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): **April 1, 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))

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 2.02. Results of Operations and Financial Condition

On April 1, 2019, Leap Therapeutics, Inc. (the "Company") provided an update on the development of the Company's product candidates since the end of the fourth quarter of 2018 and announced its financial results for the year ended December 31, 2018. The full text of the press release issued by the Company in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying exhibit shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Current Report on Form 8-K, including the information set forth under this Item 2.02 and the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Leap Therapeutics, Inc. dated April 1, 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: April 1, 2019

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

Exhibit 99.1

Leap Therapeutics Reports Clinical Update and 2018 Financial Results

Cambridge, MA — April 1, 2019 — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported an update on its clinical development programs along with financial results for the fourth quarter and year ended December 31, 2018.

Leap Highlights

- DKN-01 plus Keytruda® exceeds benchmarks in gastric cancer
- Predictive biomarker enables patient selection
- DKN-01 plus paclitaxel exceeds benchmarks in esophagogastric cancer
- Two DKN-01 monotherapy responses in endometrial cancer
- DKK1-positive prostate cancer study enrolling 97 patients
- TRX518 has first reported GITR agonist monotherapy confirmed partial response in the industry
- TRX518 combination with Keytruda or Opdivo® demonstrating durable complete and partial responses
- TRX518 combination with gemcitabine achieved partial response and meaningful clinical benefit in patients who had previously progressed on gemcitabine therapy
- Raised $13.225 million to support further clinical development

DKN-01 Clinical Update

DKN-01 is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein, a Wnt pathway modulator. DKN-01, as a single agent, has achieved partial responses in three different cancer indications. In combination with immune checkpoint inhibitors and with chemotherapy, DKN-01 has achieved overall response rates and survival data that is greater than the historical benchmarks, particularly in biomarker targeted patient populations.

- ***DKN-01 plus Keytruda (pembrolizumab) exceeds PD-1 antibody monotherapy benchmarks in gastric and gastroesophageal junction cancer*** Leap has completed the enrollment of fifty-two patients who have advanced esophagogastric cancer and who were naïve to PD-1/PD-L1 therapy. Thirty-four patients with gastric (GC) or gastroesophageal junction (GEJ) cancer were enrolled, and twenty-five are evaluable for tumor response. Five patients (20%) have had a partial response (PR) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, and eight patients (32%) have experienced a best response of stable disease (SD), representing a disease control rate (DCR) of 52%. One patient continuing on therapy for six months has 36.4% tumor reduction, a PR by immune related RECIST (iRECIST), but not considered a PR by RECIST v1.1 due to tumor growth of greater than 20% at the first assessment, likely representing pseudoprogression. All of the patients in the study have tumors that are microsatellite stable or unknown, representing a population in which the benchmark overall response rate (ORR) of PD-1 antibodies is approximately 9%.

- ***DKK1 biomarker predicts response to DKN-01 plus Keytruda*** The overall response rate (ORR) and DCR has been higher in patients with higher DKK1 expression as measured by in situ hybridization RNAscope (H-scores). DKK-1 H-scores have been determined for thirty-two evaluable PD-1 therapy naïve patients, including nineteen GC/GEJ patients. Nine GC/GEJ patients had DKK1 H-Scores of greater than 31, including the six PRs (66.7%) by RECIST and iRECIST, two patients (22.2%) experiencing SD, and one patient (11.1%) with progressive disease. In the ten GC/GEJ patients with DKK1 H-Scores of 31 or lower, two patients (20%) had a best response of SD and eight patients (80%) had progressive disease.

- ***DKN-01 plus paclitaxel exceeds chemotherapy benchmark in esophagogastric cancer patients*** In total, fifty-eight patients with advanced esophagogastric cancer were treated, with fifty-two evaluable for response. Across all lines of prior therapy and tumor types, DKN-01 plus paclitaxel generated a 25.0% ORR, 13.4 weeks median progression-free survival (PFS), and 27.9 weeks median overall survival (OS). In the fifteen evaluable second-line patients, the combination of DKN-01 plus paclitaxel generated a 46.7% ORR, 19.6 weeks PFS, and 61.1 weeks OS. In a recent benchmark study in second-line esophageal cancer patients, single agent chemotherapy achieved a 6.7% ORR, 3.4 month PFS, and 7.1 month OS.

- ***Two monotherapy and one combination therapy responses for DKN-01 in advanced gynecological cancers, with seventy-eight patients now enrolled*** DKN-01, both as a monotherapy and in combination with paclitaxel, generated PRs and durable clinical benefit, including in patients with carcinosarcoma and Wnt pathway alterations. There have now been two DKN-01 monotherapy PRs and one PR in combination with paclitaxel in patients with epithelial endometrial cancer, all of whom have had Wnt pathway alterations. In total, seventy-eight patients have now been enrolled in this study, and many are pending first efficacy evaluation.

- ***Investigator-Initiated Study in DKK1-positive prostate cancer underway*** DKK1 is upregulated in a large number of patients whose advanced prostate cancer tumors do not express the androgen receptor. A study led by NYU Langone Medical Center and funded by Leap is enrolling metastatic DKK1-positive castration-resistant prostate cancer patients who have progressed on one or more androgen receptor therapies to be treated with either DKN-01 monotherapy or DKN-01 in combination with docetaxel.

TRX518 Clinical Update

TRX518 is unique among Glucocorticoid-Induced TNF Receptor (GITR) agonist antibodies for its aglycosyl design, permitting activation of GITR signaling without depleting CD8-positive T-effector cells. TRX518 has been shown to increase CD8-positive T-effector cell infiltrate and the expression of granzyme B, as well as decrease CD4-positive T-regulatory cell infiltrate. TRX518 is the first GITR agonist antibody in the industry to have reported partial responses as a monotherapy, in combination with PD-1 antibodies, and in combination with gemcitabine chemotherapy.

- ***Monotherapy patient with partial response*** A non-virally mediated hepatocellular cancer patient, who has been treated with single agent TRX518 for nearly two years, has achieved a PR with 47% tumor reduction and continues on study. TRX518 has demonstrated safety, tolerability, and clinical benefit as a monotherapy in patients with heavily pretreated solid tumors.

- ***Combination with Keytruda or Opdivo (nivolumab) achieved durable, confirmed complete and partial responses in patients not expected to respond to anti-PD-1 therapy*** An esophageal squamous cell carcinoma patient has a confirmed complete response. The patient has been treated for ten months and continues on study. A patient with uveal melanoma achieved 23% tumor reduction and six months of SD. A patient with urothelial carcinoma who had failed prior Keytruda had a confirmed PR and remained on therapy for six months. Twelve patients have recently enrolled in the expansion cohort for the Keytruda combination.

- ***Combination with gemcitabine achieved partial response and meaningful clinical benefit in patients who had progressed on gemcitabine therapy*** A pancreatic cancer patient, who had previously progressed on gemcitabine therapy and two other prior lines of therapy, has now achieved a confirmed PR with 58% tumor reduction. The patient has been treated for nine months and continues on study.

Selected Year-End and Fourth Quarter 2018 Financial Results

Net loss was $23.1 million for the year ended December 31, 2018, compared to $29.7 million for the year ended December 31, 2017. This decrease was primarily due to a noncash charge to decrease the fair value of the warrant liability. Net income was $1.5 million for the fourth quarter of 2018, compared to a net loss of $6.6 million for the same period in 2017. The 2018 increase was due to the decrease in the fair value of the warrant liability in the fourth quarter, leading to a $11 million non-cash gain. The requirement to revalue the warrant liability each quarter has resulted in the Company's net income or net loss being highly variable.

Research and development expenses were $21.8 million for the full year 2018, compared to $22.5 million for the same period in 2017. This decrease was primarily due to reduced manufacturing expenses of our clinical product candidates and a decrease in stock based compensation expense offset by increased clinical trial costs due to increased patient enrollment. Research and development expenses were $6.9 million for the fourth quarter of 2018, compared to $4.4 million for the same period in 2017. This increase was due to increased clinical development expense associated with the start-up operations and enrollment of our ongoing clinical trials.

General and administrative expenses were $8.9 million for the full year 2018, compared to $9.8 million for the same period in 2017. This decrease was due to a decrease in stock based compensation expense. General and administrative expenses were $2.1 million for the fourth quarter of 2017, compared to $2.1 million for the same period in 2017.

Cash, cash equivalents and marketable securities totaled $16.3 million at December 31, 2018. Research and development incentive receivables totaled $0.8 million. Subsequent to the financial year end, Leap completed a public offering of $13.225 million of common stock and warrants, resulting in net cash proceeds of $12.1 million. Leap believes that its current cash and the expected receipt of research and development tax incentives will be sufficient to fund its operating expenses into the second quarter of 2020.

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 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 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 Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2018 that Leap filed with the SEC on April 1, 2019. 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. OPDIVO® is a registered trademark of Bristol Myers-Squibb Company.

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Leap Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,284	$ 25,737
Research and development incentive receivable	836	1,744
Prepaid expenses and other current assets	202	177
Total current assets	17,322	27,658
Property and equipment, net	86	135
Deferred tax asset	124	158
Other assets	1,542	1,111
Total assets	$ 19,074	$ 29,062
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,579	$ 2,622
Accrued expenses	2,872	3,461
Total current liabilities	6,451	6,083
Non current liabilities:		
Warrant liability	3,448	11,862
Total liabilities	9,899	17,945
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of December 31, 2018 and 2017, 14,703,159 and 12,354,014 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	15	12
Additional paid-in capital	162,393	141,770
Accumulated other comprehensive income (loss)	302	(268)
Accumulated deficit	(153,535)	(130,397)
Total stockholders' equity	9,175	11,117
Total liabilities and stockholders' equity	$ 19,074	$ 29,062

Leap Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31		(Unaudited) Three Months Ended December 31	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 21,830	$ 22,503	$ 6,908	$ 4,416
General and administrative	8,921	9,849	2,063	2,130
Total operating expenses	30,751	32,352	8,971	6,546
Loss from operations	(30,751)	(32,352)	(8,971)	(6,546)
Interest income	447	170	120	40
Interest expense	(19)	(528)	(1)	(516)
Interest expense - related party	—	(121)	—	—
Australian research and development incentives	756	1,715	(432)	(137)
Foreign currency gains (loss)	(835)	759	(220)	(64)
Change in fair value of warrant liability	7,284	473	11,004	473
Loss before income taxes	(23,118)	(29,884)	1,500	(6,750)
Income taxes	(20)	157	(20)	157
Net loss	(23,138)	(29,727)	1,480	(6,593)
Accretion of preferred stock to redemption value	—	(244)	—	—
Net loss attributable to common stockholders	$ (23,138)	$ (29,971)	$ 1,480	$ (6,593)
Net income (loss) per share				
Basic	$ (1.64)	$ (3.27)		
Diluted	$ (2.11)	$ (3.31)		
Weighted average common shares outstanding				
Basic	14,144,287	9,161,844		
Diluted	14,412,695	9,188,587		

Leap Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		(Unaudited) Three Months Ended December 31,	
	2018	2017	2018	2017
Cash used in operating activities	$ (26,033)	$ (22,137)	$ (7,050)	$ (6,369)
Cash used in investing activities	—	(64)	—	—
Cash provided by (used in) financing activities	15,906	47,763	(40)	17,895
Effect of exchange rate changes on cash and cash equivalents	674	(618)	125	8
Net increase (decrease) in cash and cash equivalents	(9,453)	24,944	(6,965)	11,534
Cash and cash equivalents at beginning of period	25,737	793	23,249	14,203
Cash and cash equivalents at end of period	$ 16,284	$ 25,737	$ 16,284	$ 25,737