

Aclaris Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

March 15, 2017 7:00 AM ET

- Provides Update on Clinical and Other Developments*
- Initiates Financial Guidance for Full Year 2017*
- Management to Host Conference Call at 8:00 a.m. ET today*

MALVERN, Pa., March 15, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage biotechnology company, today announced financial results for the fourth quarter and year ended December 31, 2016 and provided an update on its clinical development programs.

“The year was a transformational year as we continued to make progress toward our goal of becoming a fully integrated biotechnology company. In November 2016, we reported that two pivotal Phase 3 trials of our lead product candidate A-101 40% Topical Solution met all primary and secondary endpoints of each trial, achieving clinically and statistically significant clearance of seborrheic keratosis (SK) lesions. In February 2017, we submitted a New Drug Application (NDA) for A-101 40% Topical Solution for the treatment of SK to the U.S. Food and Drug Administration (FDA),” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “During 2016 we also reported positive data from a Phase 2 trial of A-101 45% Topical Solution for the treatment of common warts. Finally, we recently completed a Phase 1 clinical trial of ATI-50001, our investigational Janus Kinase (JAK) inhibitor, for the treatment of alopecia totalis and alopecia universalis.”

Clinical Pipeline Update

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

- In November 2016, reported positive data from two pivotal Phase 3 trials, SEBK-301 and SEBK-302, in which A-101 40% Topical Solution achieved statistically significant and clinically meaningful results on all primary and secondary endpoints. SEBK-301 and SEBK-302 enrolled 937 patients in total and were conducted at 34 investigational centers in the United States.
- There were no treatment-related serious adverse events among patients treated with A-101 40% Topical Solution, and local skin reactions (LSR), 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
- In February 2017, submitted an NDA to the FDA for A-101 40% Topical Solution as a treatment for SK.
- Plan to submit a marketing authorization application (MAA) for A-101 40% Topical Solution in the European Union in the second half of 2017.

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

- In August 2016, reported positive data from a Phase 2 trial, WART-201, in which A-101 45% Topical Solution achieved statistically significant and clinically meaningful results on all primary and secondary endpoints. WART-201 enrolled 98 patients in total and was conducted at six investigational centers in the United States.
- A-101 45% Topical Solution was well-tolerated and LSRs were primarily mild in severity and similar to placebo. The most frequently reported LSR across treatment groups was mild erythema.
- Completed an FDA teleconference and plan to initiate two Phase 2 clinical trials of A-101 45% Topical Solution for the treatment of warts in mid-2017.

- **JAK Inhibitor**

- In October 2016, we submitted an Investigational New Drug Application (IND) to the FDA for ATI-50001 for the treatment of alopecia totalis and alopecia universalis and recently completed a Phase 1 clinical trial.

- 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.
- Plan to submit IND for ATI-50002 for the topical treatment of patchy alopecia areata mid-2017.
- Plan to initiate a Phase 2 dose ranging trial with ATI-50002 for the topical treatment of patchy alopecia areata in the second half of 2017.
- Aclaris has exclusively licensed several patents and patent applications involving novel selective JAK 1/3 inhibitors, including a patent portfolio from Rigel Pharmaceuticals, Inc. that covers ATI-50001 as well as ATI-50002, a topical formulation also being developed as a potential treatment for alopecia areata. In addition, Aclaris has exclusively licensed a patent portfolio from JAKPharm and Key Organics directed to novel covalently binding, highly selective JAK 3 inhibitors. Finally, Aclaris has exclusively licensed a patent portfolio from Columbia University directed to methods of using JAK inhibitors for the treatment of alopecia areata, androgenetic alopecia, and other dermatological conditions. This portfolio includes a recently issued U.S. patent directed to methods of treating alopecia areata, androgenetic alopecia and other hair loss disorders by administering ruxolitinib, and a recently issued patent in Japan directed to pharmaceutical compositions comprising ruxolitinib, baricitinib or other JAK inhibitors for use in treating alopecia areata, androgenetic alopecia and other hair loss disorders.

Business Highlights and Recent Developments

- During 2016, raised approximately \$117 million in net proceeds from the sale of our common stock.
- Continued to build out research and development and commercial infrastructure.
- Appointed Andrew Powell to the Board of Directors – Andrew has more than 27 of experience years in the biotechnology and pharmaceutical industry. He most recently served as Senior Vice President, General Counsel and Corporate Secretary of Medivation, Inc. from May 2015 until its acquisition by Pfizer, Inc. in November 2016. Prior to Medivation, Mr. Powell served in executive leadership roles at InterMune, Inc., where he played a leadership role in InterMune’s acquisition by Roche Holdings AG, ImClone Systems, Inc., where he helped the company grow before playing a key role in its sale to Eli Lilly, Collagenex Pharmaceuticals, Inc., where he was part of a senior team that repositioned the company as a leader in dermatology before its acquisition by Galderma Pharma S.A., and Baxter International, Inc., where he was instrumental in a series of transactions that established Baxter throughout Asia.
- Appointed Bill Humphries to the Board of Directors – Bill is the Executive Vice President, Group Chairman Dermatology of Valeant Pharmaceuticals. Previously, Bill was President and Chief Executive Officer of Merz, Inc. (affiliate of Merz Pharma Group), North American business and was a member of the Merz Pharma Board and the Chairman of the Merz, Inc. Board of Directors. At Merz, Inc., Bill was responsible for the continued and accelerated growth of the Aesthetics, Dermatology, OTC/OTX and Neuroscience businesses within North America. Bill has more than 29 years of experience in the specialty pharmaceutical industry, with more than 26 of those years focused on the commercialization of products in medical dermatology and aesthetics.

2017 Financial Outlook

- Aclaris estimates net cash burn for 2017 to be in the range of \$65 million to \$70 million not including financing activities and potential acquisitions of complementary businesses or technologies.
- Aclaris estimates 2017 total operating expenses 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.
- Aclaris anticipates 2017 research and development expenses 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.

Financial Highlights

Liquidity and Capital Resources

- As of December 31, 2016, Aclaris had aggregate cash, cash equivalents and marketable securities of \$174.1 million, compared to \$92.0 million as of December 31, 2015. The \$82.1 million increase during the year ended December 31, 2016 included:
 - Net cash from financing activities of \$18.5 million in net proceeds received from a private placement financing completed in June 2016 and \$98.2 million in net proceeds received from a follow-on offering completed in November 2016.
 - Net cash used in operations of \$34.6 million during the year ended December 31, 2016. This amount was composed of a net loss of \$48.1 million, less non-cash operating expenses of \$2.8 million for the acquisition of Vixen Pharmaceuticals, Inc., and \$6.1 million in stock-based compensation expense, as well as \$4.5 million in net cash increases in working capital.
- Aclaris presently anticipates that its cash, cash equivalents and marketable securities as of December 31, 2016 will be sufficient to fund its operations through at least the end of 2018, without giving effect to potential new business development transactions or financing activities.

Fourth Quarter 2016 Financial Results

- Net loss attributable to common stockholders was \$11.5 million for the fourth quarter of 2016, compared to \$4.9 million for the fourth quarter of 2015.
- Total operating expenses for the fourth quarter of 2016 were \$11.6 million, compared to \$4.8 million for the fourth quarter of 2015.
 - Research and development expenses were \$6.9 million for the fourth quarter of 2016, compared to \$2.4 million for the fourth quarter of 2015. The increase of \$4.5 million was primarily due to a \$2.2 million increase in direct costs associated with the preclinical development expenses related to the JAK inhibitor technology, a \$1.4 million increase in the clinical development of A-101, and a \$1.1 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount.
 - General and administrative expenses were \$4.7 million for the fourth quarter of 2016, compared to \$2.4 million for the fourth quarter of 2015. The increase of \$2.3 million was primarily attributable to increases of \$1.4 million in personnel-related expenses, including stock-based compensation, due to increased headcount, and \$0.8 million in market research costs related to pre-commercial activities for A-101 40% Topical Solution.

Full Year 2016 Financial Results

- Net loss attributable to common stockholders was \$48.1 million for the year ended December 31, 2016, compared to \$23.1 million for the year ended December 31, 2015.
- Total operating expenses were \$48.6 million for the year ended December 31, 2016, compared to \$20.7 million for the year ended December 31, 2015.
 - Research and development expenses were \$33.5 million for the year ended December 31, 2016, compared to \$15.3 million for the prior year. The increase of \$18.2 million was primarily due to a \$7.3 million increase in direct costs associated with the preclinical development expenses related to the JAK inhibitor technology, a \$10.8 million increase in the clinical development of A-101, and a \$4.2 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount. The increases noted above were

partially offset by a decrease of \$4.6 million in licensing expenses as Aclaris incurred \$3.4 million of expenses associated with the Vixen acquisition in the year ended December 31, 2016, compared to \$8.0 million of expenses for the upfront payment made to a third party during the year ended December 31, 2015.

- General and administrative expenses were \$15.1 million for the year ended December 31, 2016, compared to \$5.3 million for the prior year. The increase of \$9.8 million was primarily attributable to increases of \$5.4 million in personnel-related expenses, including stock-based compensation, due to increased headcount, \$1.5 million in professional fees associated with being a public company, and \$1.5 million in market research costs related to pre-commercial activities for A-101 40% Topical Solution.

Company to Host Conference Call

Management will conduct a conference call at 8:00 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, 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 62366728 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.

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. 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		Year Ended	
December 31,		December 31,	
2016	2015	2016	2015

Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development ⁽¹⁾	6,943	2,402	33,476	15,339
General and administrative ⁽¹⁾	4,684	2,400	15,091	5,328
Total operating expenses	11,627	4,802	48,567	20,667
Loss from operations	(11,627)	(4,802)	(48,567)	(20,667)
Other income, net	152	88	488	104
Net loss	(11,475)	(4,714)	(48,079)	(20,563)
Accretion of convertible preferred stock	-	(213)	-	(2,566)
Net loss attributable to common stockholders	\$ (11,475)	\$ (4,927)	\$ (48,079)	\$ (23,129)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.49)	\$ (0.28)	\$ (2.25)	\$ (3.79)
Weighted average common shares outstanding, basic and diluted	23,390,746	17,832,264	21,415,733	6,107,042

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

Research and development	\$ 714	\$ 183	\$ 2,291	\$ 257
General and administrative	1,196	464	3,813	634
Total stock-based compensation expense	\$ 1,910	\$ 647	\$ 6,104	\$ 891

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(in thousands)

December 31, 2016 December 31, 2015

Cash, cash equivalents and investments	\$ 174,134	\$ 92,038
Total assets	176,085	94,076
Total current liabilities	6,223	1,555
Total liabilities	6,595	1,555
Total stockholders' equity	169,490	92,521

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