

Edgar Filing: Aclaris Therapeutics, Inc. - Form 424B3

Aclaris Therapeutics, Inc.
Form 424B3
November 15, 2016

Prospectus Supplement No. 7

Filed Pursuant to 424(b)(3)

(to Prospectus dated June 28, 2016)

Registration No. 333-212095

1,081,082 Shares

Common Stock

This prospectus supplement updates and should be read in conjunction with the prospectus dated June 28, 2016 (the “Prospectus”) relating to the resale or other disposition, from time to time, by the selling stockholders identified in the Prospectus under the caption “Selling Stockholders,” of up to 1,081,082 shares of our common stock, par value \$0.00001 per share. We are not selling any shares of our common stock under the Prospectus and will not receive any proceeds from the sale or other disposition of shares by the selling stockholders. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or other disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. To the extent that there is any conflict between the information contained herein and the information contained in the Prospectus, the information contained herein supersedes and replaces such information.

Current Report

This prospectus supplement incorporates into our Prospectus the information contained in our attached current report on Form 8-K that we filed with the Securities and Exchange Commission on November 15, 2016 (the “Form 8-K”). The Form 8-K, as filed, is set forth below.

The information contained in this Prospectus Supplement No. 7 supplements and supersedes, in relevant part, the information contained in the Prospectus, as amended and supplemented to date. This Prospectus Supplement No. 7 is incorporated by reference into, and should be read in conjunction with, the Prospectus, as amended and supplemented to date, and is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, as amended and supplemented to date.

The Prospectus, together with Prospectus Supplement No. 1, Prospectus Supplement No. 2, Prospectus Supplement No. 3, Prospectus Supplement No. 4, Prospectus Supplement No. 5, Prospectus Supplement No. 6 and this Prospectus

Supplement No. 7 constitutes the prospectus required to be delivered by Section 5(b) of the Securities Act of 1933, as amended, with respect to offers and sales of the securities as set forth in the Prospectus, as amended and supplemented. All references in the Prospectus to “this prospectus” are amended to read “this prospectus (as supplemented and amended to date).”

Our common stock is traded on the NASDAQ Global Select Market under the symbol “ACRS.” The last reported sale price of our common stock on November 14, 2016 was \$22.52 per share. You are urged to obtain current market quotations for the common stock.

We are an “emerging growth company” as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. Please see “Prospectus Summary—Implications of Being an Emerging Growth Company.”

Investing in our common stock is highly speculative and involves a significant degree of risk. See “Risk Factors” beginning on page 5 of the Prospectus and the Risk Factors identified in our Annual Report for the year ended December 31, 2015 and in our Quarterly Report for the quarter ended September 30, 2016 for a discussion of information that should be considered before making a decision to purchase our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 15, 2016.

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 15, 2016

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.)

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))
-

Item 8.01 Other Events.

On November 15, 2016, Aclaris Therapeutics, Inc. (the “Company”) issued a press release announcing top-line results from its Phase 3 clinical trial of A-101 for the treatment of seborrheic keratosis, as well as information regarding a conference call to discuss these results. The full text of the Company’s press release is filed 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 November 15, 2016, titled “Aclaris Therapeutics Announces Positive Top-Line Phase 3 Results for A-101 In Treating Seborrheic Keratosis, a Common Undertreated Skin Condition”

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
Date: November 15, 2016 Frank Ruffo
Chief Financial
Officer

EXHIBIT INDEX

Exhibit

Number Exhibit Description

99.1 Press Release, dated November 15, 2016, titled "Aclaris Therapeutics Announces Positive Top-Line Phase 3 Results for A-101 In Treating Seborrheic Keratosis, a Common Undertreated Skin Condition"

Exhibit 99.1

Aclaris Therapeutics Announces Positive Top-Line Phase 3 Results for A-101

In Treating Seborrheic Keratosis, a Common Undertreated Skin Condition

Pivotal Data Show Topical Treatment Delivered Statistically Significant

Results, Meeting All Primary and Secondary Endpoints

Aclaris to Submit New Drug Application to FDA in 1Q17

Company to Host Conference Call Today at 5:00 PM ET

Malvern, Pa., Nov. 15, 2016 – Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led clinical-stage pharmaceutical company focused on defining new standards of care in medical and aesthetic dermatology, today announced that two pivotal Phase 3 trials of its lead product candidate A-101 40% Topical Solution (A-101), a novel treatment for seborrheic keratosis (SK) met all primary and secondary endpoints of each trial, achieving clinically and statistically significant clearance of SK lesions.

The two trials, SEBK-301 and SEBK-302, enrolled 937 patients in total and were conducted at 34 centers in the United States. The trials were identical in design and evaluated the safety and efficacy of A-101 compared to vehicle (placebo) in patients with four target SK lesions on the face, trunk and extremities. Of the 937 patients enrolled, 467 patients received A-101 and 470 patients were administered placebo. Investigators assessed the clearance of SK lesions using the validated four-point Physician Lesion Assessment (PLA) rating scale, which characterizes lesions as either clear (PLA=0), near clear (PLA=1), thin (PLA=2), or thick (PLA=3). Patients in each trial had four target SK lesions, including at least one on the face and at least one on the trunk or extremities. Each lesion received up to two treatments three weeks apart.

Efficacy Results

Overall, results from the combined trials showed 51.3% of lesions treated with A-101 were assessed as clear or near clear (PLA<1) at trial completion versus 7.3% of

lesions in the placebo group. Notably, 65.3% of lesions on the face treated with A-101 were assessed as clear or near clear at trial completion versus 10.5% of lesions in the placebo group.

The primary endpoint of both trials was the percentage of patients treated with A-101 who achieved clearance (PLA=0) of all four target SK lesions. In the SEBK-301 trial, 4.0% of patients treated with A-101 achieved clearance of all four target SK lesions ($p<0.002$); in the SEBK-302 trial, 7.8% of treated patients achieved clearance of all four target SK lesions ($p<0.0001$). None of the patients administered placebo achieved clearance of all four target SK lesions in either trial.

The secondary endpoint of both trials was the percentage of patients treated with A-101 who achieved clearance (PLA=0) of at least three of the four target SK lesions. In the SEBK-301 trial, 13.5% of patients treated with A-101 achieved clearance of at least three of the four target SK lesions ($p<0.0001$); in the SEBK-302 trial, 23.0% of treated patients achieved clearance of at least three of the four target SK lesions ($p<0.0001$). None of the patients treated with placebo achieved this endpoint. Clearance of three out of four target lesions is the primary endpoint that Aclaris has agreed upon with European Union (EU) regulators as a basis for approval. Based on these results, Aclaris plans to submit a Marketing Authorization Application in the EU in mid-2017.

An ancillary endpoint was the mean per-patient percentage of target lesions treated with A-101 who achieved clear or near-clear of all target SK lesions (PLA<1). In SEBK-301, 47.5% of patients treated with A-101 achieved clear or near clear versus placebo which was 10.2% ($p<0.0001$). In SEBK-302, 54.3% of patients treated with A-101 achieved clear or near clear versus placebo which was 4.7% ($p<0.0001$).

“I see many SK patients who lack confidence in their appearance, especially those who have lesions in visible areas such as the face and neck,” said trial investigator Zoe Draelos, M.D., board-certified dermatologist, fellow of the American Academy of Dermatology. “For patients who seek to improve their appearance, a treatment that can achieve clearance or near clearance of lesions while delivering a favorable aesthetic result would represent a significant advance in the standard of SK treatment.”

SK lesions are common, non-cancerous skin lesions that impact more than 83 million Americans and frequently appear in highly visible locations such as the face or neck.

The lesions are typically characterized by a waxy, scaly, elevated appearance and can vary in color from light tan to dark brown or black. SK lesions can have an adverse physical and emotional impact on patients. Existing treatments are invasive, often painful, or have undesirable outcomes like scarring or dyspigmentation.

“We are extremely pleased by these top-line results,” said Aclaris President and Chief Executive Officer Dr. Neal Walker. “We had a productive pre-NDA meeting with the U.S. Food and Drug Administration earlier this year and look forward to submitting a New Drug Application to the FDA in the first quarter of 2017. We are committed to bringing this important new treatment to patients and their physicians.” If approved, A-101 would be the first FDA-approved topical treatment for SK.

Safety Results

There were no treatment-related serious adverse events among patients treated with A-101. The most common adverse events were nasopharyngitis and sinusitis which were determined to be unrelated to A-101.

Local skin reactions, if present, were predominantly classified as mild. The rates of hypopigmentation, hyperpigmentation, and scarring classified as greater than mild were less than one percent in all groups in both trials.

Additionally, Aclaris announced that initial safety results from an open-label safety trial of A-101 (SEBK-303) were consistent with the SEBK-301 and SEBK-302 trials. The SEBK-303 trial enrolled 147 patients at 10 sites across the United States.

“This safety profile in these trials is compelling since there has been a significant need for an effective, non-invasive SK treatment without long-term pigmentary changes,” said Dr. Walker.

Aclaris plans to present this data at a future medical meeting and also for consideration for publication in a peer-reviewed journal.

Management will conduct a conference call at 5:00 PM ET on November 15, 2016 to discuss these results. The conference will be webcast live over the Internet and can be accessed by logging on to the “Investors” section of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Company’s 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 21069052 prior to the start of the call.

About A-101

A-101 (40% topical solution) is a proprietary, high-concentration hydrogen peroxide formulation in late-stage development for the treatment of seborrheic keratosis (SK). It is being developed as a non-invasive, in-office therapy, able to be administered by physicians or non-physician health care providers. In clinical trials, A-101 showed statistically and clinically significant results in clearing SK lesions with an adverse event profile similar to placebo. A-101 is designed to work by penetrating into the SK lesion and causing oxidative damage, which can ultimately result in the sloughing of the SK cells. A-101 has been the focus of a robust clinical development program in which over 700 patients have been treated with A-101. Aclaris plans to submit a New Drug Application (NDA) for A-101 in the first quarter of 2017. If approved, A-101 would be the first FDA-approved topical treatment for SK. A higher concentration of A-101 is also in clinical development for the treatment of common warts (*verruca vulgaris*).

About Seborrheic Keratosis

Seborrheic keratosis (SK) is a skin condition that affects more than 83 million Americans and is characterized by non-cancerous lesions with a waxy, scaly, slightly elevated appearance that can vary in color from light tan to dark brown or black. SK lesions frequently appear in highly visible locations, such as the face or neck, and can have an adverse physical and emotional impact on people who have them. SK sufferers may be affected with just one lesion or dozens and often have a family history of SK. Prevalence of SK increases with advancing age and over three-quarters of patients seeking treatment from dermatologists are aged 40 to 69. SK is one of the most frequent diagnoses made by dermatologists, yet it remains undertreated. There are currently no FDA-approved medications for SK, and existing treatment procedures are often painful, invasive and can have undesirable outcomes like scarring or dyspigmentation.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage dermatologist-led pharmaceutical company focused on identifying, developing and commercializing innovative and

differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Aclaris is based in Malvern, Pennsylvania.

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' clinical development and potential commercialization of A-101 for the treatment of SK and common warts. 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, 2015, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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.

Contact:

Aclaris Contact

Michael Tung, M.D.

Investor Relations

484-329-2140

mtung@aclaristx.com

Media Contact

Mariann Caprino

TogoRun

917-242-1087

M.Caprino@togorun.com
