Leap Therapeutics Reports First Quarter 2019 Financial Results

May 15, 2019

- Strong clinical trial enrollment leading to significant 2019 data
- First patient enrolled in DKN-01 prostate cancer study

CAMBRIDGE, Mass., May 15, 2019 /PRNewswire/ -- Leap Therapeutics, Inc. (NASDAQ: LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported financial results for the first quarter ended March 31, 2019.

"In the first quarter, we presented important new data for both of our programs. DKN-01's activity continues to be impressive in biomarker targeted patient populations, with single agent partial responses in patients with endometrial cancer. In addition, TRX518 achieved a first partial response as a monotherapy and as a combination therapy with gemcitabine," commented Christopher K. Mirabelli, Ph.D, President and Chief Executive Officer of Leap Therapeutics. "We are looking forward to presenting additional clinical data from both programs in the second half of the year."

Recent Developments

- ***DKN-01 in ESOPHAGOGASTRIC CANCER***: Leap presented clinical data from its study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. The overall response rate and disease control rate has been higher in patients with higher DKK1 expression as measured by in situ hybridization RNAscope. Enrollment in this study is complete.
- ***DKN-01 in GYNECOLOGICAL CANCERS***: At the Society for Gynecologic Oncology 50th Annual Meeting on Women's Cancer, Leap presented an update on its clinical study evaluating DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers. DKN-01 monotherapy has generated two partial responses in patients with endometrial cancer, and DKN-01 plus paclitaxel has generated a partial response in a patient with carcinosarcoma. An additional DKN-01 monotherapy patient was initially reported by the treating investigator to have experienced a partial response; however, further follow-up identified that the patient has a tumor reduction that does not meet the threshold for a partial response and remains on treatment with ongoing clinical benefit. Eighty-seven patients have been enrolled in the study, and enrollment is ongoing.
- ***DKN-01 in PROSTATE CANCER***: The first patient has been enrolled in an investigator-initiated study of DKN-01 as a monotherapy and in combination with docetaxel in DKK1-positive metastatic prostate cancer patients.
- ***TRX518 MONOTHERAPY***: A non-virally mediated hepatocellular cancer patient, who has been treated with single agent TRX518 for two years, achieved a partial response. With recent disease progression, this patient now continues on treatment for clinical benefit.
- ***TRX518 COMBINATION THERAPY***: Leap presented data from its clinical trial evaluating TRX518 in combination with gemcitabine chemotherapy or in combination with KEYTRUDA or OPDIVO® (nivolumab), with patients from each combination arm experiencing responses and durable stable disease. Eighteen patients have been enrolled in the TRX518/KEYTRUDA expansion cohort, and enrollment is ongoing.

Selected First Quarter 2019 Financial Results

Net loss was $8.6 million for the first quarter 2019, compared to $10.6 million for the same period in 2018. This decrease was primarily due to a non-cash charge based on the change in the fair value of the warrant liability in the first quarter 2018, offset by an increase in clinical development expense.

Research and development expenses were $6.8 million for the first quarter 2019, compared to $4.2 million for the same period in 2018. This increase was primarily due to an increase in clinical trial expenses associated with an increase in patient enrollment and an increase in consulting fees and payroll expenses, partially offset by a decrease in manufacturing costs related to clinical trial material.

General and administrative expenses were $2.0 million for the first quarter 2019, compared to $2.1 million for the same period in 2018. This decrease was primarily due to a decrease in compensation expense as a result of senior management not accepting the cash bonus awarded to them by the compensation committee, partially offset by an increase in stock-based compensation expense.

Cash, cash equivalents and marketable securities totaled $21.7 million at March 31, 2019. Research and development incentive receivables, current and long term, totaled approximately $0.9 million at March 31, 2019.

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, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap's second clinical candidate, TRX518, is a humanized GITR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in advanced solid tumor studies. 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.

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

	Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
Operating expenses:		
Research and development	$ 6,790	$ 4,231
General and administrative	2,005	2,113
Total operating expenses	8,795	6,344
Loss from operations	(8,795)	(6,344)
Interest income	82	77
Interest expense	(7)	(6)
Australian research and development incentives	75	646
Foreign currency gains (loss)	42	(144)
Change in fair value of warrant liability	-	(4,851)
Net loss	(8,603)	(10,622)
Dividend attributable to down round feature of warrants	(359)	-
Net loss attributable to common stockholders	$ (8,962)	$ (10,622)
Net loss per share - basic and diluted	$ (0.47)	$ (0.85)
Weighted average common shares outstanding - basic and diluted	19,237,444	12,449,421

Leap Therapeutics, Inc.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 21,709	$ 16,284
Research and development incentive receivable	844	836
Prepaid expenses and other current assets	159	202
Total current assets	22,712	17,322
Property and equipment, net	74	86
Right of use asset, net	1,578	-
Research and development incentive receivable, net of current portion	74	-
Deferred tax assets	126	124
Other assets	1,519	1,542
Total assets	$ 26,083	$ 19,074
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,298	$ 3,579
Accrued expenses	4,150	2,872
Lease liability - current portion	738	-
Total current liabilities	8,186	6,451
Non current liabilities:		
Warrant liability	-	3,448
Lease liability, net of current portion	833	-
Total liabilities	9,019	9,899
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2019 and December 31, 2018, 22,260,301 and 14,703,159 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	22	15
Additional paid-in capital	187,635	162,393
Accumulated other comprehensive income	278	302
Accumulated deficit	(170,871)	(153,535)
Total stockholders' equity	17,064	9,175
Total liabilities and stockholders' equity	$ 26,083	$ 19,074

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

	Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
Cash used in operating activities	$ (6,868)	$ (5,478)
Cash provided by financing activities	12,322	15,005
Effect of exchange rate changes on cash and cash equivalents	(29)	112
Net increase in cash and cash equivalents	5,425	9,639
Cash and cash equivalents at beginning of period	16,284	25,737
Cash and cash equivalents at end of period	$ 21,709	$ 35,376

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