Leap Therapeutics Reports Third Quarter 2019 Financial Results

November 14, 2019

- DKN-01 data continues to show robust activity, including a monotherapy complete response, in cancer patients with high DKK-1 expression and Wnt signaling alterations

- De-prioritizing further development in TRX518 to focus resources on advancing DKN-01

CAMBRIDGE, Mass., Nov. 14, 2019 /PRNewswire/ -- Leap Therapeutics, Inc. (NASDAQ:LPTX) today reported financial results for the third quarter ended September 30, 2019.

"The body of clinical data we presented in the third quarter for both DKN-01 monotherapy and combination treatment for cancer patients continues to demonstrate impressive activity. Patients with advanced gastroesophageal junction and gastric cancer whose tumors expressed high levels of DKK1 (DKK1-high) achieved higher survival and objective response outcomes to the combination of DKN-01 and KEYTRUDA," commented Christopher K. Mirabelli, Ph.D., President and Chief Executive Officer of Leap. "DKN-01 also showed durable benefit in patients with endometrial cancer with Wnt pathway alterations, including a monotherapy complete response, highlighting the potential utility of DKN-01 for biomarker-targeted patient populations."

Dr. Mirabelli continued: "We also completed enrollment in the dose escalation phase of our clinical trial evaluating TRX518 in combination with BAVENCIO and cyclophosphamide; however, we've made the strategic decision to deprioritize further development of TRX518 at this time in order to focus our resources on our more advanced DKN-01 program. The safety profile observed to date was acceptable, and patients who are benefiting from treatment in the TRX518 program will continue to be treated."

DKN-01 Development Program Update

- ***DKN-01 in ESOPHAGOGASTRIC CANCER***: Leap presented data from the KEYNOTE-731 clinical study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. Study results demonstrated that patients with DKK1-high status had improved outcomes, including longer progression free survival (PFS) independent of PD-L1 Combined Positive Scores (CPS). In ten evaluable gastroesophageal junction and gastric cancer patients who had not received prior PD-1/PD-L1 therapy, DKK1-high patients experienced 22.1 weeks median progression free survival (PFS) and 31.6 weeks median overall survival (OS), with a 50% overall response rate (ORR) and 80% disease control rate (DCR). Fifteen evaluable DKK1-low patients experienced 5.9 weeks PFS and 17.4 weeks OS, with a 20% DCR. PD-L1 CPS did not predict efficacy to the combination of DKN-01 plus KEYTRUDA.
- ***DKN-01 in GYNECOLOGICAL CANCERS***: The Company presented data from the ongoing clinical study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers at the International Gynecologic Cancer Society Annual Global Meeting held in September. In the cohort of sixteen evaluable monotherapy patients with epithelial endometrial cancer (EEC) with identified Wnt signaling mutations, patients had higher response rates and demonstrated longer PFS as compared to patients without Wnt signaling mutations. Specifically, one patient had a complete response and one patient had a partial response, representing a 12.5% single agent ORR, seven patients had a best response of stable disease, and seven patients had progressive disease. In the six evaluable monotherapy EEC patients who did not have any identified Wnt signaling mutations, none had clinical benefit. Patient follow-up is continuing in this study, which has been expanded to include focused cohorts of patients with carcinosarcoma.
- ***DKN-01 plus OPDIVO in BILIARY TRACT CANCER***: The first patients have been dosed in an investigator-initiated clinical study to evaluate DKN-01 in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab) in previously treated patients with advanced biliary tract cancer. The study is being conducted by Massachusetts General Hospital and will enroll up to 36 biliary tract cancer patients who have progressed after one or more lines of systemic therapy for advanced biliary tract cancer. The primary endpoint of the study will be ORR, to be assessed in the overall population as well as in subgroups stratified by tumor DKK1 and PD-L1 expression. Bristol-Myers Squibb is providing OPDIVO drug supply and partial funding for the study, with Leap providing DKN-01 drug supply as well as additional partial funding.

TRX518 Development Program Update

- ***FURTHER DEVELOPMENT OF TRX518 HAS BEEN DEPRIORITIZED***: Leap has completed enrollment in dose escalation phase of the clinical trial evaluating TRX518 in combination with cyclophosphamide chemotherapy and BAVENCIO® (avelumab). However, instead of pursuing additional enrollment through the expansion cohorts in this study as initially planned, the Company has decided to reprioritize resources on the further development of the DKN-01 program. There were no safety or efficacy concerns leading to this decision, and patients who are benefitting from the combination therapy will continue to be treated in the study.

Selected Third Quarter 2019 Financial Results

Net loss was $7.9 million for the third quarter 2019, compared to $6.6 million for the same period in 2018. This increase was primarily due to the recording of a $1.8 million gain in the third quarter 2018 as a result of a change in the fair value of the warrant liability, partially offset by a decrease in research and development expense.

Research and development expenses were $5.8 million for the third quarter 2019, compared to $6.5 million for the same period in 2018. This decrease was primarily due to a decrease of $0.4 million in clinical trial costs as a result of the timing of patient enrollment and a decrease of $0.3 million in manufacturing costs related to clinical trial material manufacturing campaigns.

General and administrative expenses were $2.2 million for the third quarter 2019, compared to $2.1 million for the same period in 2018. The increase was primarily due to a $0.1 million increase in stock based compensation as a result of new stock options granted to employees and directors in 2019.

Cash, cash equivalents and marketable securities totaled $10.1 million at September 30, 2019. Research and development incentive receivables, short term, totaled approximately $752,000 at September 30, 2019.

About Leap Therapeutics

Leap Therapeutics (NASDAQ:LPTX) is focused on developing novel cancer therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. For more information about Leap Therapeutics, visit http://www.leaptx.com or 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, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements regarding Leap's expectations with respect to the development and advancement of DKN-01, TRX518, and other programs, including the initiation, timing and design of future studies, enrollment in future studies, business development, and other future expectations, plans and prospects. Leap has attempted to identify forward looking statements by such terminology as "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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: the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the ability to complete a financing or form business development relationships to fund our expenses; 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; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; 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 Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2018 that Leap filed with the SEC on April 1, 2019. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors. Any forward looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. OPDIVO® is a registered trademark of Bristol-Myers Squibb Company, New York, NY, USA. BAVENCIO® is a registered trademark of Merck KGaA, Darmstadt, Germany, and is marketed under a global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, USA.

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Leap Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				

Research and development	$ 5,772	$ 6,457	$ 18,698	$ 14,922
General and administrative	2,151	2,142	6,481	6,858
Total operating expenses	7,923	8,599	25,179	21,780
Loss from operations	(7,923)	(8,599)	(25,179)	(21,780)
Interest income	80	128	281	327
Interest expense	(5)	(4)	(21)	(18)
Australian research and development incentives	(7)	299	129	1,188
Foreign currency loss	(80)	(249)	(114)	(615)
Change in fair value of warrant liability	-	1,793	-	(3,720)
Net loss	(7,935)	(6,632)	(24,904)	(24,618)
Dividend attributable to down round feature of warrants	-	-	(359)	-
Net loss attributable to common stockholders	$ (7,935)	$ (6,632)	$ (25,263)	$ (24,618)
Net loss per share				
Basic	$ (0.33)	$ (0.45)	$ (1.15)	$ (1.76)
Diluted	$ (0.33)	$ (0.55)	$ (1.15)	$ (1.76)
Weighted average common shares outstanding				
Basic	23,923,196	14,701,785	22,039,386	13,955,949
Diluted	23,923,196	15,211,716	22,039,386	13,955,949

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

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 10,058	$ 16,284
Research and development incentive receivable	752	836
Prepaid expenses and other current assets	210	202
Total current assets	11,020	17,322
Property and equipment, net	149	86
Right of use asset, net	1,214	-
Research and development incentive receivable, net of current portion	177	-
Deferred tax assets	120	124
Other assets	1,461	1,542
Total assets	$ 14,141	$ 19,074
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,889	$ 3,579
Accrued expenses	2,317	2,872
Restricted stock liability	159	-
Lease liability - current portion	566	-
Total current liabilities	7,931	6,451
Non current liabilities:		
Warrant liability	-	3,448
Lease liability, net of current portion	648	-
Total liabilities	8,579	9,899
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 24,194,877 and 14,703,159 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	24	15
Additional paid-in capital	192,383	162,393
Accumulated other comprehensive income	327	302
Accumulated deficit	(187,172)	(153,535)
Total stockholders' equity	5,562	9,175
Total liabilities and stockholders' equity	$ 14,141	$ 19,074

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

	Nine Months Ended September 30,	
	2019	2018
	(Unaudited)	
Cash used in operating activities	$ (21,008)	$ (18,983)
Cash used in investing activities	(100)	-
Cash provided by financing activities	14,836	15,946
Effect of exchange rate changes on cash and cash equivalents	46	549
Net decrease in cash and cash equivalents	(6,226)	(2,488)
Cash and cash equivalents at beginning of period	16,284	25,737
Cash and cash equivalents at end of period	$ 10,058	$ 23,249

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