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

December 14, 2018
Date of report (Date of earliest event reported)

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):

☐ 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 December 14, 2018, Leap Therapeutics, Inc. (the "Company") issued a press release entitled "Leap Therapeutics Presents TRX518 Data at ESMO Immuno-Oncology Congress 2018 and Updated Data from DKN-01 Study in Biliary Tract Cancer".

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 December 14, 2018, entitled "Leap Therapeutics Presents TRX518 Data at ESMO Immuno-Oncology Congress 2018 and Updated Data from DKN-01 Study in Biliary Tract Cancer".

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: December 14, 2018

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

Exhibit 99.1

Leap Therapeutics Presents TRX518 Data at ESMO Immuno-Oncology Congress 2018 and Updated Data from DKN-01 Study in Biliary Tract Cancer

TRX518 (GITR Agonist) Clinical Perspectives conference call and webcast on Monday, December 17 at 8:30 AM ET

Cambridge, MA — December 14, 2018 — Leap Therapeutics, Inc. (NASDAQ:LPTX) today presented clinical data from its ongoing Phase I/II study of TRX518 in combination with gemcitabine, Keytruda® (pembrolizumab), or Opdivo® (nivolumab) in patients with advanced solid tumors at the European Society for Molecular Oncology (ESMO) Immuno-Oncology Congress 2018. In addition, Leap provided the top-line final data from the Phase I/II study of DKN-01 in combination with gemcitabine and cisplatin chemotherapy in patients with advanced biliary tract cancer.

Leap will host a conference call and webcast on Monday, December 17, 2018 at 8:30 AM US Eastern Time with Jason J. Luke, MD, Assistant Professor of Medicine, Pritzker School of Medicine at the University of Chicago and Todd M. Bauer, MD, Sarah Cannon Research Institute/Tennessee Oncology PLLC, TN. Drs. Luke and Bauer will discuss patient outcomes and provide additional perspectives about the TRX518 program.

TRX518

TRX518 is unique among Glucocorticoid-Induced TNF Receptor (GITR) agonist antibodies for its aglycosyl design, permitting activation of GITR signaling without depleting CD8+ T-effector cells. In cancer patients, TRX518 has been shown to increase CD8+ T-effector cell infiltrate and the expression of granzyme B, as well as decrease CD4+ T-regulatory cell infiltrate. The dual function of TRX518 is designed to enhance the anti-tumor activity of chemotherapies and immune checkpoint inhibitors, such as anti-PD-1/PD-L1 antibodies.

TRX518 Clinical Data Presented at ESMO Immuno-Oncology Congress 2018

The clinical trial is a continuation of the TRX518 multi-dose monotherapy study that has been expanded with three combination study arms to evaluate lower (2 mg/kg loading dose with 1 mg/kg maintenance doses) and higher (4 mg/kg loading dose with 1 mg/kg maintenance doses) dose levels of TRX518 in combination with gemcitabine chemotherapy or Keytruda or Opdivo anti-PD-1 immune checkpoint antibodies.

Key Findings:

- In monotherapy and combination studies, TRX518 demonstrated safety, tolerability, and clinical benefit in patients with heavily pretreated solid tumors.
- TRX518 in combination with Keytruda or Opdivo achieved durable complete and partial responses in patients not expected to respond to anti-PD-1 therapy alone, including a confirmed complete response in an esophageal squamous cell cancer patient and a confirmed partial response in an anti-PD-1 refractory urothelial cancer patient.
- TRX518 in combination with gemcitabine achieved meaningful clinical benefit and objective tumor reduction for heavily pretreated patients suffering from pancreatic, biliary tract, mesothelioma, appendiceal, and ovarian cancer.
- The biopsies of responding patients demonstrated an increase in CD8+ T-effector cells and granzyme B expression and a reduction in CD4+ T-regulatory cells and FoxP3 expression, hallmarks of immune activation and anti-tumor activity associated with GITR agonism.

TRX518/gemcitabine combination:

The combination arm evaluating TRX518 in combination with gemcitabine enrolled thirty patients who had received one to nine prior therapies. Four patients were treated at the lower dose of TRX518, and twenty-six patients were treated at the higher dose. The study enrolled fourteen patients with pancreatic cancer, five with biliary tract cancer, and eleven with other cancers including ovarian, appendiceal, and mesothelioma. Seventeen patients had previously progressed on gemcitabine therapy, and ten had previously progressed on anti-PD-1/PD-L1 therapy.

Clinical outcomes data as of December 5, 2018 includes:

TRX518 + gemcitabine	**N**	**Response Evaluable**	**Stable Disease**	**Progressive Disease**	**Disease Control Rate (Response Evaluable)**
Overall	30	25	13	12	52%
Lower dose TRX518	4	2	0	2	0%
Higher dose TRX518	26	23	13	10	56.5%
Pancreatic Cancer	14	10	5	5	50%
Biliary Tract Cancer (BTC)	5	5	4	1	80%
Other Cancers	11	10	4	6	40%

Nineteen pancreatic or biliary tract cancer (PBC) patients were enrolled, and nine remain on study. Nearly all of these patients had received prior gemcitabine therapy, and nine (47%) remained on study for more than four cycles. Eight (67%) of twelve evaluable PBC patients previously treated with gemcitabine who received the higher dose of TRX518 have had stable disease, including a fourth-line pancreatic cancer patient who remains on study in Cycle 9 with a 21% reduction in tumor burden. Pancreatic cancer patients who have progressed on gemcitabine have extremely poor outcomes with studies indicating a range of 1.6 to 2.9 months between median progression and median overall survival.

Additional reductions in tumor burden and durable clinical benefit have been noted in appendiceal cancer (-4% in Cycle 7), mesothelioma (-5% in Cycle 6), and two in ovarian cancer (-15% in Cycle 5, -9% off after 4 cycles).

TRX518/Keytruda or Opdivo combination

The combination arms evaluating TRX518 in combination with Keytruda or Opdivo enrolled fourteen patients in the dose escalation cohorts as of December 5, 2018. Both patients treated with the higher dose of TRX518 plus Keytruda have had clinical benefit. An esophageal squamous cell carcinoma patient has had a confirmed complete response, which remains ongoing for seven months, and an ocular melanoma patient has had a 23% reduction in tumor volume and six months of ongoing stable disease. In the low dose TRX518 plus Opdivo combination arm, a patient with urothelial carcinoma who had failed prior Keytruda had a confirmed partial response and remained on therapy for six months.

Enrollment is now complete in the dose escalation cohort for TRX518 and Keytruda and continues in the high dose escalation cohort of TRX518 and Opdivo. Leap anticipates that dose expansion cohorts for both combinations will initiate in the first quarter 2019.

DKN-01

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, hepatobiliary cancer, and gynecologic cancers.

At the Society for Immunotherapy of Cancer 33rd Annual Meeting, Leap announced that the combination of DKN-01 and paclitaxel generated a 46.7% overall response rate, 19.6 weeks median progression free survival, and 61.1 weeks median overall survival in fifteen evaluable esophagogastric cancer patients as a second-line therapy. In the subgroup of twelve evaluable patients with heavily pre-treated esophageal squamous cell carcinoma, DKN-01 and paclitaxel produced a 33.3% overall response rate, 13.7 weeks median progression free survival, and 31.0 weeks median overall survival.

At the ESMO 2018 Annual Meeting, Leap announced that the combination of DKN-01 and Keytruda 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. The combination has generated durable responses in subgroups less likely to respond to pembrolizumab monotherapy, for example, patients whose tumors are microsatellite stable and/or PD-L1 negative. Additional data from the DKN-01/Keytruda combination is expected in the second quarter of 2019.

DKN-01 in combination with gemcitabine and cisplatin in Advanced Biliary Tract Cancer

The open-label, Phase I/II study enrolled fifty-one patients with advanced biliary tract cancer (BTC). Seven patients received one of two dose levels (150 mg or 300 mg) of DKN-01 in combination with gemcitabine and cisplatin during Part A, with forty-four additional patients treated at the 300 mg dose level of DKN-01 in the Part B expansion cohort. Forty-two patients were chemotherapy treatment-naïve, and nine patients had received 1-2 prior therapies. The primary objective of this study was to evaluate the safety, pharmacokinetics, and efficacy of DKN-01 in combination with gemcitabine and cisplatin.

In the study, DKN-01 in combination with gemcitabine and cisplatin was well tolerated with no new emerging safety trends. Forty-seven patients overall were treated at the 300 mg DKN-01 dose level, and their median overall survival was 53.7 weeks (12.4 months). Median progression free survival was 37.7 weeks (8.7 months). Ten patients (21.3%) had a partial response and thirty-one patients (66.0%) experienced a best response of stable disease, representing a disease control rate of 87.2%. Two patients (4.3%) had progressive disease, and four patients (8.5%) were non-evaluable for response. The one-year probability of overall survival was 0.51, and the six-month probability of progression free survival was 0.58. The median number of cycles of DKN-01 was seven (range of 1 to 23), and the median duration on study was 331 days.

“Patients with metastatic biliary tract cancer have a poor prognosis with an unmet medical need, with median overall survival of less than one year. We are very pleased by the progression-free survival, overall survival, and favorable safety profile demonstrated by DKN-01 in combination with gemcitabine and cisplatin in this single arm study,” commented by Andrew X. Zhu, M.D., Director of Liver Cancer Research at Massachusetts General Hospital Cancer Center and Professor of Medicine at Harvard Medical School. “The activity of DKN-01 in biliary tract cancer warrants further development in the front-line setting as well as in second-line in combination with anti-PD-1/PD-L1 antibodies.”

TRX518 Clinical Perspectives Conference Call and Webcast

On Monday, December 17, 2018 at 8:30AM ET, 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 9187987. The presentation will also be webcast live and will be available on Leap’s website, https://www.leaptx.com/program-webcasts. A replay of the webcast will be available on Leap’s website 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

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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