

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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): **June 21, 2017**

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.

Introductory Comment

Throughout this Current Report on Form 8-K, the terms "Leap", "we," "us," "our" and "Company" refer to Leap Therapeutics, Inc.

Item 1.01. Entry into a Material Definitive Agreement.

On June 21, 2017, Leap entered into a clinical trial collaboration and supply agreement, or the Collaboration and Supply Agreement, with MSD International GmbH, a subsidiary of Merck (known as MSD outside the United States and Canada), or Merck, to clinically evaluate the combination of Leap's DKK1 antagonist, or DKN-01, with Merck's PD-1 antagonist, KEYTRUDA® (pembrolizumab), or KEYTRUDA®.

Under the Collaboration and Supply Agreement, Leap will sponsor and fund the Phase I/II clinical trials to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the concomitant and/or sequenced administration of the combination of DKN-01 and KEYTRUDA® in patients with relapsed or refractory advanced esophagogastric cancers. Merck will be responsible for manufacturing and supplying KEYTRUDA® for the clinical trials. This agreement provides that both Leap and Merck will jointly own clinical data generated from this clinical trial.

The Collaboration and Supply Agreement expires on delivery of the final study report concerning the results of the clinical trial, unless earlier terminated by either party in the event of the other party's uncured material breach or if there are certain safety concerns, regulatory action prevents supply of one or both of DKN-01 or KEYTRUDA®, or if either Party withdraws regulatory approval for or discontinues development of its compound.

Item 8.01. Other Events.

On June 21, 2017, Leap issued a press release announcing the Collaboration and Supply Agreement. A copy of the press release is being filed as Exhibit 99.1 to this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release of Leap Therapeutics, Inc. dated June 21, 2017.

2

SIGNATURE

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.

Date: June 21, 2017

LEAP THERAPEUTICS, INC.
(Registrant)

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

3

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release of Leap Therapeutics, Inc. dated June 21, 2017.

4



Leap Therapeutics Announces Collaboration with Merck to Evaluate KEYTRUDA® (pembrolizumab) in Combination with DKN-01 in Esophagogastric Cancer

Cambridge, MA — June 21, 2017 — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today announced that it has entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada), to investigate Leap’s DKK1 antagonist, DKN-01, in combination with Merck’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with relapsed or refractory advanced esophagogastric cancers.

“This clinical collaboration with Merck is the first of the combination immunotherapy studies we plan to initiate in each of our two programs, DKN-01 and TRX518. Combining DKN-01 with KEYTRUDA has a strong scientific rationale and offers hope to patients with few treatment options,” commented Cynthia Sirard, M.D., Vice President, Clinical Development of Leap Therapeutics.

The study is expected to begin enrolling patients in the second-half of 2017. The collaboration agreement is between Leap and Merck, through a subsidiary. Additional details of the collaboration were not disclosed.

About Leap Therapeutics

Leap Therapeutics’ (NASDAQ:LPTX) most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is in clinical trials in patients with gastroesophageal cancer, alone and in combination with paclitaxel, and in patients with biliary tract cancer, in combination with gemcitabine and cisplatin. An investigator-initiated study of DKN-01 will be conducted in hepatocellular carcinoma patients, in combination with sorafenib. DKN-01 has demonstrated single agent activity in non-small cell lung cancer patients. Leap’s second clinical candidate, TRX518, is a novel, humanized G1TR agonist monoclonal antibody designed to enhance the immune system’s anti-tumor response that is in two monotherapy 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/>.

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 relating to Leap’s 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 risks and uncertainties that could cause actual results to differ materially from our expectations. These 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; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; 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 March 31, 2017. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors. 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.

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

CONTACT:

Douglas E. Onsi
 Chief Financial Officer
 Leap Therapeutics, Inc.
donsi@leaptx.com
 617-714-0360

Argot Partners

Susan Kim
 212-203-4433
susan@argotpartners.com

or

Heather Savelle
617-663-4863
heather@argotpartners.com
