Aclaris Therapeutics Reports Third Quarter 2017 Financial Results

November 7, 2017

Management to Host Conference Call at 8:00 AM ET today

MALVERN, Pa., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), 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, today announced financial results for the third quarter of 2017 and provided an update on its clinical development programs.

“The third quarter of 2017 has been a productive one for Aclaris. In August, we closed the acquisition of Confluence Life Sciences, Inc. (“Confluence”), and we continue to prepare for our December 24th PDUFA date for A-101 40% Topical Solution for the treatment of seborrheic keratosis,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Clinical Pipeline Update

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

  • In September, published results from a Phase 2 clinical trial evaluating two concentrations (40% and 32.5%) of its drug candidate A-101 for the treatment of facial seborrheic keratosis (SK) lesions in the journal Dermatologic Surgery. In the trial, A-101 achieved statistically significant improvement in clearing SK lesions on the face in a dose-related fashion. A-101 was well tolerated at both concentrations studied.

  • The FDA’s Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) is December 24, 2017. If approved, A-101 40% Topical Solution would be the first FDA-approved medication for SK.

- **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 2 clinical trials are designed to evaluate the safety, tolerability and dose frequency of A-101 45% compared with placebo in adult and pediatric patients.

  • Enrollment in both phase 2 trials has been completed and 316 patients have been enrolled in the two double-blinded trials which are being conducted at 34 investigational centers within the United States. Aclaris expects to report data from these two trials in the first half of 2018.

- **JAK Inhibitors**

  • In October, initiated a Phase 2 clinical trial of ATI-50002, a topical Janus Kinase (JAK) 1/3 inhibitor (ATI-50002 Topical) for the treatment of alopecia areata (AA). This trial will evaluate the pharmacokinetics, pharmacodynamics and safety of ATI-50002 Topical compared with placebo in 12 patients with AA. This randomized, double-blind clinical trial is being conducted at two investigational centers within the United States, and data is expected to be available in the first half of 2018.

  • In November, initiated a Phase 2 open-label clinical trial of ATI-50002 Topical for the treatment of AA. This trial will evaluate the effect of ATI-50002 Topical on the regrowth of eyebrows in up to 24 patients with AA. This trial is being conducted at two investigational centers in Sydney and Melbourne, Australia, and data is also expected to be available in the first half of 2018.

  • Continue plans to initiate a Phase 2 dose ranging trial of ATI-50002 Topical for the treatment of AA next week. This study is a randomized, double-blinded, parallel-group, vehicle controlled trial and plan to enroll approximately 120 patients at 20 investigational centers within the United States. Data is expected to be available by year end 2018.

  • Continue plans to initiate a Phase 2 open-label clinical trial of ATI-50002 Topical for the treatment of vitiligo by the end of 2017.

• Now plan to initiate a Phase 2 dose ranging trial of ATI-50001, an oral JAK inhibitor, for the treatment of AA in the first half of 2018.

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

Business Highlights and Recent Developments

- In August, completed the acquisition of Confluence, a privately held biotechnology company focused on the discovery and development of kinase inhibitors to treat inflammatory and immunological disorders and cancer.

- In August, raised net proceeds of $80.9 million from a follow-on offering of our common stock.

- In September, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,737,469 and U.S. Patent No. 9,730,877, and the Japan Patent Office issued Japanese Letters Patent No. 6212107. These patents are directed to methods related to the use and administration of certain JAK inhibitors for treating hair loss disorders. These newly issued patents are owned by The Trustees of Columbia University in the City of New York and exclusively licensed to Aclaris.

  • U.S. Patent No. 9,730,877 covers the use of various JAK inhibitors, including tofacitinib, baricitinib, ruxolitinib and decernotinib, to treat AGA, also known as male/female pattern hair loss. The ‘877 Patent contains 22 claims and expires in November 2031.

  • U.S. Patent No. 9,737,469 covers the use of baricitinib for inducing hair growth and for treating hair loss disorders such as AA and AGA. Additional issued claims pertain to methods of using baricitinib to treat particular phenotypes of AA, as well as to treat other hair loss disorders. The ‘469 Patent contains 10 claims and expires in November 2031.

  • Japanese Letters Patent No. 6212107 covers the use of tofacitinib in a topical composition or as the sole active therapeutic agent in a pharmaceutical composition for inducing hair growth and for treating hair loss disorders, such as AA and AGA. The ‘107 patent issued with 25 claims and expires in March 2033.

- In October, Columbia University received a Notice of Allowance from the USPTO for a patent application covering methods of treating a hair-loss disorder, such as AA and AGA, or inducing hair growth, by administering tofacitinib topically or by administering tofacitinib as the sole active ingredient, and treating AGA or inducing hair growth in a subject having AGA by administering tofacitinib. The application was allowed with 66 claims.

- In October, hosted inaugural R&D and Investor Day event.

Financial Highlights

Liquidity and Capital Resources

- As of September 30, 2017, Aclaris had aggregate cash, cash equivalents and marketable securities of $227.8 million compared to $174.1 million as of December 31, 2016. The $53.7 million increase during the nine months ended September 30, 2017 included:

  • Aggregate net proceeds of $100.2 million from the public offering of common stock in August 2017 and the sale of common stock under an at-the-market facility with Cowen in May 2017.

  • $9.6 million of cash used to acquire Confluence, net of cash acquired.

  • Net loss of $45.6 million and $1.2 million of net cash used in working capital, partially offset by $10.4 million of non-cash stock-based compensation expense, depreciation and amortization.

- Aclaris anticipates that its cash, cash equivalents and marketable securities as of September 30, 2017 will be sufficient to fund its operations into the second half of 2019, without giving effect to any potential new business development transactions or financing activities.

Third Quarter 2017 Financial Results

- Net loss was $18.2 million for the third quarter of 2017, compared to $10.7 million for the third quarter of 2016.

- Revenue of $0.7 million and cost of revenue of $0.5 million for the third quarter of 2017 related to Confluence’s contract

research organization (CRO) business acquired in August 2017.

- Total operating expenses for the third quarter of 2017 were $19.0 million, compared to $10.8 million for the third quarter of 2016.

  • Research and development expenses were $10.9 million for the third quarter of 2017, compared to $7.2 million for the third quarter of 2016. The increase of $3.7 million was primarily attributable to a $1.2 million increase in expenses related to the Phase 2 clinical trials of A-101 45%, a $1.3 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount, a $0.9 million increase in preclinical and clinical trial development expenses related to the JAK inhibitor technology and a $0.9 million increase in medical affairs expenses and other costs, including early stage drug discovery, offset in part by a $1.2 million decrease in clinical costs for A-101 40% Topical Solution resulting from the completion of Phase 3 clinical trials in November 2016.

  • General and administrative expenses were $8.1 million for the third quarter of 2017, compared to $3.7 million for the third quarter of 2016. The increase of $4.4 million was primarily attributable to $1.9 million in higher personnel-related expenses, including stock-based compensation, due to increased headcount, and $0.4 million in expenses related to the acquisition of Confluence. Additionally, Aclaris had a $1.6 million increase in market research and sales operations expenses related to pre-commercial activities for A-101 40% Topical Solution.

- As of September 30, 2017, Aclaris had approximately 30.8 million shares of common stock outstanding.

2017 Financial Outlook

Aclaris is updating its estimates for the following financial metrics for the full year 2017, which estimates now incorporate the acquisition of Confluence:

- Cash burn for 2017, excluding this year's financing activities and cash paid in the Confluence acquisition, is now estimated to be in the range of $56 million to $59 million compared to previous guidance of $65 million to $70 million.

- Total operating expenses for 2017 are now estimated to be in the range of $72 million to $75 million, or $57 million to $60 million when excluding estimated stock-based compensation expense of $15 million. Prior guidance for operating expenses was $84 million to $92 million, or $70 million to $75 million when excluding stock-based compensation of $14 to $17 million.

- Research and development expenses for 2017 are now estimated to be in the range of $39 million to $42 million, or $33 million to $36 million when excluding estimated stock-based compensation expense of $6 million. Prior guidance for research and development expenses was $51 million to $58 million, or $46 million to $52 million when excluding stock-based compensation of $5 million to $6 million.

Company to Host Conference Call

Management will conduct a conference call at 8:00 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 **99295180** 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 its research and development and total operating expenses during 2017 and the clinical development of its product candidates, including the availability of data from its ongoing and planned clinical trials and timing for initiation of planned clinical trials, and its belief that its existing capital resources will be sufficient to fund its operations into the second half of 2019. 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 to be filed for the quarter ended September 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 September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 684	$ -	$ 684	$ -
Cost of revenue	453	-	453	-
Gross profit	231	-	231	-
Operating expenses:				
Research and development [1]	10,864	7,162	26,601	26,533
General and administrative [1]	8,123	3,650	20,611	10,407
Total operating expenses	18,987	10,812	47,212	36,940
Loss from operations	(18,756)	(10,812)	(46,981)	(36,940)
Other income, net	564	118	1,392	336
Net loss	$ (18,192)	$ (10,694)	$ (45,589)	$ (36,604)
Net loss per share, basic and diluted	$ (0.63)	$ (0.50)	$ (1.68)	$ (1.76)
Weighted average common shares outstanding, basic and diluted	28,834,808	21,415,871	27,180,244	20,752,590

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

Cost of revenue	$ 130	$ -	$ 130	$ -
Research and development	1,332	623	3,853	1,577
General and administrative	2,211	995	6,147	2,617
Total stock-based compensation expense	$ 3,673	$ 1,618	$ 10,130	$ 4,194

Aclaris Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(in thousands)

	September 30, 2017	**December 31, 2016**
Cash, cash equivalents and marketable securities	$ 227,848	$ 174,134
Total assets	261,391	176,085
Total current liabilities	9,993	6,223
Total liabilities	17,132	6,595
Total stockholders' equity	244,259	169,490

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