

## Aclaris Therapeutics Reports First Quarter 2016 Financial Results

May 11, 2016 7:00 AM ET

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

MALVERN, Pa., May 11, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced financial results for the first quarter ended March 31, 2016 and provided an update on its clinical development programs.

“The start of 2016 has been a busy one for Aclaris and we are pleased that 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. “In late March, we announced an agreement to acquire all of the stock of Vixen Pharmaceuticals, Inc. This transaction expands our focus in hair loss to include androgenetic alopecia (commonly referred to as female or male pattern baldness), which is consistent with our goal of developing and commercializing self-pay aesthetic and medical dermatology products that represent whitespace opportunities and provide patients and physicians with effective solutions. We view the relationship between JAK inhibition and hair loss as an exciting opportunity,” added Dr. Walker.

### Business Highlights and Recent Developments

- **Acquired Worldwide Rights to Compounds and Key Intellectual Property for Potential Treatment for Hair Loss.** In March, Aclaris entered into an agreement with the stockholders of Vixen Pharmaceuticals, Inc. (Vixen) to acquire all of the stock of Vixen. As a result of this transaction, Aclaris acquired worldwide rights to intellectual property licensed to Vixen by Columbia University covering the use of certain Janus Kinase (JAK) inhibitor compounds for the treatment of alopecia areata, androgenetic alopecia and other dermatological conditions. Aclaris made an upfront payment and has agreed to make various development and commercial milestone payments, as well as additional payments on potential sales of products using the acquired intellectual property rights.
- **Initiated Phase 3 Clinical Trials of A-101 for the Treatment of Seborrheic Keratosis.** Earlier this year, Aclaris initiated two Phase 3 clinical trials to evaluate A-101 Topical Solution for the treatment of seborrheic keratosis (SK). The two Phase 3 clinical trials will evaluate the safety and efficacy of A-101 Topical Solution compared with a vehicle solution (placebo). Approximately 800 subjects will be randomized in these multi-center, double-blinded, vehicle-controlled clinical trials, which are being conducted at 34 investigational centers within the United States.

### Financial Highlights

#### *Liquidity and Capital Resources*

- As of March 31, 2016, Aclaris had aggregate cash, cash equivalents and marketable securities of \$85.2 million, compared to \$92.0 million as of December 31, 2015. The decrease was mainly a result of a net loss of \$13.0 million for the quarter less non-cash operating expenses of \$2.8 million for the acquisition of Vixen, \$1.2 million in stock-based compensation expense and \$2.1 million in changes in working capital. Based on its current cash position and operating plan, Aclaris expects that it has sufficient cash to fund operations through at least the third quarter of 2017, without giving effect to any potential business development transactions or additional financing events.

#### *First Quarter 2016 Financial Results*

- Net loss attributable to common stockholders was \$13.0 million for the first quarter of 2016, compared to \$3.3 million for the first quarter of 2015.

- Total operating expenses for the first quarter of 2016 were \$13.1 million, compared with \$2.6 million for the first quarter of 2015.
  - Research and development expenses were \$9.5 million for the first quarter of 2016, compared with \$1.7 million for the first quarter of 2015. The increase of \$7.8 million was primarily attributable to \$3.4 million in expenses associated with the Vixen acquisition, an increase of \$1.4 million in pre-clinical development expenses related to the JAK inhibitor technology, a \$1.9 million increase in direct costs associated with the A-101 clinical trials, a \$0.8 million increase in stock-based compensation and personnel-related expenses due to increased headcount and a \$0.2 million increase in medical affairs activities.
  - General and administrative expenses were \$3.6 million for the first quarter of 2016, compared with \$0.9 million for the same period in 2015. The increase of \$2.7 million was primarily attributable to increases of \$1.2 million in stock-based compensation expense and personnel-related expenses due to increased headcount, \$0.4 million in patent filing and prosecution costs associated with the JAK inhibitor technology in the Vixen transaction, \$0.4 million in professional fees associated with being a public company, and a \$0.3 million milestone payment in the first quarter of 2016 related to the clinical development of A-101.

### **Upcoming Milestones**

- Aclaris anticipates Phase 3 results for A-101 Topical Solution for the treatment of SK in the third quarter of this year and, if the data is positive, Aclaris plans to submit an NDA to the FDA in the fourth quarter of this year.
- Aclaris anticipates Phase 2 results for A-101 Topical Solution for the treatment of common warts in the third quarter of this year.
- Aclaris plans to submit an IND in the second half of this year for ATI-50001, formerly A-201, and commence clinical trials in the first half of 2017 for the treatment of alopecia areata. For ATI-50002, formerly A-301, Aclaris anticipates submitting an IND and commencing clinical trials in the first half of 2017 for the 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 (877) 481-7177 (domestic) or (262) 558-6167 (international), and reference conference ID 86658591 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 Aclaris' A-101 drug candidate for the treatment of SK and for common warts and its JAK inhibitor drug candidates for the treatment of alopecia areata and other dermatological conditions, and Aclaris' beliefs that its capital resources will be sufficient to meet its anticipated cash requirements through at least the third quarter of 2017. 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, filed with the Securities and Exchange Commission (SEC) on March 23, 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)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	2016	2015
Revenue	\$ -	\$ -
Operating expenses:		
Research and development	9,535	1,737
General and administrative	3,604	892
Total operating expenses	13,139	2,629
Loss from operations	(13,139 )	(2,629 )
Other income, net	100	6
Net loss	(13,039 )	(2,623 )
Accretion of convertible preferred stock	-	(657 )
Net loss attributable to common stockholders	\$ (13,039 )	\$ (3,280 )
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.65 )	\$ (1.61 )
Weighted average common shares outstanding, basic and diluted	20,171,518	2,034,850

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

#### Selected Consolidated Balance Sheet Data

(in thousands)

#### **March 31, 2016    December 31, 2015**

Cash, cash equivalents and investments \$ 85,246                      \$ 92,038

Total assets	87,270	94,076
Total current liabilities	3,729	1,555
Total liabilities	4,059	1,555
Total stockholders' equity	83,211	92,521

Contact:

Aclaris Contact

Frank Ruffo

Chief Financial Officer

484-324-7933

[investors@aclaristx.com](mailto:investors@aclaristx.com)

Investor Contact

Patricia L. Bank

Westwicke Partners

Managing Director

415-513-1284

[patti.bank@westwicke.com](mailto:patti.bank@westwicke.com)

Media Contact

Mike Beyer

Sam Brown, Inc.

312-961-2502

[mikebeyer@sambrown.com](mailto:mikebeyer@sambrown.com)



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