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 13, 2020**

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. ☐

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

Item 2.02. Results of Operations and Financial Condition

On August 13, 2020, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. 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 13, 2020.

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 13, 2020

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Executive Officer and President

Exhibit 99.1

Leap Therapeutics Reports Second Quarter 2020 Financial Results

Cambridge, MA – August 13, 2020 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the second quarter ended June 30, 2020.

Leap Second Quarter Highlights:

- Completed a $51.75 million public offering of common stock and pre-funded warrants to purchase common stock
- Presented updated data for DKN-01 monotherapy that showed a complete response and partial response in endometrial cancer patients with additional responses observed for the DKN-01 plus paclitaxel combination in carcinosarcoma patients
- Announced Orphan Drug Designation of DKN-01 for the treatment of gastric and gastroesophageal junction cancer

"Our partnership with BeiGene for the clinical development and commercialization of DKN-01 is progressing extremely well, and we look forward to dosing the first patient this quarter in the combination study of DKN-01 plus tislelizumab, BeiGene's anti-PD-1 antibody, for the treatment of gastric or gastroesophageal junction cancer patients," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "DKN-01 continues to show potential to treat multiple biomarker-defined cancers, as both a single agent and in combination with chemotherapy or anti-PD-1 therapies. We are excited about the promise of this program and, with the proceeds from our recent public offering, are well funded to drive development forward."

Business Update

- ***Leap Completed $51.75 Million Public Offering of Common Stock and Pre-Funded Warrants to Purchase Common Stock*** **–** In June 2020, Leap announced the closing of an underwritten public offering yielding aggregate gross proceeds of $51.75 million, before deducting underwriting discounts and commissions and other offering expenses payable by Leap.

DKN-01 Clinical Update

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, a modulator of Wnt/Beta-catenin signaling. DKK1 has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment.

- ***Leap Presented Updated Data for DKN-01 Monotherapy and Paclitaxel Combination in Gynecologic Cancers*** – Leap announced updated clinical data from its ongoing Phase 2 clinical trial of DKN-01, as both a monotherapy and in combination with paclitaxel chemotherapy, in patients with advanced gynecological malignancies. Leap hosted a conference call with Rebecca Arend, M.D., Assistant Professor and Associate Scientist, Gynecologic Oncology Clinic, The University of Alabama at Birmingham School of Medicine Comprehensive Cancer Center Experimental Therapeutics Program, on April 23, 2020, to discuss the data. Key findings from the P204 study include the following:

    - **DKN-01 Monotherapy in Endometrial Cancer:** Twenty-nine endometrial cancer patients were enrolled in the DKN-01 monotherapy arm, over 75% of whom had experienced three or more prior lines of therapy. Of those patients, 26 were evaluable for response. In the 20 patients with a Wnt signaling alteration, one patient (5%) has an ongoing complete response, one patient (5%) had a partial response, eight patients (40%) had a best response of stable disease, and 10 patients (50%) had progressive disease, representing an overall response rate (ORR) of 10% and a disease control rate (DCR) of 50%. In the group of six patients without any Wnt signaling alterations, one patient (16.6%) had a best response of stable disease and five patients (83.3%) had progressive disease.

    - **DKN-01 plus Paclitaxel in Carcinosarcoma:** Fifteen patients with carcinosarcoma were enrolled in the DKN-01 plus paclitaxel arm, six of whom were evaluable for response as of the data-cutoff date. Two patients (33%) have had a partial response, one patient (17%) has had a best response of stable disease, and three patients (50%) had progressive disease, representing an ORR of 33% and a DCR of 50%. Nine patients had not reached their first tumor assessment.

- ***Leap Announced Orphan Drug Designation of DKN-01 for the Treatment of Gastric and Gastroesophageal Junction Cancer*** – Leap announced that the U.S. Food and Drug Administration (FDA) granted the Company Orphan Drug Designation for DKN-01 for the treatment of gastric and gastroesophageal junction cancer. The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides to Leap certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees, and tax credits for qualified clinical trials.

Selected Second Quarter 2020 Financial Results

Net loss was $6.5 million for the second quarter 2020, compared to $8.4 million for the same period in 2019. This decrease was primarily due to revenue recognized from the BeiGene agreement, a decrease in clinical development expenses and non-cash foreign currency gains associated with changes in the Australian dollar exchange rate related to certain manufacturing activities.

Research and development expenses were $5.4 million for the second quarter 2020, compared to $6.1 million for the same period in 2019. The decrease was primarily due to lower clinical trial costs due to timing of patient enrollment and lower consulting fees associated with research and development activities.

General and administrative expenses were $2.5 million for the second quarter 2020, compared to $2.3 million for the same period in 2019. The increase was primarily due to higher legal, audit and consulting fees associated with corporate and business development activities.

Cash, cash equivalents and marketable securities totaled $64.9 million at June 30, 2020. Research and development incentive receivables, current and long term, totaled approximately $0.3 million at June 30, 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 has formed a partnership with BeiGene, Ltd. for the rights to develop DKN-01 in Asia (excluding Japan), Australia, and New Zealand. For more information about Leap Therapeutics, visit http://www.leaptx.com or view 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 Leap's expectations with respect to the development and advancement of DKN-01, including the initiation, timing and design of future studies, enrollment in future studies, potential for the receipt of future option exercise, milestones or royalty payments from BeiGene, 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: that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19 related issues, the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; 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; 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's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on March 16, 2020 and as may be updated by Leap's Quarterly Reports on Form 10-Q and the other reports we file from time to time with the SEC. 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 Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 64,887	$ 3,891
Research and development incentive receivable	181	185
Prepaid expenses and other current assets	212	165
Total current assets	65,280	4,241
Property and equipment, net	81	124
Right of use assets	711	1,026
Research and development incentive receivable, net of current portion	124	-
Deferred tax assets	125	127
Deferred costs	413	831
Deposits	939	1,099
Total assets	$ 67,673	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 2,716	$ 4,571
Accrued expenses	2,232	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	388	474
Total current liabilities	6,836	8,486
Non current liabilities:		
Restricted stock liability	-	159
Deferred revenue, net of current portion	750	-
Lease liability, net of current portion	354	552
Total liabilities	7,940	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 240,000,000 shares authorized; 59,657,742 and 24,194,877 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	60	24
Additional paid-in capital	268,770	193,319
Accumulated other comprehensive income	121	76
Accumulated deficit	(209,218)	(195,168)
Total stockholders’ equity (deficiency)	59,733	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 67,673	$ 7,448

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

	(Unaudited) Three Months Ended June 30,		(Unaudited) Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
License revenue	$ 375	$ -	$ 750	$ -
Operating expenses:				
Research and development	5,350	6,136	9,953	12,926
General and administrative	2,521	2,325	4,674	4,330
Total operating expenses	7,871	8,461	14,627	17,256
Loss from operations	(7,496)	(8,461)	(13,877)	(17,256)
Interest income	20	119	88	201
Interest expense	(13)	(9)	(25)	(16)
Australian research and development incentives	30	61	115	136
Foreign currency gains (loss)	943	(76)	(48)	(34)
Net loss	(6,516)	(8,366)	(13,747)	(16,969)
Dividend attributable to down round feature of warrants	-	-	(303)	(359)
Dividend attributable to Series A & B convertible preferred stock	-	-	(372)	-
Series A & B convertible preferred stock - beneficial conversion feature	-	-	(9,399)	-
Net loss attributable to common stockholders	$ (6,516)	$ (8,366)	$ (23,821)	$ (17,328)
Net loss per share				
Basic	$ (0.12)	$ (0.37)	$ (0.57)	$ (0.82)
Diluted	$ (0.12)	$ (0.37)	$ (0.57)	$ (0.82)
Weighted average common shares outstanding				
Basic	52,442,597	22,906,025	42,037,405	21,081,869
Diluted	52,442,597	22,906,025	42,037,405	21,081,869

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

	(Unaudited) Six Months Ended June 30	
	2020	**2019**
Cash used in operating activities	$ (13,377)	$ (14,051)
Cash provided by (used in) investing activities	25	(100)
Cash provided by financing activities	74,382	13,582
Effect of exchange rate changes on cash and cash equivalents	(34)	32
Net increase in cash and cash equivalents	60,996	(537)
Cash and cash equivalents at beginning of period	3,891	16,284
Cash and cash equivalents at end of period	$ 64,887	$ 15,747