# Akero Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

March 16, 2020

SAN FRANCISCO, March 16, 2020 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic non-alcoholic steatohepatitis (NASH) Company developing pioneering medicines designed to restore metabolic balance and improve overall health of NASH patients, today reported fourth quarter and full year financial results for the period ending December 31, 2019.

"We saw in 2019 a period of continued clinical and manufacturing progress for Akero, driven by precision execution by our team," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "Our rapid progress combined with a strong cash position provide the foundation for the continued development of AKR-001, which we believe has the potential to become a cornerstone of NASH treatment."

**Fourth Quarter Business Highlights**

- Enrollment was completed in the Phase 2a BALANCED study in NASH patients. The Company remains on track to report results of the BALANCED study's primary endpoint in the first quarter of 2020. Top-line results related to secondary endpoints, including safety and tolerability as well as paired biopsies for patients who achieve at least 30% relative reduction in liver fat at week 12, will be reported in the second quarter of 2020.
- The Company has successfully manufactured AKR-001 drug substance at commercial scale as an engineering run at Boehringer Ingelheim. Yield was comparable to the Good Manufacturing Practice (GMP) drug substance originally manufactured by Amgen. Analysis of the drug substance produced by Boehringer Ingelheim confirmed it met the same release specification as previously used for Amgen GMP drug substance. The Company expects to release drug product produced in compliance with current GMP requirements by the fourth quarter of 2020.

**Full Year and Fourth Quarter 2019 Financial Results**

- Akero's cash, cash equivalents and short-term marketable securities at December 31, 2019 were $136.4 million.
- Research and development expenses for the three-month and twelve-month periods ended December 31, 2019 were $13.1 million and $37.0 million, respectively, compared to $2.0 million and $11.9 million for the comparable periods in 2018. These increases are attributable to higher costs related to Akero's AKR-001 program, including third-party contract manufacturing, contract research organization costs associated with the BALANCED study and internal personnel costs.
- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2019 were $3.1 million and $8.6 million, respectively, compared to $1.0 million and $1.9 million for the comparable periods in 2018. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with becoming a public company.
- Total operating expenses were $16.2 million and $45.7 million for the three-month and twelve-month periods ended December 31, 2019, respectively, compared to $3.0 million and $13.8 million for the comparable periods in 2018.

**About NASH**

NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) and is estimated to affect 17 million Americans. NASH is closely linked to the obesity and diabetes epidemics seen around the world. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. The progressive damage to the liver associated with NASH closely resembles damage caused by excessive alcohol consumption or viral infections, and the disorder is a leading cause of liver transplants in the US and Europe.

**About AKR-001**

AKR-001 is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2a BALANCED study. AKR-001 is designed to increase insulin sensitivity, improve lipoproteins, reduce liver fat and inflammation, and reverse fibrosis. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in physiological parameters linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, AKR-001 offers convenient once-weekly

dosing and has been well-tolerated in clinical studies to date.

**About Akero Therapeutics**

Akero is a cardio-metabolic NASH Company dedicated to reversing the escalating NASH epidemic by developing pioneering medicines designed to restore metabolic balance and improve overall health of NASH patients. The Company's lead product candidate, AKR-001 is currently being evaluated in an ongoing Phase 2a clinical trial. Akero Therapeutics is headquartered in San Francisco, CA. For more information, please visit www.akerotx.com.

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding the Company's business plans and objectives, including future plans or expectations for AKR-001 and the BALANCED study, upcoming milestones, and therapeutic effects of AKR-001; expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for AKR-001; expectations for successful completion of nonclinical studies; expectations regarding successful scale-up of drug substance manufacturing and release of new drug product for use in clinical trials; expectations regarding the Company's use of capital, expenses and other future financial results and plans related to development of the Company's current and future product candidates. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's most recently-filed Quarterly Report on 10-Q, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in Akero's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**Akero Therapeutics, Inc.**
**Condensed Consolidated Balance Sheets**
**(Unaudited)**
**(In thousands)**

| | December 31, | |
|---|---|---|
| | **2019** | **2018** |
| **Assets** | | |
| Cash, cash equivalents and short-term marketable securities | $ 136,400 | $ 75,975 |
| Other current assets | 1,649 | 1,156 |
| Non-current assets | 69 | 20 |
| Total assets | $ 138,118 | $ 77,151 |
| **Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)** | | |
| Current liabilities | $ 9,369 | $ 2,342 |
| Non-current liabilities | 23 | — |
| Redeemable convertible preferred stock | — | 124,728 |
| Stockholders' equity (deficit) | 128,726 | (49,919) |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | $ 138,118 | $ 77,151 |

**Akero Therapeutics, Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(Unaudited)**
**(In thousands, except share and per share amounts)**

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Operating expenses: | | | | |
| Research and development | $ 13,138 | $ 1,983 | $ 37,046 | $ 11,882 |
| General and administrative | 3,083 | 985 | 8,605 | 1,896 |
| Total operating expenses | 16,221 | 2,968 | 45,651 | 13,778 |
| Loss from operations | (16,221) | (2,968) | (45,651) | (13,778) |
| Other income (expense), net | 610 | (58,504) | 1,896 | (67,936) |
| Net loss | $ (15,611) | $ (61,472) | $ (43,755) | $ (81,714) |
| Comprehensive loss | $ (15,617) | $ (61,472) | $ (43,761) | $ (81,714) |
| Net loss attributable to common stockholders | $ (15,611) | $ (61,671) | $ (43,755) | $ (82,234) |
| Net loss per share attributable to common stockholders - basic and diluted | $ (0.55) | $ (449.52) | $ (2.90) | $ (795.28) |
| Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted | 28,335,405 | 137,194 | 15,070,728 | 103,403 |

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