Aclaris Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides R&D and Business Highlights

February 25, 2020

- ***Positive Preliminary Results from Phase 1 Single and Multiple Ascending Dose Trial of ATI-450, an Investigational Oral MK2 Inhibitor***
- ***Projected Cash Runway into the Third Quarter of 2021***
- ***Management to Host Conference Call at 5:00 PM ET today***

WAYNE, Pa., Feb. 25, 2020 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, today announced its financial results for the fourth quarter and full year 2019 and provided research and development (R&D) and business highlights.

"In 2019, we repositioned the company to focus on our core competency in developing small molecule kinase inhibitors. Thus far, we are very pleased with the progression of our immuno-inflammatory pipeline, as well as with the positive results from our Phase 1 clinical trial of ATI-450, an oral small molecule MK2 inhibitor," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. "We look forward to initiating a Phase 2a trial of ATI-450 in subjects with rheumatoid arthritis in the first half of this year and executing on our new business plan."

R&D Highlights:

- **ATI-450**:
  - ATI-450 is an investigational oral small molecule MK2 inhibitor.
  - **ATI-450-PKPD-101:** A Phase 1 single and multiple ascending dose (SAD/MAD) trial to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of orally administered ATI-450 in 77 healthy subjects.
    - Preliminary data from this trial demonstrated that ATI-450:
      - resulted in marked inhibition of TNFα, IL1β, IL8, and IL6;
      - was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received ATI-450) observed during the trial were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain, and nausea;
      - had dose-proportional pharmacokinetics (PK) with a terminal half-life of 9-12 hours in the MAD cohort; and
      - had no meaningful food effect or drug-drug interaction with methotrexate.
  - **ATI-450-RA-201**: Aclaris intends to initiate a Phase 2a clinical trial for ATI-450 in subjects with rheumatoid arthritis in the first half of 2020.
  - Aclaris is also planning to initiate a Phase 2a clinical trial of ATI-450 for an additional immuno-inflammatory indication.

- **ATI-1777:**
  - ATI-1777 is an investigational topical soft-Janus Kinase (JAK) inhibitor compound that Aclaris is developing as a potential treatment for moderate-to-severe atopic dermatitis.
  - Aclaris expects to submit an IND for ATI-1777 for the treatment of atopic dermatitis in mid-2020.
  - If the IND is allowed, Aclaris expects to initiate a Phase 1/2 clinical trial in both healthy subjects and subjects with atopic dermatitis in the second half of 2020 evaluating ATI-1777 as a potential topical treatment for moderate-to-severe atopic dermatitis.

- **ATI-2138:**
  - ATI-2138 is an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor compound that Aclaris is developing as a potential treatment for psoriasis and/or inflammatory bowel disease.
  - Aclaris expects to submit an IND for ATI-2138 in the fourth quarter of 2020 or the first quarter of 2021.

Corporate Highlights:

- Divested RHOFADE (oxymetazoline hydrochloride) cream, 1% to EPI Health, LLC and repaid in full $30 million term loan with Oxford Finance LLC, in October 2019.
- Appointed Vincent Milano to the Board in January 2020.

Business Development Highlights:

- Aclaris continues to pursue strategic alternatives, including seeking partners for:
    - **A-101 45% Topical Solution**: to obtain regulatory approval and commercialize A-101 45% Topical Solution, an investigational compound, as a potential treatment for common warts (verruca vulgaris);
    - **ATI-501 & ATI-502:** to further develop, obtain regulatory approval and commercialize ATI-501 (oral) and ATI-502 (topical), investigational JAK 1/3 inhibitor compounds, as potential treatments for alopecia; and
    - **ESKATA:** to commercialize ESKATA® (hydrogen peroxide) topical solution, 40% (w/w).

Financial Highlights:
Liquidity and Capital Resources

As of December 31, 2019, Aclaris had aggregate cash, cash equivalents and marketable securities of $75.0 million compared to $168.0 million as of December 31, 2018. For the quarter and year ended December 31, 2019, net cash used in operating activities was $20.4 million and $96.4 million, respectively. As of December 31, 2019, Aclaris had no long-term debt outstanding and had approximately 41.5 million shares of common stock outstanding.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of December 31, 2019, will be sufficient to fund its operations into the third quarter of 2021, without giving effect to any potential business development transactions or financing activities.

Fourth Quarter 2019 and Year-to-Date Financial Results

- The accompanying consolidated statements of operations and selected consolidated balance sheet data have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to Aclaris' commercial products as discontinued operations. The accompanying financial statement data are generally presented in conformity with Aclaris' historical format. Aclaris believes this format provides comparability with its previously filed financial statements.
- Total costs and expenses from continuing operations for the fourth quarter of 2019 were $18.4 million, compared to $26.9 million for the fourth quarter of 2018. For the year ended December 31, 2019, total costs and expenses were $115.3 million, compared to $90.9 million in 2018.
    - These amounts included non-cash stock-based compensation expenses of $3.2 million and $16.1 million for the quarter and year ended December 31, 2019, respectively, compared to $4.2 million and $16.6 million for the prior year periods, respectively.
    - For the year ended December 31, 2019, there was also a $18.5 million non-cash charge for the impairment of goodwill. There was no such charge in the prior year.
- R&D expenses were $11.5 million and $64.9 million for the quarter and year ended December 31, 2019, respectively, compared to $19.0 million and $60.8 million for the quarter and year ended December 31, 2018, respectively.
    - The year-over-year fourth quarter decrease of $7.5 million was mainly the result of Aclaris' Phase 2 clinical trials of ATI-501 and ATI-502 and two pivotal Phase 3 clinical trials of A-101 45% Topical Solution, which were at or near completion in the third quarter of 2019, as well as a reduction in personnel-related costs.
    - These reductions were offset by increased expenses related to Aclaris' preclinical development programs and the Phase 1 clinical trial for ATI-450 which was initiated in 2019, and by a milestone expense related to one of Aclaris' licensing agreements.
- General and administrative expenses were $5.8 million and $27.2 million for the quarter and year ended December 31, 2019, respectively, compared to $6.6 million and $25.6 million for the quarter and year ended December 31, 2018, respectively.
- Loss from continuing operations was $19.2 million for the fourth quarter of 2019, compared to $24.7 million for the fourth quarter of 2018. Loss from continuing operations was $113.5 million for the year ended December 31, 2019, compared to $82.1 million for the year ended December 31, 2018.
- The gain from discontinued operations was $0.6 million for the fourth quarter of 2019, compared to a loss of $13.9 million for the fourth quarter of 2018. The loss from discontinued operations was $47.8 million for the year ended December 31, 2019, compared to $50.6 million for the year ended December 31, 2018.
- Net loss was $18.6 million for the fourth quarter of 2019, compared to net loss of $38.6 million for the fourth quarter of 2018, and was $161.4 million for the year ended December 31, 2019, compared to $132.7 million for the year ended December 31, 2018.

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 9958112 prior 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 patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates 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 clinical development of Aclaris’ drug candidates, including the availability of data from its clinical trials, timing for initiation of clinical trials and timing for regulatory filings, its plan to pursue strategic alternatives for its drug candidates and for ESKATA, and its belief that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into the third quarter of 2021. 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, 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, 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.
Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales, net	$ —	$ —	$ —	$ —
Contract research	1,095	1,272	4,227	4,651
Other revenue	—	500	—	1,500
Total revenue, net	1,095	1,772	4,227	6,151
Costs and expenses:				
Cost of revenue (1)	1,028	1,266	4,055	4,329
Research and development (1)	11,540	19,022	64,899	60,841
Sales and marketing (1)	44	82	671	170
General and administrative (1)	5,765	6,561	27,156	25,591
Goodwill impairment	—	—	18,504	—
Amortization of definite-lived intangible	—	—	—	—
Total costs and expenses	18,377	26,931	115,285	90,931
Loss from operations	(17,282)	(25,159)	(111,058)	(84,780)
Other (expense) income, net	(1,895)	487	(2,484)	2,676
Loss from continuing operations	(19,177)	(24,672)	(113,542)	(82,104)
Gain / (loss) from discontinued operations (1)	583	(13,879)	(47,812)	(50,634)
Net loss	$ (18,594)	$ (38,551)	$ (161,354)	$ (132,738)
Net loss per share, basic and diluted	$ (0.45)	$ (0.99)	$ (3.90)	$ (4.03)
Weighted average common shares outstanding, basic and diluted	41,405,657	38,760,676	41,323,921	32,909,762

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

Cost of revenue	$ 249	$ 206	$ 703	$ 766
Research and development	358	1,564	5,091	6,480
Sales and marketing	—	—	—	—
General and administrative	2,581	2,381	10,288	9,317
Gain / (loss) from discontinued operations	(7)	805	95	3,492
Total stock-based compensation expense	$ 3,181	$ 4,956	$ 16,177	$ 20,055

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 75,015	$ 167,972
Total assets	98,297	275,566
Total current liabilities	22,432	27,342
Total liabilities	28,385	60,442
Total stockholders' equity	69,912	215,124

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Source: Aclaris Therapeutics, Inc.