Keros Therapeutics Reports Recent Business Highlights and Second Quarter 2022 Financial Results

August 4, 2022 8:01 PM EDT

KER-050 data from ongoing Phase 2 study in patients with lower risk myelodysplastic syndromes demonstrated meaningful responses across both ring sideroblast-positive and non-RS patients; 44% of high transfusion burden patients achieved transfusion independence

KER-012 preliminary Phase 1 data exhibited encouraging treatment profile in healthy volunteers with improvements in biomarkers of bone formation with no clinically meaningful changes in red blood cell parameters

Strengthened cash position and extended cash runway to fund operations into Q3 2024

LEXINGTON, Mass., Aug. 04, 2022 (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 musculoskeletal disorders with high unmet medical need, today provided a business update and reported financial results for the quarter ended June 30, 2022.

“We continued the positive momentum for our pipeline programs into the second quarter of 2022. The clinical data demonstrated the potential of differentiated profiles of KER-050 and KER-012,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “We shared promising clinical data for KER-050 in patients with MDS demonstrating the potential for transfusion independence in RS+ and non-RS patients and in those patients with high transfusion burden. Additionally, we also presented encouraging initial safety and biomarker data for KER-012 from our Phase 1 study in healthy volunteers. We continue making progress and remain on track to report additional data from both studies later this year.”

Recent Program Highlights

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias associated with myelodysplastic syndromes (MDS) and myelofibrosis (MF)**
  - In June 2022, Keros presented data from an ongoing, open-label, two-part Phase 2 clinical trial evaluating KER-050 for the treatment of anemia in patients with very low, low, or intermediate-risk (lower risk) MDS patients at the Annual Congress of the European Hematology Association.
  - As of the data cutoff date (April 3, 2022), 51.9 % of evaluable patients (n=27) achieved overall erythroid response.
  - Importantly, in patients with high transfusion burden (HTB), the overall erythroid response rate (hematologic improvement-erythroid (HI-E) or transfusion independence (TI)) was 68.8 % while 43.8% achieved TI. A 52.9% mean maximum increase in soluble transferrin receptor, a marker of erythropoiesis, was observed with KER-050 treatment. Additionally, a 29.1% mean maximum reduction in serum ferritin, a marker of iron overload was observed with KER-050 treatment.
  - HTB patients achieving HI-E or TI also exhibited a sustained increase in platelets further illustrating the potential that KER-050 has to treat both anemia and thrombocytopenia in MDS patients.
  - KER-050 was generally well-tolerated at all doses evaluated in Part 1, and no drug-related serious adverse events (SAE) or dose-limiting toxicities (DLT) were observed.
  - Following recommendation of the Safety Review Committee, dosing for Part 2 of the KER-050 Phase 2 MDS trial was initiated. The Company expects to report additional data from the trial by end of 2022.
  - KER-050 is also being evaluated in an ongoing Phase 2 trial for treating MF-associated cytopenias and the Company remains on track to report initial data by the end of 2022.
- **KER-012 for the treatment of pulmonary arterial hypertension (PAH) and disorders associated with bone loss**

- In May 2022, Keros announced preliminary topline data from the Phase 1 clinical study of KER-012 in healthy postmenopausal women. This is an ongoing randomized, double-blind, placebo controlled, two-part dose-escalation study to evaluate the safety, tolerability, pharmacokinetic, and pharmacodynamic effects of treatment with KER-012.
- In the single ascending dose portion of the study, dosing with KER-012 was generally observed to be well tolerated at all doses up to 5 mg/kg with no SAEs noted. Majority of adverse events were mild (Grade 1 category).
- Maximal target engagement was seen with the 5 mg/kg dose (39.6% mean reduction in follicle-stimulating hormone levels) on day 22 post-treatment.
- Robust changes in bone formation markers were also observed, with up to 36.4% mean maximal increase in bone specific alkaline phosphatase (BSAP) elicited upon a single treatment of KER-012. These increases are consistent with restoration of bone morphogenic protein (BMP) signaling. Keros believes this supports the development of KER-012 as a potential treatment for patients with PAH, which is associated with reduced BMP signaling.
- Further, no clinically meaningful changes in hemoglobin, red blood cells or reticulocytes were observed at any dose level.
- An ongoing multiple ascending dose (MAD) portion of the Phase 1 KER-012 study is expected to report additional data in the second half of 2022. The Company anticipates announcing the design of a Phase 2 trial in PAH in early 2023.

- **KER-047 for the treatment of anemias resulting from iron imbalance**
  - In June 2022, Keros commenced an open label, two-part, MAD Phase 2 clinical trial to evaluate single (Part 1) and multiple ascending doses (Part 2) of KER-047 in patients with iron-refractory iron deficiency anemia. The Company anticipates reporting initial data from this trial by the end of 2022.
  - The Company expects to initiate a Phase 2 study in iron-deficiency anemia in the second half of 2022 and anticipates reporting initial data in first half of 2023.

- **Cash position strengthened**
  - The Company has utilized its "at-the-market" shelf registration statement to sell shares of common stock, which strengthened its cash position, and extended its cash runway to fund operations into the third quarter of 2024.

Second Quarter 2022 Financial Results

Keros reported a net loss of $27.3 million in the second quarter of 2022 as compared to a net loss of $15.6 million in the second quarter of 2021. The increase in net loss for the second 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 $23.3 million for the second quarter of 2022 as compared to $10.0 million for the same period in 2021. The increase of $13.3 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 $7.4 million for the second quarter of 2022 as compared to $5.7 million for the same period in 2021. 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 June 30, 2022 was $215.6 million compared to $230.0 million as of December 31, 2021. Keros expects that the cash and cash equivalents it had on hand at June 30, 2022 will fund its operating expenses and capital expenditure requirements into the third 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 hematological, pulmonary 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 patients with 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-047; 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 May 5, 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:

Deepankar Roy
droy@kerostx.com
213-268-1878

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
REVENUE:				
License revenue	$ —	$ 100	$ —	$ 100
Total revenue	—	100	—	100
OPERATING EXPENSES:				
Research and development	(23,281)	(9,983)	(41,359)	(21,478)
General and administrative	(7,447)	(5,658)	(13,495)	(9,932)
Total operating expenses	(30,728)	(15,641)	(54,854)	(31,410)
LOSS FROM OPERATIONS	(30,728)	(15,541)	(54,854)	(31,310)
OTHER INCOME (EXPENSE), NET				
Interest expense, net	—	(1)	(1)	(2)
Research and development incentive income	3,376	—	3,376	—
Other income (expense), net	86	(80)	27	(145)
Total other income (expense), net	3,462	(81)	3,402	(147)
Loss before income taxes	(27,266)	(15,622)	(51,452)	(31,457)
Income tax provision	—	—	—	(50)
Net loss	$ (27,266)	$ (15,622)	$ (51,452)	$ (31,507)
Net loss attributable to common stockholders—basic and diluted	$ (27,266)	$ (15,622)	$ (51,452)	$ (31,507)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.13)	$ (0.67)	$ (2.14)	$ (1.35)
Weighted-average common stock outstanding—basic and diluted	24,053,977	23,305,673	24,024,004	23,267,943

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

	JUNE 30, 2022	DECEMBER 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	215,621	230,042
Accounts receivable	—	18,000
Prepaid expenses and other current assets	6,736	3,398

Total current assets	222,357	251,440
Operating lease right-of-use assets	658	1,067
Property and equipment, net	1,652	1,335
Restricted cash	1,327	1,327
Other long-term asset	667	82
TOTAL ASSETS	226,661	255,251
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	7,660	3,645
Current portion of operating lease liabilities	670	862
Accrued expenses and other current liabilities	7,123	7,339
Total current liabilities	15,453	11,846
Operating lease liabilities, net of current portion	—	231
Total liabilities	15,453	12,077
STOCKHOLDERS' EQUITY:		
Common stock, par value of $0.0001 per share; 200,000,000 authorized as of June 30, 2022 and December 31, 2021, respectively; 24,429,382 and 23,974,834 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	386,413	366,927
Accumulated deficit	(175,207)	(123,755)
Total stockholders' equity	211,208	243,174
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	226,661	255,251