Aclaris Therapeutics Reports Second Quarter 2019 Financial Results, Provides Business Strategy Update and Provides Update on Clinical and Commercial Developments

August 8, 2019

- ***Undertaking strategic review of commercial and R&D assets***
- ***IND for ATI-450, an investigational compound and oral MK2 inhibitor, allowed by the FDA in May 2019, and first patient dosed in Phase 1 clinical trial in August 2019***
- ***RHOFADE® (oxymetazoline hydrochloride) cream, 1% net sales of $4.7 million for the second quarter of 2019***
- ***Management to Host Conference Call at 5:00 PM ET today***

WAYNE, Pa., Aug. 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 second quarter of 2019, and provided a business strategy update and an update on its clinical development programs and commercial products.

Business Strategy Update:

- Aclaris announced that it is undertaking a strategic business review of its commercial and research and development (R&D) portfolio of assets to determine how to optimally deploy capital to maximize shareholder return. As part of this undertaking, Aclaris today announced the following:
  - Today, it is voluntarily discontinuing the commercialization of ESKATA® (hydrogen peroxide) Topical Solution, 40% (w/w) (ESKATA) in the United States due to the fact that revenues from product sales were insufficient for Aclaris to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients, and not for efficacy or safety reasons, and is seeking a strategic partner to commercialize this product, both in the United States and worldwide (excluding Canada).
  - Aclaris currently intends to seek a strategic partner to further develop its investigational compounds, ATI-501 (oral) and ATI-502 (topical) Janus Kinase (JAK) 1/3 inhibitors, for alopecia.
  - Aclaris plans to continue to invest in its other immuno-inflammatory drug candidates, including its internally developed investigational candidate ATI-450, an oral MK2 inhibitor. If Aclaris successfully completes its ongoing Phase 1 clinical trial for this drug candidate, Aclaris expects to advance ATI-450 into two Phase 2 clinical trials: one for patients with rheumatoid arthritis (RA) and one for an additional inflammatory indication.

Highlights:
Clinical

- Aclaris' Investigational New Drug (IND) Application for ATI-450 for the treatment of RA was allowed by the U.S. Food and Drug Administration (FDA) in May 2019. Aclaris announced today that the first patient in its Phase 1 clinical trial of ATI-450 has been dosed. ATI-450 is Aclaris' first internally developed novel compound to enter the clinical phase of development.
- In May 2019, Aclaris completed enrollment of its open-label safety extension Phase 3 clinical trial (WART-303) evaluating the long-term safety of A-101 45% Topical Solution, an investigational drug, as a potential treatment for common warts.
- Aclaris recently announced data readouts from multiple Phase 2 clinical trials of ATI-501 and ATI-502.

Commercial and Business

- During the second quarter of 2019, total net revenues were $5.9 million, which included net sales of RHOFADE® (oxymetazoline hydrochloride) cream, 1% (RHOFADE) of $4.7 million.
- In July 2019, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,335,391 covering methods of treating facial erythema associated with rosacea using a 1.0% w/w oxymetazoline hydrochloride composition. This issued U.S. Patent is the sixth patent listed in the Orange Book for RHOFADE and is set to expire in June 2035.
- In April 2019, the USPTO 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.
- Maxine Gowen, Ph.D. was appointed to the Board of Directors in July 2019.

"We have had a busy few months with the continuation of our commercial relaunch of RHOFADE, generating data from our ATI-501 and ATI-502 trials, and most recently, initiating a Phase 1 trial with ATI-450, our first internally developed compound," said Dr. Neal Walker, President and Chief Executive

Officer of Aclaris. “We look forward to reporting the results of our Phase 3 wart trials in the second half of this year and providing further updates on our business strategy review.”

Clinical Pipeline Update:

- **A-101 45% Topical Solution:**
  - Aclaris’ THWART-1 and THWART-2 Phase 3 pivotal clinical trials, assessing A-101 45% Topical Solution as a potential treatment for common warts, are progressing as planned. Aclaris has completed enrollment of more than 1,000 patients across these two trials, and data for both trials are expected in the second half of 2019.
  - An open-label safety extension Phase 3 clinical trial (WART-303) evaluating the long-term safety of A-101 45% Topical Solution as a potential treatment for common warts has also completed enrollment of 425 patients.

- **JAK Inhibitor Trials:**
  - **AA-201 Topical** – This Phase 2 randomized, double-blinded, parallel-group, vehicle-controlled trial evaluated 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. In June 2019, Aclaris announced that ATI-502 did not achieve statistical superiority at the primary or secondary endpoints in this trial due to high rates of disease resolution in vehicle-treated patients. Aclaris currently intends to seek a strategic partner to further develop ATI-502 for this indication.
  - **AGA-201 Topical** – This ongoing Phase 2 open-label uncontrolled 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 were reported in June 2019 and 12-month data are expected in the fourth quarter of 2019. If the 12-month data from this trial are positive, Aclaris currently intends to seek a strategic partner to further develop ATI-502 for this indication.
  - **VITI-201 Topical** – This ongoing Phase 2 open-label uncontrolled 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. Although an interim analysis at 6 months demonstrated evidence of repigmentation in some patients, the response rate has been slow and not sufficient to be clinically meaningful. ATI-502 has been observed to be generally well-tolerated and no treatment-related serious adverse events (SAEs) have been reported to date. Based on this interim analysis, Aclaris has decided to discontinue the further development of ATI-502 for this indication.
  - **AD-201 Topical** – This Phase 2 open-label uncontrolled clinical trial evaluated the safety and efficacy of ATI-502, a topical JAK1/3 inhibitor, in 22 adult subjects with moderate-to-severe atopic dermatitis (AD) (i.e., subjects who had a Physician’s Global Assessment (PGA) score of 3 or 4 on a 5 point scale). The primary objective was the assessment of safety and tolerability of ATI-502. In this trial, ATI-502 was observed to be generally well-tolerated and no treatment-related SAEs were reported. 7 of the 17 evaluable subjects, or 41%, met the secondary endpoint of achieving a PGA score of less than or equal to 1, with at least a two point change in the PGA score.
    - These results suggest that a topical JAK inhibitor emollient-containing solution may be a viable option for the treatment of moderate-to-severe AD. As a result, Aclaris intends to advance ATI-1777, its internally developed investigational topical soft-JAK inhibitor, as a potential treatment for AD. Aclaris currently intends to submit an IND for ATI-1777 to the FDA for the treatment of AD by the end of the first half of 2020 and, if the IND is allowed by the FDA, to commence a Phase 1/2 clinical trial in the second half of 2020.
  - **AUAT-201 Oral** – This Phase 2 randomized, double-blinded, parallel-group, placebo-controlled trial evaluated the safety, efficacy and dose response of three doses of ATI-501, an oral JAK 1/3 inhibitor, on the regrowth of hair in 87 subjects with AA. In July 2019, Aclaris announced that ATI-501 achieved statistically significant improvement over placebo in several measures of hair growth, including the primary endpoint and certain secondary endpoints of this trial. ATI-501 was observed to be generally well-tolerated at all doses. There were no SAEs reported. All adverse events (AEs) were mild or moderate in severity and rates of AEs were similar across all groups. No thromboembolic events were observed in the trial. The most common AEs across all groups were: nasopharyngitis, influenza, upper respiratory tract infection, urinary tract infection, acne, increased blood creatine phosphokinase, and sinusitis. Two subjects in each of the placebo and 400 mg groups and one subject in the 600 mg group had AEs leading to discontinuation of study drug, with no such AEs in the 800 mg group. Aclaris currently intends to seek a strategic partner to further develop ATI-501 for this indication.

- **MK2 Inhibitor Trial:**
  - **ATI-450-PKPD-101** – Aclaris’ IND for ATI-450 for the treatment of RA was allowed by the FDA in May 2019. Aclaris initiated a Single Ascending Dose / Multiple Ascending Dose pharmacokinetic and pharmacodynamic Phase 1 clinical trial of approximately 60 subjects, and announced today that the first patient has been dosed in this trial. If Aclaris successfully completes the Phase 1 clinical trial, Aclaris expects to advance ATI-450 into two Phase 2 clinical trials: one in patients with RA and one in an additional inflammatory indication.

Commercial Update:

- RHOFADE prescriptions for the second quarter of 2019 exceeded 23,200, as estimated per the IQVIA Monthly National Prescription Audit (NPA) data. This is the highest prescription count in a calendar quarter since the fourth quarter of 2017 when the product was owned by Allergan, and represents 12% growth as compared to the first quarter of 2019.
- New prescriptions for RHOFADE achieved growth of 9% in the second quarter of 2019 compared to the first quarter, as estimated per the IQVIA Monthly NPA data.
- Commercial payer coverage for RHOFADE continues to have coverage for 85% of lives and with unrestricted access for 52% of commercially insured lives, according to Managed Markets Insight & Technology data.
- Aclaris today announced that is voluntarily discontinuing the commercialization of ESKATA in the United States, and is withdrawing its marketing authorizations it had previously received for the product in all countries outside of the United States. Aclaris will continue to maintain the NDA for ESKATA in the United States, and is currently seeking a strategic partner to commercialize ESKATA, both in the United States and worldwide (excluding Canada). Aclaris made this decision due to the fact that revenues from product sales were insufficient for Aclaris to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients, and not for efficacy or safety reasons.

Financial Highlights:
Liquidity and Capital Resources

As of June 30, 2019, Aclaris had aggregate cash, cash equivalents and marketable securities of $115.5 million compared to $168.0 million as of December 31, 2018. For the quarter and six months ended June 30, 2019, net cash used in operating activities was $21.4 million and $52.7 million, respectively. As of June 30, 2019, Aclaris had approximately 41.3 million shares of common stock outstanding.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 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.

Second Quarter 2019 and Year-to-Date Financial Results

- Net revenues increased to $5.9 million and $10.9 million for the quarter and six months ended June 30, 2019, compared to $3.7 million and $4.8 million for the quarter and six months ended June 30, 2018.
    - Net RHOFADE sales increased to $4.7 million and $8.4 million for the quarter and six months ended June 30, 2019, respectively. There were no RHOFADE sales in either prior year period as Aclaris acquired the rights to the product in the fourth quarter of 2018.
    - Net ESKATA sales decreased to $0.3 million for both the quarter and six months ended June 30, 2019 from $1.5 million of net ESKATA sales in the quarter and six months ended June 30, 2018. Aclaris launched ESKATA in May 2018.
    - Contract research revenues decreased slightly to $0.9 million and $2.1 million for the quarter and six months ended June 30, 2019, respectively, compared to $1.1 million and $2.3 million for the prior year periods.
    - A one-time upfront milestone payment of $1.0 million received from Cipher Pharmaceuticals was recognized as other revenue for the quarter and six months ended June 30, 2018.
- Cost of revenue, excluding amortization, was $2.7 million and $5.5 million for the quarter and six months ended June 30, 2019, compared to $1.2 million and $2.1 million for the quarter and six months ended June 30, 2018. The amounts for the quarter and six months ended June 30, 2019 included a $0.4 million non-cash charge for the write-down of ESKATA finished inventory. Non-cash amortization expense of the definite-lived intangible asset for RHOFADE intellectual property was $1.7 million and $3.3 million for the quarter and six months ended June 30, 2019, respectively. There was no such expense in either prior year period.
- Aclaris recorded a non-cash goodwill impairment charge of $18.5 million for the quarter and six months ended June 30, 2019 as a result of recent decline in its stock price. There was no impairment charge in either prior year period.
- R&D expenses were $17.6 million and $37.5 million for the quarter and six months ended June 30, 2019, respectively, compared to $14.0 million and $27.6 million for the quarter and six months ended June 30, 2018, respectively. The increases were mainly the result of Aclaris' Phase 3 trials of A-101 45% Topical Solution for the treatment of common warts, which Aclaris initiated in the third quarter of 2018, and preclinical development activities associated with ATI-450, for which Aclaris recently initiated a Phase 1 clinical trial, along with increased headcount to support these programs. These increases were offset in part by decreases in expenses for Aclaris' JAK inhibitor programs, as several Phase 2 clinical trials of ATI-501 and ATI-502 neared their completion in 2019.

- Sales and marketing (S&M) expenses were $7.2 million and $17.0 million for the quarter and six months ended June 30, 2019, respectively, compared to $12.4 million and $23.6 million for the quarter and six months ended June 30, 2018, respectively. The decreases of $5.2 million and $6.6 million for the quarter and six months ended June 30, 2019, respectively, were mainly due to a reduction in direct marketing and professional fees, which were incurred last year related to the preparation for the commercial launch of ESKATA in May 2018. Personnel related costs, including stock-based compensation, also decreased in 2019 due to turnover in our sales force during the first half of this year. These decreases were partially offset by increases in marketing costs for RHOFADE which were incurred in 2019 to support product re-launch initiatives.

- General and administrative (G&A) expenses were $8.0 million and $16.2 million for the quarter and six months ended June 30, 2019, respectively, compared to $8.1 million and $14.4 million for the quarter and six months ended June 30, 2018, respectively. The prior year periods included a one-time $1.5 million commercial milestone payment that we made to a licensor. The increases of $1.4 million and $3.3 million, excluding the milestone payment, were mainly due to additional professional and legal fees, which included costs incurred under the transition services agreement with Allergan related to RHOFADE. Both personnel expenses and medical affairs activities also increased during the quarter and six months ended June 30, 2019 in order to support Aclaris' increased commercial activity since 2018.

- Total costs and expenses for the second quarter of 2019 were $55.7 million, compared to $35.7 million for the second quarter of 2018. For the six months ended June 30, 2019, total costs and expenses were $98.0 million, compared to $67.7 million for the same period in 2018. These amounts included non-cash stock-based compensation of $4.8 million and $9.7 million for the quarter and six months ended June 30, 2019, respectively, compared to $5.2 million and $10.4 million for the prior year periods, respectively.

- Net loss was $49.9 million for the second quarter of 2019, which included the $18.5 million non-cash goodwill impairment charge, compared to net loss of $31.2 million for the second quarter of 2018. Net loss was $87.4 million for the first half of 2019, compared to $61.4 million for the first half of 2018.

2019 Financial Outlook

- Aclaris reiterates that it expects 2019 GAAP R&D expenses to be in the range of $61 to $64 million, including estimated stock-based compensation of $7 million.

- Aclaris now expects decreased 2019 GAAP S&M expenses to be in the range of $32 to $35 million, including stock-based compensation of $3 million, compared to its original estimate of $37 to $40 million, including estimated stock-based compensation of $4 million.

- Aclaris reiterates that it expects 2019 GAAP G&A expenses to be in the range of $29 to $31 million, including estimated stock-based compensation of $10 million.

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 3391498prior 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. 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," "intend," "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 product(s), the clinical development of Aclaris' drug candidates, including the availability of data from its ongoing clinical trials, timing for initiation of planned clinical trials and timing for regulatory submissions, seeking a third-party partner to commercialize ESKATA and further develop ATI-501 and ATI-502, the strategic direction of its business, estimated R&D, S&M and G&A 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 the commercialization of products, Aclaris' reliance on third parties over which it may not always have full control, Aclaris' ability to enter into strategic partnerships on commercially reasonable terms 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, the Form 10-Q for the quarter ended June 30, 2019, 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.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales, net	$ 4,979	$ 1,533	$ 8,757	$ 1,533
Contract research	886	1,143	2,149	2,261
Other revenue	—	1,000	—	1,000
Total revenues, net	5,865	3,676	10,906	4,794
Costs and expenses:				
Cost of revenue (excludes amortization) (1)	2,703	1,181	5,480	2,148
Research and development (1)	17,622	13,984	37,541	27,590
Sales and marketing (1)	7,177	12,368	17,008	23,601
General and administrative (1)	7,990	8,121	16,180	14,381
Goodwill impairment	18,504	—	18,504	—
Amortization of definite-lived intangible	1,660	—	3,319	—
Total costs and expenses	55,656	35,654	98,032	67,720
Loss from operations	(49,791)	$ (31,978)	(87,126)	(62,926)
Other (expense) income, net	(85)	760	(315)	1,479
Net loss	$ (49,876)	$ (31,218)	$ (87,441)	$ (61,447)
Net loss per share, basic and diluted	$ (1.21)	$ (1.01)	$ (2.12)	$ (1.99)
Weighted average common shares outstanding, basic and diluted	41,274,808	30,944,899	41,261,808	30,915,577

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

Cost of revenue	$ 223	$ 190	$ 429	$ 366
Research and development	1,721	1,756	3,315	3,483
Sales and marketing	216	1,020	806	1,927
General and administrative	2,654	2,283	5,126	4,616
Total stock-based compensation expense	$ 4,814	$ 5,249	$ 9,676	$ 10,392

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

	June 30, 2019	**December 31, 2018**
Cash, cash equivalents and marketable securities	$ 115,517	$ 167,972
Total assets	217,239	275,566
Total current liabilities	42,748	27,342
Total liabilities	80,009	60,442
Total stockholders' equity	137,230	215,124

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Source: Aclaris Therapeutics, Inc.