Leap Therapeutics Reports Second Quarter 2023 Financial Results

August 14, 2023

CAMBRIDGE, Mass., Aug, 14, 2023 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for second quarter ended June 30, 2023.

Leap Highlights:

- Announced that initial data from Part A of the Phase 2 DeFianCe study of DKN-01 in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC) exceeded a twenty percent (20%) overall response rate (ORR) with a high disease control rate, leading to the initiation of the 130-patient randomized controlled Part B of the study
- Presented new long-term follow-up data from Part A of the Phase 2 DisTinGuish study of DKN-01 plus tislelizumab and chemotherapy demonstrating 19.5 months median overall survival (OS) in first-line patients with advanced gastroesophageal adenocarcinoma (GEA) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

"The Company made important progress on our DKN-01 program during the second quarter. Based on Part A of the DeFianCe study exceeding our threshold of a 20% ORR, all of which are now confirmed responses, we initiated Part B, our second randomized controlled trial," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We also presented new long-term follow-up data from Part A of the DisTinGuish study at ASCO, demonstrating 19.5 months median overall survival which exceeds current benchmarks. Additionally, enrollment continues to be strong in the 160 patient randomized controlled Part C of the DisTinGuish study, and we expect to complete enrollment in the fourth quarter of this year."

DKN-01 Development Update

- ***Announced initial results from Part A of the DeFianCe Study of DKN-01 for the treatment of colorectal cancer patients and initiation of the randomized controlled Part B of the study.*** The DeFianCe study (NCT05480306) is a Phase 2, randomized, open-label, multicenter study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy for advanced disease. The study began with an initial Part A cohort that enrolled 33 patients, including significant numbers of patients who had early progression on first-line therapy, previous exposure to bevacizumab, tumors with Ras mutations, or liver metastases. Initial results indicated an ORR above twenty percent (20%) with a high disease control rate, which exceeds the benchmarks expected for this population. The study has expanded into a 130-patient Part B randomized controlled trial. The primary endpoint of the randomized study is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival. Leap expects to be able to enroll Part B in approximately 12 months.
- ***Presented updated data from Part A of the DisTinGuish Study of DKN-01 plus tislelizumab and chemotherapy in gastric cancer patients at the 2023 ASCO Annual Meeting.*** The Company presented new long-term follow-up data in first-line patients with advanced GEA from Part A of the DisTinGuish study (NCT0436380), a Phase 2 clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab and chemotherapy. Highlights from the data include:
    - At two years follow up, DKN-01 plus tislelizumab and chemotherapy demonstrated an ORR of 73% in the modified intent-to-treat (mITT) population and 86% in the PD-L1 low-subgroup
    - Median OS of 19.5 months and median progression-free survival (PFS) of 11.3 months exceeds benchmark results in the overall population
    - Combination was well tolerated with manageable toxicity, with most adverse events related to DKN-01 being low-grade

Selected Second Quarter 2023 Financial Results

Net Loss was $13.4 million for the second quarter 2023, compared to $17.0 million for the same period in 2022. The decrease was primarily due to decreased research and development expenses and increased interest income.

Research and development expenses were $11.1 million for the second quarter 2023, compared to $14.0 million for the same period in 2022. The decrease in research and development expenses was primarily due to a decrease of $4.5 million in manufacturing costs related to clinical trial material, partially offset by an increase of $0.8 million in clinical trial costs and an increase of $0.8 million in payroll and other related expenses due to an increase in headcount of our research and development full-time employees.

General and administrative expenses were $3.6 million for the second quarter 2023, compared to $2.9 million for the same period in 2022. The increase in general and administrative expenses was primarily due to an increase of $0.6 million in professional fees due to higher finance and legal costs associated with our business development activities and a $0.3 million increase in payroll and other related expenses due to an increase in headcount of our general and administrative full-time employees, partially offset by a decrease of $0.2 million in insurance costs.

Interest income was $1.2 million for the second quarter 2023, compared to an immaterial amount for the same period in 2022. The increase reflects the increased interest rate environment applicable to the Company's cash balance.

Cash and cash equivalents totaled $91.4 million at June 30, 2023. Research and development incentive receivables totaled $2.6 million at June 30, 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 outcomes of patients in Part A of the DeFianCe study, the anticipated timing for initiation of or success of enrollment in Part B of the DeFianCe study, Part C of the DisTinGuish study, and other clinical trials and release of clinical data, and any outcomes of such trials; the potential, safety, efficacy, and regulatory and clinical progress of Leap's product candidates; our future preclinical and clinical development plans in connection with our programs; the ability to enter into a new strategic partnership for DKN-01 or any of Leap's other programs; the continuation over time of the clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the ability of NovaRock Biotherapeutics to conduct the FL-301 clinical trial in China; 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; (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) the effect of inflation and currency rate fluctuations on Leap's future expenses; (vi) fluctuations in the market price of Leap's traded securities; (vii) 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; and (viii) whether Leap's cash resources will be sufficient to fund Leap's continuing operations and planned studies. 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.
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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 11,104	$ 14,045	$ 50,046	$ 21,829

General and administrative	3,558	2,855	7,342	5,703
Total operating expenses	14,662	16,900	57,388	27,532
Loss from operations	(14,662)	(16,900)	(57,388)	(27,532)
Interest income	1,157	39	2,005	44
Interest expense	-	(17)	-	(38)
Australian research and development incentives	298	587	570	624
Foreign currency loss	(145)	(733)	(452)	(498)
Change in fair value of Series X preferred stock warrant liability	(38)	-	12	-
Net loss attributable to common stockholders	$ (13,390)	$ (17,024)	$ (55,253)	$ (27,400)
Net loss per share				
Basic & diluted	$ (0.91)	$ (1.50)	$ (4.01)	$ (2.42)
Weighted average common shares outstanding				
Basic & diluted	14,710,375	11,324,893	13,794,605	11,324,893

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

		June 30, 2023 (Unaudited)	December 31, 2022
Assets			
Current assets:			
	Cash and cash equivalents	$ 91,415	$ 65,500
	Research and development incentive receivable	2,046	2,099
	Prepaid expenses and other current assets	419	351
	Total current assets	93,880	67,950
Property and equipment, net	Property and equipment, net	13	20
Property and equipment, net	Right of use assets, net	467	669
	Research and development incentive receivable, net of current portion	563	-
	Deferred costs	-	576
	Other long term assets	-	30
Property and equipment, net	Deposits	934	1,108
	Total assets	$ 95,857	$ 70,353
Liabilities and Stockholders' Equity			
Current liabilities:			
	Accounts payable	$ 6,500	$ 5,657
	Accrued expenses	4,826	5,152
	Lease liability - current portion	436	416
	Total current liabilities	11,762	11,225
Non current liabilities:			
	Lease liability, net of current portion	38	262
	Total liabilities	11,800	11,487
Stockholders' equity:			
	Common stock, $0.001 par value; 240,000,000 shares authorized; 25,565,414 and 9,902,137 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	26	10
	Additional paid-in capital	457,038	376,896
	Accumulated other comprehensive income	414	128
	Accumulated deficit	(373,421)	(318,168)

Total stockholders' equity	84,057	58,866
Total liabilities and stockholders' equity	$ 95,857	$ 70,353

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

	(Unaudited) Three Months Ended June 30		(Unaudited) Six Months Ended June 30	
	2023	**2022**	**2023**	**2022**
Cash used in operating activities	$ (10,185)	$ (12,259)	$ (22,885)	$ (23,777)
Cash provided by (used in) investing activities	(348)	-	48,969	-
Cash used in financing activities	-	-	(29)	(210)
Effect of exchange rate changes on cash and cash equivalents	(90)	(78)	(140)	(46)
Net increase (decrease) in cash and cash equivalents	(10,623)	(12,337)	25,915	(24,033)
Cash and cash equivalents at beginning of period	102,038	103,220	65,500	114,916
Cash and cash equivalents at end of period	$ 91,415	$ 90,883	$ 91,415	$ 90,883

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