
**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**

October 21, 2018

Date of report (Date of earliest event reported)

Leap Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37990
(Commission
File Number)

27-4412575
(IRS Employer
Identification No.)

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

02141
(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.

Item 8.01 Other Events.

On October 21, 2018, Leap Therapeutics, Inc. (the “Company”) issued a press release entitled “Leap Therapeutics Presents Esophagogastric Cancer Data at ESMO 2018 Annual 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	Leap Therapeutics, Inc. Press Release dated October 21, 2018, entitled “Leap Therapeutics Presents Esophagogastric Cancer Data at ESMO 2018 Annual Congress”.

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: October 21, 2018

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



**Leap Therapeutics Presents Esophagogastric Cancer Data
at ESMO 2018 Annual Congress**

— Live conference call and webcast on Monday, October 22 at 8:00 AM ET —

Cambridge, MA — October 21, 2018 — Leap Therapeutics, Inc. (NASDAQ:LPTX) today presented clinical data from its ongoing Phase I/II study of DKN-01 in combination with Keytruda® (pembrolizumab) in patients with advanced esophagogastric cancer at the European Society for Molecular Oncology (ESMO) 2018 Annual Congress.

Leap will host a live conference call and webcast on Monday, October 22 at 8:00 AM US Eastern Time / 2:00 PM Central European Time, with Samuel Klemper, MD, Director, Precision Medicine Program, The Angeles Clinic and Research Institute, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center. Dr. Klemper will describe his experience with patients in the study.

Clinical Data Presented at ESMO

Midway through the study, the combination of DKN-01 and pembrolizumab has demonstrated promising clinical activity with a 23.5% overall response rate and 58.8% disease control rate in evaluable gastric or gastroesophageal junction cancer patients who have been heavily pretreated and have not had prior anti-PD-1/PD-L1 therapy (PD-1/PD-L1 naïve). The combination has generated durable responses in subgroups less likely to respond to pembrolizumab monotherapy, for example, patients whose tumors are microsatellite stable (MSS) and/or PD-L1 negative. The combination of DKN-01 and pembrolizumab may have additive clinical benefit through the targeting of both innate and adaptive immunity. Data to date suggest that elevated tumor expression of DKK1 may correlate with better patient outcomes. Biomarker analyses are underway to guide future clinical development in gastroesophageal malignancies.

Esophagogastric Cancer Clinical Trial (P102)

The esophagogastric cancer clinical trial (P102) is a multipart study of DKN-01 as a monotherapy and in combination with paclitaxel or pembrolizumab. The arm evaluating DKN-01 plus pembrolizumab includes both dose escalation and dose confirmation cohorts and is designed to assess the safety, pharmacokinetics and efficacy of the combination. Data from the monotherapy and paclitaxel arms of the study have been presented previously and will be updated later in the year.

As of the September 26, 2018 cut-off date for the presentation, forty-five patients have been enrolled in the DKN-01 plus pembrolizumab study, thirty-eight PD-1/PD-L1 naïve and seven refractory to PD-1/PD-L1 therapy. Two of the patients were enrolled in the 150mg DKN-01 dose, and forty-three patients at the 300mg DKN-01 dose. Leap expects that the PD-1/PD-L1 naïve group will complete enrollment before the end of 2018.

Clinical Results as of September 26, 2018

300mg DKN-01 Anti-PD1/PD-L1 Naïve	Patients	Response Rate	Disease Control Rate	Partial Response	Stable Disease	Progressive Disease	To Be Enrolled
GEJ/Gastric	17	23.5%	58.8%	4	6	7	Up to 8
EA/ESCC	6	0%	50%	0	3	3	Up to 8
Evaluable	23	17.4%	56.5%	4	9	10	8
Not Evaluable	6	—	—	—	—	—	—
Modified Intent To Treat	29	13.8%	44.8%	4	9	10	8
Pending First Scan	8	—	—	—	—	—	—
Patients Still on Study	16						

All responding patients in the study had MSS tumors. The overall response rate for Keytruda monotherapy in gastric or gastroesophageal junction patients with non-microsatellite instability high tumors in the KN-059 (n = 167) and KN-061 (n = 281) studies was 9.0% and 9.3%, respectively.

When this study is complete, Leap expects to choose an indication for a larger, controlled clinical study.

DKN-01 Clinical Perspectives Conference Call and Webcast:

On Monday, October 22, 2018 at 8:00AM ET/2:00PM CET, Leap will be hosting a conference call and webcast for the investment community. To access the conference call, please dial (866) 589-0108 (US/Canada Toll-Free) or (409) 231-2048 (international) and refer to conference ID 1249999. The presentation will also be webcast live and will be available under “Events & Presentations” in the Investor section of Leap’s website, <http://www.investors.leaptx.com>. A replay of the webcast will be available on Leap’s website approximately two hours after the event and will 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, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric cancer, biliary tract cancer, and gynecologic cancers, with an emerging focus on patients with defined mutations of the Wnt pathway and in combination with immune checkpoint inhibitors. 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 two 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 <http://www.investors.leaptx.com/>.

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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 Leap's expectations with respect to the development and advancement of DKN-01 and TRX518, including the initiation, timing, design and results of future studies, enrollment in future studies, business development, 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: 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 Securities and Exchange Commission (the "SEC"), including Leap Therapeutics' Form 10-K that Leap filed with the SEC on February 23, 2018. 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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