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Leap Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results

March 18, 2024

CAMBRIDGE, Mass., March 18, 2024 /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, 2023.

Leap Highlights:

- Presented new clinical data from Part A of the Phase 2 DeFianCe study evaluating DKN-01 in combination with standard of care bevacizumab and chemotherapy in second-line patients with advanced colorectal cancer, at the 2024 ASCO Gastrointestinal Cancers Symposium
- Completed enrollment in the randomized controlled Part C of the Phase 2 DisTinGuish study evaluating DKN-01 in combination with tislelizumab and chemotherapy in patients with advanced gastroesophageal junction and gastric cancer

"As we reflect on the fourth quarter and the achievements of the past year, we are proud of the strides we've made in advancing DKN-01 and integrating our pipeline of earlier stage biomarker-targeted antibody therapies. The data from Part A of the DeFianCe study, demonstrating a 30% overall response rate and a 93% disease control rate in second-line colorectal cancer patients, showcases a strong foundation as we move into the randomized controlled Part B of the study," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "Additionally, the completion of enrollment in Part C of the DisTinGuish study in first-line gastroesophageal junction and gastric cancer patients positions us to deliver the first randomized controlled data for DKN-01 starting in the middle of the year. As we look ahead to a data rich 2024, we remain focused on our mission to deliver new personalized medicines to patients fighting against cancer."

DKN-01 Development Update

- ***Presented initial clinical data from Part A of the DeFianCe Study of DKN-01 plus bevacizumab and chemotherapy in colorectal cancer (CRC) patients.*** The Company presented initial data from Part A of the DeFianCe study (NCT05480306), a Phase 2 study evaluating DKN-01 in combination with standard of care (SOC) bevacizumab and chemotherapy in second-line (2L) patients with advanced microsatellite stable (MSS) CRC patients at the 2024 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, held in San Francisco on January 18-20, 2024 and during the Company's conference call on January 23, 2024.

- ***Key Findings:***
- As of the December 6, 2023 data cutoff, across all patients enrolled (n=33):
    - Overall response rate (ORR) among response-evaluable patients (n=27) was 30% and disease control rate (DCR) was 93%, including 8 partial responses (PR) and 17 patients with a best response of stable disease (SD)
    - Median progression-free survival (PFS) was 6.3 months
    - 9 patients remained on therapy and were beyond 8.5 months
- Enhanced activity in patients with left-sided tumors (n=25), a group that has more frequent activation of the Wnt pathway modulated by DKK1
    - 33% ORR and 100% DCR in response-evaluable population (7 PRs, 14 SDs)
    - Preliminary median PFS of 8.6 months (9 patients continuing therapy within subgroup)
- Compelling ORR, DCR and PFS in patients with rectal/rectosigmoid carcinomas (n=15), a population with increasing incidence among young people and shown to have the highest DKK1 levels:
    - 46% ORR and 100% DCR in response-evaluable population (6 PRs, 7 SDs)
    - Preliminary median PFS of 9.4 months (6 patients continuing therapy within subgroup)
    - Higher baseline plasma DKK1 levels correlated with improved responses
- DKN-01 plus bevacizumab and chemotherapy was well-tolerated, with a majority of DKN-01 related events being low grade (Grade 1/2)

The Company expects the 130 patient randomized controlled Part B to complete enrollment in mid-2024. As of March 15, 2024, 80 patients have enrolled in Part B.

- ***Announced completion of enrollment in the randomized controlled Part C of the DisTinGuish study evaluating DKN-01 in combination with tislelizumab, BeiGene's anti-PD-1 antibody, and chemotherapy in patients with advanced gastroesophageal junction and gastric cancer***. Part C of the DisTinGuish study (NCT0436380) is a Phase 2, randomized, open-label, multicenter study of DKN-01 in combination with tislelizumab and chemotherapy in first-line patients with advanced gastroesophageal adenocarcinoma. Part C enrolled 170 first-line, HER2-negative patients randomized 1:1 to evaluate DKN-01 in combination with tislelizumab and SOC chemotherapy, compared to tislelizumab and SOC chemotherapy alone. The primary objective is progression-free survival (PFS) in DKK1-high and in all patients. Secondary objectives of Part C include overall survival and objective response rate as measured by RECIST v1.1 in DKK1-high and in all patients. The Company expects to report initial data from Part C of the DisTinGuish study in mid-2024.

Selected Year-End and Fourth Quarter 2023 Financial Results

Net Loss was $81.4 million for the year ended December 31, 2023, compared to $54.6 million for the year ended December 31, 2022. The increase was due to in-process research and development acquired in the Flame merger which was expensed during the year ended December 31, 2023, costs incurred in connection with our research and development programs, and from general and administrative costs associated with our operations.

Research and development expenses were $73.2 million for the full year 2023, compared to $45.0 million for the same period in 2022. Research and development expenses were $11.7 million for the fourth quarter ended 2023, compared to $11.0 million for the same period in 2022. The increases for the full year 2023 were primarily due to in-process research and development acquired in the Flame merger, an increase in clinical trial costs, and an increase in payroll and other related expenses due to an increase in headcount of research and development full-time employees.

General and administrative expenses were $13.8 million for the full year 2023, compared to $11.8 million for the same period in 2022. General and administrative expenses were $3.1 million for the fourth quarter ended 2023, compared to $2.9 million for the same period in 2022. The increases for the full year 2023 were primarily due to costs associated with our business development activities and an increase in payroll and other related expenses due to an increase in headcount of general and administrative full-time employees.

Cash and cash equivalents totaled $70.6 million at December 31, 2023. Research and development incentive receivables totaled $0.8 million at December 31, 2023.

About Leap Therapeutics
Leap Therapeutics (Nasdaq: LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is being developed in patients with esophagogastric, gynecologic, and colorectal cancers. FL-301, is a humanized monoclonal antibody targeting Claudin18.2, being developed in patients with gastric and pancreatic cancer. Leap also has preclinical antibody programs targeting Claudin18.2/CD137 and GDF15. 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 anticipated timing for 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) Leap's ability to successfully execute its clinical trials and the timing of enrollment in and cost of such clinical trials; (ii) the results of Leap's clinical trials and pre-clinical studies; (iii) Leap's ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs and to maintain its ongoing collaborations with BeiGene, NovaRock and Adimab; (iv) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (v) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities; and (vi) that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by global conflict, or supply chain related issues. 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 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	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 73,234	$ 44,965	$ 11,685	$ 11,034

General and administrative	13,807	11,798	3,135	2,909
Total operating expenses	87,041	56,763	14,820	13,943
Loss from operations	(87,041)	(56,763)	(14,820)	(13,943)
Interest income	4,027	925	938	521
Interest expense	-	(54)	-	(5)
Australian research and development incentives	1,101	2,051	(23)	775
Other income	500	-	500	-
Foreign currency gain (loss)	(13)	(608)	940	697
Change in fair value of Series X preferred stock warrant liability	12	-	-	-
Loss before income taxes	(81,414)	(54,449)	(12,465)	(11,955)
Provision for income taxes	-	(147)	-	(147)
Net loss attributable to common stockholders	$ (81,414)	$ (54,596)	$ (12,465)	$ (12,102)
Net loss per share				
Basic and Diluted	$ (3.98)	$ (4.82)	$ (0.46)	$ (1.07)
Weighted average common shares outstanding				
Basic and diluted	20,445,109	11,323,909	26,987,182	11,323,909

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

		December 31, 2023	2022
Assets			
Current assets:			
	Cash and cash equivalents	$ 70,643	$ 65,500
	Research and development incentive receivable	771	2,099
	Prepaid expenses and other current assets	183	351
	Total current assets	71,597	67,950
Property and equipment, net	Property and equipment, net	5	20
Property and equipment, net	Right of use assets, net	257	669
	Deferred costs	-	576
	Other long term assets	-	30
Property and equipment, net	Deposits	966	1,108
	Total assets	$ 72,825	$ 70,353
Liabilities and Stockholders' Equity			
Current liabilities:			
	Accounts payable	$ 6,465	$ 5,657
	Accrued expenses	5,957	5,152
	Lease liability - current portion	262	416
	Total current liabilities	12,684	11,225
Non current liabilities:			
	Lease liability, net of current portion	-	262
	Total liabilities	12,684	11,487
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; 25,565,414 and 9,902,137 shares issued and outstanding as of December 31, 2023 and 2022, respectively	26	10
	Additional paid-in capital	459,591	376,896
	Accumulated other comprehensive income	106	128
	Accumulated deficit	(399,582)	(318,168)
	Total stockholders' equity	60,141	58,866
	Total liabilities and stockholders' equity	$ 72,825	$ 70,353

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

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Cash used in operating activities	$ (43,753)	$ (49,044)	$ (10,380)	$ (13,014)
Cash provided by investing activities	48,969	-	-	-
Cash used in financing activities	(30)	(210)	-	-
Effect of exchange rate changes on cash and cash equivalents	(43)	(162)	280	206
Net increase (decrease) in cash and cash equivalents	$ 5,143	$ (49,416)	(10,100)	(12,808)
Cash and cash equivalents at beginning of period	65,500	114,916	80,743	78,308
Cash and cash equivalents at end of period	$ 70,643	$ 65,500	$ 70,643	$ 65,500

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