Leap Therapeutics Reports Second Quarter 2021 Financial Results and Upcoming Data Presentation

August 13, 2021

CAMBRIDGE, Mass., Aug. 13, 2021 /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, 2021 and provided upcoming company milestones.

"In the first half of the year, we made significant clinical progress in the DisTinGuish study of DKN-01 in combination with BeiGene's tislelizumab, as we completed enrollment in the first-line patient cohort," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We look forward to presenting initial data from the study in September, which we believe will show the important potential role DKN-01 can play for first-line gastric cancer patients, particularly those whose tumors express high levels of DKK1 where a great unmet medical need remains unaddressed."

Key DKN-01 2021 Clinical Milestones

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (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 made substantial progress with the clinical development of DKN-01 during the first half of 2021 and has an important clinical milestone ahead this quarter:

Completion of Enrollment in First-Line Cohort in the DisTinGuish Study of DKN-01 plus Tislelizumab and Chemotherapy in Gastric Cancer. The Company announced the completion of enrollment for the first-line patient cohort in the DisTinGuish study (NCT04363801), a Phase 2a, open-label, clinical trial evaluating DKN-01 in combination with tislelizumab, BeiGene Ltd.'s (BeiGene) anti-PD-1 antibody, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ). The study, which is being conducted in two parts in the United States and the Republic of Korea, enrolled 25 patients with first-line G/GEJ cancer and is expected to enroll up to 48 patients with second-line G/GEJ cancer whose tumors express high levels of DKK1. Leap is conducting this study as part of an exclusive option and license agreement with BeiGene for the development of DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

Initial Data from the DisTinGuish Study of DKN-01 Plus Tislelizumab and Chemotherapy to be Presented at the European Society for Medical Oncology (ESMO) Congress 2021. The Company will be presenting initial data from the cohort of 25 first-line G/GEJ cancer patients treated with DKN-01 in combination with tiselizumab and chemotherapy at the ESMO Congress 2021, being held virtually on September 16-21, 2021. Leap plans to host a conference call on Friday, September 17, 2021 to further discuss the data.

Selected Second Quarter 2021 Financial Results

Net loss was $9.5 million for the second quarter 2021, compared to $6.5 million for the same period in 2020.

License revenues were $0.4 million for each of the second quarter 2021 and the same period in 2020, and relate to the exclusive option and license agreement with BeiGene for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

Research and development expenses were $7.2 million for the second quarter 2021, compared to $5.4 million for the same period in 2020. The increase of $1.8 million in research and development expenses was primarily due to an increase of $0.8 million in payroll and other related expenses due to an increase in headcount of research and development full-time employees, an increase of $0.6 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns, an increase of $0.3 million in clinical trial costs due to timing of patient enrollment, and an increase of $0.1 million in stock based compensation expense due to new stock options granted to research and development full-time employees in 2021.

General and administrative expenses were $2.8 million for the second quarter 2021, compared to $2.5 million for the second quarter 2020. The increase of $0.3 million in general and administrative expenses was due to a $0.2 million increase in payroll and other related expenses, a $0.2 million increase in stock-based compensation expense due to new stock options granted to general and administrative full-time employees in 2021, and a $0.1 million increase in insurance costs primarily related to an increase in our directors and officers insurance. These increases were partially offset by a $0.2 million decrease in professional fees primarily due to lower recruiting and information technology costs.

Cash and cash equivalents totaled $35.7 million at June 30, 2021. Research and development incentive receivables totaled $0.2 million at June 30, 2021.

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, hepatobiliary, gynecologic, and prostate cancers. Leap has entered into a strategic partnership 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/.

RNAscope® is a registered trademark of Advanced Cell Diagnostics, Inc., Newark, CA, USA.

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 future studies, potential for the receipt of future option exercise, milestone, or royalty payments from BeiGene, 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 related issues; 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 will be 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, 2020, as filed with the SEC on March 12, 2021 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.

CONTACT:

Douglas E. Onsi
President & Chief Executive Officer
Leap Therapeutics, Inc.
617-714-0360
donsi@leaptx.com

Heather Savelle
Investor Relations
Argot Partners
212-600-1902
heather@argotpartners.com

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,	
	2021	**2020**	**2021**	**2020**
License revenue	$ 375	$ 375	$ 750	$ 750
Operating expenses:				
Research and development	7,206	5,350	14,013	9,953
General and administrative	2,795	2,521	5,535	4,674
Total operating expenses	10,001	7,871	19,548	14,627
Loss from operations	(9,626)	(7,496)	(18,798)	(13,877)
Interest income	1	20	3	88
Interest expense	(16)	(13)	(30)	(25)
Australian research and development incentives	244	30	315	115
Foreign currency gain (loss)	(129)	943	(150)	(48)
Net loss	(9,526)	(6,516)	(18,660)	(13,747)
Dividend attributable to down round feature of warrants	-	-	-	(303)
Dividend attributable to Series A & B convertible preferred stock	-	-	-	(372)
Series A & B convertible preferred stock - beneficial conversion feature	-	-	-	(9,399)
Net loss attributable to common stockholders	$ (9,526)	$ (6,516)	$ (18,660)	$ (23,821)
Net loss per share				
Basic & diluted	$ (0.12)	$ (0.12)	$ (0.24)	$ (0.57)
Weighted average common shares outstanding				
Basic & diluted	76,389,525	52,442,597	76,384,077	42,037,405

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

	June 30,	**December 31,**

	2021 (Unaudited)	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 35,734	$ 52,071
Research and development incentive receivable	22	73
Prepaid expenses and other current assets	264	130
Total current assets	36,020	52,274
Property and equipment, net	50	65
Property and equipment, net	337	528
Research and development incentive receivable, net of current portion	309	-
Deferred tax assets	176	179
Deferred costs	68	345
Deposits	980	980
Total assets	$ 37,940	$ 54,371
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,343	$ 2,717
Accrued expenses	2,609	2,747
Deferred revenue	750	1,500
Lease liability - current portion	354	408
Total current liabilities	8,056	7,372
Non current liabilities:		
Restricted stock liability	-	204
Lease liability, net of current portion	-	144
Total liabilities	8,056	7,720
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,672,014 and 59,657,742 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	60	60
Additional paid-in capital	271,918	270,155
Accumulated other comprehensive loss	(449)	(579)
Accumulated deficit	(241,645)	(222,985)
Total stockholders' equity	29,884	46,651
Total liabilities and stockholders' equity	$ 37,940	$ 54,371

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

	(Unaudited) Six Months Ended June 30	
	2021	2020
Cash used in operating activities	$ (16,339)	$ (13,377)
Cash provided by investing activities	-	25
Cash provided by financing activities	18	74,382
Effect of exchange rate changes on cash and cash equivalents	(16)	(34)
Net increase (decrease) in cash and cash equivalents	(16,337)	60,996
Cash and cash equivalents at beginning of period	52,071	3,891
Cash and cash equivalents at end of period	$ 35,734	$ 64,887

View original content to download multimedia:https://www.prnewswire.com/news-releases/leap-therapeutics-reports-second-quarter-2021-financial-results-and-upcoming-data-presentation-301354883.html

SOURCE Leap Therapeutics, Inc.