September 30, 2019, compared to $58.5 million for the nine months ended September 30, 2018.
- Loss from discontinued operations was $32.2 million for the third quarter of 2019, compared to $12.1 million for the third quarter of 2018, and was $48.7 million for the nine months ended September 30, 2019, compared to $35.6 million for the nine months ended September 30, 2018.
- Net loss, which combines loss from continuing and discontinued operations, was $55.3 million for the third quarter of 2019, compared to net loss of $32.7 million for the third quarter of 2018, and was $142.8 million for the nine months ended September 30, 2019, compared to $94.2 million for the nine months ended September 30, 2018.

2019 Financial Outlook and Cash Runway

- As a result of Aclaris' new strategic direction announced on September 5, 2019, which resulted in the reclassification of expenses related to its commercial products, Aclaris' prior full-year 2019 estimated operating expense guidance no longer represents an accurate estimate of its anticipated operating expenses, and Aclaris does not believe that updated full-year guidance for 2019 would be meaningful.
- Aclaris now anticipates that its cash, cash equivalents and marketable securities as of September 30, 2019, after giving effect to both the upfront payment from the sale of RHOFADE and the full repayment of the loan facility with Oxford Finance LLC, 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.

Company to Host Conference Call

Management will conduct a conference call **at 5:00 PM ET** today to discuss Aclaris' financial results and provide a general business update. The conference call will be webcast live over the Internet and can be accessed by logging on to the "Investors" page of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Aclaris Therapeutics website for 30 days following the call.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference conference ID 2698128 prior to the start of the call.

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's diverse and multi-stage portfolio includes one late-stage investigational drug candidate and a pipeline 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 seeking a third-party partner to commercialize A-101 45% Topical Solution, further develop and commercialize ATI-501 and ATI-502 and commercialize ESKATA, the clinical development of Aclaris' drug candidates, including the availability of data from its clinical trials, timing for initiation or completion of 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 into the third quarter of 2021. 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 the commercialization of products, 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 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, the Form

10-Q for the quarter ended September 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 Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ —	$ —	$ —	$ —
Contract research	983	1,118	3,132	3,379
Other revenue	—	—	—	1,000
Total revenues, net	983	1,118	3,132	4,379
Costs and expenses:				
Cost of revenue [1]	826	1,067	3,028	3,063
Research and development [1]	16,183	15,189	53,334	41,482
Sales and marketing [1]	112	63	629	89
General and administrative [1]	6,726	6,141	21,142	20,481
Goodwill impairment	—	—	18,504	—
Amortization of definite-lived intangible	—	—	—	—
Total costs and expenses	23,847	22,460	96,637	65,115
Loss from operations	(22,864)	(21,342)	(93,505)	(60,736)
Other (expense) income, net	(274)	710	(589)	2,189
Loss from continuing operations	(23,138)	(20,632)	(94,094)	(58,547)
Loss from discontinued operations [1]	(32,181)	(12,108)	(48,666)	(35,640)
Net loss	$ (55,319)	$ (32,740)	$ (142,760)	$ (94,187)
Net loss per share, basic and diluted	$ (1.34)	$ (1.06)	$ (3.46)	$ (3.04)
Weighted average common shares outstanding, basic and diluted	41,364,387	30,982,192	41,296,377	30,938,026

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

Cost of revenue	$ 25	$ 194	$ 454	$ 560
Research and development	1,418	1,433	4,733	4,916
Sales and marketing	—	—	—	—
General and administrative	2,581	2,320	7,707	6,936
Loss from discontinued operations	(704)	760	102	2,687
Total stock-based compensation expense	$ 3,320	$ 4,707	$ 12,996	$ 15,099

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 91,428	$ 167,972
Total assets	160,416	275,566
Total current liabilities	38,989	27,342
Total liabilities	75,141	60,442
Total stockholders' equity	85,275	215,124

Aclaris Contact
Michael Tung, M.D.
Corporate Strategy / Investor Relations
484-329-2140
mtung@aclaristx.com