# **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): October 4, 2021

# 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.)

99 Hayden Avenue, Suite 120, Building E 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))

☐ Pre-commencement communications pursuant to Rule 13	3e-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 chapter) or Rule 12b-2 of the Securities Exchange Act of 193.  Emerging growth company ⊠  If an emerging growth company, indicate by check mark if the or revised financial accounting standards provided pursuant to	4 (§240.12b-2 of this chapter). e registrant has elected not to use the	e extended transition period for complying with any new	

## Item 8.01 Other Events.

On October 4, 2021, Keros Therapeutics, Inc. (the "Company") issued a press release announcing results from a preclinical study of a research form of KER-012 in an established model of pulmonary arterial hypertension, which was presented at the American Society for Bone and Mineral Research 2021 Annual Meeting held October 1-4, 2021.

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 October 4, 2021.
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: October 4, 2021

Keros Therapeutics Presents Results from a Preclinical Study of RKER-012 in Pulmonary Arterial Hypertension-Associated Bone Loss at the American Society for Bone and Mineral Research 2021 Annual Meeting

**Lexington, Mass. – October 4, 2021 –** 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 and musculoskeletal disorders with high unmet medical need, today announced that it presented results from a preclinical study of KER-012 at the American Society for Bone and Mineral Research (ASBMR) 2021 Annual Meeting held October 1 through 4, 2021.

RKER-012 prevented loss of bone volume, bone volume fraction and trabecular number, and reduced trabecular separation in a rodent PAH model.

 RKER-012, a Novel Activin Receptor Type II Ligand Trap, Protected Rats from Pulmonary Arterial Hypertension-Associated Bone Loss in a SUGEN/Hypoxia Model

Keros combined administration of SUGEN5416, a tyrosine kinase inhibitor of vascular endothelial growth factor receptors 1/2, with exposure to chronic hypoxia to recapitulate the biology of pulmonary arterial hypertension ("PAH"). A research form of KER-012 ("RKER-012") was tested in this SUGEN/hypoxia ("SH") rat model of PAH. Adult male rats were subjected to SH and received either vehicle or 20 mg/kg RKER-012 twice weekly for four weeks. Rats maintained under normal oxygen conditions ("normoxic controls") received only vehicle. Relative to normoxic controls, vehicle-treated SH rats had reduced bone volume (-30.9%; p $\leq$ 0.05), lower bone volume fraction (-27.1%; p $\leq$ 0.05), reduced trabecular number (-27.6%; p $\leq$ 0.01) and increased trabecular separation (50.0%; p $\leq$ 0.0001). In contrast to the reduced parameters observed in vehicle-treated SH rats, treatment with RKER-012 increased bone volume, led to a higher bone volume fraction, increased trabecular number and decreased trabecular separation. Bone volume, bone volume fraction, trabecular number and trabecular separation remained equivalent to normoxic controls, which suggests that RKER-012 protected rats from PAH-induced bone loss.

"We are excited to announce additional preclinical data from our KER-012 program, which we presented at the ASBMR 2021 Annual Meeting. The results of this study suggest that RKER-012 prevented bone loss in this PAH model, which we believe supports that KER-012 has the potential to treat bone loss resulting from secondary osteoporosis, such as in PAH," said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros.

#### **About KER-012**

KER-012 is designed to bind to and inhibit the transforming growth factor-Beta ligands that suppress bone growth, including activin A and activin B, in order to promote bone growth to potentially treat diseases such as osteogenesis imperfecta and osteoporosis. 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 disorders associated with bone loss, such as osteogenesis imperfecta and osteoporosis, and for the treatment of PAH.

## 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 hematologic and musculoskeletal disorders with high unmet medical need. Keros is a leader in understanding the role of the transforming growth factor-Beta family of proteins, which are master regulators of red blood cell and platelet

production as well as of the growth, repair and maintenance of muscle and bone. 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 anemia resulting from iron imbalance, as well as for the treatment of fibrodysplasia ossificans progressiva. Keros' third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of PAH.

#### **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 "anticipates," "believes," "expects," "intends," "plans," "potential," "projects," "would" and "future" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: the potential of KER-012 to treat bone loss resulting from secondary osteoporosis, 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 lead product candidates, KER-050 and KER-047; 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; Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; Keros' ability to enter into new collaborations; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

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 5, 2021, 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:**

Mike Biega mbiega@soleburytrout.com (617) 221-9660