Keros Therapeutics Reports Recent Business Highlights and Second Quarter 2023 Financial Results

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LEXINGTON, Mass., Aug. 07, 2023 (GLOBE NEWSWIRE) -- Keros Therapeutics, Inc. (“Keros” or the “Company”) (Nasdaq: KROS), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the transforming growth factor-beta (“TGF-ß”) family of proteins, today provided a business update and reported financial results for the quarter ended June 30, 2023.

“We are excited to share our initial development plans for KER-065—an activin receptor ligand trap that is designed to increase skeletal muscle and bone mass, increase fat metabolism and reduce fibrosis—in Duchenne muscular dystrophy (“DMD”), a debilitating disease with a serious unmet need, and look forward to moving this important program into the clinic in the first quarter of 2024,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. “As highlighted by the progression of KER-065 and the initiation of our Phase 2 clinical trial of KER-012 in patients with pulmonary arterial hypertension (“PAH”), we continue to execute on our strategy of developing our pipeline of differentiated assets designed to harness the powerful biology of the TGF-ß family of proteins.”

Recent Program Highlights

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias**
  - Following recommendation by the Safety Review Committee, dosing for Cohort 4 of Keros’ ongoing Phase 2 clinical trial of KER-050 in patients with myelofibrosis-associated cytopenias was initiated at 4.5 mg/kg in both combination and monotherapy arms. Keros expects to announce dose escalation data from and initiate Part 2 of this trial in the second half of 2023.
- **KER-047 for the treatment of functional iron deficiency**
  - Keros initiated an open-label Phase 2 clinical trial in myelodysplastic syndromes (“MDS”) and myelofibrosis patients with functional iron deficiency. The Company expects to report initial data from this trial in the first half of 2024.
- **KER-012 for the treatment of PAH and for the treatment of cardiovascular disorders**
  - In July 2023, Keros announced that the U.S. Food and Drug Administration cleared the Company's investigational new drug application to conduct a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial, which Keros refers to as the TROPOS trial, of KER-012 in combination with background therapy in patients with PAH.
  - The Company is hosting a conference call and webcast tomorrow, August 8, 2023, at 8:00 a.m. Eastern time to provide an overview of the TROPOS trial design.
- **KER-065 for the treatment of neuromuscular disease**
  - KER-065, which was nominated out of Keros' proprietary library of activin receptor type II ligand traps, is being developed for the treatment of neuromuscular diseases, with an initial focus on DMD.
  - The Company plans to commence a randomized, double-blind, placebo-controlled, two-part Phase 1 clinical trial to evaluate the safety and tolerability of single and multiple ascending doses of KER-065 in healthy volunteers in the first quarter of 2024.

Second Quarter 2023 Financial Results

Keros reported a net loss of $37.5 million in the second quarter of 2023 as compared to a net loss of $27.3 million in the second quarter of 2022. The increase of $10.2 million for the second quarter was largely due to increased research and development efforts as well as additional investments to support the achievement of Keros' clinical and corporate goals.

Research and development expenses were $32.5 million for the second quarter of 2023 as compared to $23.3 million for the same period in 2022. The increase of $9.3 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 $8.8 million for the second quarter of 2023 as compared to $7.4 million for the same period in 2022. The increase of $1.4 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, 2023 was $322.0 million compared to $279.0 million as of December 31, 2022. Keros expects that the cash and cash equivalents it had on hand at June 30, 2023 will enable Keros to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025.

About Keros Therapeutics, Inc.

Keros is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapeutics to treat a wide range of patients with disorders that are linked to dysfunctional signaling of the TGF-ß family of proteins. We are a leader in understanding the role of the TGF-ß family of proteins, which are master regulators of the growth, repair and maintenance of blood cells and a number of tissues, including bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, we have discovered and are developing large and small molecules that have the potential to provide meaningful and potentially disease-modifying benefit to patients. 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. Keros' fourth product candidate, KER-065, is being developed for the treatment of neuromuscular diseases, with an initial focus on DMD.

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 "enable," "expects," "plans," "progress" 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, KER-012 and KER-065; 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 product candidates, KER-050, KER-047, KER-012 and KER-065; 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; and Keros' dependence on third parties in connection with manufacturing, clinical trials and preclinical studies.

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 4, 2023, 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2023	2022	2023	2022
OPERATING EXPENSES:				
Research and development	(32,534)	(23,281)	(63,625)	(41,359)
General and administrative	(8,803)	(7,447)	(16,581)	(13,495)
Total operating expenses	(41,337)	(30,728)	(80,206)	(54,854)
LOSS FROM OPERATIONS	(41,337)	(30,728)	(80,206)	(54,854)
OTHER INCOME (EXPENSE), NET				
Interest expense, net	—	—	—	(1)
Research and development incentive income	—	3,376	—	3,376
Other income, net	3,832	86	6,897	27
Total other income, net	3,832	3,462	6,897	3,402
Net loss	$ (37,505)	$ (27,266)	$ (73,309)	$ (51,452)
Net loss attributable to common stockholders—basic and diluted	$ (37,505)	$ (27,266)	$ (73,309)	$ (51,452)
Net loss per share attributable to common stockholders —basic and diluted	$ (1.27)	$ (1.13)	$ (2.53)	$ (2.14)
Weighted-average common stock outstanding—basic and diluted	29,602,458	24,053,977	28,989,361	24,024,004

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

	JUNE 30, 2023	DECEMBER 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	322,026	279,048
Prepaid expenses and other current assets	12,282	6,719
Total current assets	334,308	285,767
Operating lease right-of-use assets	16,010	15,548
Property and equipment, net	3,087	2,021
Restricted cash	1,327	1,327
Other long-term assets	1,574	2,118
TOTAL ASSETS	356,306	306,781
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	4,146	3,339
Current portion of operating lease liabilities	—	455
Accrued expenses and other current liabilities	11,949	12,753
Total current liabilities	16,095	16,547
Operating lease liabilities, net of current portion	13,951	12,811
Total liabilities	30,046	29,358
STOCKHOLDERS' EQUITY:		
Common stock, par value of $0.0001 per share; 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively; 29,661,005 and 27,543,453 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	628,000	505,855
Accumulated deficit	(301,743)	(228,434)
Total stockholders' equity	326,260	277,423
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	356,306	306,781