Aclaris Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Update on Clinical and Commercial Developments

March 12, 2018

- ***Initiates Financial Guidance for Full Year 2018***
- ***Management to Host Conference Call at 8:00 AM ET today***

WAYNE, Pa., March 12, 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 fourth quarter and year ended December 31, 2017 and provided an update on its clinical development and commercial programs.

"2017 was a defining year in Aclaris' history, with the FDA approval of ESKATA™ (hydrogen peroxide) Topical Solution, 40% (w/w), the first and only FDA-approved topical, non-invasive treatment of raised seborrheic keratosis (SK). We have generated a high level of excitement around ESKATA in the dermatology community, and look forward to our official launch in the second quarter of 2018," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. "In January 2018, we announced positive topline results from two Phase 2 clinical trials (WART-202 and WART-203) of A-101 45% Topical Solution (A-101 45%) for the treatment of common warts (verruca vulgaris). We also advanced our topical Janus kinase (JAK) inhibitor programs in alopecia, with results from multiple Phase 2 trials expected later 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."

Clinical Pipeline Update

- **A-101 45% Topical Solution**
  - In January 2018, reported positive results from two Phase 2 clinical trials (WART-202 and WART-203) of A-101 45%, an investigational new drug for the treatment of common warts. A-101 45% met all primary, secondary, and exploratory endpoints of each trial analyzed to date, achieving clinically and statistically significant clearance of common warts.
  - 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**
  - **AA-202 Topical** – an ongoing Phase 2 clinical trial of ATI-502 (formerly ATI-50002) 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 at 25 investigational centers within 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** – a planned 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, which is anticipated to begin in the first half of this

year. 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 (formerly ATI-50001), an oral JAK inhibitor, for the treatment of AA which is anticipated to begin in the first half of 2018. Data are expected in mid-2019.

- **ATI-450**

  - Recently presented data from pre-clinical studies of ATI-450 (formerly known as CDD-450), a selective inhibitor of the MK2 pathway, at a symposium at the American College of Rheumatology annual meeting on November 7, 2017. The abstract summarizing the data is titled “NOMID-Associated Complications in Mice Are Prevented By CDD-450, a Small Molecule Inhibitor of the Mitogen-Activated Protein Kinase-Activated Protein Kinase 2 (MK2) Pathway.”

  - Investigational New Drug application on track for submission to the FDA in mid-2019.

Commercial Update

- Expanded commercial organization to 70 people in support of a successful ESKATA launch.

  - Established Aclaris Market Research, Sales, Trade, Training, and Sales Operations teams.

  - Successfully onboarded and trained Aclaris sales force consisting of 50 Field Sales Specialists, 2 Inside Sales Representatives, 6 Regional Sales Managers, and 1 Sales Director.

- Conducted market research with over 2,500 patients and 1,400 HCPs to date.

- Developed comprehensive HCP and consumer campaigns to support a successful ESKATA launch.

  - Finalized ESKATA pricing and positioning.

  - Established ESKATA speaker bureau consisting of dermatologist and nurse practitioner (NP)/physician assistant (PA) speakers.

- Aclaris present at 30 key dermatology meetings in 2017.

  - Generated a high level of corporate awareness with the goal to position Aclaris as a leading innovative biopharmaceutical company in dermatology.

  - Raised awareness regarding SK disease state awareness and patient willingness to pay for SK removal.

  - Strong presence at 2018 Winter American Academy of Dermatology in San Diego; Generated a high level of ESKATA awareness.

- Sales force currently implementing key market readiness activities, including:

  - Establishing ESKATA Centers of Excellence.

  - Implementation of ESKATA Early Experience Initiative.

- National Sales Meeting scheduled for the second quarter of 2018, followed by official ESKATA launch.

Recent Corporate Highlights

- Promoted Brett Fair to Chief Commercial Officer

- Continued to build our research and development and commercial infrastructure.

- The United States Patent and Trademark Office recently issued U.S. Patent No. 9,895,301, which is directed to methods related to the use and administration of a certain JAK inhibitor for treating hair loss disorders.

- U.S. Patent No. 9,895,301 covers the use of tofacitinib for inducing hair growth and for treating hair loss disorders such as alopecia areata and AGA. Additional issued claims pertain to methods of using tofacitinib to treat particular phenotypes of alopecia areata, as well as to treat other hair loss disorders. The '301 Patent contains 67 claims and expires in November 2031.

- This newly allowed patent is owned by The Trustees of Columbia University in the City of New York and exclusively licensed to Aclaris and is the latest U.S. patent to issue in connection with Aclaris' JAK drug development program for hair loss disorders.

- Recently added to the NASDAQ Biotechnology Index (NASDAQ:NBI).

Financial Highlights

Liquidity and Capital Resources

As of December 31, 2017, Aclaris had aggregate cash, cash equivalents and marketable securities of $208.9 million compared to $174.1 million as of December 31, 2016. The $34.8 million increase during the year ended December 31, 2017 included:

- Aggregate net proceeds of $100.2 million from the sale of common stock under an at-the-market facility with Cowen and Company LLC in April 2017 and a follow-on public offering of common stock in August 2017.

- $9.6 million of cash used to acquire Confluence in August 2017, net of cash acquired.

- $1.2 million of purchases of property and equipment.

- Net loss of $68.5 million, offset by $0.9 million of net cash provided by working capital and $14.8 million of non-cash stock-based compensation expense, depreciation and amortization.

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

Fourth Quarter 2017 Financial Results

- Net loss was $22.9 million for the fourth quarter of 2017, compared to $11.5 million for the fourth quarter of 2016. Upon new tax legislation passed in December 2017, Aclaris recognized an income tax benefit of $1.8 million related to the reversal of the deferred tax liability associated with the In-Process Research and Development recognized in the Confluence acquisition earlier this year.

- Revenue of $1 million and cost of revenue of $0.8 million for the fourth quarter of 2017 related to our contract research business acquired in August 2017.

- Total operating expenses for the fourth quarter of 2017 were $25.7 million, compared to $11.6 million for the fourth quarter of 2016.

    - Research and development expenses were $13.2 million for the fourth quarter of 2017, compared to $6.9 million for the fourth quarter of 2016. The increase of $6.3 million was primarily attributable to a $2.3 million increase in expenses related to the WART-202 and WART-203 trials, a $1.5 million increase in personnel-related expenses, including stock-based compensation, due to increased headcount, a $2 million increase in preclinical and clinical trial development expenses related to the JAK inhibitor portfolio and a $1.5 million increase in Medical Affairs expenses and other costs, including early stage drug discovery. This increase was partially offset by a $1.3 million decrease due to the completion of our ESKATA Phase 3 clinical trials and the submission preparation of the NDA for ESKATA in November 2016.

    - General and administrative expenses were $12.5 million for the fourth quarter of 2017, compared to $4.7 million for the fourth quarter of 2016. The increase of $7.8 million was primarily attributable to $2.9 million in higher personnel-related expenses, including stock-based compensation, due to increased headcount, and a $1 million increase related to relocating our corporate headquarters and administrative costs related to our St. Louis, Missouri operations acquired in August 2017. Additionally, Aclaris incurred a $3.3 million increase in market research and sales operations expenses related to pre-commercial activities for ESKATA.

Full Year 2017 Financial Results

- Net loss was $68.5 million for the year ended December 31, 2017, compared to $48.1 million for the year ended

December 31, 2016.

- Revenue of $1.7 million and cost of revenue of $1.2 million for the year ended December 31, 2017 related to the contract research business acquired in August 2017.

- Total operating expenses were $72.9 million for the year ended December 31, 2017, compared to $48.6 million for the year ended December 31, 2016. Net cash used in operating activities was $54.7 million, compared to $34.6 million for the year ended December 31, 2016.

    - Research and development expenses were $39.8 million for the year ended December 31, 2017, compared to $33.5 million for the year ended December 31, 2016. The increase of $6.3 million was due to higher payroll-related expenses of $5.6 million due to increased headcount, including stock-based compensation expense, an increase of $4.5 million in preclinical and clinical trial development expenses related to our JAK inhibitor portfolio, an increase of $3.4 million in expenses related to the WART-202 and WART-203 trials, and a $3.6 million increase in medical affairs and early stage drug discovery activities. The increases noted above were partially offset by a $7.7 million decrease related to our ESKATA Phase 3 clinical trials costs, which were completed in November 2016, and $3.4 million in costs incurred with the acquisition of Vixen Pharmaceuticals, Inc. in the year ended December 31, 2016.

    - General and administrative expenses were $33.1 million for the year ended December 31, 2017, compared to $15.1 million for the year ended December 31, 2016. The increase of $18 million was primarily attributable to an increase of $9.3 million in payroll-related expenses due to increased headcount, including stock-based compensation expense, an increase of $6.1 million in pre-commercial launch activities for ESKATA, a $1.3 million increase in facilities-related costs, and a $1.3 million increase in other professional fees.

- As of December 31, 2017, Aclaris had approximately 30.8 million shares of common stock outstanding.

2018 Financial Outlook

- Aclaris expects 2018 GAAP research and development (R&D) expenses to be in the range of $67 to $75 million, which, when excluding estimated stock-based compensation of $9 million, results in 2018 non-GAAP R&D expense of $58 to $66 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 development of our early stage pipeline compounds.

- Aclaris expects 2018 GAAP selling, general and administrative (SG&A) expenses to be in the range of $80 to $86 million, which, when excluding estimated stock-based compensation of $14 million, results in 2018 non-GAAP SG&A expense of $66 to $72 million. The anticipated increase in SG&A expenses in 2018 is primarily the result of the deployment of our 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 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 1495576 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, research and development and selling, general and administrative expenses during 2018 and 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, 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 to be filed for the year ended December 31, 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.

Use of Non-GAAP Financial Measures

Aclaris has presented certain non-GAAP financial measures in this release. This release and the reconciliation tables included herein include total non-GAAP R&D expense and non-GAAP SG&A expense, both of which exclude stock-based compensation. Aclaris excludes stock-based compensation expense because management believes the exclusion of this item is helpful to investors to evaluate Aclaris' recurring operational performance. Aclaris management uses these non-GAAP financial measures to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. The non-GAAP financial measures should be considered in addition to results prepared in accordance with GAAP, but should not be considered a substitute for or superior to GAAP results.

Aclaris Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 999	$ -	$ 1,683	$ -
Cost of revenue	754	-	1,207	-
Gross profit	245	-	476	-
Operating expenses:				
Research and development [1]	13,189	6,943	39,790	33,476
General and administrative [1]	12,498	4,684	33,109	15,091
Total operating expenses	25,687	11,627	72,899	48,567
Loss from operations	(25,442)	(11,627)	(72,423)	(48,567)
Other income, net	678	152	2,070	488
Loss before income taxes	(24,764)	(11,475)	(70,353)	(48,079)
Provision for income taxes	(1,830)	-	(1,830)	-
Net loss	$ (22,934)	$ (11,475)	$ (68,523)	$ (48,079)
Net loss per share, basic and diluted	$ (0.74)	$ (0.49)	$ (2.44)	$ (2.25)
Weighted average common shares outstanding, basic and diluted	30,838,741	23,390,746	28,102,386	21,415,733

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

Cost of revenue	$ 81	$ -	$ 211	$ -
Research and development	1,618	714	5,471	2,291
General and administrative	2,601	1,196	8,748	3,813
Total stock-based compensation expense	$ 4,300	$ 1,910	$ 14,430	$ 6,104

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

	December 31, 2017	**December 31, 2016**
Cash, cash equivalents and marketable securities	$ 208,854	$ 174,134
Total assets	243,509	176,085
Total current liabilities	12,762	6,223
Total liabilities	18,247	6,595
Total stockholders' equity	225,262	169,490

Aclaris Therapeutics, Inc.
2018 Financial Guidance
Reconciliation of GAAP R&D Expense to Non-GAAP R&D Expense
(in thousands)

	2018 Low		2018 High	
R&D expense:				
GAAP R&D expense	$ 67,000		$ 75,000	
Adjustments:				
Stock-based compensation	(9,000	)	(9,000	)
Non-GAAP R&D expense	$ 58,000		$ 66,000	

Reconciliation of GAAP SG&A to Non-GAAP SG&A Expense
(in thousands)

	2018 Low		2018 High	
SG&A expense:				
GAAP SG&A expense	$ 80,000		$ 86,000	
Adjustments:				
Stock-based compensation	(14,000	)	(14,000	)
Non-GAAP SG&A expense	$ 66,000		$ 72,000	

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Source: Aclaris Therapeutics, Inc.