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 16, 2019**

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):

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

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

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

o 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 x

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. o

Item 7.01. Regulation FD Disclosure

On September 17, 2019, Leap Therapeutics, Inc. (the "Company") issued a press release confirming that it would be presenting at the 2019 International Gynecologic Cancer Society Annual Global Meeting (the "IGCS Conference") on September 20, 2019 in Rio de Janeiro, Brazil and furnishing a copy of the corporate poster presentation containing updated clinical data from its ongoing Phase 2 clinical trial of DKN-01 in patients with advanced gynecological malignancies (the "September 20 Presentation") which the Company intends to present at the IGCS Conference. This Current Report on Form 8-K (this "Report") is being furnished solely to satisfy the Company's obligations under Regulation FD as the September 20 Presentation was inadvertently made available on the IGCS Conference website in advance of the IGCS Conference. A copy of the press release, along with a link to the September 20 Presentation, is attached hereto as Exhibit 99.1.

This information is being furnished pursuant to Item 7.01 of this Report and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Report will not be deemed an admission as to the materiality of any information in this Report that is being disclosed pursuant to Regulation FD.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Leap Therapeutics, Inc. dated September 17, 2019.

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 17, 2019

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Financial Officer, General Counsel, Treasurer and Secretary

Exhibit 99.1

Leap Therapeutics to Present Updated Data for DKN-01 Monotherapy and Paclitaxel Combination at the 2019 International Gynecologic Cancer Society Annual Global Meeting

- *DKN-01 Monotherapy Patient with an Ongoing Complete Response*
- *Enhanced PFS in patients with Wnt Activating Mutations and DKK1-high Tumors*

Cambridge, MA — September 17, 2019 — Leap Therapeutics, Inc. (Nasdaq:LPTX) today announced an oral and poster presentation of updated clinical data from its ongoing Phase 2 clinical trial of DKN-01, its anti-Dickkopf-1 (DKK1) antibody, as both a monotherapy and in combination with paclitaxel chemotherapy in patients with advanced gynecological malignancies will be presented at the 2019 International Gynecologic Cancer Society Annual Global Meeting taking place September 19-21, 2019 in Rio de Janeiro, Brazil. The poster will be presented on Friday, September 20 at 6:15 p.m. (BRT).

"We are very enthusiastic about the single agent and combination activity of DKN-01 observed in this heavily pre-treated patient population. DKN-01 targets DKK1, which is a modulator of Wnt signaling. In this study, patients with Wnt activating mutations and high levels of DKK1 have had clinical benefit and prolonged progression-free survival (PFS)," commented Rebecca C. Arend, M.D., Department of Obstetrics and Gynecology at the University of Alabama at Birmingham School of Medicine, who presented the data on behalf of the study group. "A monotherapy complete response and the correlation of patient outcomes with prevalent tumor biomarkers are impressive signals of activity in these patients, who have poor prognosis and few treatment options."

Key Findings from the P204 Study include:

- ***DKN-01 single agent complete response*:** Following the data cut-off date, one patient with Wnt signaling alterations has had her monotherapy partial response deepen into a complete response. She has remained on DKN-01 monotherapy for 14 months after enrolling in July 2018 and having a partial response after cycle 8. This represents the first complete response for a patient on DKN-01 monotherapy.

- ***Patients with Wnt activating mutations have longer PFS*:** Across the study, patients with Wnt activating mutations have demonstrated a longer PFS (n=21, 175 days) as compared to patients without Wnt activating mutations (n=67, 63 days). The benefit observed in patients with Wnt activating mutations was statistically maintained regardless of treatment type (monotherapy or combination therapy) and cancer type (endometrial or ovarian cancer).

- ***Patients with DKK1-high tumors have longer PFS:*** DKK1 expression as measured by *in situ* hybridization RNAscope assay is currently available for 54 of the patients on the study, and 13 patients (24.1%) were identified as DKK1-high tumoral expression. Similar to the results from Leap's study in patients with esophagogastric cancer, patients whose tumors are DKK1-high have prolonged PFS (n=13, 168 days) as compared to patients with tumors that are DKK1-low (n=41, 63 days). The benefit observed in patients with DKK1-high tumors was statistically maintained regardless of monotherapy or combination therapy treatment and cancer type (endometrial or ovarian cancer).

- ***Few survival events in Wnt activating mutation or DKK1-high populations:*** Median overall survival (OS) has not yet been reached for the patients with Wnt activating mutations as compared to 321 days OS for patients without Wnt activating mutations. Only 3 of 21 patients with Wnt activating mutations (14.3%) have had events as compared to 18 of 67 patients (26.9%) without Wnt activating mutations. Median OS has also not been reached for the DKK1-high patients as compared to 365 days for the patients who are DKK1-low. Only 2 of 13 DKK1-high patients (15.4%) have had events as compared to 12 of 41 (29.3%) DKK1-low patients. Patient follow-up remains ongoing.

About the P204 Study

The P204 study is a Phase 2 basket study evaluating DKN-01 as a monotherapy and in combination with paclitaxel in patients with relapsed/refractory endometrioid endometrial cancer (EEC), endometrioid ovarian cancer (EOC) or carcinosarcoma. Ninety-two patients have been enrolled in the first four groups that were designed to evaluate the efficacy, safety, and pharmacodynamics of DKN-01 monotherapy and combination therapy in both EEC and EOC. The study has been expanded to include DKN-01 monotherapy and paclitaxel combination cohorts in patients with carcinosarcoma. Approximately fifty percent (50%) of patients in each cohort were required to have Wnt pathway alterations, which included Wnt activating mutations and Wnt signaling mutations. Additional patient follow-up is expected in the first half of 2020.

About DKN-01

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, a modulator of Wnt/Beta-catenin signaling, a signaling pathway frequently implicated in tumorigenesis and suppressing the immune system. DKK1 has 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 ligands on tumor cells.

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, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap's second clinical candidate, TRX518, is a humanized GITR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in advanced solid tumor studies. For more information about Leap Therapeutics, visit http://www.leaptx.com or 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, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements regarding expectations with respect to the development and advancement of DKN-01, TRX518, and other programs, including the initiation, timing and design of future studies, enrollment in future studies, business development, and other future expectations, plans and prospects. Leap has attempted to identify forward looking statements by such terminology as "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. 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: the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the ability to complete a financing or form business development relationships to fund our expenses; 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; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; 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, 2018, as filed with the SEC on April 1, 2019, and Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, as filed with the SEC on May 15, 2019, and for the quarter ended June 30, 2019, as filed with the SEC on August 10, 2019. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements 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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