
**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 28, 2026

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 7.01 Regulation FD Disclosure.

On September 28, 2026, Keros Therapeutics, Inc. (the “Company”) issued a press release announcing that the first patient was dosed in its Phase 2 clinical trial of rinvatercept in patients with Duchenne muscular dystrophy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be 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 dated September 28, 2026.
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 28, 2026

Keros Therapeutics Announces the First Patient Dosing in the Phase 2 Clinical Trial Evaluating Rinvatercept in DMD

- *Initial data expected in the first half of 2027*

LEXINGTON, Mass., September 28, 2026 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. ("Keros") (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 first patient was dosed in the Phase 2 clinical trial of rinvatercept in patients with Duchenne muscular dystrophy ("DMD").

"Dosing the first patient in our Phase 2 clinical trial of rinvatercept represents an important step in advancing our neuromuscular development strategy, and reflects the progress of our team as we continue to advance Keros' clinical pipeline," said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. "Rinvatercept is designed to modulate key regulators of muscle and bone biology, and we look forward to generating clinical data to inform its potential to treat patients with DMD."

"DMD, despite advances in treatment, continues to place a significant burden on patients and their families, and the need for additional options remains high," said Gina O'Grady, B.H.B., MBChB, Ph.D., pediatric neurologist at Starship Children's Hospital. "Rinvatercept's mechanism established in preclinical studies provides a compelling rationale for clinical evaluation in DMD. This trial represents an important opportunity to assess its potential impact across both ambulatory and non-ambulatory patients with DMD."

About the Rinvatercept Phase 2 Clinical Trial (NCT07704099)

The rinvatercept Phase 2 clinical trial is an open-label, multi-cohort basket clinical trial in patients with DMD. The primary objective of this trial is to assess the safety and tolerability of rinvatercept in late-ambulatory and early non-ambulatory patients with DMD. The key secondary objectives of this trial are to evaluate pharmacokinetics, anti-drug antibodies, body composition and comprehensive functional improvements (skeletal muscle, motor, cardiac and pulmonary).

About Rinvatercept

Rinvatercept is a novel ligand trap comprised of a modified ligand-binding domain derived from activin receptor type IIA and activin receptor type IIB that is fused to the portion of the human antibody known as the Fc domain. Rinvatercept is designed to act as a ligand trap and inhibit the biological effects of myostatin and activin A, which are negative regulators of muscle and bone mass and strength, to improve skeletal muscle regeneration, increase muscle size and strength, inhibit and reduce fibrosis, inhibit inflammation, reduce fat accumulation and improve

bone health through bone anabolic mechanisms. We are developing rinvatercept for the treatment of DMD and for the treatment of amyotrophic lateral sclerosis (“ALS”).

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. Keros 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 skeletal muscle, bone, adipose, heart tissue and blood. 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, rinvatercept, is being developed for the treatment of DMD and for the treatment of ALS. Keros’ most advanced product candidate, elritercept, is being developed for the treatment of cytopenias, including anemia and thrombocytopenia, in patients with myelodysplastic syndromes and in patients with myelofibrosis.

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 “forward,” “potential,” “expect” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: the expected timing of initial data from the Phase 2 clinical trial of rinvatercept in patients with DMD; the potential benefits of rinvatercept, including its potential impact in ambulatory and non-ambulatory patients with DMD; and the progress and objectives of the Phase 2 clinical trial of rinvatercept in DMD. 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, rinvatercept and elritercept; 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 3, 2026, 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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