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): December 3, 2024

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 1.01 Entry into a Material Definitive Agreement.

On December 3, 2024, Keros Therapeutics, Inc. (the "Company") entered into an Exclusive License Agreement (the "Agreement") with Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"). Under the terms of the Agreement, the Company has granted Takeda the exclusive right to develop, manufacture, and commercialize the Company's product candidate, elritercept (KER-050), and certain derivative compounds. This exclusive right applies globally, excluding the territories of mainland China, Hong Kong, and Macau (the "Territory").

Under the Agreement, Takeda will make an upfront payment to the Company of $200.0 million. In addition to the upfront payment, the Company is entitled to receive up to an aggregate of (i) $370.0 million upon the achievement of specified development and commercial milestones; and (ii) $740.0 million upon the achievement of specified sales milestones. If a licensed product is approved for marketing in the Territory, the Company will be entitled to receive royalty payments based on tiered increments of annual net sales in the Territory, with such percentage ranging from the low double-digits to high teens, subject to specified potential royalty reductions.

Takeda's obligation to pay royalties for a given licensed product in a given country in the Territory will begin on the date of the first commercial sale for such licensed product in such country and continue until the latest of (i) 10 years from the date of the first commercial sale for such licensed product in such region, (ii) the expiration of the last valid claim of certain licensed patents, and (iii) expiration of regulatory exclusivity in such region.

The Agreement will continue in force until the expiration of the royalty term. Takeda may terminate the Agreement (i) in its entirety or on a country-by-country basis for convenience, with notice or (ii) if Takeda reasonably determines that the development, manufacture, and commercialization of the licensed compound or licensed product pose a safety or public health risk. The Company may terminate the Agreement in its entirety in the event that Takeda or its affiliates bring a patent challenge. Either party may terminate the Agreement in its entirety (i) if antitrust clearance is not obtained within a specified period after the Effective Date; (ii) if the other party materially breaches the Agreement and fails to cure such breach; or (iii) upon the bankruptcy of the other party.

The foregoing summary of the Agreement is not complete and is qualified in its entirety by reference to the text of the Agreement, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2024.

Item 8.01 Other Events.

On December 3, 2024, the Company issued a press release announcing it entered into the Agreement with Takeda. 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 December 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: December 3, 2024

Exhibit 99.1

Keros Therapeutics Announces Global License Agreement with Takeda to Advance Elritercept

Keros Therapeutics to receive upfront payment of $200 million and is eligible to receive development, approval and commercial milestone payments with the potential to exceed $1.1 billion and tiered royalties on net sales

LEXINGTON, Mass., December 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-ß") family of proteins, today announced an exclusive global development and commercialization license agreement with Takeda (TSE:4502/NYSE:TAK) to advance elritercept. Elritercept is currently in two ongoing Phase 2 clinical trials; one in patients with very low-, low-, or intermediate-risk myelodysplastic syndrome ("MDS") and one in patients with myelofibrosis ("MF"). The Phase 3 RENEW clinical trial evaluating elritercept in adult patients with transfusion-dependent anemia with very low-, low-, or intermediate-risk MDS will begin enrollment soon.

Under the terms of the agreement, Takeda will obtain an exclusive license to further develop, manufacture and commercialize elritercept worldwide outside of mainland China, Hong Kong and Macau. Takeda will be responsible for all development, manufacturing and commercialization as of the effective date of the agreement. Subject to the terms of the agreement, Keros will receive a $200 million upfront cash payment and is eligible to receive development, approval and commercial milestones with the potential to exceed $1.1 billion. Keros will also be eligible to receive tiered royalties on net sales.

"We are thrilled to announce this agreement with Takeda, a leader in the hematologic oncology treatment space," said Jasbir S. Seehra, Ph.D., Chair and Chief Executive Officer of Keros. "We believe this global license further validates Keros' position as a leader in understanding the role of the TGF-ß family of proteins and the broad potential of this biological pathway."

"We believe Takeda is an ideal partner to maximize the potential of elritercept's differentiated profile and continue to build on the great progress our team has accomplished with elritercept," said Chris Rovaldi, President and Chief Operating Officer of Keros. "We expect that the net proceeds from the upfront payment will enable us to extend our operational runway into the fourth quarter of 2028, facilitating the continued advancement of cibotercept (KER-012) and KER-065, both of which are wholly-owned assets with near term clinical updates."

"We are excited to partner with Keros, an accomplished team with exceptional expertise in TGF-ß biology," said P.K. Morrow, Head of the Oncology Therapeutic Area Unit at Takeda. "Building on the promising results elritercept has shown in the clinic to date, we look forward to continuing to explore its potential and to having the opportunity to potentially deliver it to patients with hematologic disorders. This agreement aligns with our goal of advancing therapies that may shift the treatment paradigm for underserved patient populations."

The effectiveness of the agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act").

About Elritercept

Elritercept is an engineered ligand trap comprised of a modified ligand-binding domain of the TGF-ß receptor known as activin receptor type IIA that is fused to the portion of the human antibody known as

the Fc domain. Elritercept is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with MF.

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-ß family of proteins. Keros is a leader in understanding the role of the TGF-ß 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. Elritercept is being developed for the treatment of low blood cell counts, or cytopenias, including anemia and thrombocytopenia, in patients with MDS and in patients with MF. Cibotercept is being developed for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders. 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 “expect,” “enable,” “forward,” “potential” and “will” or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include statements concerning: the expected upfront payment and other potential milestone and royalty payments and development activities under the license agreement, Keros’ expectations regarding the timing of enrollment for the Phase 3 RENEW clinical trial for elritercept, the potential benefits of elritercept, Takeda’s ability to further develop and advance elritercept, Keros’ expected cash runway, Keros’ ability to advance cibotercept and KER-065, and the clearance of the license agreement under the HSR Act. 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; 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.

Investor Contact:

Justin Frantz
jfrantz@kerostx.com
617-221-6042