

Aclaris Therapeutics Reports Second Quarter 2016 Financial Results

August 11, 2016 7:01 AM ET

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

MALVERN, Pa., Aug. 11, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced financial results for the second quarter and six months ended June 30, 2016 and provided an update on its clinical development programs.

“We are pleased with our progress on several fronts as we continue along the path of becoming a fully integrated dermatology company. We recently completed the enrollment of multiple trials for our lead drug candidate A-101 Topical Solution (A-101) and, in addition, we completed a private placement equity financing, from which we raised net proceeds of \$18.5 million,” commented Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “With our initiation of preclinical development in vitiligo and androgenetic alopecia (AGA), commonly referred to as female or male pattern baldness, we now have a diverse pipeline targeting multiple dermatological conditions. We look forward to the second half of 2016, during which we expect to report results from multiple clinical trials,” added Dr. Walker.

Business Highlights and Recent Developments

- Completed patient enrollment in two Phase 3 pivotal clinical trials and a Phase 3 open-label safety trial of A-101 for the treatment of seborrheic keratosis (SK). Also completed the enrollment of a Phase 2 clinical trial of two concentrations of A-101 (40% and 45%) for the treatment of common warts (verruca vulgaris).
- Closed a private placement of 1,081,082 shares of common stock at a purchase price of \$18.50 per share, yielding net proceeds of \$18.5 million. The private placement was led by Aisling Capital with participation by additional new and existing investors.
- Commenced preclinical development of Aclaris’ Janus Kinase (JAK) inhibitor compounds for vitiligo and AGA.
- Engaged TogoRun, a global health and wellness strategic communications firm, to support corporate branding, SK awareness initiatives and drug development milestone announcements. TogoRun team members have an impressive track record of building successful aesthetic brands and driving the rapid growth of the medical aesthetics field.
- Continued to expand management team with the hiring of Kimberley Forbes-McKean, Ph.D as Senior Vice President of Drug Development and Michael Tung, M.D. as Vice President of Investor Relations.

Financial Highlights

Liquidity and Capital Resources

- As of June 30, 2016, Aclaris had aggregate cash, cash equivalents and marketable securities of \$94.0 million, compared to \$92.0 million as of December 31, 2015. The \$2.0 million increase during the six months ended June 30, 2016 included:
 - \$18.5 million of net proceeds received from a private placement financing completed in June 2016.
 - Net cash used in operations of \$16.6 million during the six months ended June 30, 2016. This amount was composed of a net loss of \$25.9 million, less non-cash operating expenses of \$2.8 million for the acquisition of Vixen Pharmaceuticals, Inc. (Vixen), \$2.6 million in stock-based compensation expense and \$3.9 million in net cash from changes in working capital.

- Aclaris presently anticipates that its cash, cash equivalents and marketable securities balances as of June 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.

Second Quarter 2016 Financial Results

- Net loss attributable to common stockholders was \$12.9 million for the second quarter of 2016, compared to \$3.3 million for the second quarter of 2015.
- Total operating expenses for the second quarter of 2016 were \$13.0 million, compared to \$2.6 million for the second quarter of 2015.
 - Research and development expenses were \$9.8 million for the second quarter of 2016, compared to \$1.8 million for the second quarter of 2015. The increase of \$8.0 million was primarily attributable to a \$5.1 million increase in direct costs associated with the clinical development of A-101, a \$1.6 million increase in preclinical development expenses related to the JAK inhibitor technology, and a \$1.1 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount.
 - General and administrative expenses were \$3.2 million for the second quarter of 2016, compared to \$0.8 million for the second quarter of 2015. The increase of \$2.4 million was primarily attributable to increases of \$1.3 million in personnel-related expenses, including stock-based compensation, due to increased headcount, \$0.6 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 2 initial results for A-101 for the treatment of common warts in the third quarter of this year.
- Aclaris expects to report Phase 3 initial results for A-101 for the treatment of SK in the fourth quarter of this year. If the data is positive, Aclaris plans to submit a new drug application (NDA) to the FDA in the first quarter of 2017 and a marketing authorization application (MAA) to the EMA in mid-2017.
- Aclaris plans to submit an IND in the second half of this year for ATI-50001, and commence clinical trials 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, 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 47292324 prior to the start of the call.

Recent Hires

Kimberley Forbes-McKean, Ph.D has over 25 years of experience in drug and device development with 20 of those years in dermatological product development. Kim has worked in the pharmaceutical industry in large companies, including Merck, Baxter Healthcare and almost 15 years at Sanofi-Aventis/Dermik Laboratories where she was responsible for the

team that developed and gained approval for a number of successful dermatology products. She also has experience as a member of executive leadership teams at smaller dermatology companies, including Isolagen and Cutanea Life Sciences. Most recently, Kim was a part of the leadership team that expanded Aqua Pharmaceuticals from a sales and marketing organization into a full product development and sales and marketing company, which was acquired by Almirall. Kim has a B.S. in Chemistry from Union College in Schenectady, NY, and a Ph.D. in Analytical Chemistry from the University of Massachusetts at Amherst.

Michael Tung, M.D. has joined Aclaris as Vice President, Investor Relations. Michael will focus on oversight and management of the Company's relationship with the investment community and corporate communications. He has 13 years of healthcare buy-side experience and was most recently a Senior Portfolio Manager at Turner Investments, where he conducted fundamental analysis of healthcare companies in all capitalization ranges to generate investment ideas for the firm's growth, global/international, and long/short separately managed accounts and mutual funds. Prior to this, Dr. Tung served as a Senior Analyst at Expo Capital Management, and served as a Vice President and Portfolio Manager at Delaware Investments. He began his professional career in the medical field first as a Physician at the Lemuel Shattuck Hospital of the Tufts University School of Medicine, and then as an Anesthesiologist at Beth Israel Deaconess Medical Center at the Harvard Medical School. Dr. Tung is a licensed Physician in Massachusetts and New York. He earned a dual Medical Doctorate and Master's in Business Administration from Tufts University School of Medicine in 2001 and a Bachelor of Science degree in Biology and a Bachelor of Arts degree in Economics from George Washington University in 1997.

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 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		Six Months Ended	
	June 30		June 30	
	2016	2015	2016	2015
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	9,836	1,793	19,371	3,530
General and administrative	3,153	803	6,757	1,695
Total operating expenses	12,989	2,596	26,128	5,225
Loss from operations	(12,989)	(2,596)	(26,128)	(5,225)
Other income, net	118	2	218	8
Net loss	(12,871)	(2,594)	(25,910)	(5,217)
Accretion of convertible preferred stock	-	(676)	-	(1,333)
Net loss attributable to common stockholders	\$ (12,871)	\$ (3,270)	\$ (25,910)	\$ (6,550)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.62)	\$ (1.52)	\$ (1.27)	\$ (3.04)
Weighted average common shares outstanding, basic and diluted	20,663,088	2,154,953	20,417,301	2,154,953

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(in thousands)

June 30, 2016 December 31, 2015

Cash, cash equivalents and marketable securities	\$ 94,010	\$ 92,038
Total assets	96,092	94,076
Total current liabilities	5,507	1,555
Total liabilities	5,852	1,555
Total stockholders' equity	90,240	92,521

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