Aclaris Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Update on Clinical and Commercial Developments

March 18, 2019

- **Product Sales of $3.9 Million for Fiscal Year 2018**
- **Initiates Financial Guidance for Full Year 2019**
- **Management to Host Conference Call at 8:00 AM ET today**

WAYNE, Pa., March 18, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on dermatological and immuno-inflammatory diseases, today announced financial results for the fourth quarter and full year 2018, and provided an update on its clinical development and commercial programs.

- In November 2018, Aclaris acquired the worldwide rights to RHOFADE® (oxymetazoline hydrochloride) cream, 1% from Allergan Sales, LLC.
- In December 2018, Aclaris began promoting RHOFADE, which is approved in the United States for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults.
- In February 2019, at the annual National Sales Meeting, Aclaris appointed Jeff Wayne as interim Head of Commercial and officially relaunched RHOFADE.
- Today Aclaris is providing an update, including new photos, from AUATB-201 Topical, an open-label clinical trial in patients with eyebrow loss due to alopecia areata (AA), including patients with alopecia totalis or alopecia universalis.

“On the commercial side of the company, we made a change in leadership as we focus on the relaunch of RHOFADE in 2019. Our development stage pipeline continues to advance with multiple data read outs expected during the course of the year across both our JAK inhibitor and A-101 clinical programs. Finally, we look to move our first Confluence originated asset into the clinic in the second half of the year; a significant milestone given we acquired and integrated the team just 18 months ago. Given the anticipated data readouts, we expect 2019 to be a watershed year as we become a fully integrated biopharmaceutical company,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Clinical Pipeline Update:

- **A-101 45% Topical Solution:**
  - Two pivotal Phase 3 trials, named THWART-1 and THWART-2, for the treatment of common warts are progressing as planned. THWART-2 has completed enrollment, and THWART-1 is expected to complete enrollment by the end of this month. These two trials will enroll a total of approximately 1,000 patients across both studies, and topline data are expected in the second half of 2019.
  - An open-label safety extension trial investigating A-101 45% Topical Solution for the treatment of common warts is also ongoing; if the results of these trials are positive, NDA submission is expected in the first half of 2020.

- **JAK Inhibitor Trials:**
  - We have completed enrollment in all of the following JAK inhibitor trials:
    - **AA-201 Topical** – This ongoing Phase 2 randomized, double-blinded, parallel-group, vehicle-controlled trial is evaluating the safety, efficacy, and dose response of two concentrations of ATI-502, a topical JAK1/3 inhibitor, on the regrowth of hair in 129 patients with AA. Data are expected in the second quarter of 2019.
    - **AGA-201 Topical** – This ongoing Phase 2 open-label clinical trial is evaluating the safety and efficacy of ATI-502, a topical JAK1/3 inhibitor, on the regrowth of hair in 31 patients with androgenetic alopecia (AGA), also known as male/female pattern hair loss. 6-month data are expected in the second quarter of 2019 and 12-month data are expected in the second half of 2019.
    - **VITI-201 Topical** – This ongoing Phase 2 open-label clinical trial is evaluating the safety and efficacy of ATI-502, a topical JAK1/3 inhibitor, on the repigmentation of facial skin in 34 patients with vitiligo. 6-month interim data are expected in the second quarter of 2019 and 12-month data are expected in the second half of 2019.
    - **AD-201 Topical** – This ongoing Phase 2 open-label clinical trial is evaluating the safety and efficacy of ATI-502, a topical JAK1/3 inhibitor, in 22 adult patients with moderate-to-severe atopic dermatitis (AD). Data are expected in mid-2019.
    - **AUAT-201 Oral** – This ongoing randomized, double-blinded, parallel-group, placebo-controlled trial is evaluating the safety, efficacy, and dose response of three concentrations of ATI-501, an oral JAK 1/3 inhibitor, on the regrowth of hair in 87 patients with AA. Data are expected in the second half of 2019.

- **ATI-450 (MK-2 Inhibitor)** – We expect to submit an Investigational New Drug (IND) application for rheumatoid arthritis to

the FDA in mid-2019. If the IND is allowed by the FDA, we expect to initiate a Phase 1 and Phase 2 trial in the second half of 2019.

Recent Corporate Highlights:

- Significant presence at 2019 Annual Academy of Dermatology (AAD) Annual Meeting to support the relaunch of RHOFADE. Aclaris also presented 6 posters, including 2 oral presentations regarding the clinical results of ESKATA® for the treatment of raised seborrheic keratosis and A-101 45% topical solution for the treatment of common warts.
- Aclaris received approval from the Swedish Medical Products Agency to market ESKATA® (hydrogen peroxide) cutaneous solution, 685 mg, for the treatment in adults of seborrheic keratoses that are not pedunculated and have up to a maximum diameter of 15 mm each. Aclaris also has received approval to market the medicine in the United Kingdom, Iceland, and Belgium. Aclaris is seeking a commercial partner or partners to market the medicine as an aesthetic skin treatment in various European countries with the brand name ESKATA® in Finland, Iceland, Netherlands, Norway, Portugal, Spain, Sweden, Czech Republic, and Belgium, and the brand name ESKERIELE® in Austria, France, Germany, Ireland, Italy, and the United Kingdom.
- Canadian partner Cipher Pharmaceuticals Inc. submitted a New Drug Submission for A-101 40% Topical Solution for the treatment of raised SKs, which was accepted for review by Health Canada in December 2018.

Commercial Update:

- Jeff Wayne, Aclaris' Vice President of Business Development, was recently appointed as interim Head of Commercial. Mr. Wayne brings over 30 years of pharmaceutical experience with the majority spent in dermatology. During his career, he has held positions of increasing responsibility in sales, marketing, and general management with Galderma, Intendis, Promius Pharma (where he built, launched, and led the commercial organization), Onset Dermatologics, and LEO Pharma. He launched METROGEL® in both the United States and Canada and was responsible for the marketing of FINACEA® in the United States; two medications prescribed for the treatment of rosacea. In his role as Vice President, Business Development, he managed the RHOFADE transaction from the beginning, providing a seamless transition of leadership.
- Following our National Sales Meeting held mid-February, RHOFADE was officially relaunched, and featured prominently at the Aclaris booth and throughout the convention venue at the 2019 AAD Annual Meeting.
- The Aclaris field sales team was realigned to optimize reach and call frequency on current and potential RHOFADE prescribers, as well as the top 10 ESKATA accounts in each territory.
    - Comparing the 4-week period ended March 8, 2019 to the immediately prior 4-week period, the IQVIA data showed an 8.4% increase in total prescriptions for RHOFADE.
    - Based on these early prescription trends, we believe the response to the RHOFADE message, which emphasizes the need to treat all rosacea patients with persistent facial erythema, appears positive.

Financial Highlights

Liquidity and Capital Resources

As of December 31, 2018, Aclaris had aggregate cash, cash equivalents and marketable securities of $168.0 million compared to $208.9 million as of December 31, 2017. The $30.9 million decrease during the year ended December 31, 2018 included:

- Aggregate net proceeds of $100.2 million from the sale of common stock in a follow-on public offering of common stock in October 2018;
- $67.1 million of cash used to acquire the global rights to RHOFADE;
- $29.9 million of cash, net of issuance costs, borrowed under the loan agreement with Oxford Finance LLC;
- $1.4 million in property and equipment purchases; and
- Net loss of $132.7 million, offset by $9.4 million of net cash provided by working capital and $21.9 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, 2018 will be sufficient to fund its operations into the fourth quarter of 2020, without giving effect to any potential new business development transactions or financing activities.

Fourth Quarter 2018 Financial Results

- Net loss was $38.6 million for the fourth quarter of 2018, compared to $22.9 million for the fourth quarter of 2017.
- Net revenues were $3.7 million for the quarter ended December 31, 2018, which consisted of $0.8 million of net ESKATA sales, $1.1 million of net RHOFADE sales (December only), $1.3 million of contract research revenues, and $0.5 million of other revenue. This compared to $1.0 million for the quarter ended December 31, 2017, all of which was contract research revenues. Cost of revenues was $3.5 million for the quarter ended December 31, 2018, compared to $0.8 million for the quarter ended December 31, 2017.
- Total operating expenses for the fourth quarter of 2018 were $39.2 million, compared to $25.7 million for the fourth quarter of 2017.

- Research and development expenses were $19.5 million for the fourth quarter of 2018, compared to $13.2 million for the fourth quarter of 2017. The increase of $6.3 million was mainly the result of the continued growth of Aclaris' JAK inhibitor and common wart programs, as multiple Phase 2 trials of ATI-501 and ATI-502 and Phase 3 trials of A-101 45% were ongoing in the fourth quarter of 2018, as well as the increased headcount to support these programs.
- Sales and marketing expenses were $13.0 million for the fourth quarter of 2018, compared to $6.6 million for the fourth quarter of 2017. The increase of $6.4 million was the result of increases in direct marketing and professional fees, as well as other commercial and personnel expenses incurred to support the continued commercialization of ESKATA following its launch in May 2018.
- General and administrative expenses were $6.7 million for the fourth quarter of 2018, compared to $5.9 million for the fourth quarter of 2017. The increase was driven by headcount increases, and legal and business development costs related to the RHOFADE acquisition in the fourth quarter of 2018.

Full Year 2018 Financial Results

- Net loss was $132.7 million for the year ended December 31, 2018, compared to $68.5 million for the year ended December 31, 2017.
- Net revenues were $10.1 million for the year ended December 31, 2018, which consisted of $2.8 million of net ESKATA sales, $1.1 million of net RHOFADE sales (December only), $4.7 million of contract research revenues, and $1.5 million of other revenue. This compared to $1.7 million for the year ended December 31, 2017, all of which was contract research revenues. Cost of revenues was $6.9 million for the year ended December 31, 2018, compared to $1.2 million for the year ended December 31, 2017.
- Total operating expenses were $138.7 million for the year ended December 31, 2018, compared to $72.9 million for the year ended December 31, 2017. Net cash used in operating activities was $100.8 million for the year ended December 31, 2018, compared to $54.7 million for the year ended December 31, 2017.
    - Research and development expenses were $63.0 million for the year ended December 31, 2018, compared to $39.8 million for the year ended December 31, 2017. The increase of $23.2 million was mainly the result of the continued growth of Aclaris' JAK inhibitor and common wart programs, as multiple Phase 2 trials of ATI-501 and ATI-502 and Phase 3 trials of A-101 45% were conducted throughout 2018, as well as the increased headcount to support these programs. These increases were offset by a decrease in costs related to the development of ESKATA as Aclaris submitted the NDA for ESKATA in February 2017 following the completion of the clinical trials.
    - Sales and marketing expenses were $48.0 million for the year ended December 31, 2018, compared to $13.8 million for the year ended December 31, 2017. The increase of $34.2 million was the result of increases in direct marketing and professional fees, as well as other commercial expenses incurred to support the launch and commercialization of ESKATA in May 2018. Personnel expenses also increased as Aclaris completed the hiring of its field sales force early in 2018.
    - General and administrative expenses were $27.6 million for the year ended December 31, 2018, compared to $19.3 million for the year ended December 31, 2017. The increase of $8.3 million was the result of higher personnel expenses, due to increased headcount to support the commercial launch of ESKATA, as well as legal and business development costs related to the RHOFADE acquisition during 2018. General and administrative expenses for the year ended December 31, 2018 also included a $1.5 million ESKATA-related milestone payment, whereas the year ended December 31, 2017 included a $1.0 million ESKATA-related milestone payment.
- As of December 31, 2018, Aclaris had 41.2 million shares of common stock outstanding.

2019 Financial Outlook

- Aclaris expects 2019 GAAP research and development (R&D) expenses to be in the range of $61 to $64 million, including estimated stock-based compensation of $7 million. This expense guidance for R&D in 2019 contemplates the completion of Aclaris' Phase 2 clinical trials in AA, open label trials in AGA, vitiligo and AD, and two pivotal Phase 3 trials in common warts, as well as the further advancement of Aclaris' preclinical pipeline compounds, including ATI-450 and ATI-1777.
- Aclaris expects 2019 GAAP sales and marketing (S&M) expenses to be in the range of $37 to $40 million, including estimated stock-based compensation of $4 million. This expense guidance for S&M in 2019 contemplates all salesforce costs and the selling and marketing initiatives to support our commercial brands.
- Aclaris expects 2019 GAAP general and administrative (G&A) expenses to be in the range of $29 to $31 million, including estimated stock-based compensation of $10 million. This expense guidance for G&A in 2019 contemplates additional medical affairs, legal, and compliance activities to support our commercial brands.

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 call 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 9765869prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with dermatological and immuno-inflammatory diseases who lack satisfactory treatment options. The company's diverse and multi-stage portfolio includes two FDA-approved medicines, one late-stage investigational medicine, and a pipeline powered by a robust R&D engine exploring protein kinase regulation. Aclaris Therapeutics' active development programs focus on areas where significant treatment gaps exist, such as common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

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 commercialization of RHOFADE and ESKATA, the clinical development of Aclaris' drug candidates, including the availability of data from its ongoing and planned clinical trials, timing for initiation of planned clinical trials and timing for regulatory submissions, estimated research and development, sales, marketing, and general and administrative expenses for 2019 ,and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the fourth quarter of 2020. 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, 2018, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC filings" 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
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product sales, net	$ 1,897	$ -	$ 3,940	$ -
Contract research	1,272	999	4,651	1,683
Other revenue	500	-	1,500	-
Total revenues, net	3,669	999	10,091	1,683
Cost of revenue (1)	3,509	754	6,850	1,207
Gross profit	160	245	3,241	476
Operating expenses:				
Research and development (1)	19,537	13,189	63,009	39,790
Sales and marketing (1)	12,967	6,585	47,997	13,769
General and administrative (1)	6,694	5,913	27,649	19,340
Total operating expenses	39,198	25,687	138,655	72,899
Loss from operations	(39,038)	(25,442)	(135,414)	(72,423)
Other income, net	487	678	2,676	2,070
Loss before income taxes	(38,551)	(24,764)	(132,738)	(70,353)
Provision for income taxes	-	(1,830)	-	(1,830)
Net loss	$ (38,551)	$ (22,934)	$ (132,738)	$ (68,523)
Net loss per share, basic and diluted	$ (0.99)	$ (0.74)	$ (4.03)	$ (2.44)
Weighted average common shares outstanding, basic and diluted	38,760,676	30,838,741	32,909,762	28,102,386

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

Cost of revenue	$ 206	$ 81	$ 766	$ 211
Research and development	1,564	1,618	6,480	5,471
Sales and marketing	805	591	3,492	1,851
General and administrative	2,381	2,010	9,317	6,897
Total stock-based compensation expense	$ 4,956	$ 4,300	$ 20,055	$ 14,430

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

	December 31, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 167,972	$ 208,854
Total assets	275,566	243,509
Total current liabilities	27,342	12,762
Total liabilities	60,442	18,247
Total stockholders' equity	215,124	225,262

Aclaris Contact
Michael Tung, M.D.
Senior Vice President
Corporate Strategy/Investor Relations
484-329-2140
mtung@aclaristx.com

Media Contact
Sheila Kennedy
Vice President, Corporate Communications
484-321-5559
media@aclaristx.com

Source: Aclaris Therapeutics, Inc.