Leap Therapeutics Reports First Quarter 2023 Financial Results

May 15, 2023

CAMBRIDGE, Mass., May 15, 2023 /PRNewswire/ -- Leap Therapeutics, Inc. (NASDAQ:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for first quarter ended March 31, 2023.

Leap Highlights:

- Presenting new long-term follow-up data from Part A of the Phase 2 DisTinGuish study of DKN-01 plus tislelizumab and chemotherapy in first-line patients with advanced gastroesophageal adenocarcinoma (GEA) at the upcoming 2023 American Society of Clinical Oncology (ASCO) Annual Meeting
- Enrollment completed in Part A of the Phase 2 DeFianCe study of DKN-01 in combination with standard of care bevaiczimab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC)
- 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, along with approximately $50 million in cash.

"We continued to execute extremely well on our DKN-01 program during the first quarter of 2023 with the completion of enrollment in Part A of the DeFianCe second-line CRC study and excellent progress in enrolling our randomized, controlled Part C of the DisTinGuish first-line GEA study," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We look forward to presenting long-term follow-up data from Part A of the DisTinGuish study at ASCO in June, including updated response and overall survival data. With the acquisition of Flame Biosciences at the beginning of the year, we are in a strong financial position to develop our pipeline of personalized medicines for cancer patients."

DKN-01 Development Update

- ***Updated data from Part A of the DisTinGuish Study of DKN-01 plus tislelizumab and chemotherapy in gastric cancer patients to be presented at the 2023 ASCO Annual Meeting.*** The Company will be presenting new long-term follow-up data in first-line patients with advanced GEA from Part A of the DisTinGuish study (NCT0436380), a Phase 2 clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab and chemotherapy at the 2023 ASCO Annual Meeting, being held in Chicago, IL on June 2-6, 2023. Details of the presentation are below:
  - **Title:** A phase 2 study (DisTinGuish) of DKN-01 in combination with tislelizumab + chemotherapy as first-line (1L) therapy in patients with advanced gastric or GEJ adenocarcinoma (GEA).
  - **Presenter:** Samuel J. Klempner, Harvard Medical School
  - **Session Type:** Poster Discussion Session
  - **Session Title:** Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
  - **Date and Time:** Monday, June 5, 2023, at 11:30 a.m. ET
  - **Abstract Number:** 4027
  - **Poster Number:** 335
- ***Announced completion of enrollment in Part A of the DeFiance Study of DKN-01 for the treatment of colorectal cancer patients.*** The DeFianCe study (NCT05480306) is a Phase 2, randomized, open-label, multicenter study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy for advanced disease. The study began with an initial Part A cohort that has enrolled 33 patients and is designed to expand into a 130-patient Part B randomized controlled trial. The primary objective is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival. Leap expects to report initial data from Part A of the study in mid-2023.

Selected First Quarter 2023 Financial Results

Net Loss was $41.9 million for the first quarter 2023, compared to $10.4 million for the same period in 2022. The increase was primarily due to in-process research & development (IPR&D) expense of $29.6 million associated with the acquisition of Flame Biosciences.

Research and development expenses were $38.9 million for the first quarter 2023, compared to $7.8 million for the same period in 2022. The increase in research and development expenses was due to IPR&D expense associated with the Flame acquisition of $29.6 million, increased headcount and compensation expense of $0.8 million, increased manufacturing costs of $0.8 million, increased stock based compensation expense of $0.1 million, partially offset by decreased clinical trial costs of $0.2 million.

General and administrative expenses were $3.8 million for the first quarter 2023, compared to $2.8 million for the same period in 2022. The increase in general and administrative expenses was due to increased finance and legal fees, primarily associated with the Flame acquisition, of $0.7 million and increased headcount and compensation expense of $0.3 million.

Cash and cash equivalents totaled $102.0 million at March 31, 2023. Research and development incentive receivables totaled $2.3 million at March

31, 2023.

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 Capital 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)

	(Unaudited) Three Months Ended March 31	
	2023	**2022**
Operating expenses:		
Research and development	$ 38,942	$ 7,784
General and administrative	3,784	2,848

Total operating expenses	42,726	10,632
Loss from operations	(42,726)	(10,632)
Interest income	848	5
Interest expense	-	(21)
Australian research and development incentives	272	37
Foreign currency gain (loss)	(307)	235
Change in fair value of Series X preferred stock warrant liability	50	-
Net loss attributable to common stockholders	(41,863)	(10,376)
Net loss per share		
Basic	$ (0.32)	$ (0.09)
Diluted	$ (0.32)	$ (0.09)
Weighted average common shares outstanding		
Basic	129,344,272	113,248,937
Diluted	129,344,272	113,248,937

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

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 102,038	$ 65,500
Research and development incentive receivable	2,071	2,099
Prepaid expenses and other current assets	590	351
Total current assets	104,699	67,950
Property and equipment, net	16	20
Right of use assets, net	569	669
Research and development incentive receivable, net of current portion	272	-
Deferred costs	-	576
Other long term assets	15	30
Deposits	976	1,108
Total assets	$ 106,547	$ 70,353
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,498	$ 5,657
Accrued expenses	4,388	5,152
Lease liability - current portion	425	416
Total current liabilities	10,311	11,225
Non current liabilities:		
Lease liability, net of current portion	152	262
Series X preferred stock warrant liability	40	-
Total liabilities	10,503	11,487
Mezzanine equity:		
Series X Convertible Preferred Stock, $0.001 par value; 10,000,000 shares authorized; 136,248 and 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	67,715	-
Stockholders' equity:		

Common stock, $0.001 par value; 240,000,000 shares authorized; 119,410,992 and 99,021,376 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	119	99
Additional paid-in capital	387,886	376,807
Accumulated other comprehensive income	355	128
Accumulated deficit	(360,031)	(318,168)
Total stockholders' equity	28,329	58,866
Total liabilities, mezzanine equity and stockholders' equity	$ 106,547	$ 70,353

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

	(Unaudited) Three Months Ended March 31,	
	2023	**2022**
Cash used in operating activities	$ (12,700)	$ (11,518)
Cash provided by investing activities	49,317	-
Cash used in financing activities	(29)	(210)
Effect of exchange rate changes on cash and cash equivalents	(50)	32
Net increase (decrease) in cash and cash equivalents	36,538	(11,696)
Cash and cash equivalents at beginning of period	65,500	114,916
Cash and cash equivalents at end of period	$ 102,038	$ 103,220

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