
**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 25, 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 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 25, 2021, 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, 2020. 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 25, 2021.

Keros Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2020 Financial Results

Lexington, Massachusetts – March 25, 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 fourth quarter and full year ended December 31, 2020.

“2020 was a transformative year for Keros, as we continued to make important preclinical and clinical progress across our pipeline and brought the company public,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “While our open-label Phase 2 clinical trial of KER-050 in patients with myelodysplastic syndromes is ongoing, we are also working to initiate three more Phase 2 clinical trials this year: a KER-050 trial in patients with myelofibrosis and two KER-047 trials, one in patients with iron deficiency anemia and one in patients with iron-refractory iron deficiency anemia. Our ability to progress multiple product candidates over the last year reflects the dedication of our team and the potential reach of our discovery approach, particularly given the many challenges resulting from the ongoing COVID-19 pandemic.”

Recent Corporate Highlights:

- **Completed public offering:** In November 2020, Keros completed its public offering of 2,990,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase up to 390,000 additional shares, at a public offering price of \$50.00 per share, for aggregate gross proceeds to Keros of \$149.5 million. Keros received approximately \$140.1 million in net proceeds after deducting underwriting discounts and commissions and offering costs.
- **Strengthened leadership with board appointment:** In December 2020, Keros appointed Mary Ann Gray, Ph.D., to its board of directors. Concurrent with Dr. Gray joining Keros’ Board of Directors, Alon Lazarus stepped down as a director of the Company.

Recent Program Highlights:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias:**
 - Keros has initiated dosing of the first two cohorts (0.75 mg/kg and 1.5 mg/kg) of Part 1 of its Phase 2 clinical trial evaluating KER-050 in patients with myelodysplastic syndromes. The Company expects to report initial data from Part 1 of this trial in mid-2021.
 - Presented preclinical data at the virtual European School of Haematology (“ESH”) 2nd Translational Research E-Conference in March 2021, demonstrating that a research form of KER-050 induced red blood cell production by promoting multiple stages of erythroid differentiation.
- **KER-047 for the treatment of anemia resulting from iron imbalance and for the treatment of fibrodysplasia ossificans progressiva:**
 - Presented preclinical data on an ALK2 inhibitor closely related to KER-047 at the March 2021 ESH E-Conference, demonstrating targeted ALK2 inhibition as a potential therapeutic approach to reducing hepcidin and elevating serum iron.
 - 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 second half of 2021 and to report initial data from both trials in 2022.

Selected Anticipated 2021 Corporate Milestones:

- Report initial data from Part 1 of the Phase 2 clinical trial of KER-050 in patients with myelodysplastic syndromes in mid-2021
- Initiate a Phase 2 clinical trial of KER-050 in patients with myelofibrosis in mid-2021
- 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 second half of 2021
- Initiate a Phase 1 clinical trial of KER-012 in the second half of 2021

2020 Financial Results

Keros reported a net loss of \$10.7 million for the fourth quarter and \$45.4 million for the year ended December 31, 2020, as compared to a net loss of \$2.8 million for the fourth quarter and \$12.3 million for the year ended December 31, 2019. The increase in net loss for the fourth quarter and the year was largely due to increased research and development efforts as well as the infrastructure to support operations as a publicly traded company.

Research and development expenses were \$9.7 million for the fourth quarter and \$33.9 million for the year ended December 31, 2020 as compared to \$4.2 million for the fourth quarter and \$17.4 million for the year ended December 31, 2019. The increase in research and development expense for the fourth quarter and the year was primarily due to additional preclinical, clinical and manufacturing activities, as well as an increase related to personnel expenses, including additional share-based compensation cost, driven primarily by increased headcount.

General and administrative expenses were \$3.6 million for the fourth quarter and \$12.8 million for the year ended December 31, 2020 as compared to \$1.1 million and \$3.2 million for the year ended December 31, 2019. 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 to support Keros' transition to a public company.

Keros' cash and cash equivalents as of December 31, 2020 was \$265.9 million compared to \$7.0 million as of December 31, 2019. Keros substantially extended its cash runway, largely by raising \$55.8 million in net proceeds from its March 2020 Series C preferred stock offering, \$100.1 million in net proceeds from its April 2020 initial public offering and \$140.1 million in net proceeds from its November 2020 public offering. Keros expects that the cash and cash equivalents it had on hand at December 31, 2020 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, 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 10, 2020, 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.

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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,	
	2020	2019	2020	2019
REVENUE:				
Research collaboration revenue	\$ —	\$ 2,500	\$ —	\$ 10,000
Total revenue	\$ —	\$ 2,500	\$ —	\$ 10,000
OPERATING EXPENSES:				
Research and development	\$ (9,674)	\$ (4,161)	\$ (33,860)	\$ (17,379)
General and administrative	\$ (3,617)	\$ (1,067)	\$ (12,797)	\$ (3,184)
Total operating expenses	\$ (13,291)	\$ (5,228)	\$ (46,657)	\$ (20,563)
LOSS FROM OPERATIONS	\$ (13,291)	\$ (2,728)	\$ (46,657)	\$ (10,563)
OTHER INCOME (EXPENSE), NET:				
Interest expense, net	\$ (1)	\$ (1)	\$ (6)	\$ (8)
Research and development incentive income	\$ 2,460	\$ —	\$ 2,460	\$ 558
Change in fair value of preferred stock tranche obligation	\$ —	\$ (78)	\$ (1,490)	\$ (2,564)
Other income (expense), net	\$ 156	\$ 56	\$ 160	\$ 241
Total other income (expense), net	\$ 2,615	\$ (23)	\$ 1,124	\$ (1,773)
Loss before income taxes	\$ (10,676)	\$ (2,751)	\$ (45,533)	\$ (12,336)
Income tax benefit	\$ —	\$ —	\$ 172	\$ —
Net loss	\$ (10,676)	\$ (2,751)	\$ (45,361)	\$ (12,336)
Net loss attributable to common stockholders—basic and diluted	\$ (10,676)	\$ (3,201)	\$ (45,361)	\$ (14,136)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.49)	\$ (1.32)	\$ (2.93)	\$ (6.08)
Weighted-average common stock outstanding—basic and diluted	21,623,123	2,416,387	15,506,397	2,326,857

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

	DECEMBER 31,	
	2020	2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 265,876	\$ 7,020
Prepaid expenses and other current assets	1,850	381
Deferred initial public offering costs	—	604
Research and development incentive receivable	—	922
Total current assets	267,726	8,927
Operating lease right-of-use assets	878	1,205
Property and equipment, net	724	708
Restricted cash	115	115
TOTAL ASSETS	\$ 269,443	\$ 10,955
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,149	\$ 2,088
Current portion of operating lease liabilities	423	376
Accrued expenses and other current liabilities	4,612	2,022
Total current liabilities	7,184	4,486
Operating lease liabilities, net of current portion	476	899
Preferred stock tranche liability	—	4,956
Other liabilities	62	119
Total liabilities	7,722	10,460
COMMITMENTS AND CONTINGENCIES		
Series A convertible preferred stock, par value of \$0.0001 per share; 0 and 10,000,000 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 0 and 4,607,652 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of December 31, 2020	—	9,891
Series A-1 convertible preferred stock, par value of \$0.0001 per share; 0 and 800,000 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 0 and 368,612 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of December 31, 2020	—	944
Series B-1 convertible preferred stock, par value of \$0.0001 per share; 0 and 3,427,004 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 0 and 1,579,043 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively; liquidation and redemption value of \$0 as of December 31, 2020	—	9,106
STOCKHOLDERS' DEFICIT:		
Common stock, par value of \$0.0001 per share; 200,000,000 and 27,000,000 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 23,192,866 and 2,429,705 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	326,730	203
Accumulated deficit	(65,011)	(19,650)
Total stockholders' equity (deficit)	261,721	(19,446)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	\$ 269,443	\$ 10,955