UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **May 13, 2022**

Leap Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37990**	**27-4412575**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

47 Thorndike Street, Suite B1-1 **Cambridge, MA**	**02141**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 714-0360**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	LPTX	Nasdaq Global Market

Item 2.02. Results of Operations and Financial Condition

On May 13, 2022, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2022. The full text of the press release issued by the Company in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Current Report on Form 8-K, including the information set forth under this Item 2.02 and the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Leap Therapeutics, Inc. dated May 13, 2022.
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LEAP THERAPEUTICS, INC.

Dated: May 13, 2022

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Executive Officer and President

Exhibit 99.1

Leap Therapeutics Reports First Quarter 2022 Financial Results

CAMBRIDGE, Mass., May 13, 2022 – 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, 2022.

Leap Highlights:

- Presented positive new data from the DisTinGuish Study of DKN-01 plus BeiGene's anti-PD-1 antibody tislelizumab and chemotherapy in gastroesophageal junction/gastric (GEJ/G) cancer patients at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium
- Completed enrollment in Part B of the DisTinGuish Study evaluating DKN-01 plus tislelizumab in second-line GEJ/G cancer patients whose tumors express high levels of DKK1 (DKK1-high)
- Entered partnership on DKK1 companion diagnostic with Leica Biosystems
- Presenting initial data from the investigator-sponsored Phase 1b/2a clinical trial of DKN-01 in prostate cancer at the 2022 ASCO Annual Meeting

"We are making consistent progress in advancing DKN-01 across multiple tumor types and look forward to Dr. David Wise of New York University presenting initial prostate cancer data at the upcoming ASCO conference," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "With compelling response and survival data for DKN-01 in combination with BeiGene's tislelizumab in gastric cancer patients presented in January, and the recent completion of enrollment in our second-line cohort, we are preparing for updated data readouts from our DisTinGuish study in the second half of the year. We are also looking forward to hosting an R&D Day in late June to outline the next phase in the clinical development strategy for DKN-01."

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.*** In January 2022, the Company presented positive new progression-free survival (PFS) and overall response data from Part A, the first-line cohort of the Phase 2a study in patients with gastroesophageal junction or gastric (GEJ/G) cancer, and initial findings from Part B of the clinical trial, studying DKN-01 and tislelizumab in second-line advanced GEJ/G cancer patients with high tumoral DKK1 expression.
    - ***Part A First-Line Patients***: Of the 25 first-line patients who received a full cycle of DKN-01 therapy, overall response rate (ORR) was 68.2%, with 90% ORR in DKK1-high patients (9 partial responses (PR)) and 56% in DKK1-low patients (1 complete response, 4 PR). Among those patients with low PD-L1 expression ORR was 79% (with 100% ORR in DKK1-high patients and 57% ORR in DKK1-low patients), and in patients with higher PD-L1 expression ORR was 67% (with 75% ORR in DKK1-high patients and 50% in DKK1-low patients). The preliminary median PFS was 10.7 months in the overall first-line population, and median overall survival had not been reached. The Company expects to present updated survival data from the study in the second half of 2022.
    - ***Part B Second-Line Patients***: Of the 30 second line DKK1-high GEJ/G cancer patients who received a full cycle of DKN-01 therapy and were response evaluable, ORR was 25%, with an additional patient who experienced an irPR by iRECIST criteria.

- ***Completed Enrollment in the DisTinGuish Clinical Trial (NCT04363801) of DKN-01 Plus Tislelizumab in DKK1-high Second Line GEJ/G Cancer Patients.*** In May 2022, the Company completed enrollment in Part B of the DisTinGuish clinical trial, studying DKN-01 and tislelizumab in second-line advanced GEJ/G cancer patients with high tumoral DKK1 expression.

- ***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 in patient tumor biopsies. 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 for DKN-01 treatment.

- ***Abstract Accepted for Poster Presentation at the Upcoming 2022 ASCO Annual Meeting Highlighting Initial Clinical Data from the Phase 1b/2a Clinical Trial (NCT03837353) of DKN-01 Plus Docetaxel in Prostate Cancer.*** The Company will present initial clinical data from the investigator-sponsored Phase 1b/2a dose escalation and dose expansion study testing DKN-01 as monotherapy or in combination with docetaxel in metastatic castration-resistant prostate cancer at the upcoming 2022 ASCO Annual Meeting taking place in Chicago, IL on June 3-7. Dr. David Wise of NYU Langone Medical Center is the lead investigator on the study.

Selected First Quarter 2022 Financial Results

Net Loss was $10.4 million for the first quarter 2022, compared to $9.1 million for the same period in 2021. The increase was primarily due to an increase in clinical trial costs due to the timing of patient enrollment and the duration of patients on study in the DisTinGuish trial and an increase in the number of research and development employees to support the development of DKN-01.

License revenues were $0.4 million for the first quarter 2021 and relate to the agreement with BeiGene for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. There were no license revenues recognized in the first quarter 2022, as the upfront payment was fully recognized as of December 31, 2021.

Research and development expenses were $7.8 million for the first quarter 2022, compared to $6.8 million for the same period in 2021. The increase in research and development expenses was due to an increase of $0.6 million in clinical trial costs due to timing of patient enrollment in the DisTinGuish study, an increase of $0.6 million in payroll and other related expenses, and an increase of $0.2 million in stock based compensation expense during the three months ended March 31, 2022. These increases were partially offset by a $0.4 million decrease in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns.

General and administrative expenses were $2.8 million for the first quarter 2022, compared to $2.7 million for the same period in 2021. The increase in general and administrative expenses was due an increase of a $0.2 million in stock based compensation expense and an increase of $0.1 million in payroll and other related expenses during the three months ended March 31, 2022. These increases were partially offset by a $0.2 million decrease in professional fees.

Cash and cash equivalents totaled $103.2 million at March 31, 2022. Research and development incentive receivables totaled $1.3 million at March 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 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)

	(Unaudited) Three Months Ended March 31	
	2022	**2021**
License revenue	$ -	$ 375
Operating expenses:		
Research and development	7,784	6,807
General and administrative	2,848	2,740
Total operating expenses	10,632	9,547
Loss from operations	(10,632)	(9,172)
Interest income	5	2
Interest expense	(21)	(14)
Australian research and development incentives	37	71
Foreign currency gain (loss)	235	(21)
Net loss attributable to common stockholders	(10,376)	(9,134)
Net loss per share		
Basic	$ (0.09)	$ (0.12)
Diluted	$ (0.09)	$ (0.12)
Weighted average common shares outstanding		
Basic	113,248,937	76,378,569
Diluted	113,248,937	76,378,569

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

	March 31, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 103,220	$ 114,916
Research and development incentive receivable	1,233	1,189
Prepaid expenses and other current assets	491	769
Total current assets	104,944	116,874
Property and equipment, net	32	36
Right of use assets, net	355	459
Research and development incentive receivable, net of current portion	38	-
Deferred tax assets	164	159
Other long term assets	75	90
Deposits	293	293
Total assets	$ 105,901	$ 117,911
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,287	$ 4,189
Accrued expenses	2,694	5,366
Lease liability - current portion	363	432
Total current liabilities	7,344	9,987
Non current liabilities:		
Lease liability, net of current portion	-	37
Total liabilities	7,344	10,024
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 88,318,454 shares issued and outstanding as of March 31, 2022 and December 31, 2021	88	88
Additional paid-in capital	372,842	371,638
Accumulated other comprehensive loss	(425)	(267)
Accumulated deficit	(273,948)	(263,572)
Total stockholders’ equity	98,557	107,887
Total liabilities and stockholders' equity	$ 105,901	$ 117,911

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

	(Unaudited) Three Months Ended March 31,	
	2022	**2021**
Cash used in operating activities	$ (11,518)	$ (8,587)
Cash provided by (used in) financing activities	(210)	14
Effect of exchange rate changes on cash and cash equivalents	32	(7)
Net decrease in cash and cash equivalents	(11,696)	(8,580)
Cash and cash equivalents at beginning of period	114,916	52,071
Cash and cash equivalents at end of period	$ 103,220	$ 43,491