Leap Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results

March 11, 2022

CAMBRIDGE, Mass., March 11, 2022 /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, 2021.

Leap Highlights:

- Presented positive new data from the DisTinGuish Study of DKN-01 plus tislelizumab and chemotherapy in gastric cancer patients at the ESMO Annual Congress and ASCO GI Cancers Symposium
- Completed a $103.6 million public offering of common stock and pre-funded warrants to purchase common stock, resulting in net proceeds of $96.8 million
- Entered partnership on companion diagnostic with Leica Biosystems to advance care for cancer patients
- Presented clinical data from its Phase 2 clinical trial of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological malignancies at the Society of Gynecologic Oncology 2021 Annual Meeting on Women's Cancer

"2021 was year of substantial clinical accomplishments for Leap as we presented positive data from our DisTinGuish clinical trial, which demonstrated compelling efficacy driven by enhanced clinical responses and survival benefit associated with high tumoral DKK1 expression that is independent of PD-L1 expression in patients with first-line gastroesophageal junction (G/GEJ) cancer," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "Following our public offering, we are well funded to advance DKN-01 into the next stages of development in G/GEJ and other cancers, and we look forward to presenting updated data from the DisTinGuish Study in the second half of 2022."

Business Update

- ***Leap Completed a $103.6 Million Public Offering of Common Stock and Pre-Funded Warrants to Purchase Common Stock.*** In September 2021, Leap announced the commencement and closing of an underwritten public offering of 27,568,072 shares of its common stock, including the sale of an additional 4,740,000 shares of its common stock pursuant to the full exercise of the underwriters' option to purchase additional shares, and of pre-funded warrants to purchase 8,771,928 shares of its common stock. Aggregate gross proceeds to Leap from the offering were $103.6 million, including $7.25 million invested by its collaborator and existing investor BeiGene, Ltd., resulting in net proceeds after underwriting discounts and commissions and offering expenses of $96.8 million.

- ***Entered Partnership on Companion Diagnostic with Leica Biosystems to Advance Care for Cancer Patients.*** In January 2022, Leap and Leica Biosystems, a cancer diagnostics company, entered into an agreement to develop a companion diagnostic to detect DKK1. The assay developed by Leica will utilize RNAscope™ technology on the BOND-III Automated Staining System, which allows for detection of DKK1 with high sensitivity and specificity to help identify patients most likely to benefit from DKN-01 treatment.

DKN-01 Development Update

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the 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.

- ***Positive New Data from the DisTinGuish Clinical Trial (NCT04363801) of DKN-01 Plus Tislelizumab and Chemotherapy Presented at the ASCO GI Cancer Symposium.*** The Company presented positive updated new data from the first-line cohort of the Phase 2a study in patients with gastric or gastroesophageal junction cancer (G/GEJ) and initial findings from the still-enrolling Part B of the clinical trial, studying DKN-01 and tislelizumab in second-line advanced G/GEJ patients with high tumoral DKK1 expression.

    - ***First-Line Part A Key Findings:***
        - Overall preliminary median progression-free survival (PFS) was 10.7 months
            - PFS was longer in DKK1-high patients at 11.9 months, compared to 10.7 months in DKK1-low patients
        - Preliminary median duration of response (DoR) was 10.7 months in DKK1-high patients, compared to 7.9 months in DKK1-low patients
        - Median overall survival has not been reached
        - Among patients who received a full first cycle of DKN-01 (modified intent to treat, n=22), the objective response rate (ORR) was 68%, including one complete response (CR) and 14 partial responses (PR)
            - 90% ORR in DKK1-high patients (n=10)
            - 56% ORR in DKK1-low patients (n=9)
        - Activity was independent of PD-L1 expression
            - 79% ORR in PD-L1-low (vCPS < 5) and 67% ORR in PD-L1-high (vCPS > 5) patients
            - 100% ORR in DKK1-high, PD-L1-low patients (n=6)

- Combination was well tolerated, safety profile consistent with previous update and reflecting the underlying patient population

- ***Second-Line Part B Key Findings:***
  - DKN-01 and tislelizumab administered in DKK1-high, PD-1 naïve patients was well tolerated at both 300mg and 600mg DKN-01 doses
  - Among evaluable patients who received a full first cycle of DKN-01 (response evaluable modified intent to treat, n=20), the objective response rate (ORR) was 25%, including 5 PRs and 4 stable disease (SD). One additional patient has had an irPR by iRECIST criteria
  - PD-L1 expression is low overall in the study population and not correlated with DKK1 expression
  - The study is ongoing and enrolling in the 600mg DKN-01 cohort. Twelve patients were on study at the time of the data cut, four of whom had not yet had their first imaging assessment

- ***Final Data for DKN-01 as a Monotherapy or in Combination with Paclitaxel in Groups Composed of Epithelial Endometrial Cancer (EEC), Epithelial Ovarian Cancer (EOC), or Carcinosarcoma (MMMT) Patients Presented at the SGO 2021 Virtual Meeting on Women's Cancer.*** The key findings from the study were:

  - ***DKN-01 has enhanced activity in patients whose tumors express high levels of DKK1:*** In the group of 23 EEC patients treated with DKN-01 monotherapy for whom DKK1 expression data was available, patients with DKK1-high tumors (n=8) achieved 1 CR and 1 PR, along with greater ORR (25% vs. 0%), DCR (63% vs. 7%), and median PFS (4.3 months vs. 1.8 months [HR 0.26; 95 CI: 0.09, 0.75]) compared to patients with DKK1-low tumors (n=15). In the group of 24 EEC patients treated with DKN-01 plus paclitaxel, 72% of whom had received three or more prior systemic therapies, DKK1-high patients (n=11) had improved median PFS (5.4 months vs. 1.8 months [HR 0.34; 95% CI: 0.12, 0.97]) compared to DKK1-low patients (n=9).

Selected Year-End and Fourth Quarter 2021 Financial Results

Net Loss was $40.6 million for the year ended December 31, 2021, compared to $27.5 million for the year ended December 31, 2020. The increase was primarily due to increased research and development expenses and general and administrative expenses.

License revenues were $1.5 million for each of the full years 2021 and 2020, and relate to the agreement with BeiGene for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. License revenues were $0.4 million for each of the fourth quarters 2021 and 2020.

Research and development expenses were $32.2 million for the full year 2021, compared to $20.4 million for the same period in 2020. Research and development expenses were $8.1 million for the fourth quarter ended 2021, compared to $5.1 million for the same period in 2020. The increases were primarily due to an increase in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns, an increase in clinical trial costs due to timing of patient enrollment in the DisTinGuish study, and an increase in payroll and other related expenses due to an increase in headcount of research and development full time employees.

General and administrative expenses were $10.8 million for the full year 2021, compared to $9.6 million for the same period in 2020. General and administrative expenses were $2.8 million for the fourth quarter ended 2021, compared to $2.4 million for the same period in 2020. The increases were primarily due to an increase in payroll and other related expenses due to an increase in headcount of general and administrative full time employees and an increase in compensation expense.

Cash and cash equivalents totaled $114.9 million at December 31, 2021. Research and development incentive receivables totaled $1.2 million at December 31, 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 collaboration 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 clinical 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; unstable global market and economic conditions; 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 is 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, 2021, as filed with the SEC on March 11, 2022 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.

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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	
	2021	**2020**	**2021**	**2020**
License revenue	$ 1,500	$ 1,500	$ 375	$ 375
Operating expenses:				
Research and development	32,160	20,423	8,070	5,101
General and administrative	10,766	9,616	2,793	2,428
Total operating expenses	42,926	30,039	10,863	7,529
Loss from operations	(41,426)	(28,539)	(10,488)	(7,154)
Interest income	9	93	5	2
Interest expense	(41)	(39)	(2)	3
Australian research and development incentives	1,226	231	(358)	(112)
Foreign currency gains (losses)	(379)	738	31	549
Loss before income taxes	(40,611)	(27,516)	(10,812)	(6,712)
Income taxes	24	2	24	2
Net loss	(40,587)	(27,514)	(10,788)	(6,710)
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	$ (40,587)	$ (37,588)	$ (10,788)	$ (6,710)
Net loss per share				
Basic	$ (0.47)	$ (0.63)	$ (0.10)	$ (0.09)
Diluted	$ (0.47)	$ (0.63)	$ (0.10)	$ (0.09)
Weighted average common shares outstanding				
Basic	85,825,283	59,327,713	113,107,809	76,376,160
Diluted	85,825,283	59,327,713	113,107,809	76,376,160

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 114,916	$ 52,071
Research and development incentive receivable	1,189	73
Prepaid expenses and other current assets	769	130
Total current assets	116,874	52,274
Property and equipment, net	36	65
Right of use assets, net	459	528
Deferred tax assets	159	179

Deferred costs	-	345
Other long term assets	90	-
Deposits	293	980
Total assets	$ 117,911	$ 54,371
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,189	$ 2,717
Accrued expenses	5,366	2,747
Deferred revenue - current portion	-	1,500
Lease liability - current portion	432	408
Total current liabilities	9,987	7,372
Non current liabilities:		
Restricted stock liability	-	204
Lease liability, net of current portion	37	144
Total liabilities	10,024	7,720
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 88,318,454 and 59,657,742 shares issued and outstanding as of December 31, 2021 and 2020, respectively	88	60
Additional paid-in capital	371,638	270,155
Accumulated other comprehensive loss	(267)	(579)
Accumulated deficit	(263,572)	(222,985)
Total stockholders' equity	107,887	46,651
Total liabilities and stockholders' equity	$ 117,911	$ 54,371

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

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Cash used in operating activities	$ (35,157)	$ (25,957)	$ (10,716)	$ (5,988)
Cash provided by investing activities	-	25	-	-
Cash provided by financing activities	98,035	73,997	755	-
Effect of exchange rate changes on cash and cash equivalents	(33)	115	106	84
Net increase (decrease) in cash and cash equivalents	$ 62,845	$ 48,180	(9,855)	(5,904)
Cash and cash equivalents at beginning of period	52,071	3,891	124,771	57,975
Cash and cash equivalents at end of period	$ 114,916	$ 52,071	$ 114,916	$ 52,071

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