Keros Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2024 Financial Results

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LEXINGTON, Mass., Feb. 26, 2025 (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 fourth quarter and full year ended December 31, 2024.

“The efforts over the past year by the team at Keros have positioned us to continue to advance our promising pipeline of novel therapeutics,” said Jasbir S. Seehra, Ph.D., Chair and Chief Executive Officer. “We are excited to report initial data from the ongoing Phase 1 clinical trial of KER-065 in healthy volunteers in the first quarter of 2025, which we believe can inform our advancement into a Phase 2 clinical trial in neuromuscular disease, with our initial focus on Duchenne muscular dystrophy. We continue to expect to report data from the Phase 2 TROPOS trial evaluating cibotercept (KER-012) in patients with pulmonary arterial hypertension, and we plan to evaluate the appropriate development strategy for cibotercept following that data readout.”

Recent Corporate Highlights:

- **Cash position strengthened:** In February 2025, Keros received a $200.0 million upfront payment pursuant to the exclusive license agreement it entered into with Takeda Pharmaceuticals U.S.A., Inc. (the “Takeda Agreement”) to further develop, manufacture and commercialize elritercept (KER-050) worldwide outside of mainland China, Hong Kong and Macau, which became effective on January 16, 2025. Based on current operating assumptions, the Company expects that its cash and cash equivalents as of December 31, 2024, together with the upfront payment received from the Takeda Agreement, will enable the Company to fund its planned operating expenses and capital expenditure requirements into 2029.

2024 Financial Results

Keros reported a net loss of $46.0 million for the fourth quarter and $187.4 million for the year ended December 31, 2024, as compared to a net loss of $40.2 million for the fourth quarter and $153.0 million for the year ended December 31, 2023. The increase in net loss for the fourth quarter and the year was largely due to increased research and development efforts as well as additional investments to support the achievement of Keros' clinical and corporate goals.

Keros generated revenue of $3.0 million for the fourth quarter and $3.6 million for the year ended December 31, 2024 compared to $0.1 million for the fourth quarter and $0.2 million for the year ended December 31, 2023. Revenue in 2024 was largely related to a milestone achieved under Keros' license agreement with Hansoh (Shanghai) Healthtech Co., Ltd. (“Hansoh”).

Research and development expenses were $45.6 million for the fourth quarter and $173.6 million for the year ended December 31, 2024, as compared to $37.5 million for the fourth quarter and $135.3 million for the year ended December 31, 2023. The increase in research and development expenses for the fourth quarter and the year was driven by the continued advancement of the Company's pipeline, notably the TROPOS trial, the ongoing Phase 1 clinical trial of KER-065 and the progression of two Phase 2 clinical trials and the Phase 3 clinical trial of elritercept, as well as an increase in personnel costs and infrastructure to support operations and expansion of the Company's pipeline.

General and administrative expenses were $10.7 million for the fourth quarter and $40.8 million for the year ended December 31, 2024, as compared to $9.1 million and $34.8 million for the fourth quarter and year ended December 31, 2023, respectively. The increase was primarily due to an increase in personnel expenses to support the Company's organizational growth and achievement of its corporate goals, an increase in facilities, supplies and other office expenses due to the growth of the Company's organization and an increase in professional fees.

Keros’ cash and cash equivalents as of December 31, 2024 was $559.9 million compared to $331.1 million as of December 31, 2023. Based on current operating assumptions, Keros expects that its cash and cash equivalents as of December 31, 2024, together with the $200 million upfront payment from the Takeda Agreement, which the Company received in February 2025, will enable the Company to fund its planned operating expenses and capital expenditure requirements into 2029.

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. Keros is a leader in understanding the role of the TGF-ß family of proteins, which are master regulators of the growth, repair and maintenance of a number of tissues, including blood, bone, skeletal muscle, adipose and heart tissue. By leveraging this understanding, Keros has discovered and is developing protein therapeutics that have the potential to provide meaningful and potentially disease-modifying benefit to patients. One of Keros’ product candidates, cibotercept, is being developed for the treatment of pulmonary arterial hypertension and for the treatment of cardiovascular disorders. The Company's second product candidate, KER-065, is being developed for the treatment of neuromuscular diseases. Keros' most advanced product candidate, elritercept, 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.

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,” “continue,” “expects,” “enable,” “potential” 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 cibotercept and KER-065; the expected timing of data readouts from the Phase 1 clinical trial of KER-065 and the TROPOS trial; Keros’ evaluation of development strategy for cibotercept; 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, cibotercept, KER-065 and elritercept; 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 November 6, 2024, and its other documents subsequently filed with or furnished to the SEC, including the Company’s Annual Report on Form 10-K as of and for the year ended December 31, 2024. 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.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2024	**2023**	**2024**	**2023**
REVENUE:				
Service and other revenue	42	143	550	151
License revenue	3,000	—	3,000	—
Total revenue	3,042	143	3,550	151
OPERATING EXPENSES:				
Research and development	(45,631)	(37,493)	(173,629)	(135,258)
General and administrative	(10,665)	(9,105)	(40,754)	(34,834)
Total operating expenses	(56,296)	(46,598)	(214,383)	(170,092)
LOSS FROM OPERATIONS	(53,254)	(46,455)	(210,833)	(169,941)
OTHER INCOME (EXPENSE), NET:				
Research and development incentive income	1,238	2,400	1,238	2,400
Dividend income	6,519	3,756	23,496	14,755
Other income (expense), net	(229)	56	(954)	(206)
Total other income, net	7,528	6,212	23,780	16,949
Loss before income taxes	(45,726)	(40,243)	(187,053)	(152,992)
Income tax provision	(300)	—	(300)	—
Net loss	$ (46,026)	$ (40,243)	$ (187,353)	$ (152,992)
Net loss attributable to common stockholders—basic and diluted	$ (46,026)	$ (40,243)	$ (187,353)	$ (152,992)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.14)	$ (1.34)	$ (5.00)	$ (5.20)
Weighted-average common stock outstanding—basic and diluted	40,337,720	30,126,578	37,437,652	29,447,119

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

	DECEMBER 31,	
	2024	**2023**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 559,931	$ 331,147
Accounts receivable	2,742	143

Prepaid expenses and other current assets	26,220	16,003
Total current assets	588,893	347,293
Operating lease right-of-use assets	19,251	15,334
Property and equipment, net	4,237	4,134
Restricted cash	1,449	1,212
Other long term assets	2,056	2,052
Total assets	$ 615,886	$ 370,025
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,602	$ 5,450
Current portion of operating lease liabilities	1,978	1,005
Accrued expenses and other current liabilities	20,870	17,918
Total current liabilities	27,450	24,373
Operating lease liabilities, net of current portion	16,883	13,439
Total liabilities	44,333	37,812
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value of $0.0001 per share; 10,000,000 shares authorized as of December 31, 2024 and December 31, 2023; no shares issued and outstanding	—	—
Common stock, par value of $0.0001 per share; 200,000,000 authorized as of December 31, 2024 and December 31, 2023; 40,554,705 and 31,841,084 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	4	3
Additional paid-in capital	1,140,328	713,636
Accumulated deficit	(568,779)	(381,426)
Total stockholders' equity	571,553	332,213
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 615,886	$ 370,025