
**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): September 3, 2024

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

Delaware
(state or other jurisdiction
of incorporation)

001-39264
(Commission
File Number)

81-1173868
(I.R.S. Employer
Identification No.)

1050 Waltham Street, Suite 302
Lexington, Massachusetts
(Address of principal executive offices)

02421
(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))
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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 September 3, 2024, Keros Therapeutics, Inc. (the “Company”) issued a press release announcing that the Company has closed screening for the TROPOS trial, a Phase 2 clinical trial of ciboterecept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension. As a result, the Company expects to complete enrollment of that trial by the end of September 2024 and present topline data in the second quarter of 2025. Attached hereto as Exhibit 99.1 and incorporated herein by reference is a copy of the press release.

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the Company’s expected timing for enrollment completion and data readout for the TROPOS trial. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Many factors could cause the actual results, performance or achievements that may be expressed or implied by such forward-looking statements to vary from those described herein should one or more of these risks or uncertainties materialize, including those risk factors discussed or referred to in the Company’s filings with the SEC, including the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2024, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. Except to the extent required by law, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit		Description
No.		
99.1	Press release dated September 3, 2024.	
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: September 3, 2024

Keros Therapeutics Announces Update on Enrollment in the Phase 2 TROPOS Trial

LEXINGTON, Mass., Sept. 3, 2024 (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- β ”) family of proteins, today announced that the Company has closed screening for the TROPOS trial, a Phase 2 clinical trial of cibotercept (KER-012) in combination with background therapy in patients with pulmonary arterial hypertension (“PAH”). As a result, Keros expects to complete enrollment by the end of September and present topline data in the second quarter of 2025.

“We are very pleased to announce the closing of screening in the TROPOS trial,” said Jasbir S. Seehra, Ph.D., Chair and Chief Executive Officer. “The tremendous demand and speed we have observed in enrolling this trial will enable us to present topline data earlier than anticipated, now expected in the second quarter of 2025.”

“We want to thank the TROPOS investigators, research staff and their patients for their participation in this important clinical research,” said Chris Rovaldi, President and Chief Operating Officer. “This milestone, which could not have been achieved without their commitment, brings us one step closer to bringing a potentially differentiated treatment option to patients living with PAH.”

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.

About Keros Therapeutics, Inc.

Keros is 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 TGF- β family of proteins. The Company is a leader in understanding the role of the TGF- β family of proteins, which are master regulators of the growth, repair and maintenance of a number of tissues, including blood, bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, Keros has discovered and is developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. Keros' lead product candidate, elritercept (KER-050), is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes and in patients with myelofibrosis. Keros' second product candidate, cibotercept, is being developed for the treatment of PAH and for the treatment of cardiovascular disorders. Keros' third product candidate, KER-065, is being developed for the treatment of obesity and for the treatment of neuromuscular diseases.

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 "expects," "enable," "potential," "will" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: Keros' expectations regarding its growth, strategy, progress and the design, objectives and timing of its clinical trials for cibotercept (including expected timing for enrollment completion and data readout for the TROPOS trial). 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, elritercept, cibotercept and KER-065; that Keros may be delayed in initiating, enrolling or completing any clinical 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 August 7, 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.

Investor Contact:

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