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, 2021**

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. ☐

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, 2021, Leap Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021 and discussing certain Company milestones. The full text of the press release issued by the Company 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, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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, 2021

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

Exhibit 99.1

Leap Therapeutics Reports Third Quarter 2021 Financial Results

Cambridge, MA – November 12, 2021 – 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, 2021.

Leap Third Quarter Highlights:

- Completed a $103.6 million public offering of common stock and pre-funded warrants to purchase common stock, resulting in net proceeds of $96.8 million
- Presented positive initial data from the DisTinGuish Study of DKN-01 plus tislelizumab and chemotherapy in gastric cancer patients at the European Society for Medical Oncology (ESMO) Congress 2021

“We presented positive new data at ESMO of DKN-01 in combination with BeiGene’s tislelizumab and chemotherapy demonstrating compelling overall response rates in patients with first-line gastric or gastroesophageal junction (G/GEJ) cancer, particularly those patients whose tumors expressed high levels of DKK1 or low PD-L1,” said Douglas E. Onsi, President and Chief Executive Officer of Leap. “We look forward to presenting additional data from the DisTinGuish study early next year and aggressively advancing DKN-01 into the next stages of development in G/GEJ and other cancers.”

Business Update

- ***Leap Completed a $103.6 Million Public Offering of Common Stock and Pre-Funded Warrants to Purchase Common Stock*** - In September 2021, Leap announced the commencement and closing of an underwritten public offering of 27,568,072 shares of its common stock, including the sale of an additional 4,740,000 shares of its common stock pursuant to the full exercise of the underwriters' option to purchase additional shares, and of pre-funded warrants to purchase 8,771,928 shares of its common stock. Aggregate gross proceeds to Leap from the offering were $103.6 million, including $7.25 million invested by its collaborator and existing investor BeiGene, Ltd., resulting in net proceeds after underwriting discounts and commissions and offering expenses of $96.8 million.

DKN-01 Clinical Milestones

DKN-01 is a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein. DKK1 modulates the Wnt/Beta-catenin and PI3kinase/AKT signaling pathways, which play an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK cell ligands on tumor cells.

- ***Initial Data from the DisTinGuish Clinical Trial of DKN-01 Plus Tislelizumab and Chemotherapy Presented at ESMO Congress 2021.*** The Company presented initial positive data from the first-line cohort of the Phase 2a study in patients with G/GEJ cancer. Of the 25 first-line HER2-G/GEJ patients who received a full cycle of DKN-01 therapy, overall response rate (ORR) was 68.2%, with 90% ORR in DKK1-high patients and 56% in DKK1-low patients. Among those patients with PD-L1-low expression, ORR was 79% (with 100% ORR in DKK1-high patients and 57% ORR in DKK1-low patients), and in patients with PD-L1-high expression, ORR was 67% (with 75% ORR in DKK1-high patients and 50% in DKK1-low patients), suggesting response to DKN-01 was independent of PD-L1 expression.

Selected Third Quarter 2021 Financial Results

Net Loss was $11.1 million for the third quarter 2021, compared to $7.1 million for the same period in 2020. License revenues were $0.4 million for each of the third quarter 2021 and the same period in 2020, and relate to the Agreement with BeiGene for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand.

Research and development expenses were $10.1 million for the third quarter 2021, compared to $5.4 million for the same period in 2020. The increase of $4.7 million in research and development expenses was due to an increase of $3.3 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns, an increase of $0.7 million in clinical trial costs due to timing of patient enrollment, an increase of $0.6 million in payroll and other related expenses due to an increase in headcount of our research and development full time employees, and an increase of $0.1 million in stock based compensation expense due to new stock options granted to research and development full time employees in 2021.

General and administrative expenses were $2.4 million for the third quarter 2021, compared to $2.5 million for the second quarter 2020. The decrease of $0.1 million in general and administrative expenses was due to a $0.4 million decrease in professional fees partially offset by an increase of $0.2 million in stock based compensation expense due to new stock options granted to general and administrative full time employees in 2021 and an increase of $0.1 million in payroll and other related expenses.

Cash and cash equivalents totaled $124.8 million at September 30, 2021. Research and development incentive receivables totaled $1.6 million at September 30, 2021.

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. DKN-01 is in clinical trials in patients with esophagogastric, hepatobiliary, gynecologic, and prostate cancers. Leap has entered into a strategic collaboration 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, milestone, 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 is 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, 2020, as filed with the SEC on March 12, 2021 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 statement contained in this release speaks only as of its date. Leap undertakes no obligation to update any forward-looking statement 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,		(Unaudited) Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
License revenue	$ 375	$ 375	$ 1,125	$ 1,125
Operating expenses:				
Research and development	10,077	5,369	24,090	15,322
General and administrative	2,438	2,514	7,973	7,188
Total operating expenses	12,515	7,883	32,063	22,510
Loss from operations	(12,140)	(7,508)	(30,938)	(21,385)
Interest income	1	3	4	91
Interest expense	(9)	(17)	(39)	(42)
Australian research and development incentives	1,269	228	1,584	343
Foreign currency gain (loss)	(260)	237	(410)	189
Net loss	(11,139)	(7,057)	(29,799)	(20,804)
Dividend attributable to down round feature of warrants	-	-	-	(303)
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	$ (11,139)	$ (7,057)	$ (29,799)	$ (30,878)
Net loss per share				
Basic & diluted	$ (0.14)	$ (0.09)	$ (0.39)	$ (0.58)
Weighted average common shares outstanding				
Basic & diluted	78,218,774	76,321,644	76,631,172	53,548,902

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 124,771	$ 52,071
Research and development incentive receivable	59	73
Prepaid expenses and other current assets	271	130
Total current assets	125,101	52,274
Property and equipment, net	43	65
Right of use assets, net	311	528
Research and development incentive receivable, net of current portion	1,508	-
Deferred tax assets	169	179
Deferred costs	34	345
Deposits	914	980
Total assets	$ 128,080	$ 54,371
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,966	$ 2,717
Accrued expenses	2,597	2,747
Deferred revenue - current portion	375	1,500
Lease liability - current portion	323	408
Total current liabilities	11,261	7,372
Non current liabilities:		
Restricted stock liability	-	204
Lease liability, net of current portion	-	144
Total liabilities	11,261	7,720
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 87,836,818 and 59,657,742 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	88	60
Additional paid-in capital	369,761	270,155
Accumulated other comprehensive loss	(246)	(579)
Accumulated deficit	(252,784)	(222,985)
Total stockholders’ equity	116,819	46,651
Total liabilities and stockholders' equity	$ 128,080	$ 54,371

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

	(Unaudited) Three Months Ended September 30		(Unaudited) Nine Months Ended September 30	
	2021	**2020**	**2021**	**2020**
Cash used in operating activities	$ (8,102)	$ (6,592)	$ (24,441)	$ (19,969)
Cash provided by investing activities	-	-	-	25
Cash provided by (used in) financing activities	97,262	(385)	97,280	73,997
Effect of exchange rate changes on cash and cash equivalents	(123)	65	(139)	31
Net increase (decrease) in cash and cash equivalents	89,037	(6,912)	72,700	54,084
Cash and cash equivalents at beginning of period	35,734	64,887	52,071	3,891
Cash and cash equivalents at end of period	$ 124,771	$ 57,975	$ 124,771	$ 57,975