# 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 4, 2022**

# 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** **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 4, 2022, Akero Therapeutics, Inc. announced its financial results for the quarter ended September 30, 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

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by Akero Therapeutics, Inc. on November 4, 2022, 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 4, 2022

**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 2022 Financial Results and Provides Business Update**

SOUTH SAN FRANCISCO, November 4, 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 third quarter financial results for the period ending September 30, 2022 and provided business updates.

"Our recently reported Week 24 results from the Phase 2b HARMONY study in patients with pre-cirrhotic NASH (F2-F3) contributes to the growing body of evidence for EFX's potential, if approved, to be a foundational monotherapy for the treatment of NASH," said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. "Our statistically significant histology results, as well as non-invasive markers of fibrosis, indicated that EFX acts both directly and indirectly to rapidly reverse fibrosis. We are encouraged by the consistency of data across four placebo-controlled clinical trials and the potential to continue to observe favorable results when we report Week 36 data from the Phase 2b SYMMETRY study in patients with cirrhotic NASH (F4, compensated) in the second half of next year."

**Third Quarter Business Highlights & Company Updates**

- Akero reported positive Week 24 results from the Phase 2b HARMONY study evaluating EFX in the treatment of adult patients with pre-cirrhotic NASH (F2-F3). These data will also be presented as a late-breaker oral presentation at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2022 at 2:00 pm ET on Monday November 7, 2022.
    - 41% and 39% of patients with 50mg and 28mg EFX, respectively, experienced at least a one-stage improvement in liver fibrosis with no worsening of NASH by week 24, double the placebo rate of 20%.
    - 76% and 47% of patients treated with 50mg and 28mg, respectively, achieved NASH resolution without worsening of fibrosis, three to five times the placebo rate of 15%.
    - 41% and 29% of patients treated with 50mg and 28mg, respectively, achieved both endpoints (NASH resolution and fibrosis improvement ≥1 stage), six to eight times the placebo rate of 5%.
    - EFX-treated patients also experienced statistically significant improvements in liver fat, liver enzymes, noninvasive fibrosis markers, glycemic control, lipoproteins and body weight.
    - EFX was reported to be generally well tolerated. Across both dose groups, the most frequent adverse events (AEs) were grade 1 or 2 gastrointestinal events (diarrhea, nausea, increased appetite and frequent bowel movements), which were transient in nature.
- In September 2022, Akero closed an upsized underwritten public offering of 8,846,154 shares of its common stock at a public offering price of $26.00 per share, which includes the exercise in full by the underwriters of their option to purchase up to an additional 1,153,846 shares of common stock. The gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses, were approximately $230.0 million. J.P. Morgan, Morgan Stanley and Jefferies acted as joint book-running managers for the offering. Canaccord Genuity acted as lead manager and H.C. Wainwright & Co. acted as co-manager for the offering.
- Akero successfully manufactured a new drug product-device combination for use in Phase 3 clinical trials. The new EFX drug product is a lyophilized powder delivered in a pre-filled, dual-chamber syringe designed for convenient patient self-administration. Initial batches have been released for clinical use, subject to review by regulatory authorities of comparability with drug product used in Phase 2 clinical trials.

**Key Milestones Anticipated for 2023**

- 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 second half of 2023.
- Akero remains on track to report results of Cohort D in the first half 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.

**Third Quarter 2022 Financial Results**

- Akero's cash and cash equivalents for the period ended September 30, 2022, were $374.0 million.
- Akero believes that its cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into 2025.
- Research and development expenses for the three-month period ended September 30, 2022, were $25.1 million, compared to $19.5 million for the comparable period in 2021. These increases are attributable to higher costs related to Akero's EFX program, including contract research organization costs associated with the HARMONY and SYMMETRY studies, stock-based compensation and internal personnel costs.
- General and administrative expenses for the three-month period ended September 30, 2022, were $11.0 million, compared to $4.9 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 $36.1 million for the three-month period ended September 30, 2022, compared to $24.4 million for the comparable period in 2021.

**About NASH**

NASH (non-alcoholic steatohepatitis) 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 the HARMONY Study**

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult NASH patients with fibrosis stage 2 or 3. The study enrolled a total of 128 patients, randomized to receive once-weekly subcutaneous doses of 28mg or 50mg EFX, or placebo for 24-weeks. The primary efficacy endpoint for the study was the proportion of subjects who achieved at least a one-stage improvement in fibrosis without worsening of NASH at week 24. Secondary Week 24 measures included NASH resolution and change from baseline in liver fat, liver enzymes, noninvasive markers of liver fibrosis, glycemic control, lipoproteins and body weight, as well as safety and tolerability measures. Patients are being followed for safety evaluation for up to a total of 96 weeks of dosing.

**About Efruxifermin**

Efruxifermin (EFX) 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 lipoproteins. 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 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), which is currently in a long-term safety follow-up phase after reporting Week 24 results, 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 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 efruxifermin (EFX), the therapeutic effects and potential 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 Akero's Phase 2b SYMMETRY study; Akero's preparations for commercialization of EFX, if approved; 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)

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Assets | | |
| Cash, cash equivalents and short-term marketable securities | $ 374,003 | $ 188,258 |
| Other current assets | 3,943 | 5,324 |
| Non-current assets | 1,462 | 1,966 |
| Total assets | $ 379,408 | $ 195,548 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | $ 25,243 | $ 25,128 |
| Non-current liabilities | 10,657 | 1,311 |
| Stockholders' equity | 343,508 | 169,109 |
| Total liabilities and stockholders' equity | $ 379,408 | $ 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 25,087 | $ 19,470 | $ 66,964 | $ 54,048 |
| General and administrative | 11,004 | 4,883 | 22,772 | 14,399 |
| Total operating expenses | 36,091 | 24,353 | 89,736 | 68,447 |
| Loss from operations | (36,091) | (24,353) | (89,736) | (68,447) |
| Interest expense | (324) | — | (377) | — |
| Other income, net | 873 | 23 | 1,139 | 94 |
| Net loss | $ (35,542) | $ (24,330) | $ (88,974) | $ (68,353) |
| Comprehensive loss | $ (35,539) | $ (24,338) | $ (88,947) | $ (68,367) |
| Net loss per common share, basic and diluted | $ (0.92) | $ (0.70) | $ (2.45) | $ (1.96) |
| Weighted-average number of shares used in computing net loss per common share, basic and diluted | 38,663,469 | 34,862,116 | 36,364,284 | 34,807,439 |