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): January 15, 2025

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

Delaware	**001-39264**	**81-1173868**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1050 Waltham Street, Suite 302	
Lexington, Massachusetts	**02421**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 314-6297

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	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**KROS**	**The Nasdaq Stock Market LLC**

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 8.01 Other Events.

On January 15, 2025, Keros Therapeutics, Inc. announced that it has voluntarily halted all dosing in the TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension, including the 1.5 mg/kg and placebo treatment arms, based on the ongoing safety review due to new observations of pericardial effusion adverse events. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 15, 2025.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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.

KEROS THERAPEUTICS, INC.

By: /s/ Jasbir Seehra

Jasbir Seehra, Ph.D.
Chief Executive Officer

Dated: January 15, 2025

Keros Therapeutics Announces Additional Update on the Phase 2 TROPOS Trial

LEXINGTON, Mass., Jan. 15, 2025 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros” or the “Company”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the transforming growth factor-beta (“TGF-ß”) family of proteins, today announced that it has voluntarily halted all dosing in the TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension (“PAH”), including the 1.5 mg/kg and placebo treatment arms, based on the ongoing safety review due to new observations of pericardial effusion adverse events. On December 12, 2024, the Company announced that it had voluntarily halted the 3.0 mg/kg and 4.5 mg/kg treatment based on the observation of pericardial effusions at those dose levels.

“While we are disappointed in this new development, patient safety is always our top priority. We continue to work with the investigators, the U.S. Food and Drug Administration (“FDA”) and other relevant regulatory authorities, and we look forward to analyzing and presenting TROPOS topline clinical data in the future,” said Jasbir S. Seehra, PhD., Chair and CEO.

The Company has notified investigators and certain regulatory authorities, including the FDA, about this decision, and is in the process of notifying other relevant regulatory authorities. The TROPOS trial is being terminated early, and patients are expected to be monitored through the end-of-trial visits. The Company continues to expect to present topline data from all treatment arms in this trial in the second quarter of 2025.

About TROPOS (NCT05975905)

TROPOS is a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial to evaluate cibotercept in combination with background therapy in patients with PAH. The primary objective of this trial is to evaluate the effect of cibotercept on pulmonary hemodynamics compared to placebo in participants on background PAH therapy. The key secondary objective of this trial is to evaluate the effect of cibotercept on exercise capacity compared to placebo on participants on background PAH therapy.

About Cibotercept

Cibotercept is designed to bind to and inhibit the signaling of TGF-β ligands that stimulate smooth muscle hypertrophy and fibrosis, including activin A, activin B and myostatin. Keros believes that cibotercept has the potential to increase the signaling of bone morphogenic protein (“BMP”) pathways through this inhibition of activin A and activin B signaling, and consequently treat diseases such as PAH that are associated with reduced BMP signaling due to inactivating mutations in the BMP receptors. Cibotercept is being developed for the treatment of PAH and for the treatment of cardiovascular disorders.

Cautionary Note Regarding 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, as amended. Words such as “continue,’ “expect” and “forward,” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros’ expectations regarding its progress and the design, objectives and timing of its clinical trial for cibotercept, including expected timing for data readout for the TROPOS trial; the response of FDA or any regulatory authorities to our voluntary actions with respect to the TROPOS trial; and the potential of cibotercept to increase the signaling of BMP pathways to treat diseases such as PAH. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include,

among others: Keros' limited operating history and historical losses; Keros' ability to raise additional funding to complete the development and any commercialization of its product candidates; Keros' dependence on the success of its product candidates, cibotercept, elritercept and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical trials; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; competition from third parties that are developing products for similar uses; Keros' ability to obtain, maintain and protect its intellectual property; and Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

These and other risks are described more fully in Keros' filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2024, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Keros 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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