
**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**

April 16, 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**

(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:

- 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 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 8.01 Other Events.

On April 16, 2018, Leap Therapeutics, Inc. (the "Company") issued a press release announcing new clinical and nonclinical data presented at the AACR Annual Meeting relating to the Company's anti-DKK1 monoclonal antibody, DKN-01. Nonclinical experiments demonstrated the activity of DKK1 inhibition in enhancing innate immunity and the potential for combination with immune checkpoint inhibitors. The presentation also highlighted the preliminary results from the Company's dose escalation phase of the clinical study evaluating DKN-01 in combination with Merck's anti-PD-1 therapy,

KEYTRUDA® (pembrolizumab). 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Leap Therapeutics, Inc. Press Release dated April 16, 2018

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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: April 16, 2018

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



**Leap Therapeutics Presents Nonclinical and Clinical Data on DKN-01
at AACR 2018 Annual Meeting**

Cambridge, MA — April 16, 2018 — Leap Therapeutics, Inc. (NASDAQ:LPTX) today presented nonclinical and clinical data on DKN-01, Leap's anti-DKK1 monoclonal antibody, at the American Association for Cancer Research (AACR) 2018 Annual Meeting. The presentation highlighted the immunomodulatory activity of DKN-01 in nonclinical experiments and preliminary results from the dose escalation phase of the clinical study evaluating DKN-01 in combination with the Merck (known as MSD outside the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with advanced esophagogastric cancer.

Nonclinical Data:

Nonclinical studies demonstrated the activity of DKK1 inhibition in enhancing innate immunity and the potential for combination with immune checkpoint inhibitors. mDKN-01, the murine form of DKN-01, reduced myeloid-derived suppressor cells (MDSCs), increased PD-L1 levels on MDSCs, and enhanced expression of T-cell chemoattractants. These innate mechanisms, promoting an inflammatory tumor microenvironment, are complementary to immune checkpoint inhibition. In a syngeneic tumor model, mDKN-01 had additive activity with anti-PD-1 therapy as compared to either antibody administered alone.

Clinical Data:

Preliminary results from the dose escalation phase of the clinical study evaluating the combination of DKN-01 and KEYTRUDA in patients with advanced esophagogastric cancer demonstrated that the combination was well tolerated with early signals of clinical activity:

- Four out of five patients enrolled at the highest tested dose of DKN-01 were naïve to anti-PD-1/PD-L1 therapy and evaluable for response. One patient had a partial response with a 66% reduction in target tumor volume. This patient had progressed on two prior systemic therapies and had a tumor that was known to be KRAS amplified, microsatellite stable (MSS), and PD-L1 negative; a phenotype typically less responsive to anti-PD-1 therapy. Three patients had stable disease, two of whom remain on study through at least four cycles.
- Two patients enrolled in the escalation phase were refractory to anti-PD-1/PD-L1 therapy and currently have had a best response of stable disease. One of these patients also had a tumor that was KRAS amplified, MSS, and PD-L1 negative and has been on study for six cycles with an initial 10% reduction in tumor burden.

The DKN-01 and KEYTRUDA expansion combination continues to enroll patients who are naïve to anti-PD-1/PD-L1 therapy (n=40) and patients who are refractory to anti-PD-1/PD-L1 therapy (n=15).

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 novel, humanized GITR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in two advanced solid tumor studies.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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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