

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

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LEXINGTON, Mass., May 04, 2023 (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 cardiovascular disorders with high unmet medical need, today provided a business update and reported financial results for the quarter ended March 31, 2023.

"We are on track to report additional data from multiple clinical trials this year, including our two Phase 2 clinical trials of KER-050, one in patients with myelodysplastic syndromes ("MDS") and one in patients with myelofibrosis," said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. "We believe these data readouts, combined with the planned commencement of our Phase 2 clinical trial of KER-012 in patients with pulmonary arterial hypertension in the first half of this year, position Keros for a year of important clinical milestones."

Recent Corporate Highlights

- Cash position strengthened: The Company has utilized its existing at the market offering to sell additional shares of common stock, which strengthened its cash position. The Company expects that its cash and cash equivalents as of March 31, 2023 will enable the Company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025.
- Strengthened leadership with board appointment: In May 2023, Keros appointed Dr. Alpna Seth, Ph.D., to its board of directors.

Recent Program Highlights

- KER-012 for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders
 - Keros will present three poster abstracts from its KER-012 program at the American Thoracic Society ("ATS") 2023 International Conference, to be held from May 19 through May 24, 2023. The following abstracts were posted to the ATS conference website on March 2, 2023:
 - Clinical Presentation: "Administration of KER-012, a Modified Activin Receptor IIB Ligand Trap, Led to Changes in Biomarkers of Cardiovascular Health in a Ph1 Study Conducted in Healthy Post-Menopausal Women"
 - Session Name: A26: Precision-Based Approaches to Pulmonary Vascular Disease
 - Date and Presentation Time: May 21, 2023; 9:00 a.m. 11:00 a.m. Eastern time
 - Preclinical Presentation: "RKER-012, a Novel Modified ActRII Ligand Trap, Attenuated Cardiac Remodeling and Fibrosis in a Transverse Aortic Constriction Model of Heart Failure"
 - Session Name: A71: Matters of the Heart: Studies on Cardiopulmonary Vascular Disease
 - Date and Presentation Time: May 21, 2023; 11:30 a.m. 1:15 p.m. Eastern time
 - Preclinical Presentation: "RKER-012, a Novel Activin Receptor Type IIB (ActRIIB) Ligand Trap, Inhibited Mediators of Dysregulated Vascular Remodeling in Pulmonary Endothelial and Smooth Muscle Cells"
 - Session Name: B59: Breaking Bad: New Drugs and Formulations for

Pulmonary Hypertension and RV Failure

 Date and Presentation Time: May 22, 2023; 11:30 a.m. - 1:15 p.m. Eastern time

First Quarter 2023 Financial Results

Keros reported a net loss of \$35.8 million in the first quarter of 2023 as compared to a net loss of \$24.2 million in the first quarter of 2022. The increase of \$11.6 million for the first 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 \$31.1 million for the first quarter of 2023 as compared to \$18.1 million for the same period in 2022. The increase of \$13.0 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 \$7.8 million for the first quarter of 2023 as compared to \$6.0 million for the same period in 2022. The increase of \$1.7 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 March 31, 2023 was \$351.4 million compared to \$279.0 million as of December 31, 2022. Keros expects that the cash and cash equivalents it had on hand at March 31, 2023 will enable Keros to fund its operating expenses and capital expenditure requirements into the fourth guarter of 2025.

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 cardiovascular 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 a number of tissues, including blood vessels and heart tissue. 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.

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 "believe," "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 and KER-012; 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 and KER-012; 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 Annual Report on Form 10-K, filed with the SEC on March 3, 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

	MARCH 31,		
	2023	2022	
REVENUE:			
License revenue	<u> </u>	<u>\$</u>	
Total revenue	_	_	
OPERATING EXPENSES:			
Research and development	(31,091)	(18,078)	
General and administrative	(7,778)	(6,048)	
Total operating expenses	(38,869)	(24,126)	
LOSS FROM OPERATIONS	(38,869)	(24,126)	
OTHER INCOME (EXPENSE), NET			
Interest expense, net	_	(1)	
Other income (expense), net	3,065	(59)	
Total other income (expense), net	3,065	(60)	

Net loss	\$ (35,804)	\$ (24,186)
Net loss attributable to common stockholders—basic and diluted	\$ (35,804)	\$ (24,186)
Net loss per share attributable to common stockholders—basic and diluted	\$ (1.26)	\$ (1.01)
Weighted-average common stock outstanding—basic and diluted	 28,369,453	23,993,698

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

	MARCH 31, 2023	DECEMBER 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	351,429	279,048
Prepaid expenses and other current assets	10,793	6,719
Total current assets	362,222	285,767
Operating lease right-of-use assets	16,364	15,548
Property and equipment, net	2,933	2,021
Restricted cash	1,327	1,327
Other long-term assets	1,590	2,118
TOTAL ASSETS	384,436	306,781
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	4,682	3,339
Current portion of operating lease liabilities	_	455
Accrued expenses and other current liabilities	10,776	12,753
Total current liabilities	15,458	16,547
Operating lease liabilities, net of current portion	13,994	12,811
Total liabilities	29,452	29,358
STOCKHOLDERS' EQUITY:		
Common stock, par value of \$0.0001 per share; 200,000,000 shares authorized as of March 31, 2023 and December 31, 2022, respectively; 29,548,649 and 27,543,453 shares issued and outstanding as of March 31, 2023		
and December 31, 2021, respectively	3	2
Additional paid-in capital	619,219	505,855
Accumulated deficit	(264,238)	(228,434)
Total stockholders' equity	354,984	277,423
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	384,436	306,781