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): **August 9, 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** (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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	LPTX	Nasdaq Global Market

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 August 9, 2019, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2019. 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 August 9, 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: August 9, 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 Second Quarter 2019 Financial Results

- *Positive data from DKN-01 plus KEYTRUDA® (pembrolizumab) combination study*
- *First patients enrolled in TRX518 plus BAVENCIO® (avelumab) and cyclophoshamide combination study*

Cambridge, MA — August 9, 2019 — Leap Therapeutics, Inc. (NASDAQ:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported financial results for the second quarter ended June 30, 2019.

"We recently presented positive data from our clinical study of DKN-01 plus KEYTRUDA which demonstrated higher survival and objective response outcomes in patients with advanced gastroesophageal junction and gastric cancer whose tumors expressed high levels of DKK1 (DKK1-high). As we have seen with the single agent partial responses in patients with endometrial cancer, DKN-01's activity continues to be impressive in biomarker-targeted patient populations," commented Christopher K. Mirabelli, Ph.D, President and Chief Executive Officer of Leap Therapeutics. "In addition, we have enrolled our first patients in the triple chemoimmunotherapy study of TRX518 in combination with BAVENCIO and cyclophosphamide."

Recent Developments

- ***DKN-01 CLINICAL INVESTIGATOR WEBCAST:*** On August 6, 2019, Leap hosted a DKN-01 program update webcast with Samuel J. Klempner, MD, Assistant Professor, Massachusetts General Hospital Cancer Center and Harvard Medical School, and Rebecca C. Arend, MD, Assistant Professor and Associate Scientist, Gynecologic Oncology Clinic, UAB Comprehensive Cancer Center Experimental Therapeutics Program. A replay of the webcast and the presentation slides are available under "Events & Presentations" in the Investor section of Leap's website, https://www.leaptx.com/program-webcasts.

- ***DKN-01 in ESOPHAGOGASTRIC CANCER***: Leap presented data from the KEYNOTE-731 clinical study evaluating DKN-01 in combination with KEYTRUDA in patients with advanced esophagogastric cancer. In gastroesophageal junction and gastric cancer patients who had not received prior PD-1/PD-L1 therapy, the combination of DKN-01 plus KEYTRUDA demonstrated improved outcomes in patients whose tumors are DKK1-high. DKK1-high patients experienced 22.1 weeks median progression free survival (PFS) and 31.6 weeks median overall survival (OS), with a 50% overall response rate (ORR) and 80% disease control rate (DCR) in ten evaluable patients. DKK1-low patients experienced 5.9 weeks PFS and 17.4 weeks OS, with a 20% DCR in fifteen evaluable patients. PD-L1 Combined Positive Scores (CPS) did not predict efficacy to the combination of DKN-01 plus KEYTRUDA. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS.

- ***DKN-01 in GYNECOLOGICAL CANCERS***: The clinical study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers has been expanded to include focused cohorts of patients with carcinosarcoma. Overall, ninety-six patients have been enrolled in the study, and enrollment is ongoing. Additional response and biomarker data will be available in September at the International Gynecologic Cancer Society Annual Global Meeting.

- ***TRX518 TRIPLE COMBINATION THERAPY***: Leap enrolled the first patients in the clinical trial evaluating TRX518 in combination with cyclophosphamide chemotherapy and BAVENCIO. Dose escalation in the study is ongoing.

- ***$21 MILLION EQUITY COMMITMENT FACILITY***: Leap entered into purchase agreements with Lincoln Park Capital Fund, LLC (LPC) pursuant to which Leap sold $1 million in common stock and has the option, but not the obligation, to sell to LPC up to an additional $20 million in shares of common stock in tranches over a twenty-four month period. The price of shares sold will be based on the market prices prevailing at the time of each sale to LPC. There is no upper limit as to the price per share that LPC may pay for future stock issuances under the agreement, and Leap will control the timing and amount of any future sales.

Selected Second Quarter 2019 Financial Results

Net loss was $8.4 million for the second quarter 2019, compared to $7.4 million for the same period in 2018. This increase was primarily due to an increase in clinical development expense and the recording of a loss in the second quarter 2018 as a result of a decrease in the fair value of the warrant liability.

Research and development expenses were $6.1 million for the second quarter 2019, compared to $4.2 million for the same period in 2018. This increase was primarily due to an increase in clinical trial expenses associated with an increase in patient enrollment and an increase in consulting fees and payroll expenses, partially offset by a decrease in manufacturing costs related to clinical trial material.

General and administrative expenses were $2.3 million for the second quarter 2019, compared to $2.6 million for the same period in 2018. This decrease was primarily due to a decrease in legal, audit and consulting fees.

Cash, cash equivalents and marketable securities totaled $15.7 million at June 30, 2019. Research and development incentive receivables, current and long term, totaled approximately $1.0 million at June 30, 2019. Subsequent to the end of the quarter, Leap announced the commitment facility with LPC and sold $1.0 million in common stock.

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. BAVENCIO® is a registered trademark of Merck KGaA, Darmstadt, Germany, and is marketed under a global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, USA.

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

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 15,747	$ 16,284
Research and development incentive receivable	836	836
Prepaid expenses and other current assets	211	202
Total current assets	16,794	17,322
Property and equipment, net	161	86
Right of use asset, net	1,398	—
Research and development incentive receivable, net of current portion	135	—
Deferred tax assets	124	124
Other assets	1,525	1,542
Total assets	$ 20,137	$ 19,074
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,325	$ 3,579
Accrued expenses	2,474	2,872
Lease liability - current portion	657	—
Total current liabilities	8,456	6,451
Non current liabilities:		
Warrant liability	—	3,448
Lease liability, net of current portion	742	—
Total liabilities	9,198	9,899
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of June 30, 2019 and December 31, 2018, 22,949,064 and 14,703,159 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	23	15
Additional paid-in capital	189,831	162,393
Accumulated other comprehensive income	322	302
Accumulated deficit	(179,237)	(153,535)
Total stockholders' equity	10,939	9,175
Total liabilities and stockholders' equity	$ 20,137	$ 19,074

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue		$ —		$ —
Operating expenses:				
Research and development	$ 6,136	$ 4,234	$ 12,926	$ 8,465
General and administrative	2,325	2,603	4,330	4,716
Total operating expenses	8,461	6,837	17,256	13,181
Loss from operations	(8,461)	(6,837)	(17,256)	(13,181)
Interest income	119	122	201	199
Interest expense	(9)	(8)	(16)	(14)
Australian research and development incentives	61	243	136	889
Foreign currency losses	(76)	(222)	(34)	(366)
Change in fair value of warrant liability	—	(662)	—	(5,513)
Net loss	(8,366)	(7,364)	(16,969)	(17,986)
Dividend attributable to down round feature of warrants	0	—	(359)	—
Net loss attributable to common stockholders	$ (8,366)	$ (7,364)	$ (17,328)	$ (17,986)
Net loss per share - basic and diluted	$ (0.37)	$ (0.50)	$ (0.82)	$ (1.32)
Weighted average common shares outstanding - basic and diluted	22,906,025	14,691,890	21,081,869	13,576,850

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

	Six Months Ended June 30,	
	2019	**2018**
	(Unaudited)	
Cash used in operating activities	$ (14,051)	$ (11,531)
Cash used in investing activities	(100)	—
Cash provided by financing activities	13,582	16,013
Effect of exchange rate changes on cash and cash equivalents	32	262
Net increase (decrease) in cash and cash equivalents	(537)	4,744
Cash and cash equivalents at beginning of period	16,284	25,737
Cash and cash equivalents at end of period	$ 15,747	$ 30,481