Aclaris Therapeutics Reports First Quarter 2019 Financial Results and Provides Update on Clinical and Commercial Developments

May 8, 2019

- ***Submitted IND for ATI-450, an oral MK2 inhibitor***
- ***RHOFADE net sales of $3.7 million for the first quarter of 2019***
- ***Management to Host Conference Call at 5:00 PM ET today***

WAYNE, Pa., May 08, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced its financial results for the first quarter of 2019, and provided an update on its clinical development and commercial programs.

Highlights:

- Aclaris submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) for ATI-450, an oral MK2 inhibitor, for the treatment of rheumatoid arthritis (RA) in April 2019. It would be Aclaris' first internally-developed novel compound to enter the clinical phase of development and its first inflammatory indication adjacent to dermatology. Aclaris expects to begin a Phase 1 clinical trial of ATI-450, an investigational compound, in the second half of 2019.
- In April 2019, Aclaris completed enrollment of more than 1,000 patients across two Phase 3 pivotal clinical trials (THWART-1 and THWART-2) investigating A-101 45% Topical Solution, an investigational drug, for the treatment of common warts, and expects to complete enrollment of Aclaris' open-label safety extension trial (WART-303) evaluating the long-term safety of A-101 45% Topical Solution during the second quarter of 2019.
- During the first quarter of 2019, total net revenues were $5.0 million, which included net sales of RHOFADE® (oxymetazoline hydrochloride) cream, 1% of $3.7 million, building on the positive momentum from December 2018.
- In April 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,265,258 covering methods of treating alopecia areata (AA) using ruxolitinib or isotopic forms of ruxolitinib. The claims in this issued patent cover the use of an effective amount of isotopic forms of ruxolitinib, such as deuterated ruxolitinib, to treat AA. This patent is exclusively licensed to Aclaris. This represents the continued expansion of the IP estate with numerous claims directed against ruxolitinib, baricitinib, tofacitinib and decernotinib.

"Our development stage pipeline continues to advance with multiple data read outs expected during the course of the year across both our Phase 2 and Phase 3 clinical programs. Additionally, we are excited to move ATI-450, our first internally generated asset, into the clinic in the second half of this year. Our drug discovery engine continues to be productive and we look forward to developing small molecule therapeutics for many inflammatory conditions that need new treatment approaches. Finally, we are pleased with the reception to the relaunch and continued growth of RHOFADE through the first quarter," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

Clinical Pipeline Update:

- **A-101 45% Topical Solution:**
  - Aclaris' THWART-1 and THWART-2 trials, investigating A-101 45% Topical Solution for the treatment of common warts, are progressing as planned. Aclaris has completed enrollment of more than 1,000 patients across these two trials, and topline data for both trials are expected in the second half of 2019.
  - An open-label safety extension trial (WART-303) evaluating the long-term safety of A-101 45% Topical Solution for the treatment of common warts is also ongoing and Aclaris expects enrollment to be completed during the second quarter of 2019.
  - If the results of these trials are positive, NDA submission is expected in the first half of 2020.
- **JAK Inhibitor Trials:**
  - Aclaris has 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 during the second quarter of 2019 and if the results from this trial are positive, Aclaris' next steps may include holding an end of Phase 2 meeting with the FDA, and initiating a Phase 3 trial of ATI-502 as a topical treatment for AA in the first half of 2020.

- **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 during the second quarter of 2019 and 12-month data are expected in the fourth quarter of 2019. If the results from this trial are positive, Aclaris expects to initiate an additional Phase 2 trial of ATI-502 for the topical treatment of AGA in the first half of 2020.

- **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 mid-2019 and 12-month data are expected in the fourth quarter 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 (MK2 Inhibitor)** – In April, Aclaris submitted an IND for ATI-450 for the treatment of RA. Aclaris expects to initiate a Single Ascending Dose / Multiple Ascending Dose Phase 1 trial in approximately 80 patients in the second half of 2019. If the IND is allowed by the FDA, Aclaris expects to initiate a Phase 1 trial in the second half of 2019. If Aclaris successfully completes the Phase 1 trial, Aclaris expects to advance ATI-450 into Phase 2 trials in patients with rheumatoid arthritis and an additional inflammatory indication.

Commercial Update:

- Based on IQVIA Xponent® data for the rolling 4-week period ended April 19, 2019 compared to the rolling 4-week period ended January 25, 2019, the average weekly RHOFADE prescriptions have increased by 20%, the average number of unique RHOFADE prescribers has increased by 18%, and the average number of RHOFADE prescriptions per HCP has increased by 3%.
- Total prescriptions for RHOFADE were 11% higher in March 2019 as compared to February 2019, according to the IQVIA Monthly National Prescription Audit data.
- RHOFADE is currently covered for 85% of commercially-insured lives and 52% of commercially-insured lives have unrestricted access, according to Managed Markets Insight & Technology data.
- Aclaris received approval 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 under the brand name ESKATA in Finland, Iceland, Netherlands, Norway, Belgium and Czech Republic, and under the brand name ESKERIELE in the United Kingdom, Germany and France. Aclaris is seeking a commercial partner or partners to market the medicine as an aesthetic skin treatment in various European countries.

Financial Highlights:
Liquidity and Capital Resources

As of March 31, 2019, Aclaris had aggregate cash, cash equivalents and marketable securities of $136.8 million compared to $168.0 million as of December 31, 2018. The $31.2 million decrease during the quarter ended March 31, 2019 included:

- Net loss of $37.6 million, $0.8 million of net cash used in working capital, and $0.3 million in property and equipment purchases. These uses were offset by $4.9 million of non-cash stock-based compensation expense and $2.2 million of non-cash depreciation and amortization expense.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of March 31, 2019 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.

First Quarter 2019 Financial Results

- Net loss was $37.6 million for the first quarter of 2019, compared to $30.2 million for the first quarter of 2018.

- Net revenues were $5.0 million for the quarter ended March 31, 2019, which consisted of $3.7 million of net RHOFADE sales, $0.1 million of net ESKATA sales, and $1.3 million of contract research revenues. This compared to total revenue of $1.1 million for the quarter ended March 31, 2018, all of which was contract research revenues. Cost of revenues (excluding amortization) was $2.8 million for the quarter ended March 31, 2019, compared to $1.0 million for the quarter

ended March 31, 2018. Amortization of definite-lived intangibles was $1.7 million for the quarter ended March 31, 2019 and related to RHOFADE intellectual property acquired in November 2018.

- Total operating expenses for the first quarter of 2019 were $37.9 million, compared to $31.1 million for the first quarter of 2018.

    - Research and development expenses were $19.9 million for the first quarter of 2019, compared to $13.6 million for the first quarter of 2018. The increase of $6.3 million was mainly the result of the continued advancement 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% Topical Solution, were ongoing in the first quarter of 2019, as well as the increased headcount to support these programs. There was also an increase in preclinical work for ATI-450, Aclaris' MK2 inhibitor, as the company prepared to file its IND in April 2019.

    - Sales and marketing expenses were $9.8 million for the first quarter of 2019, compared to $11.2 million for the first quarter of 2018. The decrease of $1.4 million was primarily the result of decreases in direct marketing and professional fees, as well as other commercial and personnel expenses that were incurred in the first quarter of 2018 to support the commercialization and launch of ESKATA in May 2018.

    - General and administrative expenses were $8.2 million for the first quarter of 2019, compared to $6.3 million for the first quarter of 2018. The increase was driven by headcount increases, professional and legal fees related to the RHOFADE acquisition in November 2018, costs incurred under a transition services agreement with Allergan related to RHOFADE, as well as increased medical affairs activities.

2019 Financial Outlook

- Aclaris reiterated its 2019 expected 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 reiterated 2019 expected 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 sales force costs and the selling and marketing initiatives to support Aclaris' marketed products.

- Aclaris reiterated 2019 expected 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 Aclaris' marketed products.

Company to Host Conference Call
Management will conduct a conference call **at 5:00 PM 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 5737199prior 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 immuno-inflammatory and dermatological 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 Aclaris' marketed products, 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 and in commercialization of products, 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 March 31,	
	2019	**2018**
Revenues:		
Product sales, net	$ 3,778	$ -
Contract research	1,263	1,118
Total revenues, net	5,041	1,118
Costs and expenses:		
Cost of revenues (excludes amortization) (1)	2,777	967
Research and development (1)	19,919	13,606
Sales and marketing (1)	9,828	11,233
General and administrative (1)	8,193	6,260
Amortization of definite-lived intangible assets	1,659	-
Total costs and expenses	42,376	32,066
Loss from operations	(37,335)	(30,948)
Other income (expense), net	(230)	719
Net loss	$ (37,565)	$ (30,229)
Net loss per share, basic and diluted	$ (0.91)	$ (0.98)
Weighted average common shares outstanding, basic and diluted	41,248,663	30,885,928

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

Cost of revenue	$ 206	$ 176
Research and development	1,594	1,727
Sales and marketing	590	907
General and administrative	2,472	2,333
Total stock-based compensation expense	$ 4,862	$ 5,143

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

	March 31, 2019	**December 31, 2018**
Cash, cash equivalents and marketable securities	$ 136,755	$ 167,972
Total assets	253,183	275,566
Total current liabilities	36,228	27,342
Total liabilities	70,930	60,442
Total stockholders' equity	182,253	215,124

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Source: Aclaris Therapeutics, Inc.