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): **November 9, 2018**

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** (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 2.02. Results of Operations and Financial Condition

On November 9, 2018, Leap Therapeutics, Inc. (the "Company") provided an update on the development of the Company's product candidates since the end of the second quarter of 2018 and announced its financial results for the quarter ended September 30, 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 herein 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 November 9, 2018.

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: November 9, 2018

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

Exhibit 99.1

Leap Therapeutics Reports Third Quarter 2018
Business Update and Financial Results

Cambridge, MA — November 9, 2018 — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported a business update and financial results for the third quarter ended September 30, 2018.

"Our team has executed extremely well over the past quarter, rapidly enrolling multiple clinical trials and presenting impressive clinical and preclinical data for both of our programs. We are excited about the potential for our DKN-01 antibody in patients with esophagogastric cancer, both in combination with KEYTRUDA® (pembrolizumab) and with paclitaxel. We believe that the emerging response and disease control rates, and now the progression-free survival and overall survival data, reflect outcomes that are clinically meaningful to patients with very difficult to treat cancer and are greater than what has previously been demonstrated with approved single agents," commented Christopher K. Mirabelli, Ph.D, President and Chief Executive Officer of Leap Therapeutics. "In addition, we look forward to presenting data from the studies of our TRX518 antibody in combination with KEYTRUDA, OPDIVO® (nivolumab) or gemcitabine at the European Society for Molecular Oncology 2018 Immuno-Oncology Congress in December."

Recent Developments

Since the end of the second quarter, the Company has continued to make strong progress with the development of their product candidates.

- ***DKN-01/KEYTRUDA***: At the European Society for Molecular Oncology (ESMO) 2018 Annual Congress, Leap presented clinical data from a study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. As of the cut-off date for the poster, DKN-01 and pembrolizumab had a 23.5% overall response rate and 58.8% disease control rate in evaluable gastric or gastroesophageal junction cancer patients who have been heavily pre-treated and not received any prior anti-PD-1/PD-L1 therapy. All four of the responding patients had tumors that were microsatellite stable, which is a subgroup of patients who have historically experienced a less than ten percent response rate to KEYTRUDA monotherapy.

- ***DKN-01/PACLITAXEL***: At the Society for Immunotherapy of Cancer 33rd Annual Meeting, Leap presented an update on a clinical study evaluating DKN-01 in combination with paclitaxel in patients with advanced esophagogastric cancer. 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 patients as a second line therapy. In the benchmark RAINBOW study, paclitaxel monotherapy in second line gastroesophageal junction or gastric cancer patients generated a 16.1% overall response rate, 2.9 months median progression free survival, and 7.4 months median overall survival. Additionally, in our study in the subgroup of twelve evaluable patients with heavily pre-treated esophageal squamous cell carcinoma, the combination of 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.

- ***DKN-01 in HCC***: The first patient has been enrolled in Leap's investigator-initiated study of DKN-01 as a monotherapy and in combination with NEXAVAR® (sorafenib) in hepatocellular carcinoma patients with Wnt pathway activation.

- ***TRX518/BAVENCIO***: In July, Leap announced a collaboration agreement with Pfizer and Merck KGaA, Darmstadt, Germany to evaluate TRX518 in combination with BAVENCIO® (avelumab) and cyclophosphamide chemotherapy. Under the terms of the collaboration, Leap will be conducting a Phase I/II clinical trial in advanced solid tumors including expansion populations in patients with relapsed/refractory ovarian, breast, and prostate cancers.

- ***TRX518/KEYTRUDA or OPDIVO or GEMCITABINE***: During the third quarter, Leap presented initial data from a clinical trial evaluating TRX518 in combination with gemcitabine chemotherapy or in combination with KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab). Three patients treated with TRX518 in combination with anti-PD1 antibodies have experienced clinical benefit. An esophageal squamous cell carcinoma patient treated with TRX518 and KEYTRUDA demonstrated a partial response with a 77% reduction in tumor volume, and an ocular melanoma patient experienced stable disease with a 23% reduction in tumor volume. An urothelial carcinoma patient who had progressed while on KEYTRUDA has had a partial response with TRX518 and OPDIVO with a 39% reduction in tumor volume. We have also fully enrolled the TRX518 and gemcitabine expansion cohort. We plan to present additional data from this trial at the ESMO Immuno-Oncology Congress in December 2018.

Selected Third Quarter 2018 Financial Results

Net loss was $6.6 million for the third quarter of 2018, compared to $6.8 million for the same period in 2017.

Research and development expenses were $6.5 million for the third quarter 2018, compared to $6.8 million for the same period in 2017. The decrease of $0.3 million was primarily due to a decrease of $1.3 million in manufacturing costs related to clinical trial material. This decrease was partially offset by an increase of $0.7 million in clinical trial costs, an increase of $0.2 million in payroll and other related costs and an increase of $0.1 million in stock based compensation expense.

General and administrative expenses were $2.1 million for the third quarter 2018, compared to $1.8 million for the same period in 2017. The increase of $0.3 million in general and administrative expenses was primarily due to a $0.2 million increase in stock based compensation expense and an increase of $0.1 million in legal, audit and consulting fees associated with corporate and business development activities.

Cash, cash equivalents and marketable securities totaled $23.2 million at September 30, 2018. Research and development incentive receivables totaled $2.1 million. In October 2018, we received $0.8 million of research and development tax incentive payments from the Commonwealth of Australia. We anticipate that our current cash resources will extend until late in the third quarter of 2019.

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, hepatobiliary cancer, and gynecologic cancer. 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 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: our ability to operate as a going concern; 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 Securities and Exchange Commission (the "SEC"), including Leap Therapeutics' Form 10-K that Leap filed with the SEC on February 23, 2018. 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.

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 6,457	$ 6,802	$ 14,922	$ 18,087
General and administrative	2,142	1,780	6,858	7,719
Total operating expenses	8,599	8,582	21,780	25,806
Loss from operations	(8,599)	(8,582)	(21,780)	(25,806)
Interest income	128	40	327	130
Interest expense	(4)	(21)	(18)	(12)
Interest expense - related party	—	—	—	(121)
Australian research and development incentives	299	961	1,188	1,852
Foreign currency gains (loss)	(249)	787	(615)	823
Change in fair value of warrant liability	1,793	—	(3,720)	—
Net loss	(6,632)	(6,815)	(24,618)	(23,134)
Accretion of preferred stock to redemption value	—	—	—	(244)
Net loss attributable to common stockholders	$ (6,632)	$ (6,815)	$ (24,618)	$ (23,378)
Net loss per share				
Basic	$ (0.45)	$ (0.73)	$ (1.76)	$ (2.72)
Diluted	$ (0.55)	$ (0.73)	$ (1.76)	$ (2.72)
Weighted average common shares outstanding				
Basic	14,701,785	9,395,920	13,955,949	8,584,558
Diluted	15,211,716	9,395,920	13,955,949	8,584,558

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

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 23,249	$ 25,737
Research and development incentive receivable	937	1,744
Prepaid expenses and other current assets	191	177
Total current assets	24,377	27,658
Property and equipment, net	98	135
Research and development incentive receivable, net of current portion	1,131	—
Deferred tax asset	147	158
Other assets	1,373	1,111
Total assets	$ 27,126	$ 29,062
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,149	$ 2,622
Accrued expenses	1,897	3,461
Total current liabilities	6,046	6,083
Non Current liabilities:		
Warrant liability	14,452	11,862
Total liabilities	20,498	17,945
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 14,703,159 and 12,354,014 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	15	12
Additional paid-in capital	161,468	141,770
Accumulated other comprehensive income (loss)	160	(268)
Accumulated deficit	(155,015)	(130,397)
Total stockholders' equity	6,628	11,117
Total liabilities and stockholders' equity	$ 27,126	$ 29,062

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

	Nine Months Ended September 30,	
	2018	2017
	(Unaudited)	
Cash used in operating activities	$ (18,983)	$ (15,768)
Cash used in investing activities	—	(64)
Cash provided by financing activities	15,946	29,868
Effect of exchange rate changes on cash and cash equivalents	549	(626)
Net increase (decrease) in cash and cash equivalents	(2,488)	13,410
Cash and cash equivalents at beginning of period	25,737	793
Cash and cash equivalents at end of period	$ 23,249	$ 14,203