Leap Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results

March 26, 2025

Leap to host a conference call to present updated CRC clinical data today, March 26, 2025, at 8:00 a.m. ET

CAMBRIDGE, Mass., March 26, 2025 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the fourth quarter and year ended December 31, 2024.

Leap Highlights:

- Reported positive updated data from Part B of the Phase 2 DeFianCe study of sirexatamab (DKN-01) in second-line patients with advanced microsatellite stable (MSS) colorectal cancer (CRC) confirming:
  - Statistically significant 32% higher overall response rate (ORR), 3.5 month longer progression-free survival (PFS), and longer overall survival (OS) in patients with high DKK1 levels
  - Statistically significant 22% higher ORR and 2.6 month longer PFS in patients who had not had prior anti-VEGF therapy
- FL-501 abstract accepted for poster presentation at the 2025 American Association for Cancer Research (AACR) Annual Meeting.

"In 2024, we continued to advance sirexatamab, our anti-DKK1 antibody, through Phase 2 randomized controlled clinical trials as part of our mission to bring personalized medicines to patients fighting against cancer. In particular, the updated data from Part B of the DeFianCe study that we announced today demonstrated significantly higher ORR and longer PFS for sirexatamab in patients who have high levels of DKK1 or who have not had prior anti-VEGF therapy, two exploratory populations with strong scientific rationale that each represent 25-50% of the second-line CRC market," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We believe that there is a compelling opportunity to move forward with a registrational study for sirexatamab in patients with CRC and to advance FL-501 towards clinical trials."

DKN-01 Development Update

- ***Reported updated clinical data from Part B of the DeFianCe Study of sirexatamab plus bevacizumab and chemotherapy in CRC patients.*** Today, 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 (Experimental Arm) compared to bevacizumab and chemotherapy (Control Arm) in patients with MSS CRC who have received one prior systemic therapy for advanced disease. In the updated data announced today,
  - Patients with high DKK1 levels, either at the upper quartile or above the median, treated in the sirexatamab Experimental Arm had significantly improved ORR, PFS, and OS compared to the Control Arm.
  - In patients who had not received prior anti-VEGF therapy, the sirexatamab Experimental Arm had significantly improved ORR and PFS compared to the Control Arm, with an early advantage in OS.
  - Across the intent-to-treat population, the sirexatamab Experimental Arm had improved ORR compared to the Control Arm, with PFS and OS maturing with a higher number of patients continuing to benefit on the sirexatamab Experimental 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.

With approximately 30,000 second-line treated CRC patients in the US and 160,000 in the next 7 largest markets, sirexatamab has a large market opportunity in the 25-50% of patients who have high DKK1 levels or in the approximately 50% of patients who did not receive prior anti-VEGF therapy. In addition, the outcomes in patients with no prior anti-VEGF therapy provides an opportunity to move into treating first-line CRC patients, where there are an estimated 45,000 patients in the US and 265,000 in the next 7 largest markets who receive therapy for their advanced disease.

Leap has engaged a leading financial advisor to explore business development opportunities to further the development of sirexatamab.

Pipeline Update

- ***Presenting preclinical FL-501 data at the 2025 American Association for Cancer Research (AACR) Annual Meeting.*** Preclinical data from FL-501, a potential best-in-class monoclonal antibody designed to neutralize GDF-15 to treat patients with cachexia and other GDF-15-driven diseases, will be featured during a poster session at the 2025 AACR Annual Meeting taking place April 25-30 in Chicago. In addition, manufacturing and non-clinical development continues with the goal of beginning a clinical trial in 2026.

Conference Call

- Leap's management team will host a conference call today, March 26, 2025 at 8:00 a.m. Eastern Time to further discuss the data. The conference call will be broadcast live in listen-only mode and can be accessed via the webcast URL: https://edge.media-server.com/mmc/p/t6576mgc. A replay of the event will be available for a limited time on the Investors page of the Company's website at https://investors.leaptx.com/.

Selected Year-End and Fourth Quarter 2024 Financial Results

Net Loss was $67.6 million for the year ended December 31, 2024, compared to $81.4 million for the year ended December 31, 2023. The decrease was primarily due to a decrease in research and development expenses.

Research and development expenses were $57.2 million for the full year 2024, compared to $73.2 million for the same period in 2023. Research and development expenses were $13.1 million for the fourth quarter ended 2024, compared to $11.7 million for the same period in 2023. The decreases for the full year 2024 were primarily due to in-process research and development acquired in the Flame merger which were expensed in the year ended December 31, 2023.

General and administrative expenses were $12.8 million for the full year 2024, compared to $13.8 million for the same period in 2023. General and administrative expenses were $3.0 million for the fourth quarter ended 2024, compared to $3.1 million for the same period in 2023. The decreases for the full year 2024 were primarily due to a decrease in professional fees due to lower finance and legal costs.

Cash and cash equivalents totaled $47.2 million at December 31, 2024.

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; 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 or Part C of the DisTinGuish 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 any of its other programs; (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; and (vi) exposure to inflation and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities. 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)

	Year Ended December 31		(Unaudited) Three Months Ended December 31	
	2024	2023	2024	2023

Operating expenses:				
Research and development	$ 57,211	$ 73,234	$ 13,112	$ 11,685
General and administrative	12,846	13,807	3,013	3,135
Total operating expenses	70,057	87,041	16,125	14,820
Loss from operations	(70,057)	(87,041)	(16,125)	(14,820)
Interest income	3,129	4,027	595	938
Australian research and development incentives	-	1,101	-	(23)
Other income	-	500	-	500
Foreign currency gain (loss)	(42)	(13)	(24)	940
Change in fair value of Series X preferred stock warrant liability	-	12	-	-
Loss before income taxes	(66,970)	(81,414)	(15,554)	(12,465)
Provision for (benefit from) income taxes	(585)	-	123	-
Net loss	(67,555)	(81,414)	(15,431)	(12,465)
Dividend attributable to common stockholders	(234)	-	-	-
Net loss attributable to common stockholders	$ (67,789)	$ (81,414)	$ (15,431)	$ (12,465)
Net loss per share				
Basic and Diluted	$ (1.81)	$ (3.98)	$ (0.37)	$ (0.46)
Weighted average common shares outstanding				
Basic and diluted	37,550,677	20,445,109	41,252,022	26,987,182

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

	December 31,	
	2024	**2023**
Cash and cash equivalents	$ 47,249	$ 70,643
Research and development incentive receivable	704	771
Prepaid expenses and other current assets	86	183
Total current assets	48,039	71,597
Property and equipment, net	-	5
Right of use assets, net	262	257
Deposits	823	966
Total assets	$ 49,124	$ 72,825
Accounts payable	$ 4,743	$ 6,465
Accrued expenses	8,536	5,957
Income tax payable	531	-
Lease liability - current portion	266	262
Total current liabilities	14,076	12,684
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; 38,329,894 and 25,565,414 shares issued and outstanding as of December 31, 2024 and 2023, respectively	38	26
Additional paid-in capital	502,501	459,591
Accumulated other comprehensive (loss) income	(120)	106
Accumulated deficit	(467,371)	(399,582)
Total stockholders' equity	35,048	60,141
Total liabilities and stockholders' equity	$ 49,124	$ 72,825

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

(Unaudited)

	Year Ended December 31,		Three Months Ended December 31,	
	2024	2023	2024	2023
Cash used in operating activities	$ (60,299)	$ (43,753)	$ (15,512)	$ (10,380)
Cash provided by investing activities	-	48,969	-	-
Cash provided by (used in) financing activities	37,184	(30)	104	-
Effect of exchange rate changes on cash and cash equivalents	(279)	(43)	(166)	280
Net increase (decrease) in cash and cash equivalents	$ (23,394)	$ 5,143	(15,574)	(10,100)
Cash and cash equivalents at beginning of period	70,643	65,500	62,823	80,743
Cash and cash equivalents at end of period	$ 47,249	$ 70,643	$ 47,249	$ 70,643

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