

Aclaris Therapeutics Reports Fourth Quarter and Full Year 2015 Operating and Financial Results

March 23, 2016 4:01 PM ET

Management to Host Conference Call at 4:30 p.m. ET today

MALVERN, Pa., March 23, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced financial results for the fourth quarter and year ended December 31, 2015 and provided an update on its clinical development programs.

“It has been an exciting time for Aclaris since our IPO in October of last year as we have made significant progress with the advancement of our development pipeline. With our lead drug candidate, A-101, in the clinic for two indications (seborrheic keratosis and common warts), we look forward to seeing the results which we anticipate later this year. We also continue to expand our pipeline by adding novel compounds to our clinical program such as our JAK (Janus Kinase) inhibitor compounds for the treatment of alopecia areata and other dermatological conditions. We continue to build a commercial infrastructure and have now assembled a senior management team with over 120 combined years of directly relevant experience in dermatology,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Business Highlights and Recent Developments

- **Initiated Phase 3 Clinical Trials of A-101 for the Treatment of Seborrheic Keratosis.** Earlier this year, the company 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.
- **Added to the Russell 2000® and Russell 3000® Indexes as part of Russell Investments' annual reconstitution effective as of December 21, 2015.**
- **Appointed Brett Fair as Senior Vice President of Commercial Operations.** In December 2015, Mr. Fair joined Aclaris, bringing more than 18 years of pharmaceutical commercialization and business development experience.
- **Initiated Phase 2 Clinical Trial of A-101 for Treatment of Common Warts.** In December 2015, the company initiated a Phase 2 clinical trial to evaluate A-101 Topical Solution for the treatment of common warts (verruca vulgaris). This double-blinded, randomized Phase 2 trial, to be conducted at six sites in the United States, will evaluate the safety, tolerability and dose-response of two concentrations of A-101 compared with a vehicle control. Aclaris intends to enroll approximately 108 subjects in this clinical trial.

Financial Highlights

Liquidity and Capital Resources

- As of December 31, 2015, Aclaris had aggregate cash, cash equivalents and marketable securities of \$92.0 million, compared to \$16.6 million as of December 31, 2014. The increase was a result of the completion of the Company's Series C preferred stock financing in the third quarter of 2015 and the completion of the Company's IPO in the fourth quarter of 2015, which yielded net proceeds of \$39.9 million and \$56.6 million, respectively. Based on our current cash position and operating plan, the Company 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.

Fourth Quarter 2015 Financial Results

- Net loss attributable to common stockholders was \$4.9 million for the fourth quarter of 2015, compared to \$3.3 million for the fourth quarter of 2014, and includes the accretion of convertible preferred stock to redemption value, as well as cumulative dividends on convertible preferred stock. Upon the closing of the IPO, all outstanding shares of convertible preferred stock were converted to common stock.
- Total operating expenses for the fourth quarter of 2015 were \$4.8 million, compared with \$2.6 million for the fourth quarter of 2014.
 - Research and development expenses were \$2.4 million for the fourth quarter of 2015, compared with \$2.1 million for the fourth quarter of 2014. The increase was largely attributable to increased headcount, stock-based compensation expense, licensing fees and higher depreciation expense resulting from an equipment impairment charge, partially offset by a decrease in costs associated with ongoing clinical trials for A-101.
 - General and administrative expenses were \$2.4 million for the fourth quarter of 2015, compared with \$0.5 million for the same period in 2014. The increase was primarily due to higher patent filing and prosecution costs associated with the JAK inhibitor technology, and increases in market research expenses, headcount, stock-based compensation expense, and the costs associated with being a public company.

Full Year 2015 Financial Results

- Net loss attributable to common stockholders was \$23.1 million for the year ended December 31, 2015, compared to \$10.6 million for the same period in 2014 and includes the accretion of convertible preferred stock to redemption value, as well as cumulative dividends on convertible preferred stock. Upon the closing of the IPO all outstanding shares of convertible preferred stock were converted to common stock.
- Total operating expenses for the year ended December 31, 2015 were \$20.7 million, compared with \$8.5 million for the year ended December 31, 2014.
 - Research and development expenses were \$15.3 million for the year ended December 31, 2015, compared with \$6.5 million for the same period in 2014. The increase was driven by an \$8.0 million upfront payment we made to Rigel Pharmaceuticals, Inc. in connection with licensing the JAK inhibitor technology, increased headcount and stock-based compensation expense, partially offset by a decrease in costs associated with ongoing clinical trials for A-101.
 - General and administrative expenses were \$5.3 million for the year ended December 31, 2015, compared with \$2.0 million for the same period in 2014. The increase was primarily due to higher patent filing and prosecution costs associated with the JAK inhibitor technology, and increases in market research expenses, headcount, stock-based compensation expense and the costs associated with being a public company.

Upcoming Milestones

- We anticipate Phase 3 results for A-101 Topical Solution for the treatment of seborrheic keratosis in the third quarter of this year and, if the data is positive, our plan is to submit an NDA to the FDA in the fourth quarter of this year.
- We anticipate Phase 2 results for A-101 Topical Solution for the treatment of common warts in the third quarter of this year.
- For our JAK inhibitor program for the treatment of alopecia areata, our plan is to submit an IND in the second half of this year for A-201 and commence a proof-of-concept trial in the first half of 2017. For A-301, we are targeting the submission of an IND and commencement of clinical trials in the first half of 2017.

Company to Host Conference Call

Management will conduct a conference call at 4:30 p.m. ET today to discuss the Company's 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 Company's 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 50890341 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.

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 seborrheic keratosis and for common warts and its JAK inhibitor drug candidates for the treatment of alopecia areata and other dermatological conditions, and our beliefs that our capital resources will be sufficient to meet our 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Securities and Exchange Commission (SEC) on November 18, 2015, 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		Year Ended	
	December 31,		December 31,	
	2015	2014	2015	2014
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	2,402	2,054	15,339	6,507
General and administrative	2,400	548	5,328	2,026
Total operating expenses	4,802	2,602	20,667	8,533
Loss from operations	(4,802)	(2,602)	(20,667)	(8,533)
Interest income	88	5	104	16
Net loss	(4,714)	(2,597)	(20,563)	(8,517)
Accretion of convertible preferred stock	(213)	(660)	(2,566)	(2,054)
Net loss attributable to common stockholders	\$ (4,927)	\$ (3,257)	\$ (23,129)	\$ (10,571)

Net loss per share attributable to common stockholders, basic and diluted	\$ (0.28)	\$ (1.76)	\$ (3.79)	\$ (6.15)
Weighted average common shares outstanding, basic and diluted	17,832,264	1,850,961	6,107,042	1,720,082

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(in thousands)

December 31, 2015 December 31, 2014

Cash, cash equivalents and investments \$	92,038	\$ 16,648
Total assets	94,076	17,377
Total current liabilities	1,555	1,451
Total liabilities	1,555	1,455
Total stockholders' equity (deficit)	92,521	(20,755)

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