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 12, 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 November 12, 2020, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 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 November 12, 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: November 12, 2020

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

Exhibit 99.1

Leap Therapeutics Reports Third Quarter 2020 Financial Results

Cambridge, MA – November 12, 2020 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for the third quarter ended September 30, 2020.

Leap Third Quarter Highlights:

- First patient dosed in Phase 2a study of Leap's anti-Dickkopf-1 (DKK1) antibody DKN-01 in combination with tislezumab, BeiGene's anti-PD-1 antibody, for the treatment of metastatic gastric or gastroesophageal junction (G/GEJ) cancer
- Presented updated data from DKN-01 in esophagogastric (EGC) cancer demonstrating positive outcomes in DKK1-high patients
- Presented updated data for DKN-01 in endometrial cancer demonstrating single agent activity in biomarker-selected patients
- U.S. Food and Drug Administration (FDA) Fast Track designation granted to DKN-01 for the treatment of G/GEJ cancer

"Data from our ongoing studies continue to demonstrate the potential of DKN-01 as both a single-agent or combination treatment with chemotherapy or anti-PD1 therapies for the treatment of biomarker-defined cancer patients," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We are also excited by the progress we've made with BeiGene this quarter, having dosed the first patient 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."

DKN-01 Development 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 and BeiGene Announced First Patient Dosed in Study of DKN-01 in Combination with Tislelizumab for the Treatment of Metastatic G/GEJ Cancer –*** Leap and BeiGene, Ltd. announced that the first patient was dosed in the DisTinGuish trial (NCT04363801), a Phase 2a, nonrandomized, open-label, multicenter study of Leap's DKN-01 in combination with BeiGene's tislelizumab with or without chemotherapy as first-line or second-line therapy in adult patients with inoperable, locally advanced G/GEJ adenocarcinoma. The study, which will be conducted in two parts, is expected to enroll up to 72 patients.

  Part A will enroll up to 24 patients with G/GEJ adenocarcinoma who have received no prior systemic treatment in the locally advanced/metastatic setting (first-line treatment), and Part B will enroll up to 48 patients with previously treated, inoperable, locally advanced or metastatic DKK1-high G/GEJ adenocarcinoma (second-line treatment). The study is designed to evaluate safety, tolerability, and efficacy of the combination therapy of intravenous DKN-01 and tislelizumab ± CAPOX (capecitabine + oxaliplatin) in G/GEJ adenocarcinoma patients. Treatment will be conducted in repeating 21-day cycles until the patient meets pre-established criteria for discontinuation or is no longer deriving clinical benefit. Part A and Part B of the study will be conducted concurrently.

- ***Leap Presented Updated Data from DKN-01 in EGC Demonstrating Positive Outcomes in DKK1-high Patients –*** At the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting, Leap presented clinical data from the Phase 1b/2a clinical trial of DKN-01 in patients with advanced EGC. In the study, high levels of tumoral DKK1 expression correlated with improved clinical outcomes in heterogeneous EGC patients treated with DKN-01 monotherapy or in combination with paclitaxel or the anti-PD-1 antibody, pembrolizumab. Important patient subgroups in this study demonstrated consistent benefit in DKK1-high patients, including:

    - **Anti-PD-1/PD-L1 refractory patients (all)**: The four DKK1-high patients had a significantly longer median progression-free survival (PFS) of 12.8 weeks and median overall survival (OS) of 46 weeks as compared to the five DKK1-low patients who experienced PFS of 6 weeks and OS of 16 weeks.

    - **Anti-PD1/PD-L1 refractory GEJ/GC patients:** The three DKK1-high patients had a best response of stable disease (SD) and a longer PFS of 13.4 weeks and OS of 37.4 weeks, as compared to the two DKK1-low patients who both had progressive disease (PD) with a PFS of 3.6 weeks and OS of 11.7 weeks.

    - **Anti-PD-1/PD-L1 naïve GEJ/GC patients:** As previously reported, DKK1-high patients experienced over 22 weeks PFS and nearly 32 weeks OS, with a 50% overall response rate (ORR) and 80% disease control rate (DCR) in ten evaluable patients. DKK1-low patients experienced nearly 6 weeks PFS and over 17 weeks OS, with a 20% DCR in fifteen evaluable patients. PD-L1 Combined Positive Scores (CPS) did not predict efficacy on the combination of DKN-01 plus pembrolizumab. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS scores.

- ***Leap Presented Updated Data for DKN-01 in Endometrial Cancer Demonstrating Single Agent Activity in Biomarker-selected Patients –*** At the American Association for Cancer Research (AACR) Virtual Special Conference on Endometrial Cancer: New Biology Driving Research and Treatment, Leap presented additional clinical data from the epithelial cancer (EEC) patients treated with DKN-01 monotherapy as part of its ongoing Phase 2 clinical trial for DKN-01, as both a monotherapy and in combination with paclitaxel chemotherapy, in patients with advanced gynecological malignancies. Twenty-nine EEC 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. Three important biomarker-selected subgroups were the focus of the data presentation:

    - **Patients with Wnt Signaling Alterations:** Patients with a Wnt signaling alteration had a higher response rate, greater clinical benefit, and longer PFS and OS compared to patients without a Wnt signaling alteration. In the group of 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 SD, and 10 patients (50%) had PD, representing an ORR of 10% and a DCR of 50%. In the group of six patients without any Wnt signaling alterations, one patient (16.6%) had a best response of SD and five patients (83.3%) had PD. The patients with a Wnt signaling alteration experienced PFS of 1.9 months and OS of 15.1 months, compared to the patients without a Wnt signaling alteration who experienced PFS of 1.8 months and OS of 8.4 months.

    - **Patients with Wnt Activating Mutations:** Patients with Wnt activating mutations had longer PFS and OS than patients without Wnt activating mutations. The nine patients with a Wnt activating mutation experienced PFS of 5.5 months and had not reached a median OS, compared to the 20 patients without a Wnt activating mutation who experienced PFS of 1.8 months and OS of 12.2 months.

    - **Patients expressing high tumor levels of DKK1:** DKK1 expression data was available for 19 EEC patients treated with DKN-01 monotherapy. DKK1-high patients had a higher response rate, greater clinical benefit, and longer PFS than patients who were DKK1-low. In the group of seven patients with DKK1-high tumors, one patient (14.3%) had a partial response, three patients (42.9%) had SD, and three patients (42.9%) had PD, representing an ORR of 14.3% and a DCR of 57.1%. In the group of 12 patients with DKK1-low tumors, one patient (8.3%) had SD and 11 patients (91.7%) had PD. The DKK1-high patients experienced PFS of 3.0 months, compared to the DKK1-low patients who experienced PFS of 1.8 months.

- **Leap Announced FDA Fast Track Designation Granted to DKN-01 for the Treatment of Gastric or Gastroesophageal Junction Cancer –** Leap announced that the FDA granted Fast Track designation to DKN-01 for the treatment of patients with G/GEJ adenocarcinoma whose tumors express high DKK1, following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy. The Fast Track program is intended to facilitate the development and expedite the review of drug candidates and vaccines that treat serious conditions and fill an unmet medical need. The purpose of Fast Track is to get important new drugs to the patient earlier. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application. DKN-01 has also received Orphan Drug Designation for the treatment of G/GEJ cancer from the FDA.

Selected Third Quarter 2020 Financial Results

Net loss was $7.1 million for the third quarter 2020, compared to $7.9 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 third quarter 2020, compared to $5.8 million for the same period in 2019. The decrease was primarily driven by reductions in clinical trial costs due to the deprioritization of the TRX518 program in November 2019 and the timing of patient enrollment. These decreases were partially offset by an increase in payroll and other related expeneses for research and development employees.

General and administrative expenses were $2.5 million for the third quarter 2020, compared to $2.2 million for the same period in 2019. The increase was due to higher professional fees primarily attributable to recruiting and information technology costs.

Cash, cash equivalents and marketable securities totaled $58.0 million at September 30, 2020. Research and development incentive receivables, current and long term, totaled approximately $0.2 million at September 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 entered into a strategic 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, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, 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 Leap files from time to time with the SEC. Any forward-looking statements contained in this release speak only as of its date. Leap undertakes 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
Consolidated Statement of Operations

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,	
	2020	2019	2020	2019
License revenue	$ 375	$ -	$ 1,125	$ -
Operating expenses:				
Research and development	5,369	5,772	15,322	18,698
General and administrative	2,514	2,151	7,188	6,481
Total operating expenses	7,883	7,923	22,510	25,179
Loss from operations	(7,508)	(7,923)	(21,385)	(25,179)
Interest income	3	80	91	281
Interest expense	(17)	(5)	(42)	(21)
Australian research and development incentives	228	(7)	343	129
Foreign currency gains (loss)	237	(80)	189	(114)
Loss before income taxes	(7,057)	(7,935)	(20,804)	(24,904)
Income taxes	-	-	-	-
Net loss	(7,057)	(7,935)	(20,804)	(24,904)
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	$ (7,057)	$ (7,935)	$ (30,878)	$ (25,263)
Net loss per share				
Basic	$ (0.09)	$ (0.33)	$ (0.58)	$ (1.15)
Diluted	$ (0.09)	$ (0.33)	$ (0.58)	$ (1.15)
Weighted average common shares outstanding				
Basic	76,321,644	23,923,196	53,548,902	22,039,386
Diluted	76,321,644	23,923,196	53,548,902	22,039,386

Leap Therapeutics, Inc
Consolidated Balance Sheet

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

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 57,975	$ 3,891
Research and development incentive receivable	209	185
Prepaid expenses and other current assets	217	165
Total current assets	58,401	4,241
Property and equipment, net	73	124
Right of use assets, net	620	1,026
Deferred tax assets	130	127
Deferred costs	379	831
Deposits	941	1,099
Total assets	$ 60,544	$ 7,448
Liabilities and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	$ 2,547	$ 4,571
Accrued expenses	2,270	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	398	474
Total current liabilities	6,715	8,486
Non current liabilities:		
Restricted stock liability	66	159
Deferred revenue, net of current portion	375	-
Lease liability, net of current portion	250	552
Total liabilities	7,406	9,197
Stockholders' equity (deficiency):		
Common stock, $0.001 par value; 240,000,000 and 100,000,000 shares authorized as of September 30, 2020 and December 31, 2019, repectively; 59,657,742 and 24,194,877 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	60	24
Additional paid-in capital	269,440	193,319
Accumulated other comprehensive income (loss)	(87)	76
Accumulated deficit	(216,275)	(195,168)
Total stockholders’ equity (deficiency)	53,138	(1,749)
Total liabilities and stockholders' equity (deficiency)	$ 60,544	$ 7,448

Leap Therapeutics, Inc
Consolidated Statement of Cash Flows

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

	Nine Months Ended September 30,	
	2020	**2019**
	(Unaudited)	
Cash used in operating activities	$ (19,969)	$ (21,008)
Cash provided by (used) in investing activities	25	(100)
Cash provided by financing activities	73,997	14,836
Effect of exchange rate changes on cash and cash equivalents	31	46
Net increase (decrease) in cash and cash equivalents	54,084	(6,226)
Cash and cash equivalents at beginning of period	3,891	16,284
Cash and cash equivalents at end of period	$ 57,975	$ 10,058