Leap Therapeutics Reports First Quarter 2020 Financial Results

May 14, 2020

CAMBRIDGE, Mass., May 14, 2020 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the first quarter ended March 31, 2020.

Leap First Quarter Highlights:

- Entered into an exclusive option and license agreement with BeiGene, Ltd. for the clinical development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand
- Completed a $27 million equity financing with BeiGene, Perceptive Advisors, and a lead institutional investor
- Presented updated data for DKN-01 monotherapy that showed a complete response and partial response in endometrial cancer patients with additional responses observed for the DKN-01 plus paclitaxel combination in carcinosarcoma patients
- Presented final data from its Phase 1/2 clinical trial of DKN-01 plus Keytruda® (pembrolizumab) in patients with advanced or recurrent esophagogastric cancer at the American Society of Clinical Oncology 2020 Gastrointestinal Cancers Symposium
- Announced Executive Leadership Team and Board of Directors changes

"We've made great strides in the first quarter, as we continue to generate compelling data demonstrating DKN-01's potential as a single agent or in combination with PD-1 antibody therapy or chemotherapy in treating multiple biomarker-defined cancer indications," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "Our partnership with BeiGene for the clinical development and commercialization of DKN-01 is off to a strong start. Site initiation activities are now underway for our combination study of DKN-01 plus tislelizumab, BeiGene's anti-PD-1 antibody, in patients with gastric or gastroesophageal junction cancer, and we look forward to dosing the first patients in the second half of this year."

Business Update

- ***Leap and BeiGene Sign Exclusive Option and License Agreement for DKN-01*** - Leap and BeiGene announced an exclusive option and license agreement for the clinical development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. Under the terms of the agreement, Leap received an upfront cash payment of $3 million from BeiGene. Leap will be eligible to receive an additional payment from BeiGene upon BeiGene's exercise of the option and payments based upon the achievement of certain development, regulatory, and sales milestones, for a total deal value of up to $132 million. In addition, Leap is entitled to receive tiered royalties on any product sales of DKN-01 in the licensed territory. Leap will retain exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the United States, Europe, Japan, and the rest of the world.

- ***Leap Completes $27 Million Equity Financing with BeiGene, Perceptive Advisors and Another Institutional Investor*** - Simultaneous with the BeiGene Agreement, Leap also entered into a securities purchase agreement and issued and sold 1,421,801 shares of Series A mandatorily convertible preferred stock to a lead investor and an aggregate of 1,137,442 shares of Series B mandatorily convertible preferred stock to BeiGene and Perceptive Advisors. On March 5, 2020, the Leap stockholders approved the conversion of the Series A preferred stock into a pre-funded warrant to purchase 14,413,902 shares of common stock and the conversion of the Series B preferred stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares at an exercise price of $2.11 per share. In addition, the lead investor has the right to appoint a member to Leap's Board of Directors.

- ***Leap Makes Executive Leadership Changes*** – Leap announced the following changes to the Company's Executive Leadership Team and Board of Directors:
  - Christopher K. Mirabelli, Ph.D., stepped down from his role as President and Chief Executive Officer and will continue to serve as the Chairman of Leap's Board of Directors and an employee, providing ongoing leadership around the Company's research and development efforts.
  - Douglas E. Onsi was named President and Chief Executive Officer, while maintaining his previous role as Chief Financial Officer. Mr. Onsi will also serve as a member of the Board of Directors.
  - John Littlechild stepped down from Leap's Board of Directors.
  - Cynthia Sirard, M.D., was promoted to Chief Medical Officer from Vice President, Clinical Research and Development.
  - Mark O'Mahony was promoted to Chief Manufacturing Officer from Vice President of Chemistry, Manufacturing, and Controls.

DKN-01 Clinical Update

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, a modulator of Wnt/Beta-catenin signaling. DKK1 has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment.

- ***Leap Presented Updated Data for DKN-01 Monotherapy and Paclitaxel Combination in Gynecologic Cancers*** – Leap announced updated clinical data from its ongoing Phase 2 clinical trial of DKN-01, as both a monotherapy and in combination with paclitaxel chemotherapy, in patients with advanced gynecological malignancies. Leap hosted a conference call with Rebecca Arend, M.D., Assistant Professor and Associate Scientist, Gynecologic Oncology Clinic, The University of Alabama at Birmingham School of Medicine Comprehensive Cancer Center Experimental Therapeutics Program, on April 23, 2020, to discuss the data. Key findings from the P204 Study include the following:

DKN-01 Single Agent Activity

  - **Endometrial Cancer:** Twenty-nine endometrial cancer patients were enrolled in the DKN-01 monotherapy arm, over 75% of whom had experienced three or more prior lines of therapy. Of those patients, 26 were evaluable for response. In the 20 patients with a Wnt signaling alteration, one patient (5%) has an ongoing complete response, one patient (5%) had a partial response, eight patients (40%) had a best response of stable disease, and 10 patients (50%) had progressive disease, representing an overall response rate (ORR) of 10% and a disease control rate (DCR) of 50%. In the group of six patients without any Wnt signaling alterations, one patient (16.6%) had a best response of stable disease and five patients (83.3%) had progressive disease.

  - **Carcinosarcoma:** Ten patients with carcinosarcoma have been enrolled in the DKN-01 monotherapy arm, five of whom were evaluable for response as of the data-cut off date. Two patients (40%) had a best response of stable disease, one of whom has continued on monotherapy for nearly two years, and three patients (60%) had progressive disease. Five patients had not reached their first tumor assessment.

DKN-01 plus Paclitaxel Combination Activity

  - **Carcinosarcoma:** Fifteen patients with carcinosarcoma were enrolled in the DKN-01 plus paclitaxel arm, six of whom were evaluable for response as of the data-cut off date. Two patients (33%) have had a partial response, one patient (17%) has had a best response of stable disease, and three patients (50%) had progressive disease, representing an ORR of 33% and a DCR of 50%. Nine patients had not reached their first tumor assessment.

  - **Endometrial Cancer:** Twenty-five patients with heavily pretreated endometrial cancer were enrolled in the DKN-01 plus paclitaxel arm. All of these patients had previously received paclitaxel, 44% had received hormonal therapies, 32% had received bevacizumab, 20% had received immunotherapy, and 12% had received a PARP inhibitor. Of those patients, 22 were evaluable for response. A total of 12 patients (55%) have had a best response of stable disease, and ten patients (45%) had progressive disease.

  - **Monotherapy Patients with Wnt activating mutations have longer Progression-Free Survival (PFS) and Overall Survival (OS):** In a pooled analysis of all DKN-01 monotherapy patients, patients with Wnt activating mutations have demonstrated a longer median PFS of 168 days as compared to patients without Wnt activating mutations with median PFS of 56 days. Median OS has not been reached in the Wnt activating mutation group in the pooled analysis as compared to median OS of 328 days in the non-Wnt activating mutation group.

  - **Monotherapy Patients with DKK1-high tumors have longer PFS and OS:** DKK1 expression as measured by *in situ* hybridization RNAscope assay is currently available for 68 of the patients on the study, 32 of whom were treated with DKN-01 monotherapy. Seven patients (22%) were identified as having DKK1-high tumoral expression (DKK1-high). Consistent with the results from Leap's study in patients with esophagogastric cancer, patients whose tumors are DKK1-high have prolonged median PFS of 168 days as compared to patients with tumors that are DKK1-low with median PFS of 56 days. Median OS was 450 days in the DKK1-high group in the pooled analysis as compared to 276 days in the DKK1-low group.

- **Leap Presented Final Data for DKN-01 plus KEYTRUDA® (pembrolizumab) in Esophagogastric Cancer:** Leap completed its multi-part Phase 1/2 clinical study of DKN-01, as a monotherapy and in combination with paclitaxel or KEYTRUDA® (pembrolizumab), in patients with advanced esophagogastric cancer. At the American Society of Clinical Oncology 2020 Gastrointestinal Cancers Symposium, Leap presented final data for the combination of DKN-01 plus pembrolizumab. The combination of DKN-01 and pembrolizumab in gastroesophageal junction cancer (GEJ) and gastric cancer (GC) patients demonstrated improved outcomes in DKK1-high patients who had not previously been treated with PD-1/PD-L1 therapy. DKK1-high patients experienced over 22 weeks median PFS and nearly 32 weeks median OS, with a 50% ORR and 80% DCR in ten evaluable patients. DKK1-low patients experienced nearly 6 weeks median PFS and over 17 weeks OS, with a 20% DCR in 15 evaluable patients.

- **Site Initiation Activities Underway for DKN-01 plus Tislelizumab Combination Study:** As part of the collaboration with BeiGene, Leap intends to study the combination of DKN-01 and BeiGene's anti-PD-1 antibody, tislelizumab. The Company plans to evaluate approximately 40 patients with second-line GC or GEJ whose tumors are DKK1-high. In addition, Leap will evaluate the combination of DKN-01 with tislelizumab and chemotherapy in approximately 20 patients with first-line GC or GEJ. Site initiation activities for this clinical trial are underway, and the Company expects to dose the first patients in the second half of 2020.

Selected First Quarter 2020 Financial Results

Net loss was $7.2 million for the first quarter 2020, compared to $8.6 million for the same period in 2019. This decrease was primarily due to revenue recognized from the BeiGene agreement and a decrease in clinical development expenses, offset by a non-cash charge for foreign currency losses associated with changes in the Australian dollar exchange rate related to activities of Leap's Australian subsidiary.

Research and development expenses was $4.6 million for the first quarter 2020, compared to $6.8 million for the same period in 2019. The decrease was primarily due to decreases in clinical trial costs due to timing of patient enrollment and decreases in consulting fees associated with research and development activities.

General and administrative expenses was $2.2 million for the first quarter 2020, compared to $2.0 million for the same period in 2019. The increase was primarily due to increases in legal, audit and consulting fees associated with corporate and business development activities.

Cash, cash equivalents and marketable securities totaled $25.5 million at March 31, 2020. Research and development incentive receivables, current and long term, totaled approximately $0.2 million at March 31, 2020.

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 has formed a 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/.

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 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, milestones 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, 2019, as filed with the SEC on March 16, 2020 and as may be updated by Leap's Quarterly Reports on Form 10-Q and the other reports we file from time to time with the SEC. 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)

	(Unaudited) Three Months Ended March 31,	
	2020	**2019**

License revenue	$ 375	$ -
Operating expenses:		
Research and development	4,603	6,790
General and administrative	2,153	2,005
Total operating expenses	6,756	8,795
Loss from operations	(6,381)	(8,795)
Interest income	68	82
Interest expense	(12)	(7)
Australian research and development incentives	85	75
Foreign currency gains (loss)	(991)	42
Net loss	(7,231)	(8,603)
Dividend attributable to down round feature of warrants	(303)	(359)
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	$ (17,305)	$ (8,962)
Net loss per share		
Basic	$ (0.55)	$ (0.47)
Diluted	$ (0.55)	$ (0.47)
Weighted average common shares outstanding		
Basic	31,632,213	19,237,444
Diluted	31,632,213	19,237,444

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

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 25,465	$ 3,891
Research and development incentive receivable	247	185
Prepaid expenses and other current assets	272	165
Total current assets	25,984	4,241
Property and equipment, net	114	124
Right of use assets	835	1,026
Deferred tax assets	112	127
Deferred costs	623	831
Deposits	1,074	1,099
Total assets	$ 28,742	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 4,933	$ 4,571
Accrued expenses	2,387	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	379	474
Total current liabilities	9,199	8,486
Non current liabilities:		
Restricted stock liability	-	159
Deferred revenue, net of current portion	1,125	-
Lease liability, net of current portion	454	552
Total liabilities	10,778	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 100,000,000 shares authorized, 35,799,488 and 24,194,877 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	36	24
Additional paid-in capital	219,642	193,319
Accumulated other comprehensive income	988	76
Accumulated deficit	(202,702)	(195,168)
Total stockholders' equity (deficiency)	17,964	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 28,742	$ 7,448

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

	(Unaudited) Three Months Ended March 31,	
	2020	**2019**
Cash used in operating activities	$ (3,926)	$ (6,868)
Cash provided by financing activities	25,605	12,322
Effect of exchange rate changes on cash and cash equivalents	(105)	(29)
Net increase in cash and cash equivalents	21,574	5,425
Cash and cash equivalents at beginning of period	3,891	16,284
Cash and cash equivalents at end of period	$ 25,465	$ 21,709

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