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): July 24, 2023

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 July 24, 2023, Keros Therapeutics, Inc. (the "Company") issued a press release announcing that it will host a conference call and webcast to provide an overview of TROPOS, its global Phase 2 clinical trial to evaluate KER-012 in combination with background therapy in patients with pulmonary arterial hypertension, on August 8, 2023 at 8:00 a.m. Eastern time. The Company also announced that the U.S. Food and Drug Administration cleared its investigational new drug application to conduct the TROPOS trial. 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 July 24, 2023.
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: July 24, 2023

Exhibit 99.1

Keros Therapeutics to Host Conference Call and Webcast to Provide an Overview of TROPOS, the KER-012 Phase 2 Clinical Trial in Patients with Pulmonary Arterial Hypertension

- Keros Therapeutics announces U.S. Food and Drug Administration ("FDA") has cleared its investigational new drug application to conduct a Phase 2 clinical trial of KER-012 in combination with background therapy in patients with pulmonary arterial hypertension

July 24, 2023 at 8:00 AM EDT

LEXINGTON, Mass., July 24, 2023 – Keros Therapeutics, Inc. ("Keros") (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel treatments for patients suffering from hematological, pulmonary and cardiovascular disorders with high unmet medical need, today announced that Keros will host a conference call and webcast to provide an overview of TROPOS, its global Phase 2 clinical trial to evaluate KER-012 in combination with background therapy in patients with pulmonary arterial hypertension ("PAH"), on August 8, 2023 at 8:00 a.m. Eastern time.

"PAH is a debilitating disease potentially driven by imbalanced signaling of the transforming growth factor-beta ("TGF-β") family of proteins, with no treatments available that halt or reverse the disease's progression. The predicted mechanism-of-action of KER-012—based on preclinical and Phase 1 clinical data—suggests that KER-012 could potentially correct dysfunctional activin signaling in PAH without a dose-limiting red blood cell effect," said Dr. Mardi Gomberg-Maitland, M.D., M.Sc., Chief Clinical Research Officer, School of Medicine Health Sciences at George Washington University and the Director of the Pulmonary Hypertension Program. "The TROPOS trial offers hope for improving and potentially extending the lives of those suffering from this devastating disease."

"Achieving FDA clearance to initiate our Phase 2 PAH trial of KER-012 in the United States is an important milestone for Keros," said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. "We believe this brings us one step closer to bringing a potentially differentiated treatment option to patients living with this disease."

Conference Call and Webcast Information

Keros will host a conference call and webcast on August 8, 2023, at 8:00 a.m. Eastern time, to provide an overview of the TROPOS trial design. Joining Keros management on the call will be Dr. Gomberg-Maitland, who serves as the TROPOS Steering Committee Chair.

The conference call will be webcast live at https://event.webcasts.com/starthere.jsp?ei=1626165&tp_key=42564576c9. The live teleconference may be accessed by dialing (877) 407-0309 (domestic) or (201) 389-0853 (international). An archived version of the call will be available in the Investors section of the Keros website at https://ir.kerostx.com/ for 90 days following the conclusion of the call.

About TROPOS

TROPOS is a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial to evaluate KER-012 in combination with background therapy in patients with PAH. The primary objective of this trial is to evaluate the effect of KER-012 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 KER-012 on exercise capacity compared to placebo on participants on background PAH therapy.

About KER-012

KER-012 is designed to bind to and inhibit the signaling of TGF-β ligands that that stimulate smooth muscle hypertrophy and fibrosis, including activin A, activin B and myostatin. Keros believes that KER-012 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. KER-012 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 the discovery, development and commercialization of novel treatments for patients suffering from hematological, pulmonary and cardiovascular disorders with high unmet medical need. Keros is a leader in understanding the role of the TGF-β family of proteins, which are master regulators of red blood cell and platelet production as well as of the growth, repair and maintenance of a number of tissues, including blood vessels and heart tissue. Keros’ lead protein therapeutic product candidate, 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’ lead small molecule product candidate, KER-047, is being developed for the treatment of functional iron deficiency. Keros’ third product candidate, KER-012, 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 "believe," “hope,” “potential,” "suggest" and “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, results and timing of its clinical trials for KER-012; and the potential of KER-012 to correct dysfunctional activin signaling in PAH without a dose-limiting red blood cell effect. 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, KER-050, KER-047 and KER-012; 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 Keros' Quarterly Report on Form 10-Q, filed with the SEC on May 4, 2023, 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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