Aclaris Therapeutics Reports First Quarter 2018 Financial Results and Provides Update on Clinical and Commercial Developments

May 8, 2018

• Management to Host Conference Call at 5:00 PM ET today

WAYNE, Pa., May 08, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology, and immunology, today announced financial results for the first quarter 2018 and provided an update on its clinical development and commercial programs.

“The first quarter of 2018 was a busy one as we prepared for the launch of ESKATA™ (hydrogen peroxide) Topical Solution, 40% (w/w), the first and only FDA-approved topical treatment for raised seborrheic keratosis (SK). We held the ESKATA Launch Meeting last week, and ESKATA is now officially available for physicians and their patients,” said Brett Fair, Chief Commercial Officer of Aclaris.

Commercial Update:

- Successful rollout and implementation of the ESKATA Early Experience Initiative (EEI).
    - Program expanded to over 700 accounts to accommodate market demand for ESKATA.
    - Ongoing in-service programs to support successful training and product integration.
    - Positive initial ESKATA feedback from EEI program captured in physician and patient post-application surveys.
- Aclaris sales force successful in generating a significant number of ESKATA pre-orders from targeted accounts ahead of official launch meeting.
    - Commenced health care provider (HCP) order processing and shipping the week of April 23, 2018.
- ESKATA Launch Campaign Highlights:
    - ESKATA Launch Meeting held April 30 – May 4, 2018; Unveiled New ESKATA Campaign; sales force trained on new tools and resources to support a successful ESKATA launch.
    - ESKATA Consumer website (www.eskata.com) launched May 1, 2018; includes “Find A Doctor” resource for patients seeking ESKATA treatment.
    - ESKATA HCP website (www.eskatahcp.com) updated with new campaign and downloadable tools/resources for offices.
    - ESKATA Peer-to-peer Speaker Programs beginning in May 2018.

“In March, we announced positive results from the 3-month follow-up portion of the WART-203 Phase 2 clinical trial of A-101 45% Topical Solution (A-101 45%) for the treatment of common warts (verruca vulgaris). We are also advancing our topical Janus kinase (JAK) inhibitor programs, with results from multiple Phase 2 trials expected this year. As our early-stage pipeline compounds advance towards the clinic, we continue to progress towards our goal of becoming a vertically integrated, commercial-stage biopharmaceutical company with a robust clinical-stage pipeline and drug discovery engine,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Clinical Pipeline Update:

- **A-101 45% Topical Solution**
  - In March 2018, announced positive results from the 3-month, post-treatment, follow-up evaluation period of the twice-weekly placebo-controlled Phase 2 trial (WART-203) of A-101 45% Topical Solution (A-101 45%), an investigational new drug consisting of a proprietary high-concentration stabilized hydrogen peroxide topical solution being developed as a prescription treatment for common warts (verruca vulgaris).
  - Over the 3-month post-treatment follow-up period, clinically and statistically significant greater improvements in common wart reduction and clearance vs. placebo were observed among subjects treated with A-101 45%.
  - Scheduled an End of Phase 2 meeting with the FDA for mid-2018, and plan to initiate two pivotal Phase 3 trials in the second half of 2018.

- **JAK Inhibitor Candidates**
  - **AA-202 Topical** – an ongoing Phase 2 clinical trial of ATI-502 for the topical treatment of alopecia areata (AA). This trial will evaluate the pharmacokinetics, pharmacodynamics and safety of ATI-502 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 topline data are expected in the first half of 2018. After completing the 28-day portion of the trial, patients will then enter a 6-month open label extension during which all patients will receive drug.
  - **AUATB-201 Topical** – an ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of AA. This trial will evaluate the effect of ATI-502 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 topline qualitative data are expected mid-2018.
  - **AA-201 Topical** – an ongoing Phase 2 dose ranging trial of ATI-502 for the topical treatment of AA. This trial will evaluate the effect of two concentrations of ATI-502 on the regrowth of hair in a randomized, double-blinded, parallel-group, vehicle-controlled trial in up to 120 patients with AA. This trial is being conducted in the United States and data are expected by year end 2018.
  - **VITI-201 Topical** – an ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of vitiligo. This trial will evaluate the effect of ATI-502 on the repigmentation of facial skin in up to 24 patients with vitiligo and data are expected in the first half of 2019.
  - **AGA-201 Topical** – an ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of androgenetic alopecia (AGA), also known as male/female pattern hair loss. This trial will evaluate the effect of ATI-502 on the regrowth of hair in up to 24 patients with AGA and data are expected in first half of 2019.
  - **AUAT-201 Oral** – a planned Phase 2 dose ranging trial of ATI-501, an oral JAK inhibitor for the treatment of AA, which is anticipated to begin in the first half of 2018. This trial will evaluate the effect of two concentrations of ATI-501 on the regrowth of hair in a randomized, double-blinded, parallel-group, vehicle-controlled trial in 120 to 160 patients with AA. This trial will be conducted in the United States and data are expected in mid-2019.

- **ATI-450 (MK-2 Inhibitor)**
  - Investigational New Drug application on track for submission to the FDA in mid-2019.

Recent Corporate Highlights

- Exclusively licensed the Canadian rights to commercialize A-101 40% Topical Solution for the treatment of raised seborrheic keratoses to Cipher Pharmaceuticals.

- Appointed Bryan Reasons as a director and Chairman of the Audit Committee.

Financial Highlights

Liquidity and Capital Resources

As of March 31, 2018, Aclaris had aggregate cash, cash equivalents and marketable securities of $187.0 million compared to $208.9 million as of December 31, 2017. The $21.9 million decrease during the quarter ended March 31, 2018 included:

- Net loss of $30.2 million, offset by $5.4 million of non-cash stock-based compensation expense, depreciation and amortization, $2.1 million of net cash provided by changes in operating assets and liabilities, and $0.9 million for a non-cash expense associated with an increase in the fair value of a contingent consideration liability.
- $0.3 million of cash used for purchases of property and equipment.
- $0.4 million in cash proceeds from the exercise of employee stock options.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of March 31, 2018 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.

First Quarter 2018 Financial Results

- Net loss was $30.2 million for the first quarter of 2018, compared to $12.6 million for the first quarter of 2017.
- Revenue of $1.1 million and cost of revenue of $1.0 million for the first quarter of 2018 related to Aclaris's contract research business acquired in August 2017.
- Total operating expenses for the first quarter of 2018 were $31.1 million, compared to $12.9 million for the first quarter of 2017.
    - Research and development expenses were $13.6 million for the first quarter of 2018, compared to $7.8 million for the first quarter of 2017. The increase of $5.8 million was primarily attributable to a $2.7 million increase in expenses related to the preclinical and clinical development of Aclaris's JAK inhibitor portfolio, a $1.3 million increase in medical affairs activities and early-stage drug discovery, a $0.9 million increase in fair value of the contingent consideration liability, a $0.8 million increase in Aclaris's A-101 45% topical solution program as Phase 2 clinical trials were initiated in June 2017, and a $0.6 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount. These increases were partially offset by a $0.5 million decrease in ESKATA development expenses in the first quarter of 2018.
    - Sales and marketing expenses were $11.2 million for the first quarter of 2018, compared to $1.4 million for the first quarter of 2017. The $9.8 million increase is mainly due to increases in direct marketing and professional fees, as well as other sales and marketing expenses of $5.8 million, in preparation for the commercial launch of ESKATA in the second quarter of 2018. Personnel expenses, including stock-based compensation, increased by $4.0 million as Aclaris completed the hiring of its field sales force in the first quarter of 2018.
    - General and administrative expenses were $6.3 million for the first quarter of 2018, compared to $3.7 million for the first quarter of 2017. The increase of $2.6 million was primarily attributable to $1.6 million in higher personnel-related expenses, including stock-based compensation, due to increased headcount, a $0.4 million increase in professional and legal fees, and a $0.5 million increase in facility, support and other general and administrative expenses.

2018 Financial Outlook

- Aclaris reiterated its expected 2018 GAAP research and development (R&D) expenses to be in the range of $67 to $75 million, including estimated stock-based compensation of $9 million. The anticipated increase in R&D expenses in 2018 is mainly due to the planned execution of Phase 2 clinical trials in AA, AGA, and vitiligo, two planned pivotal Phase 3 trials in common warts, and the development of our early stage pipeline compounds.

- Aclaris reiterated its expected 2018 GAAP selling, general and administrative (SG&A) expenses to be in the range of $80 to $86 million, including estimated stock-based compensation of $14 million. The anticipated increase in SG&A expenses in 2018 is primarily the result of the deployment of Aclaris's new sales force in January 2018 and the additional selling, marketing and consumer initiatives to support the commercial launch of ESKATA.

Company to Host Conference Call
Management will conduct a conference call at 5:00 P.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 7386579 prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology, and immunology. Aclaris is focused on market segments with no FDA-approved medications or where treatment gaps exist. Aclaris is based in Wayne, Pennsylvania and more information about the company 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' commercial launch of ESKATA, the clinical development of its drug candidates, including the availability of data from its ongoing and planned clinical trials and timing for initiation of planned clinical trials, estimated research and development and selling, general and administrative expenses for 2018 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, 2017, Aclaris' Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 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.

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Aclaris Therapeutics, Inc.
Condensed Consolidated Statements of Operations

(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2018	**2017**
Revenue	$ 1,118	$ -
Cost of revenue	967	-
Gross profit	151	-
Operating expenses:		
Research and development [1]	13,606	7,772
Sales and marketing [1]	11,233	1,438
General and administrative [1]	6,260	3,720
Total operating expenses	31,099	12,930
Loss from operations	(30,948)	(12,930)
Other income, net	719	371
Net loss	$ (30,229)	$ (12,559)
Net loss per share, basic and diluted	$ (0.98)	$ (0.48)
Weighted average common shares outstanding, basic and diluted	30,885,928	26,080,806

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

Cost of revenue	$ 176	$ -
Research and development	1,727	1,217
Sales and marketing	907	380
General and administrative	2,333	1,556
Total stock-based compensation expense	$ 5,143	$ 3,153

Aclaris Therapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited, in thousands)

	March 31, 2018	**December 31, 2017**
Cash, cash equivalents and marketable securities	$ 186,977	$ 208,854
Total assets	220,622	243,509
Total current liabilities	13,823	12,762
Total liabilities	20,150	18,247
Total stockholders' equity	200,472	225,262

Source: Aclaris Therapeutics, Inc.