# 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): December 15, 2017**

## 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.) |

**101 Lindenwood Drive, Suite 400**
**Malvern, PA 19355**
(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 8.01 Other Events.**

On December 15, 2017, Aclaris Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration has approved ESKATA™ (hydrogen peroxide) topical solution, 40% (w/w), for the treatment of raised seborrheic keratoses. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Exhibit Description |
|---|---|
| 99.1 | Press Release, dated December 15, 2017. |

**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: December 15, 2017

**Exhibit 99.1**

# Aclaris Therapeutics Receives FDA Approval for ESKATA™ (Hydrogen Peroxide) Topical Solution, 40% (w/w) for Treatment of Raised Seborrheic Keratoses (SKs)

***ESKATA™ is the First and Only FDA-Approved Topical, Non-invasive Treatment for Raised SKs***

***Management to Hold Conference Call at 8:00 AM ET today.***

MALVERN, Pa., Dec. 15, 2017 -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved ESKATA™ (hydrogen peroxide) topical solution, 40% (w/w) for the treatment of raised seborrheic keratoses, or SKs. SKs are non-cancerous skin growths that affect more than 83 million American adults and can be an aesthetic skin concern. SKs tend to increase in size and number with age. The condition is more prevalent than acne, psoriasis and rosacea combined.

“This achievement delivers on Aclaris’ commitment to bringing innovative therapies to market that address significant unmet needs in dermatology,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “For the first time, with the approval of ESKATA, patients will have access to an FDA-approved topical, non-invasive treatment for raised SKs.”

ESKATA is a proprietary, high-concentration hydrogen peroxide-based topical solution designed for in-office application by a healthcare provider. It is a targeted treatment applied directly to the raised SK using a pen-like applicator.

“We are proud to offer ESKATA to dermatologists and their patients as a treatment that can clear raised SKs without cutting, burning or freezing the skin. As a clinician, I saw first-hand that patients preferred non-invasive treatments,” said Stuart D. Shanler, M.D., Chief Scientific Officer of Aclaris. “We believe ESKATA may appeal to patients who are bothered by the appearance of their raised SKs — especially in highly visible areas such as the face and neck — and that patients are looking for a treatment that is safe and effective.”

“Many of my patients begin to notice SKs around age 40 and feel self-conscious about them,” said Anne M. Chapas, M.D., FAAD, Founder and Medical Director of Union Square Dermatology; Clinical Instructor of Dermatology, Mount Sinai Medical Center, New York; and a consultant for Aclaris. “With the approval of ESKATA, I am pleased to be able to offer my patients a topical treatment option that is well tolerated and can clear raised SKs with a low risk of scarring.”

The FDA approval of ESKATA is based on two pivotal Phase 3 trials that demonstrated the safety and efficacy of ESKATA for the treatment of raised SKs. In these trials, patients received up to two

treatments with ESKATA,  with one at treatment initiation and a second at week three. Patients treated with ESKATA were more likely to have all four treated SKs completely cleared after two treatments than patients who received placebo.  Treatment with ESKATA was generally well tolerated, with the most common side effects being itching, stinging, crusting, swelling, redness and scaling at the site of application.

It is important to see a healthcare provider with expertise in diagnosing skin conditions to confirm the diagnosis of SKs and determine whether ESKATA is an appropriate treatment.

“A recent consumer survey by the American Society for Dermatologic Surgery (ASDS) supports the need for an effective treatment of SKs,” said Lisa Donofrio, M.D., ASDS President. “ESKATA provides physicians with the first topical treatment option to satisfy this unmet patient need.”

ESKATA will be offered to patients as a self-pay aesthetic treatment and is expected to be commercially available in the spring of 2018. Visit www.ESKATA.com for more information and to view the full Prescribing Information. In addition, Aclaris has also submitted a Marketing Authorization Application (MAA) for ESKATA for the treatment of SKs in select countries in the European Union.

Management will conduct a conference call at 8:00 AM ET today to discuss the approval of ESKATA. A live webcast of the event can be accessed on the Events and Presentations page on the Investors section of the Aclaris website at www.aclaristx.com/events-and-webcasts.  A replay of the webcast will be archived on the Aclaris website following the event.

To participate on the live call, please dial 844-776-7782 (domestic) or 661-378-9535 (international), and reference conference ID 8793369 prior to the start of the call.

**Important Safety Information**
ESKATA™ (hydrogen peroxide) topical solution, 40% (w/w) is for use as an in-office treatment. ESKATA is applied by your healthcare provider and is not for use at home.

Serious eye problems can happen if ESKATA gets into your eyes. If ESKATA accidentally gets into your eyes, your healthcare provider will tell you to flush them well with water for 15 to 30 minutes. Your healthcare provider may send you to another healthcare provider if needed.

Skin reactions occurred in and around the treatment area after application of ESKATA. Some were severe, including breakdown of the outer layer of the skin (erosion), ulcers, blisters and scarring.

The most common side effects of ESKATA include itching, stinging, crusting, swelling, redness and scaling.

Tell your healthcare provider about any side effects that bother you or do not go away. Tell your healthcare provider right away if ESKATA gets into your eyes, mouth or nose during application.

**Approved Use for ESKATA**

ESKATA is a prescription medicine used to treat seborrheic keratoses that are raised.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Please see ESKATA Full Prescribing Information at www.ESKATA.com.

**About Seborrheic Keratoses**
Seborrheic keratoses (SKs) are non-cancerous skin growths that affect more than 83 million Americans and are most commonly seen in middle-aged and older adults. SKs vary in color from flesh-colored to pink, yellow, gray, tan, brown, or black; can range in size from a millimeter to a few centimeters wide; and typically have a slightly elevated, waxy or scaly appearance. The number and size of SKs tends to increase with advancing age. SKs frequently appear in highly visible locations, such as the face or neck, but can also appear anywhere on the body, except the palms, soles and mucous membranes.

**About Aclaris Therapeutics, Inc.**
Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunodermatology. The Company is focused on market segments with no FDA-approved medications or where treatment gaps exist. Aclaris is based in Malvern, Pennsylvania and more information can be found by visiting the Aclaris website at 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,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Aclaris’ current beliefs and expectations. These forward-looking statements include expectations regarding the commercial availability of ESKATA in the spring of 2018 and the expected market opportunity for ESKATA. 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 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, 2016, Aclaris’ Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the “Financial Information” 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.

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