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Leap Therapeutics Reports First Quarter 2025 Financial Results

May 13, 2025

CAMBRIDGE, Mass., May 13, 2025 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the first quarter of 2025.

Leap Highlights:

- Reported positive data from the randomized, controlled Part B of the Phase 2 DeFianCe study of sirexatamab (DKN-01) plus bevacizumab and chemotherapy in second-line colorectal cancer (CRC) patients demonstrating significantly higher overall response rate (ORR) and longer progression-free survival (PFS) across DKK1-high and VEGF-naïve subgroups
- Hosted virtual key opinion leader (KOL) event featuring Zev A. Wainberg, MD, to further discuss the positive data and patient benefit from the DeFianCe study
- Presented preclinical data of FL-501, a novel GDF-15 neutralizing antibody, at the American Association for Cancer Research (AACR) 2025 Annual Meeting
- Strategic restructuring to prioritize clinical development of sirexatamab in CRC and advancing FL-501 in preclinical development, resulting in an approximately 50% reduction in workforce

"In the first quarter of 2025, sirexatamab, our novel anti-DKK1 antibody, continued to demonstrate encouraging efficacy, including statistically significant higher ORR and longer PFS in both DKK1-high and VEGF-naïve second-line CRC patients. With 42 patients currently remaining on study drug, 25 in the sirexatamab arm and 17 in the control arm, we continue to be optimistic about the maturing dataset in the full population and look forward to upcoming data updates this quarter," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "In this difficult market environment, we focused our resources to position Leap to advance sirexatamab in CRC and FL-501 preclinically in order to provide the greatest value for our shareholders. I would like to personally thank all of our colleagues who have been impacted by this decision and express my appreciation for their contributions and dedication to provide meaningful new treatment options to cancer patients."

DKN-01 Development Update

- ***Reported updated clinical data from Part B of the DeFianCe Study of sirexatamab plus bevacizumab and chemotherapy in CRC patients.*** In March 2025, the Company announced updated preliminary data from Part B of the DeFianCe study (NCT05480306), a Phase 2, open-label, global study of sirexatamab in combination with bevacizumab and chemotherapy (Sirexatamab Arm) compared to bevacizumab and chemotherapy (Control Arm) in patients with MSS CRC who have received one prior systemic therapy for advanced disease. Updated data from the study is expected this quarter.
    - In patients with high DKK1 levels (upper quartile, n=44), the Sierxatamab Arm had a statistically significant 32% higher ORR, 3.5 month longer PFS, and OS compared to the Control Arm
    - In patients who had not received prior anti-VEGF therapy (n=95), the Sirexatamab Arm had a statistically significant 22% higher ORR and 2.6 month longer PFS compared to the Control Arm, with OS not mature but favoring the Sirexatamab Arm
    - With a higher number of patients remaining on study drug in the Sirexatamab Arm compared to the Control Arm (25 vs. 17), PFS in the full intent-to-treat population continues to mature with a tail population advantage for the Sirexatamab Arm
    - The strong signal from the DeFianCe study supports a registrational Phase 3 clinical trial to evaluate sirexatamab plus bevacizumab and chemotherapy in second-line MSS CRC patients with high DKK1 levels or in patients who have not received prior anti-VEGF therapy

- ***Hosted a virtual KOL event featuring Dr. Zev Wainberg, Co-Director of the UCLA GI Oncology Program and a globally recognized leader in gastrointestinal cancer research, to discuss sirexatamab in second-line patients with advanced MSS CRC.*** Dr. Wainberg discussed the unmet need and how sirexatamab may improve upon the current treatment landscape for previously treated patients with advanced MSS CRC and reviewed the positive data from Part A and Part B of the Phase 2 DeFianCe study.

Pipeline Updates

- ***Presented new preclinical data of FL-501 at the AACR 2025 Annual Meeting.*** FL-501 is a first-in-class GDF-15 neutralizing antibody targeting the cachexia pathway, a condition commonly associated with poor outcomes in cancer patients.
    - In humanized FcRn mouse studies, FL-501 demonstrated a 2-3-fold longer half-life and 50% reduced clearance compared to its wild-type precursor and ponsegromab
    - In mouse cachexia models using GDF-15-overexpressing colorectal cancer cells, FL-501 fully restored body

composition, comparably or better than clinical-stage antibodies visugromab and ponsegromab
- In a non-small cell lung cancer patient-derived xenograft model, FL-501 effectively countered cisplatin-induced weight loss, restoring body weight, composition, and condition scores
- These findings, as well as a favorable safety profile and strong pharmacodynamic activity, support advancing FL-501 as a potentially best-in-class molecule

Business Updates

- ***Engaged leading financial advisor to explore business development opportunities to further the development of sirexatamab.*** Strong signals from the DeFianCe study supports a registrational Phase 3 clinical trial in second-line CRC, which represents a significant potential global market opportunity.

- ***Announced strategic restructuring to prioritize clinical focus on the development of sirexatamab in CRC.*** Leap is realigning its resources in order to prioritize the clinical development of sirexatamab in CRC and advancing FL-501 preclinically. As part of the strategic restructuring, the Company has reduced its workforce by approximately 50%.

Selected First Quarter 2025 Financial Results

Net Loss was $15.4 million for the first quarter 2025, compared to $13.8 million for the first quarter 2024. The increase was primarily due to an increase in research and development expenses.

Research and development expenses were $12.9 million for the first quarter of 2025, compared to $11.3 million for the same period in 2024. The increase was primarily due to an increase of $1.4 million in clinical trial costs due to the expansion of the size of Part B of the DeFianCe study and the increase in activity associated with the end of Part C of the DisTinGuish study. There was also an increase of $0.1 million in manufacturing costs related to clinical trial material and manufacturing campaigns and an increase of $0.1 million in consulting fees associated with research and development activities.

General and administrative expenses were $3.0 million for the first quarter 2025, compared to $3.5 million for the same period in 2024. The decrease was primarily due to a $0.4 million decrease in professional fees and a $0.1 million decrease in stock based compensation expense.

Cash and cash equivalents totaled $32.7 million at March 31, 2025.

About Leap Therapeutics
Leap Therapeutics (Nasdaq: LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, sirexatamab (DKN-01), is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. Sirexatamab is being studied in patients with colorectal cancer. Leap's pipeline also includes FL-501, a humanized monoclonal antibody targeting the growth and differentiation factor 15 (GDF-15) protein, in preclinical development. For more information about Leap Therapeutics, visit http://www.leaptx.com or view our public filings with the SEC that are available via EDGAR at http://www.sec.gov or via https://investors.leaptx.com/.

FORWARD-LOOKING STATEMENTS
This press release contains forward-looking statements within the meaning of the federal securities laws. Such statements are based upon current plans, estimates and expectations of the management of Leap that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements.

All statements, other than historical facts, including statements regarding the potential safety, efficacy, and regulatory and clinical progress of Leap's product candidates, including sirexatamab and FL-501; the size of the potential addressable market for sirexatamab, including the number or percentage of patients with advanced CRC that have or are likely to have high levels of DKK1 or that have not had or are likely not to have prior anti-VEGF therapy; the anticipated timing for initiation or completion of clinical trials and release of clinical trial data and the expectations surrounding the outcomes thereof; Leap's future clinical or preclinical product development plans for any of Leap's product candidates; Leap's estimations of projected cash runway; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from Leap's plans, estimates or expectations could include, but are not limited to: (i) the results of Leap's clinical trials and pre-clinical studies, including whether the final data from Part B of the DeFianCe study are the same as the initial data reported, (ii) the actual size of the potential addressable market for sirexatamab, including the number or percentage of patients with advanced CRC that have or are likely to have high levels of DKK1 or that have not had or are likely not to have prior anti-VEGF therapy, may be smaller than estimated, (iii) Leap's ability to successfully finance or enter into new strategic partnerships for sirexatamab or FL-501; (iv) any regulatory feedback that Leap may receive from U.S. Food and Drug Administration (FDA) or equivalent foreign regulatory agency with respect to the registrational Phase III clinical trials that Leap proposes to conduct using sirexatamab for the treatment of patients with second-line CRC or with respect to any other pre-clinical or clinical development activities that Leap will be required to conduct in order to obtain regulatory approval of sirexatamab for the treatment of second-line CRC; (v) whether any Leap products will receive approval from the FDA or equivalent foreign regulatory agencies; (vi) exposure to inflation and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities; (vii) Leap's ability to regain compliance with the Nasdaq Capital Market listing criteria; and (viii) Leap's ability to remain a going concern. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Leap may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Leap's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Leap, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. These

forward-looking statements should not be relied upon as representing Leap's views as of any date subsequent to the date hereof.

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Leap Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	(Unaudited) Three Months Ended March 31	
	2025	**2024**
Operating expenses:		
Research and development	$ 12,911	$ 11,299
General and administrative	3,006	3,526
Total operating expenses	15,917	14,825
Loss from operations	(15,917)	(14,825)
Interest income	437	775
Interest expense	(6)	-
Australian research and development incentives	55	246
Foreign currency loss	(4)	(16)
Net loss	$ (15,435)	$ (13,820)
Net loss per share		
Basic and Diluted	$ (0.37)	$ (0.51)
Weighted average common shares outstanding		
Basic and diluted	41,268,894	27,014,100

Leap Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2025 (Unaudited)	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 32,713	$ 47,249
Research and development incentive receivable	711	704
Prepaid expenses and other current assets	446	86
Total current assets	33,870	48,039
Right of use assets, net	152	262
Research and development incentive receivable, net of current portion	55	-
Deposits	802	823
Total assets	$ 34,879	$ 49,124
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 6,357	$ 4,743
Accrued expenses	6,992	8,536
Income tax payable	536	531
Lease liability - current portion	154	266
Total current liabilities	14,039	14,076
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 240,000,000 shares authorized; 41,439,529 and 38,329,894 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	41	38
Additional paid-in capital	503,718	502,501
Accumulated other comprehensive loss	(113)	(120)
Accumulated deficit	(482,806)	(467,371)
Total stockholders' equity	20,840	35,048
Total liabilities and stockholders' equity	$ 34,879	$ 49,124

Leap Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	(Unaudited) Three Months Ended March 31,	
	2025	**2024**
Cash used in operating activities	$ (14,480)	$ (15,516)
Cash provided by (used in) financing activities	(61)	29
Effect of exchange rate changes on cash and cash equivalents	5	(235)
Net decrease in cash and cash equivalents	(14,536)	(15,722)
Cash and cash equivalents at beginning of period	47,249	70,643
Cash and cash equivalents at end of period	$ 32,713	$ 54,921

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