Akero Therapeutics Reports Second Quarter 2022 Financial Results and Provides Business Update

August 4, 2022

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2022 (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 second quarter financial results for the period ending June 30, 2022 and provided business updates.

“During the second quarter of this year we took important steps toward optimizing our capital structure to support the ongoing development of efruxifermin (EFX) by closing a $25 million equity investment from Pfizer and a $100 million term loan facility from Hercules Capital,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “We look forward to reporting Week 24 results of our ongoing Phase 2b HARMONY study in patients with pre-cirrhotic NASH in September of this year, consistent with prior guidance.”

Second Quarter Business Highlights

- Akero announced a $25 million equity investment from Pfizer Inc. and up to a $100 million term loan facility through Hercules Capital, Inc., to support continued development of EFX, Akero’s lead product candidate.
- Akero presented an analysis at the 2022 International Liver Congress demonstrating the potential for EFX to treat patients at the highest genetic risk for progressive NASH and end-stage liver disease, including hepatocellular carcinoma. Data showed that EFX improved histopathology and noninvasive markers of liver injury to a similar extent in patients carrying the highest risk PNPLA3 genotype as patients who were not carriers.
- Akero presented a new post hoc analyses of the BALANCED study at the 2022 Keystone Symposium on Tissue Fibrosis and Repair: Mechanisms, Human Disease and Therapies, which highlighted how treatment with EFX was associated with a coordinated reduction in synthesis of 4 different collagen subtypes implicated in liver fibrosis. The reduction in synthesis of one of these subtypes, collagen III, was sufficient to normalize levels of the marker pro-C3 in 30% of EFX-treated compared to 0% of placebo patients. In addition, the proportion of collagen area in biopsy samples from cirrhotic NASH patients, quantitated by digital pathology, tended to be lower in EFX -treated than placebo patients.

HARMONY Update

- All required visits for the Week 24 primary analysis in the ongoing Phase 2b HARMONY study in patients with pre-cirrhotic (F2-F3 fibrosis) NASH have been completed.
- Akero expects to report HARMONY results for the Week 24 primary endpoint (change from baseline in liver fibrosis with no worsening of steatohepatitis) and multiple secondary endpoints—including histology, noninvasive markers of liver injury, lipoproteins, measures of glycemic control, liver fat, body weight, and safety/tolerability—in September.

SYMMETRY Update

- Based on enrollment to date, Akero expects to report results from the ongoing Phase 2b SYMMETRY main study in patients with cirrhosis due to NASH in the second half of 2023.
- In July, the first patient was randomized into Cohort D, an expansion cohort of the Phase 2b SYMMETRY study that will evaluate the safety and tolerability of EFX compared to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 Diabetes Mellitus.

Second Quarter 2022 Financial Results

- Akero's cash, cash equivalents and short-term marketable securities for the period ended June 30, 2022 were $180.7 million.
- On June 15, 2022, Akero secured a $25 million equity investment from Pfizer, Inc. and an up to $100 million term loan facility from Hercules Capital, Inc., of which (i) $10.0 million was drawn at closing, (ii) an incremental $10.0 million is available to Akero at its sole discretion, (iii) $35 million will become available upon the achievement of certain clinical development and financial milestones, and (iv) $45.0 million will become available at Hercules’ sole discretion.
- Akero believes that its cash, cash equivalents and marketable securities, plus cash from the Hercules facility (if fully drawn), will be sufficient to fund its current operating plan until the third quarter of 2024.
- Research and development expenses for the three-month period ended June 30, 2022 were $21.4 million, compared to $24.0 million for the comparable period in 2021. These changes are mainly attributable to timing of completion of certain EFX manufacturing activities, including third-party contract manufacturing of Phase 3 drug product, contract research organization costs associated with the HARMONY and SYMMETRY studies, and internal personnel costs.

- General and administrative expenses for the three-month period ended June 30, 2022 were $6.2 million, compared to $5.0 million for the comparable period 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 $27.6 million for the three-month period ended June 30, 2022, compared to $29.0 million for the comparable period in 2021.

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 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 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 Akero's business plans and objectives, including future plans or expectations for efruxifermin (EFX), upcoming milestones, and therapeutic effects of EFX, including expected timing to report results of Akero's Phase 2b HARMONY and SYMMETRY studies; and expectations regarding Akero's use of capital, expenses and other future financial results, including the potential benefits and impact of the equity investment by Pfizer Inc. and the loan facility with Hercules Capital, Inc., and the potential impact of COVID-19 on strategy, future operations, manufacturing, and clinical trial enrollment and data collection. 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. 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)

	June 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and short-term marketable securities	$ 180,725	$ 188,258
Other current assets	3,422	5,324
Non-current assets	1,528	1,966
Total assets	$ 185,675	$ 195,548
Liabilities and Stockholders' Equity		
Current liabilities	$ 26,697	$ 25,128
Non-current liabilities	10,606	1,311
Stockholders' equity	148,372	169,109
Total liabilities and stockholders' equity	$ 185,675	$ 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 June 30,	Six Months Ended June 30,

	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 21,363	$ 23,976	$ 41,877	$ 34,578
General and administrative	6,231	4,990	11,768	9,516
Total operating expenses	27,594	28,966	53,645	44,094
Loss from operations	(27,594)	(28,966)	(53,645)	(44,094)
Interest expense	(53)	-	(53)	-
Other income	244	33	266	71
Net loss	$ (27,403)	$ (28,933)	$ (53,432)	$ (44,023)
Comprehensive loss	$ (27,376)	$ (28,940)	$ (53,408)	$ (44,029)
Net loss per common share, basic and diluted	$ (0.77)	$ (0.83)	$ (1.52)	$ (1.27)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	35,383,685	34,814,631	35,195,638	34,779,647

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