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): March 3, 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 2.02 Results of Operations and Financial Condition.

On March 3, 2023, Keros Therapeutics, Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the quarter and year ended December 31, 2022. 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 March 3, 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: March 3, 2023

Exhibit 99.1

Keros Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2022 Financial Results

LEXINGTON, Mass., March 3, 2023 (GLOBE NEWSWIRE) -- 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, pulmonary and cardiovascular disorders with high unmet medical need, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2022.

“2022 was another momentous year for Keros - consistent execution throughout last year has positioned Keros to deliver on several key upcoming milestones in 2023,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “We are excited by the momentum and engagement around our two ongoing Phase 2 clinical trials of KER-050, one in patients with myelodysplastic syndromes ("MDS") and one in patients with myelofibrosis, as we believe KER-050 has significant potential to address unmet patient need in a differentiated way. Additionally, we will continue to leverage our understanding of the transforming growth factor-beta family of proteins to research our library of proprietary molecules, in order to expand our development programs related to hematological, pulmonary and cardiovascular disorders.”

Recent Corporate Highlights:

- **Cash position strengthened:** The Company has utilized its existing at the market offering ("ATM") to sell additional shares of common stock, which strengthened its cash position. The Company expects that its cash and cash equivalents as of December 31, 2022, together with the net proceeds from the ATM through February 28, 2023, will enable the Company to fund its operating expenses and capital expenditure requirements into the third quarter of 2025.

Selected Anticipated 2023 Corporate Milestones:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias:**
  - Complete enrollment in transfusion-dependent cohorts in the ongoing Phase 2 clinical trial of KER-050 in patients with MDS in the second half of 2023
  - Report additional data from Part 2 of the ongoing Phase 2 clinical trial of KER-050 in patients with MDS in the first and second half of 2023
  - Expand the Phase 2 clinical trial of KER-050 in patients with MDS to MDS patients with iron overload in the second half of 2023
  - Report additional dose escalation data from and commence Part 2 of the ongoing Phase 2 clinical trial of KER-050 in patients with myelofibrosis in the second half of 2023
- **KER-047 for the treatment of functional iron deficiency:**
  - Report additional dose escalation data from the ongoing Phase 2 clinical trial of KER-047 in patients with iron-refractory iron deficiency anemia in the second half of 2023
  - Commence an open-label Phase 2 clinical trial of KER-047 in MDS and myelofibrosis patients with functional iron deficiency in the first half of 2023, and report initial data from this trial in the second half of 2023
- **KER-012 for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders:**
  - Commence a Phase 2 clinical trial evaluating KER-012 in patients with pulmonary arterial hypertension in the first half of 2023
  - Commence an open-label Phase 2 biomarker clinical trial of KER-012 in the second half of 2023

2022 Financial Results

Keros reported a net loss of $29.7 million for the fourth quarter and $104.7 million for the year ended December 31, 2022, as compared to a net loss of $6.9 million for the fourth quarter and $58.7 million for the year ended December 31, 2021. The increase in net loss for the fourth quarter and the increase in net loss for the year was largely due to increased research and development efforts, including the progression of the Company's two Phase 2 clinical trials in KER-050, one in patients with MDS and one in patients with myelofibrosis, plus an upfront payment from the Company's license agreement with Hansoh (Shanghai) Healthtech Company Limited (“Hansoh”) in the fourth quarter of 2021.

Keros did not generate any revenue for the year ended December 31, 2022. The revenue for the year ended December 31, 2021 was $20.1 million, which was primarily related to the license agreement Keros entered into with Hansoh.

Research and development expenses were $24.9 million for the fourth quarter and $87.3 million for the year ended December 31, 2022, as compared to $18.8 million for the fourth quarter and $55.1 million for the year ended December 31, 2021. The increase in research and development expenses for the fourth quarter and the year was driven by the continued advancement of the Company's pipeline, notably the progression of its two Phase 2 clinical trials of KER-050, as well as an increase in the infrastructure to support operations and expansion of its programs.

General and administrative expenses were $7.1 million for the fourth quarter and $27.5 million for the year ended December 31, 2022, as compared to $6.0 million and $21.3 million for the year ended December 31, 2021. The increase was primarily due to an increase in personnel expenses, which includes additional stock-based compensation costs to support the Company's organizational growth and achievement of its corporate goals, an increase in facilities, supplies and other office expenses due to growth of the Company's organization, and an increase in professional fees and director and officer insurance premiums.

Keros’ cash and cash equivalents as of December 31, 2022 was $279.0 million compared to $230.0 million as of December 31, 2021. Keros expects that the cash and cash equivalents it had on hand at December 31, 2022, together with the net proceeds from the ATM through February 28, 2023, will fund its operating expenses and capital expenditure requirements into the third quarter of 2025.

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 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 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 MDS 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 pulmonary arterial hypertension 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 "anticipates," "believes," “continue,” "expects," “potential” 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 and timing of its clinical trials for KER-050, KER-047 and KER-012, including its regulatory plans; the potential of KER-050 to address unmet patient need in a differentiated way; 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 pre-clinical studies; 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 November 3, 2022, 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.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2022	**2021**	**2022**	**2021**
REVENUE:				
Research collaboration revenue	$ —	$ 20,000	$ —	$ 20,100
Total revenue	—	20,000	—	20,100
OPERATING EXPENSES:				
Research and development	(24,867)	(18,834)	(87,265)	(55,143)
General and administrative	(7,093)	(6,033)	(27,525)	(21,330)
Total operating expenses	(31,960)	(24,867)	(114,790)	(76,473)
LOSS FROM OPERATIONS	(31,960)	(4,867)	(114,790)	(56,373)
OTHER INCOME (EXPENSE), NET:				
Interest expense, net	—	(1)	(1)	(4)
Research and development incentive income	—	—	7,081	—
Other income (expense), net	2,242	(74)	3,031	(356)
Total other income (expense), net	2,242	(75)	10,111	(360)
Loss before income taxes	(29,718)	(4,942)	(104,679)	(56,733)
Income tax provision	—	(1,998)	—	(2,011)
Net loss	$ (29,718)	$ (6,940)	$ (104,679)	$ (58,744)
Net loss attributable to common stockholders—basic and diluted	$ (29,718)	$ (6,940)	$ (104,679)	$ (58,744)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.09)	$ (0.30)	$ (4.15)	$ (2.52)
Weighted-average common stock outstanding—basic and diluted	27,326,726	23,435,383	25,241,030	23,333,914

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

	DECEMBER 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 279,048	$ 230,042
Accounts receivable	—	18,000
Prepaid expenses and other current assets	6,719	3,398
Total current assets	285,767	251,440
Operating lease right-of-use assets	15,548	1,067
Property and equipment, net	2,021	1,335
Restricted cash	1,327	1,327
Other long term asset	2,118	82
TOTAL ASSETS	$ 306,781	$ 255,251
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,339	$ 3,645
Current portion of operating lease liabilities	455	862
Accrued expenses and other current liabilities	12,753	7,339
Total current liabilities	16,547	11,846
Operating lease liabilities, net of current portion	12,811	231
Total liabilities	29,358	12,077
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT:		
Preferred stock, par value of $0.0001 per share; 10,000,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; no shares issued and outstanding	—	—
Common stock, par value of $0.0001 per share; 200,000,000 authorized 27,543,453 and 23,974,834 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	505,855	366,927
Accumulated deficit	(228,434)	(123,755)
Total stockholders' equity	277,423	243,174
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 306,781	$ 255,251