

Aclaris Therapeutics Reports Second Quarter 2017 Financial Results

August 8, 2017 7:02 AM ET

Management to Host Conference Call at 8:30 AM ET today

MALVERN, Pa., Aug. 08, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company, today announced financial results for the second quarter of 2017 and provided an update on its clinical development programs.

“The second quarter of 2017 has been a busy one for Aclaris and today we are pleased to announce we have acquired Confluence Life Sciences,” commented Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “This acquisition is an important step in Aclaris becoming a fully integrated biopharmaceutical company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology.”

Clinical Pipeline Update

- **A-101 40% Topical Solution**

-- Earlier this month, submitted a Marketing Authorization Application (MAA) for A-101 40% Topical Solution (A-101 40%) for the treatment of seborrheic keratosis (SK) with the Medicines Product Agency (MPA) in Sweden. The MPA will act as the reference member state in this decentralized procedure for review of the MAA for potential marketing approval throughout Europe. If approved, A-101 40% would be available to be commercialized in 16 countries in the European Union.

- **A-101 45% Topical Solution**

-- In June, initiated two Phase 2 clinical trials of A-101 45% Topical Solution (A-101 45%) for the treatment of common warts. The Phase 2b clinical trials are designed to evaluate the safety, tolerability and dose frequency of A-101 45% compared with its vehicle (placebo). Approximately 240 patients are expected to be randomized in the two double-blinded trials, which are being conducted at 30 investigational centers within the United States.

- **JAK Inhibitors**

-- Continue plans to initiate a Phase 2 dose ranging trial of ATI-50001, an oral Janus kinase (JAK) inhibitor, for the treatment of alopecia totalis and alopecia universalis in the second half of 2017.

-- Earlier this month, submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration for another JAK inhibitor, ATI-50002, for the treatment of patchy alopecia areata (AA). Following FDA clearance of the IND, Aclaris expects to initiate two Phase 2 clinical trials of ATI-50002, a topical Janus Kinase (JAK) 1/3 inhibitor in the second half of 2017. These trials will be conducted at multiple investigational centers across the United States.

-- Continue plans to initiate a Phase 2 trial of ATI-50002 for the topical treatment of vitiligo in the second half of 2017.

-- Continue to develop another series of topical JAK inhibitors for the treatment of androgenetic alopecia (AGA).

Business Highlights and Recent Developments

- In June, the United States Patent and Trademark Office has issued U.S. Patent 9,675,639 covering the formulation and methods of use of A-101 40%, an investigational drug being developed for the treatment of seborrheic keratosis

(SK) and A-101 45%, an investigational drug being developed for the treatment of common warts. This patent contains 70 claims and expires in July 2035.

- Recently acquired Confluence Life Sciences.

Financial Highlights

Liquidity and Capital Resources

- As of June 30, 2017, Aclaris had aggregate cash, cash equivalents and marketable securities of \$170.5 million compared to \$174.1 million as of December 31, 2016. The \$3.6 million decrease during the six months ended June 30, 2017 included a net loss of \$27.4 million and \$2.0 million of net cash used in working capital, partially offset by \$19.3 million in net proceeds from sales of Aclaris' common stock under an at-the-market equity facility and \$6.5 million of non-cash stock-based compensation expense.
- Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 2017, after deducting the upfront cash payment of \$10.0 million in connection with the Confluence acquisition in August 2017, will be sufficient to fund its operations through at least the end of 2018, without giving effect to any potential milestone payments payable under the Confluence agreement or any potential new business development transactions or financing activities.

Second Quarter 2017 Financial Results

- Total operating expenses for the second quarter of 2017 were \$15.3 million, compared to \$13.0 million for the second quarter of 2016.
 - Research and development expenses were \$8.0 million for the second quarter of 2017, compared to \$9.8 million for the second quarter of 2016. The decrease of \$1.8 million was primarily attributable to a \$4.6 million decrease in costs associated with the development of A-101, \$1.4 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount, and a \$0.8 million increase in preclinical development expenses related to the JAK inhibitor technology.
 - General and administrative expenses were \$7.3 million for the second quarter of 2017, compared to \$3.2 million for the second quarter of 2016. The increase of \$4.1 million was primarily attributable to \$1.6 million in higher personnel-related expenses, including stock-based compensation, due to increased headcount, a \$1.0 million milestone payment pursuant to the finder's services agreement for A-101, a \$0.8 million increase in market research expenses related to pre-commercial activities for the A-101 program, and \$0.5 million in higher legal fees.
- Net loss was \$14.8 million for the second quarter of 2017, compared to \$12.9 million for the second quarter of 2016.
- As of June 30, 2017, Aclaris had approximately 26.7 million shares of common stock outstanding.

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 excluding \$10 million used for Confluence acquisition as well as potential financing activities and other 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 (without giving effect to additional stock-based compensation expense for employees who joined Aclaris as part of the Confluence acquisition).

- 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 (without giving effect to anticipated expenses associated with the integration of Confluence's business).

Company to Host Conference Call

Management will conduct a conference call at 8:30 AM 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 **54200846** prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Aclaris is focused on large, underserved 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 Aclaris' use of cash and research and development and total operating expenses during 2017, development programs in skin and hair conditions, and the clinical development of JAK inhibitors, including the initiation of planned clinical trials. 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, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 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.

Aclaris Therapeutics, Inc.

Consolidated Statements of Operations(in thousands, except share and per share data)

**Three Months Ended
June 30,**

**Six Months Ended
June 30,**

	2017	2016	2017	2016
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development ⁽¹⁾	7,965	9,836	15,737	19,371
General and administrative ⁽¹⁾	7,330	3,153	12,488	6,757
Total operating expenses	15,295	12,989	28,225	26,128
Loss from operations	(15,295)	(12,989)	(28,225)	(26,128)
Other income, net	457	118	828	218
Net loss	\$ (14,838)	\$ (12,871)	\$ (27,397)	\$ (25,910)
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.62)	\$ (1.04)	\$ (1.27)
Weighted average common shares outstanding, basic and diluted	26,594,854	20,663,088	26,339,250	20,417,301

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

Research and development	\$ 1,304	\$ 533	\$ 2,521	\$ 954
General and administrative	2,000	821	3,936	1,622
Total stock-based compensation expense	\$ 3,304	\$ 1,354	\$ 6,457	\$ 2,576

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data
(in thousands)

June 30, 2017 December 31, 2016

Cash, cash equivalents and marketable securities	\$ 170,497	\$ 174,134
Total assets	176,808	176,085
Total current liabilities	8,369	6,223
Total liabilities	8,664	6,595
Total stockholders' equity	168,144	169,490

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