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 30, 2024**

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 September 30, 2024, Leap Therapeutics, Inc. (the "Company") issued a press release entitled "Leap Therapeutics Announces Completion of Enrollment in Part B of the DeFianCe Study of DKN-01 for the Treatment of 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated September 30, 2024.
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: September 30, 2024

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

Exhibit 99.1

Leap Therapeutics Announces Completion of Enrollment in Part B of the DeFianCe Study of DKN-01 for the Treatment of Colorectal Cancer Patients

Cambridge, MA – September 30, 2024 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that enrollment of 188 patients has been completed in the randomized controlled Part B of the DeFianCe study evaluating DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC).

"The completion of enrollment in Part B of the DeFianCe study marks a significant achievement and highlights the enthusiasm in the potential of DKN-01 from both patients and healthcare providers," said Cynthia Sirard, M.D., Chief Medical Officer of Leap. "The encouraging data from Part A of the study which showed clinically meaningful response rates and durable tumor reductions, as well as a favorable safety profile in advanced CRC patients, provides a strong foundation to the expanded Part B of the study. We look forward to sharing initial data from Part B, including the subpopulation of patients with left-sided CRC, in mid 2025."

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. Part B of the study expanded from a 130 to a 188-patient randomized controlled trial, with the primary endpoint being progression free survival (PFS). An additional primary endpoint will measure PFS in the subpopulation of patients with left-sided CRC. Secondary objectives include objective response rate, duration of response, and overall survival.

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. 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 anticipated timing of the release of clinical data, and any outcomes of such trials; the interpretation or signficiance of, or any conclusions or suggestions that can or should be drawn from, the results of, and the clinical data generated from, any of our clinical 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 strategic partnership for DKN-01 or any of Leap's other programs; 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, including that subsequent or final results from Leap's clinical trials or pre-clinical studies may supersede, qualify, limit, or change the interpretation or significance of, preliminary or earlier results of Leap's clinical trials or 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 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; and (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 global conflict or supply chain related issues. 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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