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): **July 12, 2023**

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 Capital 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 July 12, 2023, Leap Therapeutics, Inc. (the "Company") issued a press release entitled "Leap Therapeutics Announces Initiation of Randomized Controlled Part B of the DeFianCe Study of DKN-01 in Colorectal Cancer Patients."

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.

On July 7, 2023, the Company received written notice (the "Compliance Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") stating that the Company has regained compliance with Nasdaq Listing Rule 5550(a)(2) requiring maintenance of a minimum bid price of at least $1.00 per share (the "Bid Price Requirement"). The Company previously disclosed in its Current Report on Form 8-K filed November 2, 2022 that the Company received written notice from Nasdaq indicating that it no longer satisfied the Bid Price Requirement and providing the Company 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 per share for a minimum of 10 consecutive business days. The Compliance Letter states that Nasdaq determined that the closing bid price of the Company's common stock was at or above $1.00 for 11 consecutive business days (from June 21, 2023 to July 6, 2023) and considers the matter closed.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated July 12, 2023.
104	Cover Page Interactive Data File. (Embedded within the Inline XBRL document.)

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: July 12, 2023

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

Leap Therapeutics Announces Initiation of Randomized Controlled Part B of the DeFianCe Study of DKN-01 in Colorectal Cancer Patients

Cambridge, MA – July 12, 2023 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that, based on the early efficacy and momentum seen in the enrollment of 33 patients with colorectal cancer (CRC) in its DeFianCe study, it has initiated the 130 patient randomized controlled Part B of the Phase 2 study. The study evaluates Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced CRC.

"Part A of the DeFianCe study enrolled an aggressive heterogenous population of second-line CRC patients representative of the second-line population that we see in the clinic who have poor outcomes on standard of care drugs and are in need of new therapies," said Zev Wainberg, MD, Professor Medicine at UCLA and co-director of the UCLA GI Oncology Program. "Exceeding a 20% overall response rate with a high disease control rate in second-line CRC patients is a clinically meaningful efficacy signal and worthy of further exploration."

"The study enrolled quickly and has already exceeded the 20% overall response rate threshold. After the planned safety review meeting with our investigators, we decided to initiate the randomized controlled study," said Cynthia Sirard, MD, Chief Medical Officer of Leap. "We continue to follow these Part A patients to assess durability of response, progression-free survival, and to determine whether additional patients with stable disease may become responders over time. We very much look forward to presenting this maturing data set at an upcoming meeting."

About the DeFiance Study

The DeFianCe study (NCT05480306) is a Phase 2, open-label, global 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 Part A cohort enrolled 33 patients, including significant numbers of patients who had early progression on first-line therapy, previous exposure to bevacizumab, tumors with Ras mutations, or liver metastases. The study has expanded into a 130-patient Part B randomized controlled trial. The primary objective of the study is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival. Leap expects to be able to enroll Part B in approximately 12 months and have initial data in late 2024.

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 outcomes of patients in Part A of the DeFianCe study, the anticipated timing for initiation of or success of enrollment in Part B of the DeFianCe study and other 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 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 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; and (vii) whether Leap's cash resources will be sufficient to fund Leap's continuing operations and planned studies. 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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