Leap Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results

March 12, 2021

CAMBRIDGE, Mass., March 12, 2021 /PRNewswire/ -- Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the fourth quarter and year ended December 31, 2020.

2020 Leap Highlights:

- Signed agreement with BeiGene, Ltd. for rights to Leap's anti-DKK1 antibody, DKN-01, in Asia (excluding Japan), Australia and New Zealand
- Completed a $51.75 million public offering of common stock and pre-funded warrants to purchase common stock
- Presented updated data from study of DKN-01 plus pembrolizumab in esophagogastric (EGC) cancer demonstrating positive outcomes in DKK1-high patients
- Data for DKN-01 in endometrial cancer demonstrates single agent activity in biomarker-selected patients
- First patient dosed in Phase 2a study of DKN-01 in combination with tislelizumab, BeiGene's anti-PD-1 antibody, for the treatment of metastatic gastric or gastroesophageal junction (G/GEJ) cancer
- Received Orphan Drug Designation and Fast Track Designation for DKN-01 from FDA

"2020 was a transformative year for Leap as we executed our first strategic alliance with BeiGene and advanced our DKN-01 development program, initiating our Phase 2a combination study with BeiGene's tislelizumab in gastric cancer patients," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "The data for DKN-01 to date, both as a monotherapy and in combination approaches, provide evidence of the potential utility of DKN-01 as an attractive treatment option for multiple biomarker-focused cancer indications."

DKN-01 Development 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 and PI3K/AKT signaling pathways. DKK1 has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment.

- ***Leap and BeiGene Announced First Patient Dosed in Study of DKN-01 in Combination with Tislelizumab for the Treatment of Metastatic Gastric/Gastroesophageal Junction (G/GEJ) Cancer –*** In September 2020, Leap and BeiGene announced that the first patient was dosed in the DisTinGuish trial (NCT04363801), a Phase 2a, nonrandomized, open-label, multicenter study of Leap's DKN-01 in combination with BeiGene's tislelizumab with or without chemotherapy as first-line or second-line therapy in adult patients with inoperable, locally advanced G/GEJ adenocarcinoma. The study, which will be conducted in two parts, is currently evaluating approximately forty patients with second-line G/GEJ cancer whose tumors are DKK1-high per perspective analysis. In addition, the study is evaluating the combination of DKN-01 with tislelizumab and capecitabine and oxaliplatin in approximately twenty patients with first-line G/GEJ cancer. Initial data is expected in the second half of 2021.

- ***Leap Presented Updated Data from DKN-01 in EGC Demonstrating Positive Outcomes in DKK1-high Patients –*** At the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting, Leap presented clinical data from the Phase 1b/2a clinical trial of DKN-01 in patients with advanced EGC. In the study, high levels of tumoral DKK1 expression correlated with improved clinical outcomes in heterogeneous EGC patients treated with DKN-01 monotherapy or in combination with paclitaxel or the anti-PD-1 antibody, pembrolizumab.

- ***Leap Presented Updated Data for DKN-01 in Endometrial Cancer Demonstrating Single Agent Activity in Biomarker-selected Patients –*** At the American Association for Cancer Research (AACR) Virtual Special Conference on Endometrial Cancer: New Biology Driving Research and Treatment, Leap presented additional clinical data from the epithelial endometrial cancer (EEC) patients treated with DKN-01 monotherapy as part of its ongoing Phase 2 clinical trial for DKN-01, as both a monotherapy and in combination with paclitaxel chemotherapy, in patients with advanced gynecological malignancies. In the study, DKN-01 demonstrated single agent activity in biomarker-selected EEC patients, including an ongoing complete response that is over 2.5 years in duration and prolonged progression-free survival. Additional data from this study will be presented at the Society of Gynecologic Oncology 2021 Annual Meeting on Women's Cancer.

- ***Leap Receives Orphan Drug Designation and Fast Track Designation –*** On June 11, 2020, the FDA granted Orphan Drug Designation to DKN-01 for the treatment of gastroesophageal junction and gastric cancer. On September 24, 2020,

the FDA granted Fast Track Designation to DKN-01 in combination with tislelizumab for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1, following disease progression on or after prior fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

Selected Year-End and Fourth Quarter 2020 Financial Results

Net Loss was $27.5 million for the year ended December 31, 2020, compared to $32.9 million for the year ended December 31, 2019. This decrease was primarily due to decreased research and development expenses following the deprioritization of the TRX518 program in 2019.

License revenues were $1.5 million for the full year 2020 and relate to the BeiGene Agreement for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. License revenues were $0.4 million for the fourth quarter 2020. The BeiGene Agreement became effective on January 3, 2020. As the BeiGene Agreement is the first such license agreement, no license revenues were recorded during the year ended December 31, 2019.

Research and development expenses were $20.4 million for full year 2020, compared to $24.4 million for same period in 2019. Research and development expenses were $5.1 million for the fourth quarter of 2020, compared to $5.7 million for the same period in 2019. These decreases were primarily due to decreased clinical trial costs due to deprioritizing the continued development of TRX518 in 2019 and timing of patient enrollment, decreased consulting fees associated with research and development activities, and decreased rent expense due to the closing of our research laboratory in April of 2020. These decreases were partially offset by increases in payroll and other related expenses due to an increase in headcount of our research and development full time employees and increases in stock-based compensation expense due to new stock options granted to employees.

General and administrative expenses were $9.6 million for the full year 2020, compared to $9.1 million for the same period in 2019. The increase was due to an increase in professional fees primarily due to increased legal, recruiting and information technology costs, an increase in payroll and other related expenses due to an increase in compensation expense, and an increase in insurance expense. These increases were partially offset by a decrease in stock-based compensation expense. General and administrative expenses were $2.4 million for the full year 2020 compared to $2.6 million for the same period in 2019. This decrease was due to a decrease in stock-based compensation expense, partially offset by increased recruiting and information technology costs.

Cash and cash equivalents totaled $52.1 million at December 31, 2020. Research and development incentive receivables totaled $0.1 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, a Wnt pathway modulator. 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/.

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 a 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, 2020, as filed with the SEC on March 12, 2021. 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.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31		(Unaudited) Three Months Ended December 31	
	2020	**2019**	**2020**	**2019**
License revenue	$ 1,500	$ -	$ 375	$ -
Operating expenses:				
Research and development	20,423	24,366	5,101	5,668
General and administrative	9,616	9,085	2,428	2,604
Total operating expenses	30,039	33,451	7,529	8,272
Loss from operations	(28,539)	(33,451)	(7,154)	(8,272)
Interest income	93	313	2	32
Interest expense	(39)	(23)	3	(2)
Australian research and development incentives	231	132	(112)	3
Foreign currency gains	738	126	549	240
Loss before income taxes	(27,516)	(32,903)	(6,712)	(7,999)
Income taxes	2	3	2	3
Net loss	(27,514)	(32,900)	(6,710)	(7,996)
Dividend attributable to down round feature of warrants	(303)	(359)	0	-
Dividend attributable to Series A & B convertible preferred stock	(372)	-	0	-
Series A & B convertible preferred stock - beneficial conversion feature	(9,399)	-	-	-
Net loss attributable to common stockholders	$ (37,588)	$ (33,259)	$ (6,710)	$ (7,996)
Net loss per share				
Basic	$ (0.63)	$ (1.47)	$ (0.09)	$ (0.33)
Diluted	$ (0.63)	$ (1.47)	$ (0.09)	$ (0.33)
Weighted average common shares outstanding				
Basic	59,327,713	22,582,687	76,376,160	24,194,877
Diluted	59,327,713	22,582,687	76,376,160	24,194,877

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 52,071	$ 3,891
Research and development incentive receivable	73	185
Prepaid expenses and other current assets	130	165
Total current assets	52,274	4,241
Property and equipment, net	65	124
Right of use assets, net	528	1,026
Deferred tax assets	179	127
Deferred costs	345	831
Deposits	980	1,099
Total assets	$ 54,371	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 2,717	$ 4,571
Accrued expenses	2,747	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	408	474
Total current liabilities	7,372	8,486
Non current liabilities:		

Restricted stock liability	204	159
Lease liability, net of current portion	144	552
Total liabilities	7,720	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,657,742 and 24,194,877 shares issued and outstanding as of December 31, 2020 and 2019, respectively	60	24
Additional paid-in capital	270,155	193,319
Accumulated other comprehensive income (loss)	(579)	76
Accumulated deficit	(222,985)	(195,168)
Total stockholders' equity (deficiency)	46,651	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 54,371	$ 7,448

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

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Cash used in operating activities	$ (25,957)	$ (26,902)	$ (5,988)	$ (5,894)
Cash provided by (used in) investing activities	25	(85)	-	15
Cash provided by (used in) financing activities	73,997	14,817	-	(19)
Effect of exchange rate changes on cash and cash equivalents	115	(223)	84	(269)
Net increase (decrease) in cash and cash equivalents	$ 48,180	$ (12,393)	(5,904)	(6,167)
Cash and cash equivalents at beginning of period	3,891	16,284	57,975	10,058
Cash and cash equivalents at end of period	$ 52,071	$ 3,891	$ 52,071	$ 3,891

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