Akero Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results

March 16, 2021

SOUTH SAN FRANCISCO, Calif., March 16, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for non-alcoholic steatohepatitis (NASH), today reported fourth quarter and full year financial results for the period ending December 31, 2020.

"In 2020 we reported strong results from our Phase 2a BALANCED study in biopsy-confirmed NASH patients suggesting that our lead asset, efruxifermin (EFX), has the potential to be a foundational monotherapy for treatment of NASH," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "We have been particularly pleased with biopsy data that showed rapid improvements in both fibrosis and NASH resolution and look forward to reporting additional biopsy data among cirrhotic patients by April of this year."

Fourth Quarter Business Highlights

- During the fourth quarter, the Company reported additional analyses for the main portion of the Phase 2a BALANCED study, including proportion of patients who achieved 50% and 70% relative reductions in liver fat, and extent of improvement in fibrosis among patients with F2 or F3 fibrosis at baseline and of glycemic control among patients with Type 2 diabetes mellitus.
- Among all EFX-treated patients who were fibrosis stage F2 or F3 at baseline (n=22), 50% experienced a two-stage improvement in fibrosis (n=11), while 68% experienced at least a one-stage improvement in fibrosis (n=15).
- Based on these rapid improvements in fibrosis observed after only 16 weeks of treatment, the Company believes that EFX has the potential to play an important role in reversing fibrosis for NASH patients.

Phase 2a BALANCED Study Cohort C Update

- Data collection for Cohort C of the BALANCED study, including voluntary end-of-treatment biopsies, was completed in February 2021.
- The Company expects to report preliminary results from Cohort C by April 2021, including safety and tolerability of EFX along with analyses of paired biopsies and non-invasive measures of liver health.

Phase 2b HARMONY Study Update

- Screening of subjects for the HARMONY study, a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3, began in February 2021.
- The Company expects to complete enrollment in 2021 and report preliminary results in the second half of 2022.

Regulatory Update

- An end-of-phase 2 meeting with the U.S. Food and Drug Administration (FDA) to review HARMONY study results and finalize the proposed Phase 3 protocol, including dose selection and study size, will be requested prior to initiating Phase 3.

Manufacturing Update

- Drug substance manufactured by Akero for use in the Phase 2b HARMONY study has been shown to be comparable to that previously manufactured by Amgen.
- The Company anticipates that a lyophilized formulation of drug product will be available for Phase 3 initiation in the first half of 2023.

COVID-19 Update

- The Company’s financial results for the year ended December 31, 2020 were not significantly impacted by COVID-19.
- The COVID-19 pandemic did not materially impact data collection for Cohort C, ongoing enrollment in the Phase 2b HARMONY study or manufacturing of drug substance.

Full Year and Fourth Quarter 2020 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the year ended December 31, 2020 were $268.4 million.

- Research and development expenses for the three-month and twelve-month periods ended December 31, 2020 were $25.7 million and $64.9 million, respectively, compared to $13.1 million and $37.0 million for the comparable periods in 2019. These increases are attributable to higher costs related to Akero's EFX program, including third-party contract manufacturing, contract research organization costs associated with the BALANCED and HARMONY studies and internal personnel costs.
- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2020 were $4.1 million and $15.2 million, respectively, compared to $3.1 million and $8.6 million for the comparable periods in 2019. These increases are attributable to higher expenses for personnel, including non-cash stock-based compensation, and professional services and other costs associated with operating as a public company.
- Total operating expenses were $29.8 million and $80.2 million for the three-month and twelve-month periods ended December 31, 2020, respectively, compared to $16.2 million and $45.7 million for the comparable periods in 2019.

About NASH
Non-alcoholic steatohepatitis (NASH) is a serious, life-threatening disease that has rapidly emerged as a leading cause of liver failure in the world and is the leading indication for liver transplant among women. An estimated 17.3 million Americans had NASH in 2016, a number that is expected to increase to 27.0 million by 2030. NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) characterized by hepatocyte injury, liver inflammation, and fibrosis that can progress to scarring (cirrhosis), liver failure, cancer and death. There are currently no approved therapies for the disease.

About Cohort C
Cohort C is an expansion cohort of the Phase 2a BALANCED study evaluating EFX in the treatment of patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A. Thirty cirrhotic NASH subjects with a biopsy-confirmed fibrosis score of F4 were randomized 2:1 to receive either 50mg of EFX or placebo for 16 weeks. The primary objective of the expansion cohort is to assess safety and tolerability of EFX in NASH patients at the greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. The trial design includes various non-invasive measures of liver health, including fibrosis markers such as the Enhanced Liver Fibrosis (ELF) score and Pro-C3, as well as liver imaging. The trial design also provided that all patients could volunteer to have end-of-treatment biopsies.

About the HARMONY Study
The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in biopsy-confirmed NASH patients with fibrosis stage 2 or 3. Patients will be randomized to receive once-weekly subcutaneous dosing of 28 or 50mg EFX or placebo. The primary endpoint for the trial is fibrosis regression at 24 weeks. Patients will continue to receive EFX or placebo during a long-term follow-up period to provide additional safety data.

About Efruxifermin
Efruxifermin (EFX) is an Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. Previous clinical trials show that EFX has the potential to reverse fibrosis, resolve NASH, reduce liver fat, improve glycemic control, improve lipoprotein profile, and reduce body weight. EFX is designed to offer convenient once-weekly subcutaneous dosing.

About Akero Therapeutics
Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, EFX, an engineered Fc-FGF21 fusion protein, is currently being evaluated in Phase 2 clinical trials as a potential treatment for NASH. Akero is headquartered in South San Francisco. Visit us at www.akerotx.com for more information.

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 EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the Company's plans to report preliminary results for Cohort C of the Phase 2a BALANCED study; the Company's Phase 2b HARMONY study including expected timing to complete enrollment and report preliminary results; the availability of a new drug product formulation to support Phase 3 clinical trials; expectations regarding the Company's use of capital, expenses and other future financial results; statements regarding a potential meeting with the FDA and timing thereof and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials. 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: risks related to the impact of COVID-19 on the Company's ongoing and future operations, including potential negative impacts on the Company's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; 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 Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in the Company'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. The Company 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, 2020	December 31, 2019
Assets		
Cash, cash equivalents and short-term marketable securities	$ 268,387	$ 136,400
Other current assets	2,958	1,649
Non-current assets	1,994	69
Total assets	$ 273,339	$ 138,118
Liabilities and Stockholders' Equity		
Current liabilities	$ 13,111	$ 9,369
Non-current liabilities	1,516	23
Stockholders' equity	258,712	128,726
Total liabilities and stockholders' equity	$ 273,339	$ 138,118

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 25,709	$ 13,138	$ 64,916	$ 37,046
General and administrative	4,074	3,083	15,238	8,605
Total operating expenses	29,783	16,221	80,154	45,651
Loss from operations	(29,783)	(16,221)	(80,154)	(45,651)
Other income	72	610	947	1,896
Net loss	$ (29,711)	$ (15,611)	$ (79,207)	$ (43,755)
Comprehensive loss	$ (29,730)	$ (15,617)	$ (79,204)	$ (43,761)
Net loss per common share, basic and diluted	$ (0.86)	$ (0.55)	$ (2.52)	$ (2.90)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	34,684,466	28,335,405	31,463,248	15,070,728

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