Akero Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

March 17, 2023

SOUTH SAN FRANCISCO, Calif., March 17, 2023 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, today reported fourth quarter and full year financial results for the period ending December 31, 2022.

“The wins we celebrated in 2022 further solidify our confidence in efruxifermin (EFX) as a potential best-in-class FGF21 analog addressing all core drivers of NASH disease progression,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “The statistically significant histology and secondary endpoint results from September’s topline HARMONY trial readout followed by EFX’s Breakthrough Therapy Designation in December further validate EFX’s potential to address high, global unmet need for patients living with NASH, and we look forward to reporting results from the SYMMETRY study in 2023.”

Phase 2b SYMMETRY Study Update

- Akero remains on track to report Week 36 results of the Phase 2b SYMMETRY main study in adult patients with cirrhotic NASH (F4, compensated) in the fourth quarter of 2023.
- Akero remains on track to report results of Cohort D in the second quarter of 2023. This is an expansion cohort of the Phase 2b SYMMETRY evaluating safety and tolerability of EFX compared to placebo, when dosed for 12 weeks on top of an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes.

Full Year and Fourth Quarter 2022 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the year ended December 31, 2022 were $351.4 million.
- Akero believes that its cash, cash equivalents and short-term marketable securities will be sufficient to fund its current operating plan into 2025.
- Research and development expenses for the three-month and twelve-month periods ended December 31, 2022 were $18.3 million and $85.3 million, respectively, compared to $27.7 million and $81.8 million for the comparable periods in 2021. The decrease in the three-month period ended December 31, 2022 compared to the comparable period in 2021 is attributable to the timing of third-party contract manufacturing expenses for EFX. The increase for the twelve-month period ended December 31, 2022 compared to the comparable period in 2021 is attributable to higher expenses associated with the SYMMETRY and HARMONY studies and to higher expenses for personnel, including non-cash stock-based compensation.
- General and administrative expenses for the three-month and twelve-month periods ended December 31, 2022 were $7.1 million and $29.9 million, respectively, compared to $4.7 million and $19.1 million for the comparable periods in 2021. 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 $25.4 million and $115.2 million for the three-month and twelve-month periods ended December 31, 2022, respectively, compared to $32.4 million and $100.9 million for the comparable periods in 2021.

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 (fibrosis stages 1-4) in 2016, a number that is predicted 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 Akero Therapeutics
Akero Therapeutics is a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (EFX), is a differentiated bivalent 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. EFX is designed to offer convenient once-weekly subcutaneous dosing. The consistency and magnitude of observed effects position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in two Phase 2b clinical trials: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). EFX is also being evaluated in an expansion cohort of the SYMMETRY study, comparing the safety and tolerability of EFX to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. Akero is headquartered in South San Francisco.

Visit akerotx.com and follow us on LinkedIn and Twitter 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: Akero's business plans and objectives, including future plans or expectations for EFX; the therapeutic effects and potential benefits of EFX, as well as the dosing, safety and tolerability of EFX; upcoming milestones, including the results, and expected timing to report such results of Cohort D and the Phase 2b SYMMETRY study; and Akero's growth as a company and expectations regarding its uses of capital, expenses and financial results, including the expected cash runway. 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 Akero's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero'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; Akero'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 recent Annual Report on Form 10-K and Quarterly Report on Form 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.

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

	December 31, 2022	December 31, 2021
Assets		
Cash, cash equivalents and short-term marketable securities	$ 351,449	$ 188,258
Other current assets	3,724	5,324
Non-current assets	1,397	1,966
Total assets	$ 356,570	$ 195,548
Liabilities and Stockholders' Equity		
Current liabilities	$ 19,083	$ 25,128
Non-current liabilities	10,925	1,311
Stockholders' equity	326,562	169,109
Total liabilities and stockholders' equity	$ 356,570	$ 195,548

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,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 18,320	$ 27,711	$ 85,284	$ 81,759
General and administrative	7,100	4,728	29,872	19,127
Total operating expenses	25,420	32,439	115,156	100,886
Loss from operations	(25,420)	(32,439)	(115,156)	(100,886)
Interest expense	(362)	-	(739)	-

Other income, net	2,723	15	3,862	109
Net loss	$ (23,059)	$ (32,424)	$ (112,033)	$ (100,777)
Comprehensive loss	$ (23,022)	$ (32,434)	$ (111,969)	$ (100,801)
Net loss per common share, basic and diluted	$ (0.49)	$ (0.93)	$ (2.87)	$ (2.89)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	46,760,783	34,886,574	38,984,772	34,827,385