Akero Therapeutics Reports Recent Highlights and Third Quarter 2019 Financial Results

November 12, 2019

SAN FRANCISCO, Nov. 12, 2019 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage biotechnology company developing transformational treatments for patients with non-alcoholic steatohepatitis (NASH) and other serious metabolic disorders, today reported third quarter 2019 financial results for the period ending September 30, 2019.

"The third quarter of 2019 was a period of continued clinical and manufacturing progress for Akero," said Andrew Cheng, M.D., Ph.D., President and Chief Executive Officer. "We remain on track to report results of the BALANCED study's primary endpoint in the first quarter of 2020 and full study results in the second quarter of 2020. We have successfully completed laboratory-scale transfer of AKR-001 drug substance manufacturing to Boehringer Ingelheim with yield and biological activity comparable to the drug substance originally manufactured by Amgen. We expect to release drug product produced in compliance with current good manufacturing practice requirements and to complete all nonclinical toxicology studies required to support a Phase 2b trial by the fourth quarter of 2020. These actions – and our $147.8 million cash position – provide a strong foundation for the continued development of AKR-001, which we believe has the potential to become a cornerstone of NASH treatment."

Third Quarter 2019 Financial Results

- Akero's cash and cash equivalents at September 30, 2019 were $147.8 million.
- Research and development expenses for the three-month and nine-month periods ended September 30, 2019 were $13.9 million and $23.9 million, respectively, compared to $1.2 million and $9.9 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 nine-month periods ended September 30, 2019 were $2.4 million and $5.5 million, respectively, compared to $0.5 million and $0.9 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 $16.3 million and $29.4 million for the three-month and nine-month periods ended September 30, 2019, respectively, compared to $1.7 million and $10.8 million for the comparable periods in 2018.

About NASH

NASH is a leading cause of liver failure around the world, driven by the growing global epidemic of obesity. NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) characterized by liver cell (hepatocyte) damage, liver inflammation, and fibrosis that can progress to cirrhosis, liver failure, cancer and death.

About AKR-001

AKR-001 is an engineered human Fc-FGF21 fusion protein designed to harness the inherent benefits of an endogenous hormone called FGF21, with the potential to reduce liver fat, mitigate inflammation, and reverse fibrosis in NASH patients. AKR-001 is uniquely designed to deliver sustained signaling through FGF21's receptors with once-weekly subcutaneous dosing.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage biotechnology company focused on the development and commercialization of transformative treatments for patients with NASH and other serious metabolic diseases with high unmet medical need. The Company's lead program AKR-001 is being evaluated in a Phase 2a clinical trial for the treatment of NASH. 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 the final prospectus dated June 19, 2019 and filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the United States Securities and Exchange Commission (SEC) and elsewhere in Akero's

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)

	September 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 147,835	$ 75,975
Other current assets	2,238	1,156
Non-current assets	70	20
Total assets	$ 150,143	$ 77,151
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities	$ 6,725	$ 2,342
Non-current liabilities	34	—
Redeemable convertible preferred stock	—	124,728
Stockholders' equity (deficit)	143,384	(49,919)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 150,143	$ 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 13,885	$ 1,253	$ 23,908	$ 9,899
General and administrative	2,424	474	5,522	911
Total operating expenses	16,309	1,727	29,430	10,810
Loss from operations	(16,309)	(1,727)	(29,430)	(10,810)
Other income (expense), net	755	(9,421)	1,286	(9,432)
Net loss and comprehensive loss	$ (15,554)	$ (11,148)	$ (28,144)	$ (20,242)
Net loss attributable to common stockholders	$ (15,554)	$ (11,399)	$ (28,144)	$ (20,563)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.56)	$ (89.66)	$ (2.66)	$ (236.67)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	28,024,779	127,141	10,589,119	86,884

View original content to download multimedia:http://www.prnewswire.com/news-releases/akero-therapeutics-reports-recent-highlights-and-third-quarter-2019-financial-results-300955617.html

SOURCE Akero Therapeutics, Inc.

Media Contact: Marites Coulter, Verge Scientific Communications, 415.819.2214, mcoulter@vergescientific.com; Investor Contact: Christina Tartaglia, Stern Investor Relations, 212-362-1200, akero@sternir.com