

## Aclaris Therapeutics Reports Third Quarter 2016 Financial Results

November 3, 2016 7:01 AM ET

### Management to Host Conference Call at 8:30 a.m. ET today

MALVERN, Pa., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced financial results for the third quarter and nine months ended September 30, 2016 and provided an update on its clinical development programs.

“During the third quarter we continued to advance our pipeline programs across a broad range of dermatological diseases. We reported positive results from the Wart-201 Phase 2 study and are planning the next clinical development steps. The company recently submitted an investigational new drug application (IND) for our drug candidate ATI-50001 for the oral treatment of alopecia totalis and alopecia universalis. We also look forward to reporting the results from our Phase 3 clinical trials for our lead drug candidate A-101 Topical Solution (A-101) for the treatment of seborrheic keratosis (SK) in the coming weeks,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

WART-201 was a randomized, double-blind, vehicle-controlled clinical trial designed to evaluate the safety and dose-response of 40% and 45% concentrations of A-101, compared with placebo (vehicle) in patients with common warts. Ninety-eight patients were enrolled in the study at six investigational centers within the United States. The primary endpoint of the trial was the mean change from baseline in the Physician’s Wart Assessment (PWA) score one week after the last of eight weekly treatments. Secondary endpoints included the proportion of patients whose target wart was judged to be clear on the PWA scale and the proportion of patients whose target wart was judged to be either clear or barely evident on the PWA scale. Of the 98 patients enrolled, 90 completed the 8-week treatment period.

- WART-201 Efficacy Results:
  - Patients treated with the 45% concentration of A-101 achieved a statistically significant improvement in PWA score as compared to patients receiving placebo (p=0.01).
  - The proportion of patients treated with the 45% concentration of A-101 who achieved complete clearance of the target wart one week after the last treatment was also statistically significant as compared to the placebo group (p=0.02).
  - The proportion of patients treated with the 45% concentration of A-101 who achieved a PWA score of clear or barely evident one week after the last treatment was also statistically significant as compared to the placebo group (p=0.02).
- WART-201 Safety Results: Both concentrations of A-101 were well-tolerated, and local skin reactions were primarily mild in severity and similar to those observed in patients receiving placebo. The most frequently reported side effect across the two treatment groups was mild erythema.

### Business Highlights and Recent Developments

- Submitted an IND for ATI-50001 for the oral treatment of alopecia totalis and alopecia universalis.
- Presented results from a prospective observational SK study at the annual Fall Clinical Dermatology Conference. This was the first study to evaluate the burden on patients with asymptomatic SK lesions and included 406 patients. The study found patients with asymptomatic SKs are bothered by their highly visible skin lesions and very interested in treatment options to improve their appearance, even if a cost were associated with treatment. In addition, SK lesions were found to frequently appear in highly visible locations, with the majority of SK patients having lesions on the face or neck. The study was conducted in dermatology practices by Burke, Inc. on behalf of Aclaris.

## Financial Highlights

### *Liquidity and Capital Resources*

- As of September 30, 2016, Aclaris had aggregate cash, cash equivalents and marketable securities of \$84.0 million, compared to \$92.0 million as of December 31, 2015. The \$8.0 million decrease during the nine months ended September 30, 2016 included:
  - Net cash used in operations of \$26.5 million during the nine months ended September 30, 2016. This amount was composed of a net loss of \$36.6 million, less non-cash operating expenses of \$2.8 million for the acquisition of Vixen Pharmaceuticals, Inc., \$4.2 million in stock-based compensation expense and \$3.0 million in net cash from changes in working capital.
  - The above amounts were offset by \$18.5 million of net proceeds received from a private placement financing completed in June 2016.
- Aclaris presently anticipates that its cash, cash equivalents and marketable securities as of September 30, 2016 will be sufficient to fund its operations through at least the fourth quarter of 2017, without giving effect to potential new business development transactions or financing activities.

### *Third Quarter 2016 Financial Results*

- Net loss attributable to common stockholders was \$10.7 million for the third quarter of 2016, compared to \$11.7 million for the third quarter of 2015.
- Total operating expenses for the third quarter of 2016 were \$10.8 million, compared to \$10.6 million for the third quarter of 2015.
  - Research and development expenses were \$7.2 million for the third quarter of 2016, compared to \$9.4 million for the third quarter of 2015. The decrease of \$2.2 million was primarily attributable to an \$8.0 million upfront payment to Rigel in 2015 for ATI-50001 and ATI-50002 JAK inhibitor drugs. This was partially offset by a \$2.4 million increase in direct costs associated with the clinical development of A-101, a \$1.9 million increase in preclinical development expenses related to the JAK inhibitor technology, and a \$1.2 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount.
  - General and administrative expenses were \$3.7 million for the third quarter of 2016, compared to \$1.2 million for the third quarter of 2015. The increase of \$2.4 million was primarily attributable to increases of \$1.5 million in personnel-related expenses, including stock-based compensation, due to increased headcount, \$0.3 million in professional fees associated with being a public company, and \$0.3 million in market research costs related to the A-101 program.

## Upcoming Milestones

- Aclaris expects to report Phase 3 results for A-101 for the treatment of SK in the fourth quarter of this year. If the data are positive, Aclaris plans to submit a new drug application to the FDA in the first quarter of 2017 and a marketing authorization application to the European Medicines Agency in mid-2017.
- Aclaris plans to commence clinical trials for ATI-50001 in the first half of 2017 for the oral treatment of alopecia totalis and alopecia universalis.

- Aclaris plans to submit an IND and commence clinical trials for ATI-50002 in the first half of 2017 for the topical treatment of patchy alopecia areata.

### Company to Host Conference Call

Management will conduct a conference call at 8:30 a.m. 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](http://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 97609147 prior to the start of the call.

### About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage specialty pharmaceutical company focused on identifying, developing, and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Aclaris Therapeutics, Inc. is based in Malvern, Pennsylvania and more information can be found by visiting the company's website at [www.aclaristx.com](http://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 clinical development of A-101 for the treatment of SK and for common warts and the development of ATI-50001, ATI-50002, and other JAK inhibitor compounds for other dermatological conditions. 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 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 June 30, 2016, and other filings Aclaris makes with the SEC 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		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	7,162	9,407	26,533	12,937

General and administrative	3,650	1,233	10,407	2,928
Total operating expenses	10,812	10,640	36,940	15,865
Loss from operations	(10,812 )	(10,640 )	(36,940 )	(15,865 )
Other income, net	118	8	336	16
Net loss	(10,694 )	(10,632 )	(36,604 )	(15,849 )
Accretion of convertible preferred stock	-	(1,020 )	-	(2,353 )
Net loss attributable to common stockholders	\$ (10,694 )	\$ (11,652 )	\$ (36,604 )	\$ (18,202 )
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.50 )	\$ (5.12 )	\$ (1.76 )	\$ (8.44 )
Weighted average common shares outstanding, basic and diluted	21,415,871	2,274,617	20,752,590	2,155,685

### **Aclaris Therapeutics, Inc.**

#### Selected Consolidated Balance Sheet Data

(in thousands)

#### **September 30, 2016    December 31, 2015**

Cash, cash equivalents and marketable securities	\$ 84,042	\$ 92,038
Total assets	86,071	94,076
Total current liabilities	4,591	1,555
Total liabilities	4,949	1,555
Total stockholders' equity	81,122	92,521

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