Keros Therapeutics Reports Recent Business Highlights and Third Quarter 2020 Financial Results

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LEXINGTON, Mass., Nov. 10, 2020 (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 and musculoskeletal disorders with high unmet medical need, today provided a business update and reported financial results for the third quarter of 2020.

“We are very pleased to reach the significant milestone of dosing the first patients in our Phase 2 clinical trial of KER-050. The initiation of this trial is a tremendous accomplishment for Keros and moves us closer to proof-of-concept by potentially demonstrating therapeutic benefit for patients with myelodysplastic syndromes ("MDS"),” said Jasbir S. Seehra, Ph.D., President and Chief Executive Officer. “This Phase 2 clinical trial, along with the completion of our expanded Phase 1 clinical trial of KER-047, positions us to potentially have multiple ongoing Phase 2 clinical trials in 2021. Additionally, by regaining the rights to development programs in metabolic diseases and continuing rapid development of KER-012, Keros continues to further expand its already deep pipeline.

Recent Corporate Highlights:

- **Return of worldwide rights to development programs in metabolic diseases:** On October 26, 2020, Keros announced that it received notice from Novo Nordisk A/S ("Novo Nordisk") that Novo Nordisk had elected to terminate the Research Collaboration and Exclusive License Agreement, dated December 14, 2017 (the "Collaboration Agreement"), between Novo Nordisk and the Company, for strategic and business reasons. As a result of the termination of the Collaboration Agreement, the Company will regain worldwide rights to all ligand traps selected under the Collaboration Agreement, along with all rights to develop Keros molecules in diabetes, obesity, nonalcoholic steatohepatitis and cachexia. The termination of the Collaboration Agreement will be effective on April 26, 2021.

Recent Program Highlights:

- **KER-050 for the treatment of ineffective hematopoiesis to address cytopenias:**
  - On October 20, 2020, Keros announced the dosing of the first two participants in its open-label, Phase 2 clinical trial evaluating KER-050 for the treatment of anemia and thrombocytopenia in very low-, low- or intermediate-risk MDS. Keros expects to report initial data from Part 1 of this trial in mid-2021, subject to any delays related to the COVID-19 pandemic.
  - Keros will present two preclinical abstracts on a mouse version of KER-050 highlighting the differentiated mechanism of action and potential of KER-050 to address multiple types of cytopenias at the 62nd American Society of Hematology ("ASH") Annual Meeting and Exposition, to be held virtually December 5-8, 2020.

- **KER-047 for the treatment of anemia arising from iron imbalance and for the treatment of fibrodysplasia ossificans progressiva ("FOP"):**
  - In August 2020, Keros announced the completion of its planned single and multiple ascending dose cohorts in a Phase 1 clinical trial of KER-047 in healthy volunteers, as well as the expansion of this trial to evaluate additional cohorts of healthy volunteers.
    - In this expanded Phase 1 clinical trial, Keros observed rapid and dose-related increases in serum iron and transferrin saturation in the volunteers who received KER-047. Keros also observed a reduction in hepcidin at each dose level tested in Part 2 of this expanded trial.
    - Keros terminated the trial after determining that the data from the additional cohort, in addition to the data from the planned cohorts, was sufficient to inform the design of the expected Phase 2 clinical trials of KER-047, and expects to report topline data at a scientific conference by the end of 2020.
    - Keros also expects to commence separate Phase 2 clinical trials in patients with iron deficiency anemia ("IDA") and patients with iron-refractory iron deficiency anemia in 2021. Following the completion of the expected Phase 2 clinical trial of KER-047 in patients with IDA, Keros plans to commence a Phase 2 clinical trial in patients with FOP.
  - Keros will present final data from the KER-047 Phase 1 clinical trial at the 62nd ASH Annual Meeting, along with a preclinical abstract highlighting the observed effects of activin receptor-like kinase-2 inhibition on hepcidin levels and iron metabolism.

Third Quarter 2020 Financial Results

Keros reported a net loss of $12.0 million in the third quarter of 2020 as compared to a net loss of $3.5 million in the third quarter of 2019. The increase in net loss for the second quarter was largely due to increased research and development efforts as well as the infrastructure needed as a publicly traded company.

Research and development expenses were $8.4 million for the third quarter of 2020 as compared to $3.9 million for the same period in 2019. The increase of $4.5 million was primarily due to additional toxicology studies and manufacturing activities, as well as an increase related to personnel expenses, including additional share-based compensation cost, driven by increased headcount to support the advancement of Keros’ pipeline.

General and administrative expenses were $3.6 million for the third quarter of 2020 as compared to $1.0 million for the same period in 2019. The increase of $2.6 million was primarily due to an increase in personnel expenses to support Keros' organizational growth and achievement of Keros' corporate goals, additional share-based compensation costs and an increase in professional fees to support Keros' transition to a public company.

Keros’ cash and cash equivalents as of September 30, 2020 was $133.8 million compared to $144.7 million as of June 30, 2020. Keros expects that the cash and cash equivalents it had on hand at September 30, 2020 will fund its operating expenses and capital expenditure requirements into the second half of 2022.

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 hematologic and musculoskeletal disorders with high unmet medical need. Keros is a leader in understanding the role of the transforming growth factor-Beta, or TGF-ß, 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 myelodysplastic syndromes 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, as well as for the treatment of fibrodysplasia ossificans progressiva. Keros' third product candidate, KER-012, is being developed for the treatment of disorders associated with bone loss, such as osteoporosis and osteogenesis imperfecta, and for the treatment of pulmonary arterial hypertension.

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 preclinical studies and clinical trials for KER- KER-047, including its regulatory plans; the potential impact of COVID-19 on Keros' ongoing and planned preclinical studies, clinical trials, business and operations; Keros' plans to present preclinical and clinical data at an upcoming conference; 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 August 13, 2020, 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,	
	2020	2019	2020	2019
REVENUE:				
Research collaboration revenue	$ —	$ 2,500	$ —	$ 7,500
Total revenue	—	2,500	—	7,500
OPERATING EXPENSES:				
Research and development	(8,395)	(3,854)	(24,186)	(13,218)
General and administrative	(3,553)	(972)	(9,180)	(2,117)
Total operating expenses	(11,948)	(4,826)	(33,366)	(15,335)
LOSS FROM OPERATIONS	(11,948)	(2,326)	(33,366)	(7,835)
OTHER INCOME (EXPENSE), NET				
Interest expense, net	(2)	(3)	(5)	(7)
Research and development incentive income	—	—	—	558
Change in fair value of preferred stock tranche obligation	—	(1,235)	(1,490)	(2,486)
Other income (expense), net	(86)	15	4	185
Total other income (expense), net	(88)	(1,223)	(1,491)	(1,750)
Loss before income taxes	(12,036)	(3,549)	(34,857)	(9,585)
Income tax benefit	—	—	172	—
Net loss	$ (12,036)	$ (3,549)	$ (34,685)	$ (9,585)
Net loss attributable to common stockholders—basic and diluted (Note 10)	$ (12,036)	$ (3,999)	$ (35,697)	$ (10,935)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.60)	$ (1.71)	$ (2.65)	$ (4.76)
Weighted-average common stock outstanding—basic and diluted	20,175,883	2,342,782	13,452,606	2,296,701

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

(Unaudited)

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 133,810	$ 7,020
Prepaid expenses and other current assets	2,606	381
Deferred IPO costs	—	604
Research and development incentive receivable	—	922
Total current assets	136,416	8,927
Operating lease right-of-use assets	976	1,205
Property and equipment, net	739	708
Restricted cash	115	115
TOTAL ASSETS	138,246	10,955
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	1,716	2,088
Current portion of operating lease liabilities	412	376
Accrued expenses and other current liabilities	4,697	2,022
Total current liabilities	6,825	4,486
Operating lease liabilities, net of current portion	586	899
Preferred stock tranche liability	—	4,956
Other liabilities	77	119
Total liabilities	7,488	10,460
Series A convertible preferred stock, par value of $0.0001 per share; 0 and 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 4,607,652 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of $0 as of September 30, 2020	—	9,891
Series A-1 convertible preferred stock, par value of $0.0001 per share; 0 and 800,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 368,612 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of $0 as of September 30, 2020	—	944
Series B-1 convertible preferred stock, par value of $0.0001 per share; 0 and 3,427,004 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 and 1,579,043 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation and redemption value of $0 as of September 30, 2020	—	9,106
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock, par value of $0.0001 per share; 200,000,000 and 27,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 20,185,730 and 2,429,705 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	185,091	203
Accumulated deficit	(54,335)	(19,650)
Total stockholders' equity (deficit)	130,758	(19,446)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	138,246	10,955