Leap Therapeutics Reports Second Quarter 2024 Financial Results

August 12, 2024

CAMBRIDGE, Mass., Aug. 12, 2024 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the second quarter ended June 30, 2024.

Leap Highlights:

- Overall response rate (ORR) increases to 33% across all evaluable patients and 38% across evaluable patients with left-sided CRC in updated data from Part A of the Phase 2 DeFianCe study evaluating DKN-01 in combination with bevacizumab and chemotherapy in second-line patients with advanced colorectal cancer (CRC)
- Expanded the randomized controlled Part B of the DeFianCe study to 180 patients; enrollment expected to be completed by end of September 2024 with data expected in mid-2025
- Patient follow-up continues in the randomized controlled Part C of the Phase 2 DisTinGuish study evaluating DKN-01 in combination with tislelizumab and chemotherapy in first-line patients with advanced gastroesophageal junction (GEJ) and gastric cancer; data expected in Q4 2024 or early 2025
- Completed $40 million private placement with new and existing investors, including Gilead Sciences, Inc.

"With the momentum provided by our $40 million private placement, we are positioned to achieve our critical company milestones," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We have executed well on our two DKN-01 randomized controlled trials and on preparatory activities for registrational studies. We look forward to sharing initial data from both randomized controlled studies over the next 12 months as we strive to deliver new treatments for patients fighting against cancer."

DKN-01 Development Update

- ***ORR increases in updated data from Part A of the DeFianCe Study.*** The DeFianCe study (NCT05480306) is a Phase 2 study evaluating DKN-01 in combination with bevacizumab and chemotherapy in second-line patients with advanced microsatellite stable CRC. Preliminary results from Part A of the study were previously reported at the 2024 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium in January 2024. In April 2024, a ninth Part A patient was identified as having a partial response (PR). This patient, who has left-sided Consensus Molecular Subtype 4 CRC with APC and TP53 mutations and KRAS wildtype genetics, had been previously treated with cetuximab and chemotherapy. The patient enrolled in Part A in March 2023 and had a best response of stable disease (SD) for over a year before the tumor reduction deepened into a PR. The patient remains on study with a confirmed PR.
- ***Key Updated Part A Findings*** *(as of June 7, 2024 data cut-off)**:***
  - Across all patients enrolled (n=33):
    - ORR among response-evaluable patients (n=27) was 33% and disease control rate (DCR) was 93%, including 9 PRs and 16 patients with a best response of SD
    - Median progression-free survival (PFS) was unchanged at 6.3 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
    - 38% ORR and 100% DCR in response-evaluable population (8 PRs, 13 SDs)
    - Median PFS was unchanged at 8.6 months
  - DKN-01 plus bevacizumab and chemotherapy was well-tolerated, with a majority of DKN-01 related events being low grade (Grade 1/2)
- ***Enrollment in Part B of the DeFianCe Study in CRC patients is ongoing and expected to be completed by the end of September 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. As of August 9, 2024, 161 patients have enrolled in Part B. The Company expects to complete enrollment by the end of September 2024, with data expected mid-2025.
- ***Randomized controlled Part C of the DisTinGuish study in patients with GEJ and gastric cancer is ongoing, with initial data expected in Q4 2024 or early 2025***. 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, HER-2 negative patients with GEJ and gastric cancer. Part C enrolled 170 patients randomized 1:1 to evaluate DKN-01 in combination with tislelizumab and chemotherapy, compared to tislelizumab and chemotherapy alone. The Company expects to report initial data from Part C of the DisTinGuish study in Q4 2024 or early 2025.

Business Update:

- ***Completed a $40 million private placement.*** In April 2024, Leap entered into a securities purchase agreement with a select group of new and existing investors including Gilead Sciences, Inc., a life sciences-focused investor, Samsara BioCapital, LP, 683 Capital Partners, LP, Laurion Capital Management LP, and Rock Springs Capital Management LP. Gross proceeds from the private placement were approximately $40 million. 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.

Selected Second Quarter 2024 Financial Results

Net Loss was $20.4 million for the second quarter 2024, compared to $13.4 million for the same period in 2023. The increase was primarily due to an increase in research and development expenses.

Research and development expenses were $17.9 million for the second quarter 2024, compared to $11.1 million for the same period in 2023. The increase of $6.8 million was primarily due to an increase of $5.7 million in clinical trial costs due to patient enrollment, the duration of patients on study, the enhancement of correlative studies, increase in site activity associated with Part C of the DisTinGuish study, and the expansion of the size of Part B of the DeFianCe study. There was also an increase of $0.6 million in manufacturing costs related to clinical trial material and manufacturing campaigns 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 $3.4 million for the second quarter 2024, compared to $3.6 million for the same period in 2023. The decrease was due to a decrease of $0.3 million in professional fees associated with our business development activities, partially offset by a $0.1 million increase in payroll and other related expenses.

Cash and cash equivalents totaled $78.5 million at June 30, 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 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; and (v) exposure to inflation, currency rate 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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Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	(Unaudited) Three Months Ended June 30,		(Unaudited) Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 17,885	$ 11,104	$ 29,184	$ 50,046
General and administrative	3,367	3,558	6,893	7,342
Total operating expenses	21,252	14,662	36,077	57,388
Loss from operations	(21,252)	(14,662)	(36,077)	(57,388)
Interest income	865	1,157	1,640	2,005
Australian research and development incentives	253	298	499	570
Foreign currency gain (loss)	6	(145)	(10)	(452)
Change in fair value of Series X preferred stock warrant liability	-	(38)	-	12
Net loss	(20,128)	(13,390)	(33,948)	(55,253)
Dividend attributable to down round feature of warrants	(234)	-	(234)	-
Net loss attributable to common stockholders	$ (20,362)	$ (13,390)	$ (34,182)	$ (55,253)
Net loss per share				
Basic & diluted	$ (0.52)	$ (0.91)	$ (1.01)	$ (4.01)
Weighted average common shares outstanding				
Basic & diluted	39,122,662	14,710,375	33,830,083	13,794,605

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 78,479	$ 70,643
Research and development incentive receivable	754	771
Prepaid expenses and other current assets	354	183
Total current assets	79,587	71,597
Property and equipment, net	-	5
Right of use assets, net	475	257
Research and development incentive receivable, net of current portion	505	-
Deposits	859	966
Total assets	$ 81,426	$ 72,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,809	$ 6,465
Accrued expenses	7,347	5,957
Lease liability - current portion	443	262
Total current liabilities	15,599	12,684
Non current liabilities:		
Lease liability, net of current portion	39	-
Total liabilities	15,638	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; 38,264,464 and 25,565,414 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	38	26
Additional paid-in capital	499,511	459,591
Accumulated other comprehensive income	3	106
Accumulated deficit	(433,764)	(399,582)
Total stockholders' equity	65,788	60,141
Total liabilities and stockholders' equity	$ 81,426	$ 72,825

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

	(Unaudited) Three Months Ended June 30		(Unaudited) Six Months Ended June 30	
	2024	**2023**	**2024**	**2023**
Cash used in operating activities	$ (13,671)	$ (10,185)	$ (29,187)	$ (22,885)
Cash provided by (used in) investing activities	-	(348)	-	48,969
Cash provided by (used in) financing activities	37,117	-	37,146	(29)
Effect of exchange rate changes on cash and cash equivalents	112	(90)	(123)	(140)
Net increase (decrease) in cash and cash equivalents	23,558	(10,623)	7,836	25,915
Cash and cash equivalents at beginning of period	54,921	102,038	70,643	65,500
Cash and cash equivalents at end of period	$ 78,479	$ 91,415	$ 78,479	$ 91,415

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