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Leap Therapeutics Reports First Quarter 2024 Financial Results

May 13, 2024

CAMBRIDGE, Mass., May 13, 2024 /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 ended March 31, 2024.

Leap Highlights:

- Completed $40 million private placement financing with participation from Gilead Sciences, Inc., a life sciences-focused investor, Samsara BioCapital, 683 Capital Partners, LP, Laurion Capital Management, and Rock Springs Capital
- Presented 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 (CRC), at the 2024 ASCO Gastrointestinal Cancers Symposium
- Expanded the ongoing randomized controlled Part B of the DeFianCe study from 130 patients to 180 patients to enhance the statistical power for patients with left-sided CRC; enrollment now expected to be completed in late Q3 or early Q4 2024
- 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 (GEJ) and gastric cancer; first randomized controlled data for DKN-01 expected in the second half of 2024 or early 2025

"We appreciate the strong support of Gilead and the new and existing institutional investors who participated in our recent $40 million financing that will enable the expansion and continued execution of the DKN-01 development program," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "The financing provides cash runway into the second quarter of 2026, allowing the expansion of Part B of the DeFianCe CRC study to 180 patients, the full maturation of data in Part C of the DisTinGuish GEJ/gastric cancer study, and the manufacturing of Phase 3 clinical trial material. We are well positioned for continued success and look forward to achieving major clinical milestones in the year ahead."

Business Update:

- ***Completed a $40 million private placement.*** In April 2024, Leap entered into a securities purchase agreement with a select group of institutional investors to issue and sell an aggregate of 12,660,993 shares of its common stock ("Common Stock") at a price of $2.82 per share and pre-funded warrants to purchase 1,523,404 shares of Common Stock at a price of $2.819 per share of Common Stock issuable upon exercise of the pre-funded warrants, in a private placement. Gross proceeds from the private placement were approximately $40 million with participation from new and existing investors, including Gilead Sciences, Inc., a life sciences-focused investor, Samsara BioCapital, 683 Capital Partners, LP, Laurion Capital Management, and Rock Springs Capital. The net proceeds from this financing, combined with existing cash, cash equivalents and marketable securities, are expected to fund Leap's operating and capital expenditures into the second quarter of 2026 and enable expansion of the DKN-01 DeFianCe clinical trial and development program.

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)

- ***Part B of the DeFianCe Study of DKN-01 plus bevacizumab and chemotherapy in CRC patients is ongoing, with enrollment expanded to 180 patients and expected to be completed in late Q3/early Q4 2024.*** The Company expanded the randomized controlled Part B of the DeFianCe study from 130 to 180 patients and included PFS in the subpopulation of patients with left-sided CRC as an additional primary endpoint. The Company expects to complete enrollment in late Q3 or early Q4 2024 with data expected in mid-2025. As of May 8, 2024, 114 patients have enrolled in Part B.
- ***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 PFS in DKK1-high and in all patients. Secondary objectives of Part C include OS and ORR 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 the second half of 2024 or early 2025 when the PFS data are mature.

Selected First Quarter 2024 Financial Results

Net Loss was $13.8 million for the first quarter 2024, compared to $41.9 million for the same period in 2023. The decrease was primarily due to $29.6 million of in-process research and development ("IPR&D") expense associated with the Flame merger in January 2023.

Research and development expenses were $11.3 million for the first quarter 2024, compared to $38.9 million for the same period in 2023. The decrease of $27.6 million was primarily due to $29.6 million of IPR&D associated with the Flame merger. In addition, there was a decrease of $0.4 million in manufacturing costs related to clinical trial material manufacturing campaigns and a decrease of $0.1 million in consulting fees associated with R&D activities. These decreases were partially offset by an increase of $2.0 million in clinical trial costs and an increase of $0.5 million in payroll and other related expenses due to an increase in headcount of our R&D full-time employees.

General and administrative expenses were $3.5 million for the first quarter 2024, compared to $3.8 million for the same period in 2022. The decrease was due to a decrease of $0.3 million in professional fees associated with our business development activities.

Cash and cash equivalents totaled $54.9 million at March 31, 2024, exclusive of the $37.2 million net proceeds of the private placement completed in April 2024. Research and development incentive receivables, current portion, totaled $0.7 million at March 31, 2024.

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 expansion of the DeFianCe study and 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; the anticipated closing date of the private placement; the amount of proceeds to be received by Leap and Leap's intended use of proceeds from the private placement; 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)

	(Unaudited) Three Months Ended March 31	
	2024	**2023**
Operating expenses:		
Research and development	$ 11,299	$ 38,942
General and administrative	3,526	3,784
Total operating expenses	14,825	42,726
Loss from operations	(14,825)	(42,726)
Interest income	775	848
Australian research and development incentives	246	272
Foreign currency loss	(16)	(307)
Change in fair value of Series X preferred stock warrant liability	-	50
Net loss	$ (13,820)	$ (41,863)
Net loss per share		
Basic and Diluted	$ (0.51)	$ (3.24)
Weighted average common shares outstanding		
Basic and diluted	27,014,100	12,934,427

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 54,921	$ 70,643
Research and development incentive receivable	738	771
Prepaid expenses and other current assets	526	183
Total current assets	56,185	71,597
Property and equipment, net	-	5
Right of use assets, net	577	257
Research and development incentive receivable, net of current portion	245	-
Deferred costs	39	-

Deposits	917	966
Total assets	$ 57,963	$ 72,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,951	$ 6,465
Accrued expenses	4,056	5,957
Lease liability - current portion	430	262
Total current liabilities	10,437	12,684
Non current liabilities:		
Lease liability, net of current portion	154	-
Total liabilities	10,591	12,684
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; 25,603,471 and 25,565,414 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	26	26
Additional paid-in capital	460,868	459,591
Accumulated other comprehensive income (loss)	(120)	106
Accumulated deficit	(413,402)	(399,582)
Total stockholders' equity	47,372	60,141
Total liabilities and stockholders' equity	$ 57,963	$ 72,825

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

	(Unaudited) Three Months Ended March 31,	
	2024	**2023**
Cash used in operating activities	$ (15,516)	$ (12,700)
Cash provided by investing activities	-	49,317
Cash provided by (used in) financing activities	29	(29)
Effect of exchange rate changes on cash and cash equivalents	(235)	(50)
Net increase (decrease) in cash and cash equivalents	(15,722)	36,538
Cash and cash equivalents at beginning of period	70,643	65,500
Cash and cash equivalents at end of period	$ 54,921	$ 102,038

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