Leap Therapeutics Reports Second Quarter 2022 Financial Results

August 12, 2022

CAMBRIDGE, Mass., Aug. 12, 2022 /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, 2022.

Leap Highlights:

- Initiation of Part C of the ongoing DisTinGuish study to evaluate DKN-01, Leap's anti-Dickkopf 1 (DKK1) antibody, in combination with tislelizumab, BeiGene's anti-PD-1 antibody, and chemotherapy compared to a tislelizumab and chemotherapy control arm, in patients with gastric or gastroesophageal junction cancer (G/GEJ)
- Initiation of a new company-sponsored trial of DKN-01 in combination with standard of care bevacizumab and chemotherapy in second-line patients with colorectal cancer (CRC)
- Supporting an investigator-initiated trial of DKN-01 plus pembrolizumab in patients with endometrial cancer to be conducted at The University of Texas M.D. Anderson Cancer Center and at the University of Alabama at Birmingham
- Presented initial clinical data from an investigator-sponsored Phase 1b/2a dose escalation and dose expansion study of DKN-01 as a monotherapy or in combination with docetaxel in metastatic castration-resistant prostate cancer (mCRPC) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting
- Cash and cash equivalents totaled $90.9 million at June 30, 2022, expected to provide financial runway to mid-2024

"The Company has made important steps during the second quarter to expand the development of DKN-01 with the initiation of a randomized controlled clinical trial in combination with BeiGene's tislelizumab and chemotherapy in first-line G/GEJ cancer patients. The results to date from Part A and B of our DisTinGuish study have been compelling, and we look forward to further data readouts in the second half of the year," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We are also excited to initiate a company-sponsored study in second-line colorectal cancer patients and to support an investigator-initiated study with Merck's anti-PD-1 antibody pembrolizumab in endometrial cancer patients, as part of a broad strategy for the global development of DKN-01."

DKN-01 Development Update

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the DKK1 protein. DKK1 modulates the Wnt/Beta-catenin and PI3kinase/AKT signaling pathways, which play an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK cell ligands on tumor cells.

- ***Leap and BeiGene Announced Initiation of Part C of the Ongoing DisTinGuish Study to Evaluate DKN-01, in Combination with Tislelizumab and Chemotherapy Compared to a Tislelizumab and Chemotherapy Control Arm, in Patients with G/GEJ.*** The DisTinGuish study (NCT04363801) is a Phase 2 study of DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. Part C of the DisTinGuish study will enroll approximately 160 first-line, HER2-negative patients who have had no prior therapy for unresectable locally advanced or metastatic G/GEJ adenocarcinoma. Patients will be randomized 1:1 to study DKN-01 in combination with tislelizumab and SOC chemotherapy, compared to tislelizumab and SOC chemotherapy. The primary objective of Part C is progression-free survival (PFS) in patients whose tumors express high levels of DKK1 (DKK1-high). Secondary objectives of Part C include PFS in all patients regardless of DKK1 expression, as well as overall survival (OS) and objective response rate (ORR) as measured by RECIST v1.1 in DKK1-high and all patients.
- ***Leap Announced Initiation of the DeFiance Study of DKN-01 in Combination with SOC Bevacizumab and Chemotherapy in Second-line Patients with CRC.*** The DeFianCe study (NCT05480306) is a Phase 2 study of DKN-01 in combination with bevacizumab and SOC chemotherapy in patients with advanced CRC who have received one prior systemic therapy. The study is designed with an initial 20 patient cohort and to then expand into a 130 patient randomized controlled trial against bevacizumab and SOC chemotherapy. The primary objective is PFS. Secondary objectives include ORR, duration of response (DOR), and OS.
- ***Leap Announced the Support of an Investigator-initiated Trial of DKN-01 Plus Pembrolizumab in Patients with Endometrial Cancer to be Conducted at The University of Texas M.D. Anderson Cancer Center and at the***

University of Alabama at Birmingham. The investigator-initiated trial of DKN-01 in combination with pembrolizumab is an open-label, Bayesian design, Phase 2 trial and will initially enroll 15 patients each into DKK1-high and DKK1-low cohorts. If the efficacy criteria is met in either or both of the 15 patient cohort(s), then the cohort(s) will be expanded by an additional 15 patients. The primary objective of the study is ORR. Secondary objectives include clinical benefit rate (CBR), PFS, OS, and DOR.

- ***Leap Presented Initial Clinical Data from the Investigator-Sponsored Study of DKN-01 Plus Docetaxel in Patients with Prostate Cancer at the 2022 ASCO Annual Meeting.*** In May 2022, the Company presented initial clinical data from the investigator-sponsored Phase 1b/2a dose escalation and dose expansion study testing DKN-01 as monotherapy or in combination with docetaxel in mCRPC. Highlights from the data include:
    - No DLTs were observed at DKN-01 300mg or 600mg dose levels as monotherapy or in combination with docetaxel, and no treatment-related adverse events occurred in either cohort
    - No partial responses (PR) were seen in the monotherapy cohort with best overall response of stable disease in 2 out of 5 evaluable patients
    - In the combination cohort, all 6 patients had a greater than 50% reduction in PSA levels (PSA50), and the 5 patients with measurable disease each had a PR by RECIST (3 confirmed, 2 unconfirmed)
    - Confirmed partial responses in the combination cohort were observed in both DKK1 high and low expressing tumors, including in 2 out of 3 patients with aggressive variant prostate cancer

Selected Second Quarter 2022 Financial Results

Net Loss was $17.0 million for the second quarter 2022, compared to $9.5 million for the same period in 2021. The increase was primarily due to an increase in manufacturing costs related to clinical trial material, an increase in clinical trial costs due to patient enrollment and the duration of patients on study in the DisTinGuish trial and an increase in the number of research and development employees to support the development of DKN-01.

Research and development expenses were $14.0 million for the three months ended June 30, 2022, compared to $7.2 million for the three months ended June 30, 2021. The increase in research and development expenses was due to an increase of $5.2 million in manufacturing costs related to clinical trial material and manufacturing campaigns, an increase of $1.2 million in clinical trial costs due to patient enrollment and duration of patients on study, an increase of $0.4 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees, and an increase of $0.2 million in stock based compensation expense due to new stock options and restricted stock units granted to research and development full time employees, offset by a decrease of $0.2 million in consulting fees.

General and administrative expenses were $2.9 million for the three months ended June 30, 2022, compared to $2.8 million for the three months ended June 30, 2021. The increase in general and administrative expenses was due to an increase of $0.1 million in stock based compensation expense due to new stock options and restricted stock units granted to general and administrative full time employees.

Cash and cash equivalents totaled $90.9 million at June 30, 2022. Additionally, short-term research and development incentive receivable totaled $1.1 million.

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 in clinical trials in patients with esophagogastric, colorectal, and gynecologic cancers. Leap has entered into a strategic collaboration with BeiGene, Ltd. for the rights to develop DKN-01 in Asia (excluding Japan), Australia, and New Zealand. 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 Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include Leap's expectations with respect to the development and advancement of DKN-01, including the initiation, timing and design of future studies, enrollment in clinical studies, potential for the receipt of future option exercise, milestone, or royalty payments from BeiGene, financial runway, and other future expectations, plans and prospects. Although Leap believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from our expectations. Such risks and uncertainties include, but are not limited to: that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19, global conflict or supply chain related issues; unstable global market and economic conditions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; the size and growth potential of the markets for our drug product candidates; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially is included in Leap Therapeutics' periodic filings with the SEC, including Leap's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on March 11, 2022 and as may be updated by Leap's Quarterly Reports on Form 10-Q and the other reports Leap files from time to time with the SEC. Any forward-looking statement contained in this release speaks only as of its date. Leap undertakes no obligation to update any forward-looking statement contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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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,	
	2022	2021	2022	2021
License revenue	$ -	$ 375	$ -	$ 750
Operating expenses:				
Research and development	14,045	7,206	21,829	14,013
General and administrative	2,855	2,795	5,703	5,535
Total operating expenses	16,900	10,001	27,532	19,548
Loss from operations	(16,900)	(9,626)	(27,532)	(18,798)
Interest income	39	1	44	3
Interest expense	(17)	(16)	(38)	(30)
Australian research and development incentives	587	244	624	315
Foreign currency loss	(733)	(129)	(498)	(150)
Net loss attributable to common stockholders	$ (17,024)	$ (9,526)	$ (27,400)	$ (18,660)
Net loss per share				
Basic & diluted	$ (0.15)	$ (0.12)	$ (0.24)	$ (0.24)
Weighted average common shares outstanding				
Basic & diluted	113,248,937	76,389,525	113,248,937	76,384,077

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

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 90,883	$ 114,916
Research and development incentive receivable	1,130	1,189
Prepaid expenses and other current assets	428	769
Total current assets	92,441	116,874
Property and equipment, net	28	36
Right of use assets, net	863	459
Research and development incentive receivable, net of current portion	610	-
Deferred tax assets	150	159
Other long term assets	60	90
Deposits	51	293
Total assets	$ 94,203	$ 117,911
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$ 7,553	$ 4,189
Accrued expenses	2,463	5,366
Lease liability - current portion	395	432
Total current liabilities	10,411	9,987
Non current liabilities:		
Lease liability, net of current portion	474	37
Total liabilities	10,885	10,024
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 88,318,454 shares issued and outstanding	88	88
Additional paid-in capital	374,108	371,638
Accumulated other comprehensive income (loss)	94	(267)
Accumulated deficit	(290,972)	(263,572)
Total stockholders' equity	83,318	107,887
Total liabilities and stockholders' equity	$ 94,203	$ 117,911

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

	(Unaudited) Three Months Ended June 30		(Unaudited) Six Months Ended June 30	
	2022	**2021**	**2022**	**2021**
Cash used in operating activities	$ (12,259)	$ (7,752)	$ (23,777)	$ (16,339)
Cash provided by (used in) financing activities	-	4	(210)	18
Effect of exchange rate changes on cash and cash equivalents	(78)	(9)	(46)	(16)
Net decrease in cash and cash equivalents	(12,337)	(7,757)	(24,033)	(16,337)
Cash and cash equivalents at beginning of period	103,220	43,491	114,916	52,071
Cash and cash equivalents at end of period	$ 90,883	$ 35,734	$ 90,883	$ 35,734

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