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): **September 13, 2021**

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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ 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)).

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

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. ☐

Item 8.01. Other Events

On September 13, 2021, Leap Therapeutics, Inc. (the "Company") issued a press release entitled "Leap Therapeutics to Present New Data from the DisTinGuish Study of DKN-01 Plus Tislelizumab at the ESMO 2021 Congress."

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference; provided, however that information on or connected to our website referenced in the Company's press release is expressly not incorporated by reference into or intended to be filed as a part of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated September 13, 2021.
104	Cover Page Interactive Data File

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: September 13, 2021

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

Leap Therapeutics to Present New Data from the DisTinGuish Study of DKN-01 Plus Tislelizumab at the ESMO 2021 Congress

- *DKN-01 plus tislelizumab and chemotherapy demonstrated compelling activity in first-line patients with gastric or gastroesophageal junction cancer*

- *In patients who received a full cycle of DKN-01 therapy, the ORR was 68.2%, with 90% ORR in patients with DKK1-high tumors*

- *Further results will be presented at the ESMO 2021 Congress from September 16 to 21, 2021*

- *Company to host conference call on Friday, September 17, 2021 at 8:00 a.m. ET*

Cambridge, MA – September 13, 2021 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced the Company will be presenting initial data from the first-line cohort of the DisTinGuish study, a Phase 2a clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab, BeiGene Ltd.'s anti-PD-1 antibody, and chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ), at the European Society for Medical Oncology (ESMO) Congress, being held virtually on September 16-21, 2021. The Company will host a conference call on Friday, September 17, 2021 to discuss preliminary results from the study.

"Initial data from the DisTinGuish study is extremely promising as it shows DKN-01 in combination with tislelizumab and chemotherapy to have high response rates in first-line patients suffering from gastric and gastroesophageal junction cancer," said Cynthia Sirard, MD, Chief Medical Officer of Leap. "Patients whose tumors have high levels of DKK1 expression, which is known to correlate with aggressive disease and poor prognosis, showed the highest response rates, suggesting how important the biomarker may be in predicting response to therapy. Additional data will be presented at ESMO and in our conference call to demonstrate the potential DKN-01 has as part of first-line therapy in this difficult-to-treat indication."

About the DisTinGuish Study

The DisTinGuish study (NCT04363801) is a Phase 2a study of DKN-01 in combination with tislelizumab, an anti-PD-1 antibody, with or without chemotherapy as first-line or second-line therapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. The study is being conducted in two parts, in the United States and the Republic of Korea. Enrollment of Part A has been completed with 25 first-line HER2- G/GEJ cancer patients whose tumors express either high levels of DKK1 (DKK1-high) or low levels of DKK1 (DKK1-low). Part B of the study will enroll up to 48 patients with second-line, DKK1-high G/GEJ cancer. 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.

Key Findings

- DKN-01 in combination with tislelizumab and chemotherapy demonstrated compelling overall response rates (ORR) as a first-line treatment for advanced G/GEJ cancer
- In the primary efficacy analysis, including all patients who received a full cycle of DKN-01 therapy, the ORR was 68.2%, with 90% ORR in DKK1-high patients as compared to a 56% ORR in DKK1-low patients
- In the overall intent to treat population, including those patients who did not receive a full cycle of therapy, the ORR was 60%, with 75% ORR in DKK1-high patients as compared to a 56% ORR in DKK1-low patients

As of the date of the abstract, 13 patients had experienced a partial response (PR), six patients had a best response of stable disease (SD), one patient was non-evaluable for response (NE), three patients were unable to complete a full cycle of therapy (non-modified ITT (mITT)), and two patients were pending their first tumor assessment. Of the 18 patients that had RNAscope® DKK1 expression available for the abstract, 9 were DKK1-high [6 PR, 1 NE, and 2 non-mITT] and 9 were DKK1-low [5 PR, 4 SD]. Subsequent to the date of the abstract, the two patients who were pending their first scan for response to therapy were determined to have had PRs, and three additional patients were determined to have had DKK1-high tumors, each of whom experienced a PR.

Further results will be presented at the ESMO 2021 Congress from September 16 to 21, 2021.

Leap Presentation Details:

Title: DKN-01 in combination with tislelizumab and chemotherapy as a first-line therapy in unselected patients with advanced gastroesophageal adenocarcinoma (GEA): DisTinGuish Trial

Abstract Number: 2218

Session type: E-Poster Presentation

Presenter: Samuel J. Klempner, Harvard Medical School

Date and time: Thursday, September 16, 2021; 2:30 a.m. ET

Conference Call

Leap will host a conference call on Friday, September 17, 2021 at 8:00 a.m. Eastern Time to further discuss the data. In addition to Leap’s executive management team, Dr Jaffer Ajani of M.D. Anderson Cancer Center and Dr. Samuel Klempner of Massachusetts General Hospital will be on the call. The call can be accessed by dialing (866) 589-0108 (U.S. and Canada) or (409) 231-2048 (international). The passcode for the conference call is 1729397. The presentation will be webcast live and may be accessed on the Investors page of the Company's website at https://investors.leaptx.com/, where a replay of the event will also be available for a limited time.

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.

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