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 9, 2022

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.)**

99 Hayden Avenue, Suite 120, Building E
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 9, 2022, 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, 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 March 9, 2022.
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 9, 2022

Exhibit 99.1

Keros Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2021 Financial Results

Lexington, Mass. – March 9, 2022 – 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 fourth quarter and full year ended December 31, 2021.

“I am exceptionally proud of the Keros team's performance in 2021, as we advanced all aspects of our business, including securing a strategic partnership with Hansoh for KER-050 in mainland China, Hong Kong and Macau,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “Our momentum is accelerating, as we reported positive initial data from our open-label Phase 2 clinical trial of KER-050 in patients with myelodysplastic syndromes (“MDS”). I am confident that our financial strength, dedicated workforce and proven ability to execute will enable us to continue to advance our pipeline and position the company to execute against our key milestones in 2022.”

Recent Corporate Highlights:

- **Entered into license agreement and strategic partnership for rights to KER-050 in China:** Entered into a license agreement with Hansoh (Shanghai) Healthtech Company Limited (“Hansoh”), whereby Hansoh will obtain an exclusive license from Keros to develop, manufacture and commercialize KER-050 within the territories of mainland China, Hong Kong, and Macau. In exchange, Keros received an upfront net payment of $18.0 million in January 2022, extending expected cash runway into the first quarter of 2024. Keros is also eligible to receive up to an additional $170.5 million in development and commercial milestones, plus tiered royalties on net product sales ranging from the low double digit to high teens.
- **Strengthened leadership with key appointment:** In February 2022, Keros appointed Christopher Rovaldi as Chief Operating Officer. Prior to joining Keros, Mr. Rovaldi served as a consultant to biotechnology companies. Prior to that, he held multiple positions of increasing responsibility at Acceleron Pharma Inc., including his most recent role there as Senior Vice President, Program Management and Operations. Mr. Rovaldi has over 20 years of program and portfolio management experience.

Recent Program Highlights:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias**
  - In December 2021, the Company commenced its open label, two-part, multiple ascending dose Phase 2 clinical trial to evaluate KER-050 as a monotherapy and in combination with ruxolitinib in participants with myelofibrosis-associated cytopenias.
- **KER-012 for the treatment of pulmonary arterial hypertension and for the treatment of disorders associated with bone loss**
  - The Company has completed dosing of Part 1 of its randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate single and multiple ascending doses of KER-012 in healthy volunteers.

Selected Anticipated 2022 Corporate Milestones:

- Keros expects to report additional data from the ongoing Phase 2 clinical trial of KER-050 in patients with myelodysplastic syndromes in mid-2022
- Keros expects to report initial data from the ongoing Phase 2 clinical trial of KER-050 in patients with myelofibrosis by the end of 2022

- Keros expects to initiate two Phase 2 clinical trials of KER-047, one in patients with iron deficiency anemia and one in patients with iron-refractory iron deficiency anemia, in the first half of 2022, and report initial data from both trials by the end of 2022
- Keros expects to report initial data from Part 1 of the ongoing Phase 1 clinical trial of KER-012 in healthy volunteers in the second quarter of 2022 and additional data from Part 2 of this trial in the second half of 2022

2021 Financial Results

Keros reported a net loss of $6.9 million for the fourth quarter and $58.7 million for the year ended December 31, 2021, as compared to a net loss of $10.7 million for the fourth quarter and $45.4 million for the year ended December 31, 2020. The decrease in net loss for the fourth quarter and the increase in net loss for the year was largely due to the upfront payment from the Company's license agreement with Hansoh in the fourth quarter of 2021, offset by 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, and the manufacturing and commencement of its Phase 1 clinical trial activities for KER-012, as well as an increase in the infrastructure to support operations and expansion of its programs.

Revenue for the year ended December 31, 2021 was $20.1 million. The revenue for the year ended December 31, 2020 was zero. The revenue in the year ended December 31, 2021 was primarily related to the license agreement Keros entered into with Hansoh.

Research and development expenses were $18.8 million for the fourth quarter and $55.1 million for the year ended December 31, 2021, as compared to $9.7 million for the fourth quarter and $33.9 million for the year ended December 31, 2020. 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 and the commencement of its Phase 1 clinical trial activities for KER-012, as well as an increase in the infrastructure to support operations and expansion of its programs.

General and administrative expenses were $6.0 million for the fourth quarter and $21.3 million for the year ended December 31, 2021, as compared to $3.6 million and $12.8 million for the year ended December 31, 2020. The increase was primarily due to an increase in personnel expenses to support Keros' organizational growth, additional share-based compensation costs, and an increase in professional fees primarily attributable to legal expenses related to data privacy law compliance and the maintenance and expansion of the Company's intellectual property portfolio.

Keros’ cash and cash equivalents as of December 31, 2021 was $230.0 million compared to $265.9 million as of December 31, 2020. Keros expects that the cash and cash equivalents it had on hand at December 31, 2021, along with the net $18.0 million upfront payment pursuant to the license agreement with Hansoh, which the Company received in January 2022, will fund its operating expenses and capital expenditure requirements into the first quarter of 2024.

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 MDS 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. Keros' third product candidate, KER-012, is being developed for the treatment of pulmonary arterial hypertension and for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta.

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 clinical trials for KER-050, KER-047 and KER-012, including its regulatory plans; 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 4, 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 DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2021	**2020**	**2021**	**2020**
REVENUE:				
Research collaboration revenue	$ 20,000	$ —	$ 20,100	$ —
Total revenue	20,000	—	20,100	—
OPERATING EXPENSES:				
Research and development	(18,834)	(9,674)	(55,143)	(33,860)
General and administrative	(6,033)	(3,617)	(21,330)	(12,797)
Total operating expenses	(24,867)	(13,291)	(76,473)	(46,657)
LOSS FROM OPERATIONS	(4,867)	(13,291)	(56,373)	(46,657)
OTHER INCOME (EXPENSE), NET:				
Interest expense, net	(1)	(1)	(4)	(6)
Research and development incentive income	—	2,460	—	2,460
Change in fair value of preferred stock tranche obligation	—	—	—	(1,490)
Other income (expense), net	(74)	156	(356)	160
Total other income (expense), net	(75)	2,615	(360)	1,124
Loss before income taxes	(4,942)	(10,676)	(56,733)	(45,533)
Income tax (provision) benefit	(1,998)	—	(2,011)	172
Net loss	$ (6,940)	$ (10,676)	$ (58,744)	$ (45,361)
Net loss attributable to common stockholders—basic and diluted	$ (6,940)	$ (10,676)	$ (58,744)	$ (45,361)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.30)	$ (0.49)	$ (2.52)	$ (2.93)
Weighted-average common stock outstanding—basic and diluted	23,435,383	21,623,123	23,333,914	15,506,397

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

	DECEMBER 31,	
	2021	**2020**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 230,042	$ 265,876
Accounts receivable	18,000	—
Prepaid expenses and other current assets	3,398	1,850
Total current assets	251,440	267,726
Operating lease right-of-use assets	1,067	878
Property and equipment, net	1,335	724
Restricted cash	1,327	115
Other long term asset	82	—
TOTAL ASSETS	$ 255,251	$ 269,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,645	$ 2,149
Current portion of operating lease liabilities	862	423
Accrued expenses and other current liabilities	7,339	4,612
Total current liabilities	11,846	7,184
Operating lease liabilities, net of current portion	231	476
Other liabilities	—	62
Total liabilities	12,077	7,722
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT:		
Common stock, par value of $0.0001 per share; 200,000,000 authorized, 23,974,834 and 23,192,866 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	366,927	326,730
Accumulated deficit	(123,755)	(65,011)
Total stockholders' equity	243,174	261,721
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 255,251	$ 269,443