# Aclaris Therapeutics Reports Second Quarter 2018 Financial Results and Provides Update on Clinical and Commercial Developments

August 3, 2018

***Management to Host Conference Call at 8:00 AM ET today***

WAYNE, Pa., Aug. 03, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology, today announced financial results for the second quarter of 2018 and provided an update on its clinical development and commercial programs.

- During the second quarter of 2018 Aclaris launched ESKATA® (hydrogen peroxide) Topical Solution, 40% (w/w), recording $1.5 million in net product sales.
- In July, Aclaris held an end of Phase 2 meeting with the FDA regarding A-101 45% Topical Solution (A-101 45%) for the treatment of common warts (verruca vulgaris) and is on track to start its planned Phase 3 program in the second half of 2018.
- Aclaris is seeing encouraging results which validate the topical approach in the ongoing open label studies of its topical Janus kinase (JAK) inhibitor ATI-502 in patients with Alopecia Areata (AA) and the more severe and refractory phenotypes - Alopecia Totalis (AT) and Alopecia Universalis (AU).
- Aclaris remains confident in the ongoing AA-201 Topical trial of ATI-502 in patients with the less severe phenotype of patchy AA, data from which is expected in the first half of 2019.
- Aclaris recently started a Phase 2 clinical trial of its investigational JAK inhibitor ATI-501 oral suspension in patients with AA, including AT and AU.

“The second quarter represents an important milestone with the launch of ESKATA. This is an exciting time for Aclaris as we establish ourselves as a fully integrated commercial organization with a robust clinical-stage pipeline and drug discovery engine,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

**Commercial Update:**

Sales Force Activity:

- Sales force focused on driving clinical and business integration in ESKATA accounts; ongoing in-service programs to support successful training and product integration.
- Over 800 ESKATA accounts opened to date
- Over 40 ESKATA peer-to-peer speaker programs conducted to date

ESKATA Campaign Highlights:

- ESKATA branded HCP journal ads introduced in major dermatology journals
- Supported 30 conferences in the second quarter of 2018.
- Continued positive feedback from ESKATA Early Experience Initiative (EEI) captured in physician and patient post-application surveys.

**Clinical Pipeline Update:**

- **A-101 45% Topical Solution**
  - Completed an End of Phase 2 meeting with the FDA in July and plan to initiate a Phase 3 program for the treatment of common warts in the second half of 2018.

- **JAK Inhibitor Trials:**
  - **AA-202 Topical** –
    - An ongoing Phase 2 clinical trial of ATI-502 for the topical treatment of AA. Recently reported interim pharmacokinetic and pharmacodynamic results for 6 of the 11 enrolled patients; two patients have withdrawn.
    - After completing the 28-day portion of the trial, patients entered a 6-month open label extension during

which all patients will receive drug.
    - Demonstrated drug levels in skin and pharmacodynamic effect as measured by RNA sequencing.
    - Evidence of hair regrowth in the open label extension portion of this study has been observed.
    - Safety results - generally well-tolerated; no treatment related serious adverse events reported to date.
    - The range of time on drug for the nine patients in the open label extension is 6 to 20 weeks.

  - **AUATB-201 Topical** – an ongoing Phase 2 open-label clinical trial of ATI-502 for the topical treatment of AA in Australia. In this trial Aclaris is evaluating the efficacy of ATI-502 on the regrowth of eyebrows in patients with AA, including AT and AU. Interim update:
    - 12 patients enrolled; 2 patients have withdrawn.
    - Evidence of early signs of hair regrowth has been observed.
    - Safety results - generally well-tolerated; no treatment-related serious adverse events reported to date.
    - The range of time on drug for the 10 patients is 5 to 23 weeks.

  - **AA-201 Topical** – an ongoing Phase 2 dose ranging trial of ATI-502 for the topical treatment of AA. This trial will evaluate the efficacy 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 in the United States and data are expected in the first half of 2019.

  - **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 efficacy 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** – an ongoing 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. This trial will evaluate the efficacy of ATI-502 on the regrowth of hair in up to 24 patients with AGA and data are expected in the first half of 2019.

- **AUAT-201 Oral** – an ongoing Phase 2 dose ranging trial of ATI-501, an oral JAK inhibitor for the treatment of AA. This trial will evaluate the efficacy of two concentrations of ATI-501 on the regrowth of hair in a randomized, double-blinded, parallel-group, vehicle-controlled trial in up to 80 patients with AA. This trial will be conducted in the United States and data are expected in the second half of 2019.

- **AD-201 Topical –** the first patient has been dosed in an ongoing Phase 2 clinical trial of ATI-502 in patients with atopic dermatitis (AD). This open label trial will evaluate the safety, tolerability and efficacy of ATI-502 applied twice daily to affected skin for four weeks in up to 30 adult subjects with moderate-to-severe AD. This trial will be conducted in the United States and data are expected in mid-2019.

- **ATI-450 (MK-2 Inhibitor)**
  - Investigational New Drug application on track for submission to the FDA in mid-2019.

**Recent Corporate Highlights**

- Presented at the recent American Hair Research Society (AHRS) and International Investigative Dermatology (IID) meetings.
- United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,980,983 covering methods of treating seborrheic keratosis using a stabilized hydrogen peroxide composition. This patent is listed in the Orange Book for ESKATA and is set to expire in April 2035, subject to any patent term adjustment or extension.
- Received Fast Track designation for ATI-502 for the treatment of AA, including patchy AA, AT and AU.
- Appointed David Gordon, MB, ChB, as Chief Medical Officer.

**Financial Highlights**

***Second Quarter 2018 Financial Results***

- For the quarter ended June 30, 2018, total net revenues were $3.7 million, which consisted of ESKATA sales of $1.5 million, contract research revenues of $1.1 million, and other revenue of $1.0 million. For the six months ended June 30, 2018, total net revenues were $4.8 million, which consisted of ESKATA sales of $1.5 million, contract research revenues of $2.3 million, and other revenue of $1.0 million. Cost of revenues for the quarter and six months ended June 30, 2018 were $1.2 million and $2.1 million, respectively. There were no revenues or cost of revenues in either prior year period.

- For the quarter ended June 30, 2018, total operating expenses were $34.5 million, compared to $15.3 million for the second quarter of 2017. For the six months ended June 30, 2018, total operating expenses were $65.6 million, compared

to $28.2 million for the same period in 2017.

- Research and development (R&D) expenses for the quarter and six months ended June 30, 2018 were $14.0 million and $27.6 million, respectively, compared to $8.0 million and $15.7 million, respectively, for the same periods of 2017. The increases of $6.0 million and $11.9 million, respectively, were mainly the result of the expansion of Aclaris' JAK inhibitor programs, as multiple Phase 2 trials of ATI-501 and ATI-502 are ongoing in 2018, as well as medical affairs activities and drug discovery programs, both of which were not incurred in 2017. Personnel related expenses, including stock-based compensation, also increased due to increased headcount to support these programs and as the result of the acquisition of Confluence in August 2017.

- Sales and marketing (S&M) expenses for the quarter and six months ended June 30, 2018 were $12.4 million and $23.6 million, respectively, compared to $2.2 million and $3.6 million, respectively, for the same periods of 2017. The increases of $10.2 million and $20.0 million, respectively, were mainly the result of increases in direct marketing and professional fees, as well as other commercial expenses incurred in preparation for the launch of ESKATA, which occurred in May 2018. Personnel expenses, including stock-based compensation, increased as Aclaris completed the hiring of its field sales force in the first quarter of 2018.

- General and administrative (G&A) expenses for the quarter and six months ended June 30, 2018 were $8.1 million and $14.4 million, respectively, compared to $5.1 million and $8.9 million, respectively, for the same periods of 2017. The increases of $3.0 million and $5.5 million, respectively, were mainly the result of higher personnel-related expenses, including stock-based compensation, due to increased headcount to support the commercial launch of ESKATA, and as the result of the acquisition of Confluence in August 2017. G&A expenses for the quarter and six months ended June 30, 2018 also included a $1.5 million payment based on an ESKATA-related milestone, whereas the quarter and six months ended June 30, 2017 included a $1.0 million ESKATA-related milestone payment.

- For the quarter ended June 30, 2018, net loss was $31.2 million, or $1.01 per basic and diluted share, as compared to $14.8 million, or $0.56 per basic and diluted share, for the second quarter of 2017. For the six months ended June 30, 2018, net loss was $61.4 million, or $1.99 per basic and diluted share, as compared to $27.4 million, or $1.04 per basic and diluted share, for the same period of 2017.

***Liquidity and Capital Resources***

As of June 30, 2018, Aclaris had aggregate cash, cash equivalents and marketable securities of $164.6 million compared to $208.9 million as of December 31, 2017.

Aclaris anticipates that its cash, cash equivalents and marketable securities as of June 30, 2018 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.

**2018 Financial Outlook**

- Aclaris reiterated its expected 2018 GAAP R&D expenses to be in the range of $67 to $75 million, including estimated stock-based compensation of $9 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 the development of Aclaris' early stage pipeline compounds.

- Aclaris reiterated its expected 2018 GAAP selling, general and administrative (SG&A) expenses, which combine its Sales & marketing, and General & administrative line items, to be in the range of $80 to $86 million, including estimated stock-based compensation of $14 million. The anticipated increase in SG&A expenses in 2018 is primarily the result of the deployment of Aclaris' 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 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 8189419 prior to the start of the call.**

**About Aclaris Therapeutics, Inc.**
Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology. Aclaris' focus on market segments with no

FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised SKs and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

**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, the clinical development of its 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 and selling, general and administrative expenses for 2018 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 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 Reporting" 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, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Revenues: | | | | |
| ESKATA product sales, net | $ 1,533 | $ - | $ 1,533 | $ - |
| Contract research | 1,143 | - | 2,261 | - |
| Other revenue | 1,000 | - | 1,000 | - |
| Total revenues, net | 3,676 | - | 4,794 | - |
| Cost of revenue | 1,181 | - | 2,148 | - |
| Gross profit | 2,495 | - | 2,646 | - |
| Operating expenses: | | | | |
| Research and development (1) | 13,984 | 7,965 | 27,590 | 15,737 |
| Sales and marketing (1) | 12,368 | 2,188 | 23,601 | 3,626 |
| General and administrative (1) | 8,121 | 5,142 | 14,381 | 8,862 |
| Total operating expenses | 34,473 | 15,295 | 65,572 | 28,225 |
| Loss from operations | (31,978) | (15,295) | (62,926) | (28,225) |
| Other income, net | 760 | 457 | 1,479 | 828 |
| Net loss | $ (31,218) | $ (14,838) | $ (61,447) | $ (27,397) |
| Net loss per share, basic and diluted | $ (1.01) | $ (0.56) | $ (1.99) | $ (1.04) |
| Weighted average common shares outstanding, basic and diluted | 30,944,899 | 26,594,854 | 30,915,577 | 26,339,250 |

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

| | | | | |
|---|---|---|---|---|
| Cost of revenue | $ 190 | $ - | $ 366 | $ - |
| Research and development | 1,756 | 1,304 | 3,483 | 2,521 |
| Sales and marketing | 1,020 | 400 | 1,927 | 780 |
| General and administrative | 2,283 | 1,600 | 4,616 | 3,156 |
| Total stock-based compensation expense | $ 5,249 | $ 3,304 | $ 10,392 | $ 6,457 |

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

| | **June 30, 2018** | **December 31, 2017** |
|---|---|---|

| | | |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 164,604 | $ 208,854 |
| Total assets | 201,819 | 243,509 |
| Total current liabilities | 20,069 | 12,762 |
| Total liabilities | 27,616 | 18,247 |
| Total stockholders' equity | 174,203 | 225,262 |

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Source: Aclaris Therapeutics, Inc.