Leap Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

March 24, 2023

CAMBRIDGE, Mass., March 24, 2023 /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, 2022.

Leap Highlights:

- Acquired Flame Biosciences, adding FL-301, a clinical stage anti-Claudin18.2 antibody, and preclinical antibody programs targeting Claudin18.2/CD137 and GDF15 to Leap's pipeline
- Presented clinical data from Part B of the Phase 2 DisTinGuish study of DKN-01 plus tislelizumab in gastroesophageal (GEA) cancer patients whose tumors express high levels of DKK1 (DKK1-high) and preclinical data supporting the activity of DKN-01 in colorectal cancer (CRC) at the Society for Immunotherapy of Cancer (SITC) Annual Meeting
- Enrolled the first patient into Part C of the DisTinGuish study, the randomized controlled trial of DKN-01 plus tislelizumab and chemotherapy in first-line GEA cancer patients
- Enrolled the first patient into the Phase 2 DeFianCe study of DKN-01 in second-line CRC patients
- Promotion of Jason Baum, Ph.D. to Chief Scientific Officer, effective April 1, 2023

"Over the past year, we advanced DKN-01, our anti-DKK1 antibody, into its first randomized controlled clinical trial in gastric cancer, entered into the new indication of colorectal cancer, and facilitated an endometrial cancer investigator-sponsored trial. We enhanced Leap's pipeline and financial strength through the acquisition of Flame Biosciences, which included FL-301, a clinical stage anti-Claudin18.2 antibody, preclinical programs targeting Claudin18.2/CD137 and GDF15, as well as approximately $50 million in cash," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "In 2023, we are focused on executing our development plan for DKN-01 by completing enrollment in Part C of the DisTinGuish study and Part A of the DeFianCe study, with the objective of presenting new data over the course of the year and identifying a new strategic partner as data is generated. Our plan for our Claudin18.2 and GDF15 programs is to generate additional preclinical data to differentiate these antibodies from their competitors and to prepare for future clinical trials, while our collaborator continues a monotherapy study of FL-301 in China. We are looking forward and fully committed to our mission to acquire and develop a pipeline of biomarker-focused antibody therapies for cancer patients."

Business Update

- ***Leap completed the acquisition of Flame Biosciences and added FL-301 and two preclinical antibody programs to Leap's pipeline***. In January 2023, Leap acquired Flame and its assets, including FL-301, its clinical stage anti-Claudin18.2 monoclonal antibody, FL-302, its preclinical anti-Claudin18.2/CD137 bispecific monoclonal antibody, FL-501, its preclinical anti-GDF15 monoclonal antibody, and cash of approximately $50 million as of December 31, 2022. In the merger, Leap issued approximately 19,794,373 shares of its common stock and approximately 136,833 shares of a newly designated Series X non-voting convertible preferred stock to Flame stockholders. Leap will seek stockholder approval for the conversion of the preferred stock into common stock, pursuant to the terms of the Certificate of Designation and Nasdaq rules, at the 2023 Annual Meeting of Stockholders, which is expected to be held in June. Subject to and upon receipt of stockholder approval for such conversion, the 136,833 shares of Series X non-voting convertible preferred stock will convert into 136,833,000 shares of common stock of Leap.
- ***Leap provided an update on the agreement with BeiGene***. In March 2023, Leap announced that BeiGene's option under the Exclusive Option and License Agreement between Leap and BeiGene granting rights in certain Asian territories to DKN-01 has expired in accordance with the terms of the agreement. Leap and BeiGene will continue to collaborate on the ongoing Part C of the DisTinGuish trial, a randomized controlled trial of DKN-01 in combination with tislelizumab and chemotherapy in first-line gastric cancer patients, as a clinical collaboration with BeiGene supplying tislelizumab.
- ***Promotion of Jason Baum, Ph.D. to Chief Scientific Officer***. Dr. Baum has served as our Vice President and Head of Translational Research since August 2020 and is being promoted to Chief Scientific Officer effective April 1, 2023.

DKN-01 Development Update

- ***Updated data from Part B of the DisTinGuish Study of DKN-01 plus tislelizumab in second-line patients with advanced GEA cancer whose tumors express high levels of DKK1, presented at the SITC Annual Meeting.***
    - DKN-01 and tislelizumab were well tolerated at both 300mg and 600mg DKN-01 doses with no Grade 5 treatment-

emergent AEs (TEAE) and no TEAEs leading to study drug discontinuation or dose reduction
    - In evaluable anti-PD-1/PD-L1 naïve mITT population (n=43), 27% overall response rate (ORR) and 43% disease control rate (DCR), exceeding the benchmark studies for anti-PD-1 monotherapy
        - In DKK1-high/PD-L1-high CPS ≥ 10 patients: 55% ORR, 73% DCR, 7.7 months median progression-free survival (PFS), median overall survival (OS) not reached
        - In DKK1-high/PD-L1 CPS > 1 and < 10 patients: 8% ORR, 1.4 months PFS, 5.2 months OS
        - In DKK1-high/PD-L1-negative CPS < 1 patients: 27% ORR, 1.4 months PFS, 3.9 months OS

- ***New preclinical data in CRC models, presented at the SITC Annual Meeting.***
    - DKN-01 additive activity with 5-fluorouracil (5FU) and can overcome 5FU-resistance in two xenograft models, resulting in tumor regressions. 5FU-resistant models are reflective of a second-line CRC population currently being recruited in the DeFianCe study.
    - Treatment with DKN-01 as monotherapy or in combination with anti-PD-1 resulted in tumor regression in a CT26 syngeneic CRC model.

- ***Announced first patient enrolled in randomized, controlled Part C of the DisTinGuish Study.*** Part C of the DisTinGuish study will enroll approximately 160 first-line, HER2-negative patients who have had no prior therapy for unresectable locally advanced or metastatic G/GEJ adenocarcinoma and randomized on a 1:1 basis to DKN-01 in combination with tislelizumab and chemotherapy compared to tislelizumab and chemotherapy. Enrollment in Part C is currently expected to be completed in late 2023, with initial response rate data expected to be available year end 2023/early 2024 and PFS data in 2024.

- ***Announced first patient enrolled in DeFianCe Study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in second-line CRC patients.*** The DeFianCe study (NCT05480306) is a Phase 2 study of DKN-01 in combination with bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy. The study is designed with an initial approximately 20 patient Part A cohort and to then expand into a 130 patient Part B randomized controlled trial. Enrollment in Part A is currently expected to be completed in the coming weeks, with initial data to be available mid-2023.

Selected Year-End and Fourth Quarter 2022 Financial Results

Net Loss was $54.6 million for the year ended December 31, 2022, compared to $40.6 million for the year ended December 31, 2021. The increase was primarily due to increased research and development expenses and general and administrative expenses, partially offset by an increase in interest income and increase in research and development incentive income.

There were no license revenues for the year ended December 31, 2022, compared to $1.5 million for the year ended December 31, 2021. The upfront payment was recognized in full as of December 31, 2021 for the agreement with BeiGene.

Research and development expenses were $45.0 million for the full year 2022, compared to $32.2 million for the same period in 2021. Research and development expenses were $11.0 million for the fourth quarter ended 2022, compared to $8.1 million for the same period in 2021. 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 and duration of patients on study, an increase in payroll and other related expenses due to an increase in headcount of research and development full time employees, and an increase in stock based compensation expense.

General and administrative expenses were $11.8 million for the full year 2021, compared to $10.8 million for the same period in 2021. General and administrative expenses were $2.9 million for the fourth quarter ended 2022, compared to $2.8 million for the same period in 2021. 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 stock based compensation expense.

Cash and cash equivalents totaled $65.5 million at December 31, 2022, which excludes the approximately $50 million cash received from the Flame Biosciences acquisition. Research and development incentive receivables totaled $2.1 million at December 31, 2022.

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 being developed in patients with esophagogastric, gynecologic, and colorectal cancers. FL-301, is a humanized monoclonal antibody targeting Claudin18.2, being developed in patients with gastric and pancreatic cancer. Leap also has preclinical antibody programs targeting Claudin18.2/CD137 and GDF15. 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 the federal securities laws. Such statements are based upon current plans, estimates and expectations of the management of Leap that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements.

All statements, other than historical facts, including statements regarding the continuation over time of the clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the expected benefits of the merger with Flame Biosciences; the cash runway into mid-2025 and the sufficiency of Leap's cash, cash equivalents and short-term investments to fund operations; stockholder approval of the conversion rights of the Series X Non-Voting Convertible Preferred Stock; the anticipated timing for initiation of or success of enrollment in clinical

trials and release of clinical data, and any outcomes of such trials; the potential, safety, efficacy, and regulatory and clinical progress of Leap's product candidates; our future preclinical and clinical development plans in connection with our programs; the ability to enter into a new strategic partnership for DKN-01 or any of Leap's other programs; the ability of NovaRock Biotherapeutics to conduct the FL-301 clinical trial in China; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from Leap's plans, estimates or expectations could include, but are not limited to: (i) Leap's ability to successfully execute its clinical trials and the timing of enrollment in and cost of such clinical trials; (ii) the results of Leap's clinical trials and pre-clinical studies; (iii) Leap's ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs; (iv) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (v) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities; (vi) 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, global conflict, or supply chain related issues; (vii) Leap's ability to successfully integrate the Flame operations and realize the anticipated benefits of the acquisition of Flame; (viii) whether Leap's stockholders approve the conversion of the Series X Non-Voting Convertible Preferred Stock; (ix) whether Leap's cash resources will be sufficient to fund Leap's continuing operations and the newly acquired Flame operations, including the liabilities of Flame incurred in connection with the completion of the merger; and (x) Leap's ability to comply with the continued listing requirements of the Nasdaq Global Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or Implied) are made about the accuracy of any such forward-looking statements. Leap may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Leap's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Leap, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Leap's views as of any date subsequent to the date hereof.

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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	
	2022	2021	2022	2021
License revenue	$ -	$ 1,500	$ -	$ 375
Operating expenses:				
Research and development	44,965	32,160	11,034	8,070
General and administrative	11,798	10,766	2,909	2,793
Total operating expenses	56,763	42,926	13,943	10,863
Loss from operations	(56,763)	(41,426)	(13,943)	(10,488)
Interest income	925	9	521	5
Interest expense	(54)	(41)	(5)	(2)
Australian research and development incentives	2,051	1,226	775	(358)
Foreign currency loss	(608)	(379)	697	31
Loss before income taxes	(54,449)	(40,611)	(11,955)	(10,812)
Benefit from (provision for) income taxes	(147)	24	(147)	24
Net loss attributable to common stockholders	$ (54,596)	$ (40,587)	$ (12,102)	$ (10,788)
Net loss per share				
Basic	$ (0.48)	$ (0.47)	$ (0.11)	$ (0.10)
Diluted	$ (0.48)	$ (0.47)	$ (0.11)	$ (0.10)
Weighted average common shares outstanding				
Basic	113,239,092	85,825,283	113,239,092	113,107,809

Diluted	113,239,092	85,825,283	113,239,092	113,107,809

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 65,500	$ 114,916
Research and development incentive receivable	2,099	1,189
Prepaid expenses and other current assets	351	769
Total current assets	67,950	116,874
Property and equipment, net	20	36
Right of use assets, net	669	459
Deferred tax assets, net	-	159
Deferred costs	576	-
Other long term assets	30	90
Deposits	1,108	293
Total assets	$ 70,353	$ 117,911
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,657	$ 4,189
Accrued expenses	5,152	5,366
Lease liability - current portion	416	432
Total current liabilities	11,225	9,987
Non current liabilities:		
Lease liability, net of current portion	262	37
Total liabilities	11,487	10,024
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 99,021,376 and 88,318,454 shares issued and outstanding as of December 31, 2022 and 2021,respectively	99	88
Additional paid-in capital	376,807	371,638
Accumulated other comprehensive income (loss)	128	(267)
Accumulated deficit	(318,168)	(263,572)
Total stockholders' equity	58,866	107,887
Total liabilities and stockholders' equity	$ 70,353	$ 117,911

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

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2022	2021	2022	2021
Cash used in operating activities	$ (49,044)	$ (35,157)	$ (13,014)	$ (10,716)
Cash provided by (used in) financing activities	(210)	98,035	-	755
Effect of exchange rate changes on cash and cash equivalents	(162)	(33)	206	106
Net increase (decrease) in cash and cash equivalents	$ (49,416)	$ 62,845	(12,808)	(9,855)
Cash and cash equivalents at beginning of period	114,916	52,071	78,308	124,771
Cash and cash equivalents at end of period	$ 65,500	$ 114,916	$ 65,500	$ 114,916

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