
**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 6, 2018

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))

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 6, 2018, Aclaris Therapeutics, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 2018, 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

| <u>Exhibit Number</u> | <u>Exhibit Description</u> |
|---------------------------|---|
| 99.1 | Press Release, dated November 6, 2018 |

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: November 6, 2018

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

**Aclaris Therapeutics Reports Third Quarter 2018 Financial Results and Provides Update
on Clinical and Commercial Developments**

Management to Host Conference Call at 5:00 PM ET today

Wayne, PA – November 6, 2018 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology, today announced financial results for the third quarter of 2018 and provided an update on its clinical development and commercial programs.

- In October, Aclaris entered into a definitive asset purchase agreement with Allergan Sales, LLC to acquire worldwide rights to RHOFADÉ® (oxymetazoline hydrochloride) cream, 1% and additional intellectual property. The acquisition includes an exclusive license to certain intellectual property for RHOFADÉ, which is approved in the United States for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. Aclaris expects this acquisition to close in the fourth quarter of 2018.
- During the third quarter of 2018, total net revenue was \$1.6 million, which consisted of net sales of ESKATA® (hydrogen peroxide) Topical Solution, 40% (w/w) of \$0.5 million and contract research revenue of \$1.1 million.
- In September, Aclaris initiated the Phase 3 program for A-101 45% Topical Solution (A-101 45%) for the treatment of common warts (verruca vulgaris).
- Aclaris has completed enrollment in the ongoing AA-201 topical formulation trial of ATI-502 in patients with patchy alopecia areata (AA), a less severe phenotype of AA, data from which is expected in the first half of 2019.

“This is an exciting time for Aclaris. With the anticipated closing of the acquisition of RHOFADÉ in the fourth quarter, we will take another major step toward establishing ourselves as a fully integrated biopharmaceutical company with multiple commercial products, a robust clinical-stage pipeline and drug discovery engine,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Clinical Pipeline Update:

- **A-101 45% Topical Solution** –
 - Initiated Phase 3 program (THWART-1 and THWART-2) for the treatment of common warts in September 2018. Topline data are expected in the second half of 2019.
 - Plan to commence an open-label safety extension trial investigating A-101 45% for the treatment of common warts in 2019.
 - **JAK Inhibitor Trials:**
 - **AA-202 Topical** –
 - § An ongoing Phase 2 clinical trial of ATI-502, a topical JAK 1/3 inhibitor, for the treatment of AA.
 - § Data from the full cohort of patients expected before year end.
 - § After completing the 28-day portion of the trial, patients entered a 6-month open-label extension during which all continuing patients will receive drug. Treatment period extended in August 2018 for an additional 6 months to allow for full year of drug exposure.
 - § Evidence of hair regrowth in the open-label extension portion of this trial has been observed.
 - § Safety results - generally well-tolerated; no treatment related serious adverse events reported to date.

 - **AUATB-201 Topical** –
 - § An ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of AA in Australia.
 - § In this trial, Aclaris is evaluating the safety and efficacy of ATI-502 on the regrowth of eyebrows in patients with AA, including patients with alopecia totalis (AT) and alopecia universalis (AU). Interim update:
 - 12 patients have been enrolled; 5 continue in the trial. Patients will also enroll in a 12 month extension phase of the trial after completing 6 months.
 - Evidence of eyebrow hair regrowth has been observed in two patients.
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- § Safety results - generally well-tolerated; no treatment-related serious adverse events reported to date.
 - **AA-201 Topical** –
 - § Completed enrollment of this ongoing Phase 2 clinical trial of ATI-502 for the topical treatment of AA.
 - § This randomized, double-blinded, parallel-group, vehicle-controlled trial will evaluate the safety, efficacy and dose response of two concentrations of ATI-502 on the regrowth of hair in approximately 120 patients with AA. This trial is being conducted in the United States and data are expected in the first half of 2019.
 - **VITI-201 Topical** – Completed enrollment of this ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of vitiligo. This trial will evaluate the safety and efficacy of ATI-502 on the repigmentation of facial skin in 33 patients with vitiligo, and data are expected in 2019.
 - **AGA-201 Topical** – Completed enrollment of this ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of androgenetic alopecia (AGA), also known as male/female pattern hair loss. This trial will evaluate the safety and efficacy of ATI-502 on the regrowth of hair in 31 patients with AGA, and data are expected in the first half of 2019.
 - **AD-201 Topical** – an ongoing Phase 2 open-label clinical trial of ATI-502 in patients with atopic dermatitis (AD). This trial will evaluate the safety and efficacy of ATI-502 applied twice daily to affected skin for four weeks in approximately 30 adult patients with moderate-to-severe AD, and data are expected in mid-2019.
 - **AUAT-201 Oral** – an ongoing Phase 2 dose ranging trial of ATI-501, an oral JAK 1/3 inhibitor for the treatment of AA. This randomized, double-blinded, parallel-group, placebo-controlled trial will evaluate the safety, efficacy and dose response of three concentrations of ATI-501 on the regrowth of hair in approximately 80 patients with AA, and data are expected in the second half of 2019.
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- **ATI-450 (MK-2 Inhibitor)** – Investigational New Drug application on track for submission to the FDA in mid-2019.

Recent Corporate Highlights:

- In October, Aclaris entered into a Loan and Security Agreement with Oxford Finance LLC. The Loan Agreement provides for up to \$65 million in term loans. Of the \$65 million, Aclaris borrowed \$30 million on October 31, 2018. The remaining \$35 million will become available for draw beginning on the closing date of the RHOFADe acquisition and ending on the earlier of March 31, 2019 or an event of default.
- In October, Aclaris closed an underwritten public offering of 9,941,750 shares of Aclaris' common stock at a price to the public of \$10.75 per share, which includes the full exercise of the underwriters' option to purchase 1,296,750 additional shares, for total gross proceeds of \$106.9 million. Aclaris paid underwriting discounts and commissions of \$6.4 million. All of the common stock in the offering was sold by Aclaris.
- Issued US Patent # 10,098,910 - In October, Aclaris was issued a U.S. patent with 18 claims directed to an applicator containing a formulation of high concentration hydrogen peroxide and methods of using such an applicator to treat seborrheic keratosis (SK), warts and other indications, which is scheduled to expire in 2035. Orange Book listed.
- Co-authored an article titled: "Inhibition of the Stromal p38MAPK/MK2 Pathway Limits Breast Cancer Metastases and Chemotherapy-Induced Bone Loss" in the journal *Cancer Research*. ATI-450, an investigational drug, is a selective inhibitor of p38 mitogen-activated protein kinase-activated protein kinase 2 (p38MAPK/MK2) interface and an attractive candidate for stromal-targeted therapy.

Commercial Update:

- Over 1,050 ESKATA accounts opened to date.
- Sales force focused on driving clinical and business integration in existing ESKATA accounts in addition to expanding account base.
- National DTC campaign initiated on October 1.

Financial Highlights:

Third Quarter 2018 Financial Results

- For the quarter ended September 30, 2018, total net revenues were \$1.6 million, which consisted of net sales of ESKATA of \$0.5 million and contract research revenue of \$1.1 million, compared to \$0.7 million for the quarter ended September 30, 2017, all of which was contract research revenue. For the nine months ended September 30, 2018, total net revenues were \$6.4 million, which consisted of net sales of ESKATA of \$2.0 million, contract research revenue of \$3.4 million, and other revenue of \$1.0 million, compared to \$0.7 million for the nine months ended September 30, 2017, all of which was contract research revenue. Cost of revenues for the quarter and nine months ended September 30, 2018 were \$1.2 million and \$3.3 million, respectively, compared to \$0.5 million for both the quarter and nine months ended September 30, 2017.
 - For the quarter ended September 30, 2018, total operating expenses were \$33.9 million, compared to \$19.0 million for the third quarter of 2017. For the nine months ended September 30, 2018, total operating expenses were \$99.5 million, compared to \$47.2 million for the same period in 2017.
 - Research and development (R&D) expenses for the quarter and nine months ended September 30, 2018 were \$15.9 million and \$43.5 million, respectively, compared to \$10.9 million and \$26.6 million, for the same periods of 2017. The increases of \$5.0 million and \$16.9 million were mainly the result of the expansion of Aclaris' JAK inhibitor and common wart programs, as multiple Phase 2 trials of ATI-501 and ATI-502 and Phase 3 trials of A-101 45% are ongoing in 2018. There were also increases in medical affairs activities related to ESKATA and costs associated with drug discovery programs as a result of the acquisition of Confluence in August 2017. Personnel expenses, including stock-based compensation, increased due to increased headcount to support these programs and as a result of the acquisition of Confluence in August 2017. These increases were offset by a decrease in costs related to the development of ESKATA leading to Aclaris' NDA submission in February 2017 following the completion of the clinical trials.
 - Sales and marketing (S&M) expenses for the quarter and nine months ended September 30, 2018 were \$11.4 million and \$35.0 million, respectively, compared to \$3.6 million and \$7.2 million, for the same periods of 2017. The increases of \$7.8 million and \$27.8 million were mainly the result of increases in direct marketing and professional fees, as well as other commercial expenses incurred to support the launch of ESKATA in May 2018. Personnel
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expenses, including stock-based compensation, increased as Aclaris completed the hiring of its field sales force in the first quarter of 2018.

- o General and administrative (G&A) expenses for the quarter and nine months ended September 30, 2018 were \$6.6 million and \$21.0 million, respectively, compared to \$4.6 million and \$13.4 million, for the same periods of 2017. The increases of \$2.0 million and \$7.6 million were mainly the result of higher personnel expenses, including stock-based compensation, due to increased headcount to support the commercial launch of ESKATA, and as a result of the acquisition of Confluence in August 2017. G&A expenses for the nine months ended September 30, 2018 also included a \$1.5 million ESKATA-related milestone payment, whereas the nine months ended September 30, 2017 included a \$1.0 million ESKATA-related milestone payment.
- For the quarter ended September 30, 2018, net loss was \$32.7 million, or \$1.06 per basic and diluted share, as compared to \$18.2 million, or \$0.63 per basic and diluted share, for the third quarter of 2017. For the nine months ended September 30, 2018, net loss was \$94.2 million, or \$3.04 per basic and diluted share, as compared to \$45.6 million, or \$1.68 per basic and diluted share, for the same period of 2017.

Liquidity and Capital Resources

As of September 30, 2018, Aclaris had aggregate cash, cash equivalents and marketable securities of \$134.3 million compared to \$208.9 million as of December 31, 2017.

Aclaris anticipates that its cash, cash equivalents and marketable securities balances, including the proceeds from the public offering of common stock in October and the initial drawdown from the loan facility with Oxford, will be sufficient to fund its operations into the second half of 2020, without giving effect to any potential new business development transactions or financing activities.

2018 Financial Outlook

- Aclaris has updated its expected 2018 GAAP R&D expenses to be in the range of \$62 to \$64 million, including estimated stock-based compensation of \$7 million.
 - Aclaris updated its expected 2018 GAAP selling, general and administrative (SG&A) expenses, which combine its Sales and marketing and General and administrative line items, to be in the range of \$77 to \$79 million, including estimated stock-based compensation of \$14 million.
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Aclaris updated its full year 2018 financial guidance, as detailed below.

| | <u>Current</u> | <u>Previous</u> |
|------------------------------------|---------------------|---------------------|
| GAAP R&D Expense | \$62 – \$64 million | \$67 – \$75 million |
| GAAP R&D Stock-based Compensation | \$7 million | \$9 million |
| GAAP SG&A Expense | \$77 – \$79 million | \$80 – \$86 million |
| GAAP SG&A Stock-based Compensation | \$14 million | \$14 million |

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 7694929 prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised SKs and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

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 expectations regarding Aclaris' expectations with respect to the closing of the RHOFADÉ transaction, expectations regarding Aclaris' commercial launch of ESKATA, the clinical development of its drug candidates, including the availability of data from its ongoing and planned clinical trials, timing for initiation of planned clinical trials and timing for regulatory submissions, estimated research and development and selling, general and administrative expenses for 2018 and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the second half of 2020. 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, 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, 2017, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 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 | | Nine Months Ended | |
|---|--------------------|-------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| ESKATA product sales, net | \$ 510 | \$ - | \$ 2,043 | \$ - |
| Contract research | 1,118 | 684 | 3,379 | 684 |
| Other revenue | - | - | 1,000 | - |
| Total revenues, net | 1,628 | 684 | 6,422 | 684 |
| Cost of revenue ⁽¹⁾ | 1,193 | 453 | 3,341 | 453 |
| Gross profit | 435 | 231 | 3,081 | 231 |
| Operating expenses: | | | | |
| Research and development ⁽¹⁾ | 15,931 | 10,864 | 43,472 | 26,601 |
| Sales and marketing ⁽¹⁾ | 11,380 | 3,557 | 35,030 | 7,183 |
| General and administrative ⁽¹⁾ | 6,574 | 4,566 | 20,955 | 13,428 |
| Total operating expenses | 33,885 | 18,987 | 99,457 | 47,212 |
| Loss from operations | (33,450) | (18,756) | (96,376) | (46,981) |
| Other income, net | 710 | 564 | 2,189 | 1,392 |
| Net loss | \$ (32,740) | \$ (18,192) | \$ (94,187) | \$ (45,589) |
| Net loss per share, basic and diluted | \$ (1.06) | \$ (0.63) | \$ (3.04) | \$ (1.68) |
| Weighted average common shares outstanding, basic and diluted | 30,982,192 | 28,834,808 | 30,938,026 | 27,180,244 |

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

| | | | | | | | | |
|--|----|-------|----|-------|----|--------|----|--------|
| Cost of revenue | \$ | 194 | \$ | 130 | \$ | 560 | \$ | 130 |
| Research and development | | 1,433 | | 1,332 | | 4,916 | | 3,853 |
| Sales and marketing | | 760 | | 480 | | 2,687 | | 1,260 |
| General and administrative | | 2,320 | | 1,731 | | 6,936 | | 4,887 |
| Total stock-based compensation expense | \$ | 4,707 | \$ | 3,673 | \$ | 15,099 | \$ | 10,130 |

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

| | <u>September 30, 2018</u> | <u>December 31, 2017</u> |
|--|---------------------------|--------------------------|
| Cash, cash equivalents and marketable securities | \$ 134,271 | \$ 208,854 |
| Total assets | 176,176 | 243,509 |
| Total current liabilities | 22,280 | 12,762 |
| Total liabilities | 29,848 | 18,247 |
| Total stockholders' equity | 146,328 | 225,262 |

Aclaris Contact

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