# 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): November 13, 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**<br>**South San Francisco, CA** | **94080** |
|---|---|
| **(Address of principal executive offices)** | **(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 November 13, 2023, Akero Therapeutics, Inc. announced its financial results for the quarter ended September 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 November 13, 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: November 13, 2023

**AKERO THERAPEUTICS, INC.**

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

**Akero Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update**

*— Phase 3 SYNCHRONY studies actively screening and on track to begin enrolling by the end of 2023 —*

SOUTH SAN FRANCISCO, Calif. November 13, 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 third quarter financial results for the period ending September 30, 2023 and provided business updates.

“We continue to be encouraged by the totality of evidence supporting clinical development of EFX for both pre-cirrhotic and cirrhotic NASH,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “We look forward to enrolling the first patients in our Phase 3 SYNCHRONY Histology and SYNCHRONY Real-World studies later this year.”

**Phase 3 SYNCHRONY Program**

- The SYNCHRONY Histology and SYNCHRONY Real-World studies began screening in September 2023 and remain on track to begin enrollment by the end of this year.
    - SYNCHRONY Histology will evaluate the efficacy of 28mg and 50mg doses of efruxifermin (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.
    - A Type B, End-of-Phase-2 meeting request to review the design of the planned SYNCHRONY Outcomes study in light of the Week 36 Phase 2b SYMMETRY data was submitted to FDA in October. As currently planned, SYNCHRONY Outcomes will evaluate EFX in the treatment of patients with compensated cirrhosis (F4) due to NASH.

**Phase 2b SYMMETRY Study Week 36 Analysis**

- In October 2023, Akero reported Week 36 results from SYMMETRY, a 96-week Phase 2b study evaluating the efficacy and safety of its lead product candidate EFX in patients with compensated cirrhosis (F4) due to NASH.
- Although the primary endpoint of at least a one-stage improvement in liver fibrosis with no worsening of NASH at week 36 was not met, statistically significant results for NASH resolution, as well as non-invasive markers of liver injury and fibrosis, insulin sensitization and lipoproteins were observed, including:
    - 22% (28mg EFX) and 24% (50mg EFX) of patients experienced at least a one-stage improvement in liver fibrosis with no worsening of NASH, compared to 14% for placebo (not statistically significant);

- 4% of patients in each EFX dose group experienced a three- or two-stage reversal of fibrosis with no worsening of NASH, compared to 0% for placebo; and
- 63% (28mg EFX) and 60% (50mg EFX) of patients experienced statistically significant resolution of NASH, compared to 26% for placebo—the first known public report of a clinical trial showing statistically significant NASH resolution, in patients with cirrhosis irrespective of development stage, treatment duration or mechanism of action.

- Across EFX groups, the most frequent adverse events were gastrointestinal, and mainly of mild to moderate severity.

**Phase 2b HARMONY Study Week 96 Analysis**

- Week 96 results from HARMONY, a 96-week Phase 2b HARMONY study evaluating the efficacy and safety of EFX in biopsy-confirmed patients with F2-F3 NASH, remain on track to be reported in the first quarter of 2024.

**Third Quarter 2023 Financial Results**

- Akero's cash, cash equivalents and short-term and long-term marketable securities for the period ended September 30, 2023 were $613.0 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 September 30, 2023 were $38.6 million, compared to $25.1 million for the comparable period in 2022. Direct EFX program costs increased $14.1 million related to CRO and CMO expenses for our ongoing HARMONY and SYMMETRY studies as well as the initiation of the Phase 3 SYNCHRONY program and personnel and other R&D expenses decreased $0.5 million.
- General and administrative expenses for the three-month period ended September 30, 2023 were $8.0 million, compared to $11.0 million for the comparable period in 2022. The decrease is attributable primarily to lower non-cash stock-based compensation expense, offset by an increase in expenses for personnel and professional services.
- Total operating expenses were $46.6 million for the three-month period ended September 30, 2023, compared to $36.1 million for the comparable period in 2022.

**About NASH**

NASH is a serious form of non-alcoholic fatty liver disease (NAFLD) 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. Approximately 20% of patients with NASH will progress to cirrhosis, which has a higher risk of mortality. 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 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. 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 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 the availability of sufficient cash to fund Akero's operating plan into 2026; the potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the SYNCHRONY Phase 3 program, including the SYNCHRONY Histology and SYNCHRONY Real-World studies and design of trials, the expectation to begin enrollment of Akero's Phase 3 SYNCHRONY program by end of 2023 and expectations regarding potential communications with the FDA; and upcoming milestones, including the results, and expected timing to report the long-term follow-up week 96 results of Akero's Phase 2b HARMONY and SYMMETRY studies; 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 any of its clinical studies 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)

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Assets | | |
| Cash, cash equivalents and short-term marketable securities | $ 554,732 | $ 351,449 |
| Prepaid expenses and other current assets | 21,247 | 3,724 |
| Non-current assets | 59,352 | 1,397 |
| Total assets | $ 635,331 | $ 356,570 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | $ 28,447 | $ 19,083 |
| Non-current liabilities | 23,749 | 10,925 |
| Stockholders' equity | 583,135 | 326,562 |
| Total liabilities and stockholders' equity | $ 635,331 | $ 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses: | | | | |
| Research and development | $ 38,634 | $ 25,087 | $ 88,406 | $ 66,964 |
| General and administrative | 7,981 | 11,004 | 22,591 | 22,772 |
| Total operating expenses | 46,615 | 36,091 | 110,997 | 89,736 |
| Loss from operations | (46,615) | (36,091) | (110,997) | (89,736) |
| Interest expense | (888) | (324) | (2,202) | (377) |
| Other income, net | 7,844 | 873 | 16,626 | 1,139 |
| Net loss | $ (39,659) | $ (35,542) | $ (96,573) | $ (88,974) |
| Comprehensive loss | $ (39,914) | $ (35,539) | $ (97,116) | $ (88,947) |
| Net loss per common share, basic and diluted | $ (0. 71) | $ (0.92) | $ (1.87) | $ (2.45) |
| Weighted-average number of shares used in computing net loss per common share, basic and diluted | 55,613,120 | 38,663,469 | 51,506,766 | 36,364,284 |