
**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): November 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))
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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 2.02 Results of Operations and Financial Condition.

On November 4, 2021, Keros Therapeutics, Inc. (the “Company”) issued a press release announcing its recent business highlights and financial results for the quarter ended September 30, 2021. A copy of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02, 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 in this Item 2.02 and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended (the “Securities Act”), 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 November 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: November 4, 2021

Keros Therapeutics Reports Recent Business Highlights and Third Quarter 2021 Financial Results

Lexington, Mass. – November 4, 2021 – Keros Therapeutics, Inc. (“Keros” or the “Company”) (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 provided a business update and reported financial results for the quarter ended September 30, 2021.

“As we enter the last quarter of the year, we are approaching the conclusion of Part 1 of our Phase 2 clinical trial of KER-050 in patients with myelodysplastic syndromes (“MDS”). In preparation for Part 2 of this trial, we are excited to bring on additional clinical sites to increase patient recruitment, and look forward to providing a clinical data update at the 63rd American Society of Hematology (“ASH”) Annual Meeting and Exposition held December 11 through 14,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “As we look to the remainder of 2021 and into 2022, I am very excited by the potential of the company as we continue to advance and expand our pipeline across a wide range of serious hematological and musculoskeletal disorders.”

Recent Corporate Highlights:

- **Entrance into lease for new headquarters:** In September 2021, the Company announced that it entered into an indenture of lease with Revolution Labs Owner, LLC, pursuant to which the Company will lease approximately 35,662 square feet of office and laboratory space located at 1050 Waltham Street, Lexington, Massachusetts for its new principal executive office. The Company expects to move into its new headquarters in the fourth quarter of 2022.

Recent Program Highlights:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias**
 - Keros will present an abstract announcing additional preliminary results from Keros’ Phase 2 clinical trial of KER-050 in patients with very low-, low-, or intermediate-risk MDS at the 63rd ASH Annual Meeting and Exposition, to be held both in person and virtually from December 11 through 14, 2021.
 - Keros has initiated dosing for Cohort 4 of its Phase 2 clinical trial of KER-050 at 3.75 mg/kg of KER-050, to be administered once every four weeks for 12 weeks, following Safety Review Committee recommendation.
- **KER-012 for the treatment of disorders associated with bone loss and for the treatment of pulmonary arterial hypertension**
 - In September 2021, the Company commenced a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-012 in healthy volunteers. Keros expects to report initial data from Part 1 of this trial in the first half of 2022 and additional data from Part 2 of this trial in the second half of 2022.

Third Quarter 2021 Financial Results

Keros reported a net loss of \$20.3 million in the third quarter of 2021 as compared to a net loss of \$12.0 million in the third quarter of 2020. The increase in net loss for the third quarter was largely due to increased research and development efforts as well as additional infrastructure expenses to support the achievement of Keros’ corporate goals.

Research and development expenses were \$14.8 million for the third quarter of 2021 as compared to \$8.4 million for the same period in 2020. The increase of \$6.4 million was primarily due to additional

research and development efforts, manufacturing activities, and personnel expenses to support the advancement of Keros' pipeline.

General and administrative expenses were \$5.4 million for the third quarter of 2021 as compared to \$3.6 million for the same period in 2020. The increase of \$1.8 million was primarily due to increase in personnel expenses and other external expenses to support Keros' organizational growth.

Keros' cash and cash equivalents as of September 30, 2021 was \$221.3 million compared to \$265.9 million as of December 31, 2020. Keros expects that the cash and cash equivalents it had on hand at September 30, 2021 will fund its operating expenses and capital expenditure requirements into the fourth quarter of 2023.

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 pulmonary arterial hypertension.

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: Keros' expectations regarding its growth, strategy, progress and timing of its preclinical studies and clinical trials for KER-050, KER-047 and KER-012; the potential impact of COVID-19 on Keros' ongoing and planned preclinical studies, clinical trials, business and operations; and Keros' expected cash runway. 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; and risks relating to the impact on Keros' 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:

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KEROS THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2021	2020	2021	2020
REVENUE:				
License revenue	\$ —	\$ —	\$ 100	\$ —
Total revenue	<u>—</u>	<u>—</u>	<u>100</u>	<u>—</u>
OPERATING EXPENSES:				
Research and development	(14,832)	(8,395)	(36,310)	(24,186)
General and administrative	(5,365)	(3,553)	(15,297)	(9,180)
Total operating expenses	<u>(20,197)</u>	<u>(11,948)</u>	<u>(51,607)</u>	<u>(33,366)</u>
LOSS FROM OPERATIONS	(20,197)	(11,948)	(51,507)	(33,366)
OTHER INCOME (EXPENSE), NET				
Interest expense, net	(1)	(2)	(3)	(5)
Change in fair value of preferred stock tranche obligation	—	—	—	(1,490)
Other income (expense), net	(137)	(86)	(282)	4
Total other expense, net	<u>(138)</u>	<u>(88)</u>	<u>(285)</u>	<u>(1,491)</u>
Loss before income taxes	(20,335)	(12,036)	(51,792)	(34,857)
Income tax (provision) benefit	38	—	(12)	172
Net loss	<u>\$ (20,297)</u>	<u>\$ (12,036)</u>	<u>\$ (51,804)</u>	<u>\$ (34,685)</u>
Net loss attributable to common stockholders—basic and diluted	<u>\$ (20,297)</u>	<u>\$ (12,036)</u>	<u>\$ (51,804)</u>	<u>\$ (35,697)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.87)</u>	<u>\$ (0.60)</u>	<u>\$ (2.22)</u>	<u>\$ (2.65)</u>
Weighted-average common stock outstanding—basic and diluted	<u>23,362,237</u>	<u>20,175,883</u>	<u>23,299,720</u>	<u>13,452,606</u>

KEROS THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	SEPTEMBER 30, 2021	DECEMBER 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	221,349	265,876
Accounts receivable	—	—
Prepaid expenses and other current assets	4,725	1,850
Total current assets	226,074	267,726
Operating lease right-of-use assets	1,265	878
Property and equipment, net	1,295	724
Restricted cash	1,328	115
TOTAL ASSETS	229,962	269,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	2,811	2,149
Current portion of operating lease liabilities	843	423
Accrued expenses and other current liabilities	7,361	4,612
Total current liabilities	11,015	7,184
Operating lease liabilities, net of current portion	453	476
Other liabilities	16	62
Total liabilities	11,484	7,722
STOCKHOLDERS' EQUITY:		
Common stock, par value of \$0.0001 per share; 200,000,000 authorized as of September 30, 2021 and December 31, 2020, respectively; 23,396,793 and 23,192,866 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	335,291	326,730
Accumulated deficit	(116,815)	(65,011)
Total stockholders' equity	218,478	261,721
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	229,962	269,443