Leap Therapeutics Reports First Quarter 2021 Financial Results

May 14, 2021

CAMBRIDGE, Mass., May 14, 2021 /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, 2021.

Leap First Quarter Highlights:

- Completed enrollment for first-line patient cohort in the DisTinGuish study, a clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ)
- Presented updated clinical data from the Phase 2 study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological malignancies at the Society of Gynecologic Oncology (SGO) 2021 Virtual Annual Meeting on Women's Cancer
- Announced partnership to use a clinically validated tumor expression assay utilizing RNAscope® and image analysis with Flagship Biosciences for patient enrollment

"We're off to a strong start this year as we've continued to advance our understanding of DKN-01 and the potential role it can play as both a monotherapy or in combination with existing treatments in multiple DKK1 biomarker defined cancer indications," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "The completion of enrollment of the first-line patient cohort in the DisTinGuish study brings us one step closer to an important milestone for us with our partner BeiGene, anticipated later this year."

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 have 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.

- ***Leap Announced Completion of Enrollment in First-Line Cohort in the DisTinGuish Study of DKN-01 plus Tislelizumab and Chemotherapy in Gastric Cancer –*** In April 2021, Leap announced the completion of enrollment for the first-line patient cohort in the DisTinGuish study (NCT04363801), a clinical trial evaluating DKN-01 in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, with or without chemotherapy, in patients with G/GEJ. The study, which is being conducted in two parts in the United States and the Republic of Korea, enrolled 25 patients with first-line G/GEJ cancer and will enroll up to 48 patients with second-line G/GEJ cancer whose tumors express high levels of DKK1. Initial data is expected in the second half of 2021. Leap is conducting this combination study as part of an exclusive option and license agreement with BeiGene for the development of DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

- ***Leap Presented Final Data for DKN-01 in Gynecologic Cancers –*** At the SGO 2021 Virtual Annual Meeting on Women's Cancer, Leap presented the final data from the study of 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. The key findings from the study were:

    - ***EEC patients and patients with Wnt activating mutations express higher levels of DKK1:*** EEC patients expressed higher levels of DKK1 and had a higher frequency of Wnt activating mutations than patients with EOC. Within EEC, patients with endometrioid histology had higher DKK1 expression than those with non-endometrioid histology. Patients whose tumors had Wnt activating mutations expressed 14.4 times higher levels of DKK1.

    - ***DKN-01 has enhanced activity in patients whose tumors express high levels of DKK1:*** In the group of 22 EEC patients treated with DKN-01 monotherapy for whom DKK1 expression data was available, patients with DKK1-high tumors (n=7) had greater ORR (14% vs. 0%), DCR (57% vs. 7%), and median PFS (3.0 months vs. 1.8 months [HR 0.39; 95% CI: 0.14, 1.1]) compared to patients with DKK1-low tumors (n=15). Additionally, seven patients did not have DKK1 expression results available, of whom one had a complete response (14%) and five (72%) had a best response of stable disease, including three patients with Wnt activating mutations. 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). Four patients did not have DKK1 expression data available.

- ***Presented DKK1 Biomarker Assay Validation Data –*** At the American Association for Cancer Research Annual Meeting 2021, Leap and its clinical laboratory partner, Flagship Biosciences, presented data on the validation of a DKK1 RNAscope chromogenic in situ hybridization (CISH) assay and digital image analysis solution. Leap and Flagship have demonstrated that the DKK1 RNAscope assay and accompanying digital image analysis solution is specific, sensitive, accurate and reproducible according to Clinical Laboratory Improvements Amendments (CLIA) guidelines. The assay is currently being used to prospectively identify G/GEJ patients with elevated tumoral expression of DKK1 in the ongoing DisTinGuish clinical trial.

Selected First Quarter 2021 Financial Results

Net Loss was $9.1 million for the first quarter 2021, compared to $7.2 million for the same period in 2020. This increase was primarily due to increased development activity for the DKN-01 program and an increase in headcount and compensation expense as the Company has grown throughout the year.

License revenues for each of the first quarter 2021 and 2020 were $0.4 million, and relate to the BeiGene Agreement for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The BeiGene Agreement became effective on January 3, 2020.

Research and development expenses were $6.8 million for the first quarter 2021, compared to $4.6 million for the same period in 2020. The increase of $2.2 million in research and development expenses was primarily due to an increase of $0.8 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees, an increase of $0.6 million in manufacturing costs related to clinical trial material and an increase of $0.8 million in clinical trial costs due to timing of patient enrollment.

General and administrative expenses were $2.7 million for the first quarter 2021, compared to $2.2 million for the same period in 2020. The increase of $0.5 million in general and administrative expenses was due to a $0.3 million increase in payroll and other related expenses during the three months ended March 31, 2021 as compared to the same period in 2020 and a $0.2 million increase in professional fees primarily due to increased recruiting and information technology costs.

Cash and cash equivalents totaled $43.5 million at March 31, 2021. Research and development incentive receivables totaled $0.02 million at March 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 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/.

RNAscope® is a registered trademark of Advanced Cell Diagnostics, Inc., Newark, CA, USA.

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 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; 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 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.

CONTACT:

Douglas E. Onsi
President & Chief Executive Officer
Leap Therapeutics, Inc.
617-714-0360
donsi@leaptx.com

Heather Savelle
Investor Relations
Argot Partners
212-600-1902

heather@argotpartners.com

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

	(Unaudited) Three Months Ended March 31	
	2021	**2020**
License revenue	$ 375	$ 375
Operating expenses:		
Research and development	6,807	4,603
General and administrative	2,740	2,153
Total operating expenses	9,547	6,756
Loss from operations	(9,172)	(6,381)
Interest income	2	68
Interest expense	(14)	(12)
Australian research and development incentives	71	85
Foreign currency gains	(21)	(991)
Loss before income taxes	(9,134)	(7,231)
Dividend attributable to down round feature of warrants	-	(303)
Dividends 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	$ (9,134)	$ (17,305)
Net loss per share		
Basic & diluted	$ (0.12)	$ (0.55)
Weighted average common shares outstanding		
Basic & diluted	76,378,569	31,632,213

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

	March 31, 2021 (Unaudited)	**December 31, 2020**
Cash and cash equivalents	$ 43,491	$ 52,071
Research and development incentive receivable	22	73
Prepaid expenses and other current assets	266	130
Total current assets	43,779	52,274
Property and equipment, net	56	65
Right of use assets, net	433	528
Research and development incentive receivable, net of current portion	70	-
Deferred tax assets	178	179
Deferred costs	311	345
Deposits	980	980
Total assets	$ 45,807	$ 54,371
Accounts payable	$ 3,514	$ 2,717
Accrued expenses	2,335	2,747
Deferred revenue - current portion	1,125	1,500
Lease liability - current portion	418	408
Total current liabilities	7,392	7,372
Restricted stock liability	-	204

Lease liability, net of current portion	36	144
Total liabilities	7,428	7,720
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,669,722 and 59,657,742 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	60	60
Additional paid-in capital	271,002	270,155
Accumulated other comprehensive loss	(564)	(579)
Accumulated deficit	(232,119)	(222,985)
Total stockholders' equity	38,379	46,651
Total liabilities and stockholders' equity	$ 45,807	$ 54,371

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

	(Unaudited) Three Months Ended March 31,	
	2021	**2020**
Cash used in operating activities	$ (8,587)	$ (3,926)
Cash provided by financing activities	14	25,605
Effect of exchange rate changes on cash and cash equivalents	(7)	(105)
Net increase (decrease) in cash and cash equivalents	(8,580)	21,574
Cash and cash equivalents at beginning of period	52,071	3,891
Cash and cash equivalents at end of period	$ 43,491	$ 25,465

View original content to download multimedia:http://www.prnewswire.com/news-releases/leap-therapeutics-reports-first-quarter-2021-financial-results-301291636.html

SOURCE Leap Therapeutics, Inc.