

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 6, 2022**

**Akero Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38944**  
(Commission  
File Number)

**81-5266573**  
(I.R.S. Employer  
Identification No.)

**601 Gateway Boulevard, Suite 350**  
**South San Francisco, CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

**Registrant's telephone number, including area code (650) 487-6488**

**Not Applicable**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition**

On May 6, 2022, Akero Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release issued by Akero Therapeutics, Inc. on May 6, 2022, furnished herewith.</a>
104	Cover Page Interactive Data File

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2022

**AKERO THERAPEUTICS, INC.**

By: /s/ Andrew Cheng

Name: Andrew Cheng, M.D., Ph.D.

Title: President and Chief Executive Officer

**Akero Therapeutics Reports First Quarter 2022 Financial Results**

*Akero Remains on Track to Report Phase 2b HARMONY Study Results in the Third Quarter of This Year*

SOUTH SAN FRANCISCO, May 6, 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 first quarter financial results for the period ending March 31, 2022.

“Our dedicated team continues to advance our two Phase 2b clinical trials evaluating efruxifermin (EFX) in biopsy-confirmed patients with nonalcoholic steatohepatitis (NASH), a disease with growing prevalence but without approved therapies,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “Momentum grew this quarter as we completed enrollment for our HARMONY study in patients with pre-cirrhotic NASH, and continued enrolling patients in our SYMMETRY study in patients with cirrhotic NASH. We look forward to reporting the results of our HARMONY study in the third quarter of this year.”

**First Quarter 2022 Financial Results**

- Akero’s cash, cash equivalents and short-term marketable securities for the period ended March 31, 2022 were \$165.4 million.
- Akero believes that its cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into the third quarter of 2023.
- Research and development expenses for the three-month period ended March 31, 2022 were \$20.5 million, compared to \$10.6 million for the comparable period in 2021. 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 HARMONY and SYMMETRY studies and internal personnel costs.
- General and administrative expenses for the three-month period ended March 31, 2022 were \$5.5 million, compared to \$4.5 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 \$26.1 million for the three-month period ended March 31, 2022, compared to \$15.1 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). Akero is headquartered in South San Francisco. Visit us at [www.akerotx.com](http://www.akerotx.com) for more information.

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## 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 Akerō’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 Akerō’s Phase 2b HARMONY study; and expectations regarding Akerō’s use of capital, expenses and other future financial results 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 Akerō’s ongoing and future operations, including potential negative impacts on Akerō’s employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akerō’s product candidate development activities and planned clinical trials; Akerō’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; Akerō’s ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption “Risk Factors” in Akerō’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 Akerō’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)

	March 31, 2022	December 31, 2021
<b>Assets</b>		
Cash, cash equivalents and short-term marketable securities	\$ 165,376	\$ 188,258
Other current assets	2,558	5,324
Non-current assets	1,953	1,966
<b>Total assets</b>	<b>\$ 169,887</b>	<b>\$ 195,548</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities	\$ 22,097	\$ 25,128
Non-current liabilities	1,255	1,311
Stockholders' equity	146,535	169,109
<b>Total liabilities and stockholders' equity</b>	<b>\$ 169,887</b>	<b>\$ 195,548</b>

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

	Three Months Ended March 31,	
	2022	2021
<b>Operating expenses:</b>		
Research and development	\$ 20,514	\$ 10,602
General and administrative	5,537	4,526
<b>Total operating expenses</b>	<b>26,051</b>	<b>15,128</b>
Loss from operations	(26,051)	(15,128)
Other income	22	38
<b>Net loss</b>	<b>\$ (26,029)</b>	<b>\$ (15,090)</b>
Comprehensive loss	\$ (26,032)	\$ (15,089)
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.74)</b>	<b>\$ (0.43)</b>
Weighted-average number of shares used in computing net loss per common share, basic and diluted	35,005,501	34,744,275

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