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): August 11, 2023

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38944**	**81-5266573**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 August 11, 2023, Akero Therapeutics, Inc. announced its financial results for the quarter ended June 30, 2023. 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

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on August 11, 2023, furnished herewith.
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: August 11, 2023

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Name: Andrew Cheng, M.D., Ph.D.
Title: President and Chief Executive Officer

Akero Therapeutics Reports Second Quarter 2023 Financial Results and Provides Business Update

— Positive Results from Phase 2b SYMMETRY Cohort D, an expansion cohort of Type 2 diabetic, pre-cirrhotic NASH patients treated with EFX or placebo in combination with a GLP-1 receptor agonist, reported during the second quarter of 2023 —

— Phase 3 SYNCHRONY studies on track to begin enrolling in the second half of 2023 —

— 36 Weeks Results from the Phase 2b SYMMETRY study, evaluating treatment of patients with compensated cirrhosis due to NASH, on track to be reported in the fourth quarter of this year —

— $334.8 million in net proceeds raised through Akero's ATM Facility and underwritten registered direct offering of common stock —

SOUTH SAN FRANCISCO, Calif. August 11, 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 second quarter financial results for the period ending June 30, 2023 and provided business updates.

"We achieved important progress in the clinical development of EFX during the second quarter of this year, including attaining strong and consistent results across our Phase 2 studies to date as reinforced by the Phase 2b SYMMETRY Cohort D study results," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "These results add to the growing body of evidence supporting the ongoing clinical development of EFX and its potential as a transformative NASH therapy. Bolstered by $334.8 million in net proceeds raised in the second quarter, we look forward to initiating our Phase 3 SYNCHRONY Histology and SYNCHRONY Real-World studies later this year to further our goal of developing meaningful therapies for patients living with NASH."

Phase 3 SYNCHRONY Program

- SYNCHRONY Histology and SYNCHRONY Real-World studies remain on track to begin enrollment by the end of this year.
    - SYNCHRONY Histology will evaluate the efficacy of 28mg and 50mg doses of EFX in patients with biopsy confirmed pre-cirrhotic NASH, fibrosis stage 2 or 3 (F2-F3). The primary endpoint will be ≥ 1-stage fibrosis improvement AND resolution of NASH.
    - SYNCHRONY Real-World will assess safety and tolerability of EFX in patients with non-invasively diagnosed NASH or NAFLD. Key secondary endpoints will include changes in biomarkers of liver fibrosis as well as measures of glycemic control and lipids.

Phase 2b SYMMETRY Study Update

- Akero reported topline data from an expansion cohort (N=31) of the Phase 2b SYMMETRY study known as Cohort D.
    - The primary aim of the 12-week study was to assess safety and tolerability of EFX compared to placebo when added to an existing GLP-1 receptor agonist (GLP-1) in patients with Type 2 diabetes and F1-F3 liver fibrosis due to NASH.
    - Results of the Cohort D study showed safety and tolerability endpoints were met. The study also showed that adding EFX to GLP-1 therapy significantly improved non-invasive markers of NASH-related disease, including a 65% relative reduction in liver fat for the EFX-treated group compared with a 10% reduction for the placebo group treated only with GLP-1. In addition, 88% of EFX-treated patients normalized their liver fat to 5% or less, compared with 10% for the placebo group.

- 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.

Second Quarter 2023 Financial Results

- The company raised $334.8 million in net proceeds through an At-the-Market facility (ATM) and underwritten registered direct offering, enhancing the company's cash position in the second half of 2023 as it nears initiation of the Phase 3 SYNCHRONY Histology and SYNCHRONY Real-World studies of Efruxifermin (EFX) in NASH.
- Akero's cash, cash equivalents and short-term and long-term marketable securities for the period ended June 30, 2023 were $658.9 million.
- Akero believes that its current cash, cash equivalents, short-term and long-term marketable securities will be sufficient to fund its current operating plan into 2026.
- Research and development expenses for the three-month period ended June 30, 2023 were $28.0 million, compared to $21.4 million for the comparable period in 2022. Direct EFX program costs increased $5.4 million related to CRO and CMO expenses for our ongoing HARMONY and SYMMETRY studies and personnel and other R&D expenses increased $1.2 million.
- General and administrative expenses for the three-month period ended June 30, 2023 were $7.6 million, compared to $6.2 million for the comparable period in 2022. The increase is 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 $35.6 million for the three-month period ended June 30, 2023, compared to $27.6 million for the comparable period in 2022.

About NASH

NASH is a serious form of NAFLD (non-alcoholic fatty liver disease) that is estimated to affect 17 million Americans. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. There are no approved treatments for the condition and NASH is the fastest growing cause of liver transplants and liver cancer in the US and Europe.

About Efruxifermin

Efruxifermin (EFX), formerly known as AKR-001, is Akero's lead product candidate for NASH, currently being evaluated in the ongoing Phase 2b HARMONY and SYMMETRY studies. EFX is designed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipids. This holistic approach offers the potential to address the complex, multi-system disease state of NASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

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 NASH, a disease without any approved therapies. Akero's lead product candidate, 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 has also been evaluated in an expansion cohort of the SYMMETRY study, Cohort D, 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, for which topline results were reported on June 5, 2023. Akero is headquartered in South San Francisco. Visit us at 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 of EFX, as well as the dosing, safety and tolerability of EFX, including in combination with GLP-1 therapies; and upcoming milestones, including the results, and expected timing to report such results of Akero’s Phase 2b SYMMETRY study, the SYNCHRONY Phase 3 program, including the SYNCHRONY Histology and SYNCHRONY Real-World studies and design of trials and expected timing thereof; and Akero’s growth as a company and expectations regarding its uses of capital, expenses, and financial results. 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 Akero’s product candidate development activities and planned clinical trials; Akero’s ability to execute on its strategy; positive results from a clinical study, including Cohort D, 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.

Investor Contact:

Austin Murtagh
212.698.8696
IR@akerotx.com

Media Contact:

Sarah O’Connell
732.456.0092
soconnell@vergescientific.com

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

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and short-term marketable securities	$ 639,444	$ 351,449
Other current assets	3,759	3,724
Long-term marketable securities	19,451	—
Non-current assets	1,152	1,397
Total assets	$ 663,806	$ 356,570
Liabilities and Stockholders' Equity		
Current liabilities	$ 21,602	$ 19,083
Non-current liabilities	25,767	10,925
Stockholders' equity	616,437	326,562
Total liabilities and stockholders' equity	$ 663,806	$ 356,570

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 27,985	$ 21,363	$ 49,772	$ 41,877
General and administrative	7,644	6,231	14,610	11,768
Total operating expenses	35,629	27,594	64,382	53,645
Loss from operations	(35,629)	(27,594)	(64,382)	(53,645)
Interest expense	(857)	(53)	(1,314)	(53)
Other income, net	5,403	244	8,782	266
Net loss	$ (31,083)	$ (27,403)	$ (56,914)	$ (53,432)
Comprehensive loss	$ (31,355)	$ (27,376)	$ (57,202)	$ (53,408)
Net loss per common share, basic and diluted	$ (0.60)	$ (0.77)	$ (1.15)	$ (1.52)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	51,867,854	35,383,685	49,419,558	35,195,638