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

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LEXINGTON, Mass., Nov. 06, 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 September 30, 2023.

“Over the last quarter, we made strong progress across our pipeline and executed upon our corporate goals. We continued to advance our two open-label Phase 2 clinical trials evaluating KER-050, one in patients with myelodysplastic syndrome (“MDS”) and one in patients with myelofibrosis, and we look forward to sharing additional data from both trials at the 65th American Society of Hematology (“ASH”) Annual Meeting and Exposition later this quarter,” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer of Keros. “We also continued to progress our ongoing TROPOS Phase 2 clinical trial evaluating KER-012 in patients with pulmonary arterial hypertension (“PAH”), and activities related to global clinical trial site activation ramped up and continue to be a primary focus of our team.”

Recent Program Updates

- **KER-050 (elritercept) for the treatment of ineffective hematopoiesis to address cytopenias**
  - In November 2023, Keros announced that five abstracts will be presented at the 65th ASH Annual Meeting and Exposition, which will include clinical data from its two ongoing Phase 2 clinical trials of KER-050, one in patients with very low-, low-, or intermediate-risk MDS and one in patients with myelofibrosis.
  - Following recommendation by the Safety Review Committee, dosing for Part 2 of the KER-050 Phase 2 clinical trial in patients with myelofibrosis was initiated at a starting dose of 3.75 mg/kg, with an opportunity for patients to dose escalate to 5.0 mg/kg, in both combination and monotherapy arms, and the first patient has been dosed.
- **KER-012 for the treatment of PAH and for the treatment of cardiovascular disorders**
  - Keros has continued to build momentum for the TROPOS trial, following dosing of the first patient.
- **KER-065 for the treatment of neuromuscular disease**
  - Keros expects to initiate the KER-065 Phase 1 clinical trial in a healthy adult population in the first quarter of 2024. This trial has been designed to enable the evaluation of any treatment-related increases in skeletal muscle, decreases in fat and improvements in bone health, and, as a consequence, the potential of KER-065 for development opportunities ranging from neuromuscular indications to metabolic syndromes, including obesity.
- **KER-047 for the treatment of functional iron deficiency**
  - As part of its ongoing portfolio management activities, Keros has decided to deprioritize the KER-047 program. Accordingly, Keros is in the process of early terminating the open-label Phase 2 clinical trial of KER-047 in MDS and myelofibrosis patients with functional iron deficiency. Keros will continue to evaluate strategic partnerships and/or transactions to progress development of KER-047.

Third Quarter 2023 Financial Results

Keros reported a net loss of $39.4 million in the third quarter of 2023 as compared to a net loss of $23.5 million in the third quarter of 2022. The increase of $15.9 million for the third 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 $34.1 million for the third quarter of 2023 as compared to $21.0 million for the same period in 2022. The increase of $13.1 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 $9.1 million for the third quarter of 2023 as compared to $6.9 million for the same period in 2022. The increase of $2.2 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 September 30, 2023 was $287.9 million compared to $279.0 million as of December 31, 2022. Keros expects that the cash and cash equivalents it had on hand at September 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 (elritercept), 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' second product candidate, KER-012, is being developed for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders. Keros' third product candidate, KER-065, is being developed for the treatment of neuromuscular diseases, with an initial focus on Duchenne muscular dystrophy.

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," "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-012 and KER-065; the potential of KER-065 for development opportunities in neuromuscular indications and metabolic syndromes, including obesity; 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-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 August 7, 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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2023	2022	2023	2022
REVENUE:				
Service revenue	$ 8	$ —	$ 8	$ —
Total revenue	8	—	8	—
OPERATING EXPENSES:				
Research and development	(34,140)	(21,039)	(97,765)	(62,398)
General and administrative	(9,148)	(6,937)	(25,729)	(20,432)
Total operating expenses	(43,288)	(27,976)	(123,494)	(82,830)
LOSS FROM OPERATIONS	(43,280)	(27,976)	(123,486)	(82,830)
OTHER INCOME (EXPENSE), NET				
Interest expense, net	—	—	—	(1)
Research and development incentive income	—	3,705	—	7,081
Other income, net	3,840	762	10,737	789
Total other income, net	3,840	4,467	10,737	7,869
Net loss	$ (39,440)	$ (23,509)	$ (112,749)	$ (74,961)
Net loss attributable to common stockholders—basic and diluted	$ (39,440)	$ (23,509)	$ (112,749)	$ (74,961)
Net loss per share attributable to common stockholders —basic and diluted	$ (1.33)	$ (0.92)	$ (3.86)	$ (3.05)
Weighted-average common stock outstanding—basic and diluted	29,668,247	25,549,701	29,218,143	24,538,159

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

	SEPTEMBER 30, 2023	DECEMBER 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	287,893	279,048
Prepaid expenses and other current assets	16,542	6,719
Total current assets	304,435	285,767
Operating lease right-of-use assets	15,669	15,548
Property and equipment, net	3,357	2,021
Restricted cash	1,212	1,327
Other long-term assets	1,574	2,118
TOTAL ASSETS	326,247	306,781
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	3,867	3,339
Current portion of operating lease liabilities	611	455
Accrued expenses and other current liabilities	12,223	12,753
Total current liabilities	16,701	16,547
Operating lease liabilities, net of current portion	13,704	12,811
Total liabilities	30,405	29,358
STOCKHOLDERS' EQUITY:		
Common stock, par value of $0.0001 per share; 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 29,679,143 and 27,543,453 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	637,022	505,855
Accumulated deficit	(341,183)	(228,434)
Total stockholders' equity	295,842	277,423
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	326,247	306,781