

Aclaris Therapeutics Reports First Quarter 2017 Financial Results

May 9, 2017 4:03 PM ET

Management to Host Conference Call at 4:30 PM ET today

MALVERN, Pa., May 09, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biotechnology company, today announced financial results for the first quarter of 2017 and provided an update on its clinical development programs.

“The start of 2017 has been a busy one for Aclaris and we are pleased the momentum from last year has continued into the first quarter of this year,” commented Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “Our New Drug Application (NDA) for A-101 40% Topical Solution (A-101 40%) for the treatment of seborrheic keratosis (SK) was accepted for review by the U.S. Food and Drug Administration (FDA). We continue to advance our pipeline and broaden our intellectual property estate as we focus our efforts on developing innovative treatments for patients.”

Clinical Pipeline Update

• A-101 40% Topical Solution

- The NDA for A-101 40% for the topical treatment of SK has been accepted by the FDA for review.
- The NDA contains data from three Phase 3 trials that included more than 1,000 patients.
- Plan to submit a marketing authorization application (MAA) for A-101 40% for the treatment of SK in the European Union in the second half of 2017.

• A-101 45% Topical Solution

- Plan to initiate two Phase 2 clinical trials of A-101 45% Topical Solution (A-101 45%) for the treatment of common warts in mid-2017.

• JAK Inhibitor

- Recently completed a Phase 1 clinical trial of ATI-50001, an investigational oral Janus Kinase (JAK) 1/3 inhibitor. This Phase 1 cross-over trial was conducted in 12 healthy volunteers at one investigational center in the United States to assess safety, bioavailability, and pharmacodynamics.
- In the Phase 1 trial, treatment with ATI-50001 capsules was well tolerated. No clinically significant laboratory abnormalities were observed. These data are consistent with results from an earlier Phase 1 clinical trial in 44 healthy volunteers conducted by Rigel Pharmaceuticals in which the study drug was well tolerated at all doses.
 - Plan to initiate a Phase 2 dose ranging trial with ATI-50001 for the oral treatment of alopecia totalis and alopecia universalis in the second half of 2017.
- In addition, Aclaris also plans to develop an investigational topical JAK 1/3 inhibitor, known as ATI-50002, for the treatment of AA and vitiligo.
 - Plan to submit an Investigational New Drug application (IND) for ATI-50002 for the topical treatment of patchy AA in mid-2017.
 - Plan to initiate a Phase 2 dose ranging trial of ATI-50002 for the topical treatment of patchy AA in the second half of 2017.
 - Plan to initiate a Phase 2 trial of ATI-50002 for the topical treatment of vitiligo in the second half of 2017.
- Finally, Aclaris is developing another series of topical JAK inhibitors for the treatment of androgenetic alopecia (AGA).

Business Highlights and Recent Developments

- In April, Aclaris received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent application covering the formulation and methods of use of A-101 40% and A-101 45%. This newly allowed patent application contains 70 allowed claims and expires in 2035.
- In April, Columbia University received a Notice of Allowance from the USPTO for two patent applications covering methods related to the use and administration of baricitinib (LY3009104) and decernotinib (VX-509), respectively, for the treatment of hair loss disorders and for inducing hair growth. These newly allowed patent applications are owned by Columbia University and exclusively licensed to Aclaris. These patent applications are the latest U.S. applications to be allowed in connection with Aclaris' JAK drug development program for hair loss disorders.
- In April, Aclaris raised an additional \$19.4 million in net proceeds from sales of its common stock under its at-the-market sales agreement with Cowen. With these additional funds, Aclaris estimates that its cash, cash equivalents and marketable securities will fund its current operations through the first quarter of 2019.
- In April, Aclaris hosted a symposium on JAK Inhibitors at the 76th Annual Society for Investigative Dermatology Meeting titled “You Don’t Know JAK,” with over 700 attendees.

Financial Highlights

Liquidity and Capital Resources

- As of March 31, 2017, Aclaris had aggregate cash, cash equivalents and marketable securities of \$161.4 million, compared to \$174.1 million as of December 31, 2016. The \$12.7 million decrease during the three months ended March 31, 2017 included a net loss of \$12.6 million, less \$3.2 million in non-cash stock-based compensation expense, plus \$3.3 million of net cash used in working capital.
- In April, Aclaris raised an additional \$19.4 million in net proceeds from sales of our stock. As a result of this latest financing, Aclaris estimates that its cash, cash equivalents and marketable securities will fund its current operations through the first quarter of 2019.

First Quarter 2017 Financial Results

- Net loss was \$12.6 million for the first quarter of 2017, compared to \$13.0 million for the first quarter of 2016.
- Total operating expenses for the first quarter of 2017 were \$12.9 million, compared to \$13.1 million for the first quarter of 2016.
 - Research and development expenses decreased \$1.8 million to \$7.8 million for the first quarter of 2017, compared to \$9.5 million for the first quarter of 2016. The decrease was primarily due to a \$3.4 million expense incurred related to the Vixen acquisition and a \$1.8 million decrease in spending for the A-101 development program during the first quarter of 2016 offset by increased expenditures in the first quarter of 2017 of:
 - \$1.1 million for pre-clinical development expenses related to the JAK inhibitor program;
 - \$1.3 million for personnel-related expenses, including stock-based compensation, due to increased headcount; and
 - \$1.0 million for medical affairs activities.
 - General and administrative expenses increased \$1.6 million to \$5.2 million during the first quarter of 2017, compared to \$3.6 million for the first quarter of 2016. The increase was primarily attributable to increases of \$1.5 million in personnel-related expenses, including stock-based compensation, due to increased headcount, \$0.4 million in market research costs related to pre-commercial activities for A-101 40%, partially offset by a \$0.3 million milestone payment related to A-101 40% which was incurred in the first quarter of 2016.

2017 Financial Outlook

Aclaris reiterates the following financial guidance:

- Net cash burn for 2017 estimated to be in the range of \$65 million to \$70 million not including financing activities and potential acquisitions of complementary businesses or technologies.
- Total operating expenses for 2017 estimated to be in the range of \$84 million to \$92 million, or \$70 million to \$75 million when excluding estimated stock-based compensation expense of \$14 million to \$17 million.
- Research and development expenses for 2017 estimated to be in the range of \$51 million to \$58 million, or \$46 million to \$52 million when excluding estimated stock-based compensation expense of \$5 million to \$6 million.

Company to Host Conference Call

Management will conduct a conference call at 4:30 PM ET today to discuss Aclaris' financial results and provide a general business update. The conference 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 5101760 prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biotechnology 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 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 Aclaris' use of cash and research and development and total operating expenses during 2017, development programs in skin and hair conditions, the clinical development of JAK inhibitors and the broadening of Aclaris' intellectual property estate. 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, 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.

Aclaris Therapeutics, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2017	2016
Revenue	\$ -	\$ -
Operating expenses:		

Research and development ⁽¹⁾	7,772	9,535
General and administrative ⁽¹⁾	5,158	3,604
Total operating expenses	12,930	13,139
Loss from operations	(12,930)	(13,139)
Other income, net	371	100
Net loss	\$ (12,559)	\$ (13,039)
Net loss per share, basic and diluted	\$ (0.48)	\$ (0.65)
Weighted average common shares outstanding, basic and diluted	26,080,806	20,171,518

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

Research and development	\$ 1,217	\$ 421
General and administrative	1,936	801
Total stock-based compensation expense	\$ 3,153	\$ 1,222

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data
(in thousands)

March 31, 2017 December 31, 2016

Cash, cash equivalents and investments	\$ 161,437	\$ 174,134
Total assets	166,210	176,085
Total current liabilities	5,637	6,223
Total liabilities	5,921	6,595
Total stockholders' equity	160,289	169,490

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