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 14, 2022**

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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ 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 November 14, 2022, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2022. 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.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated November 14, 2022 (Quarterly Financial Results)
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 14, 2022

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

Exhibit 99.1

Leap Therapeutics Reports Third Quarter 2022 Financial Results

CAMBRIDGE, Mass., November 14, 2022 – 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, 2022.

Leap Highlights:

- Presented clinical data from Part A of the DisTinGuish study of DKN-01 plus BeiGene's tislelizumab in gastroesophageal adenocarcinoma (GEA) cancer patients, and the Phase 2 WAKING study of DKN-01 plus Tecentriq® in oesophagogastric adenocarcinoma (OGA), at the European Society for Medical Oncology (ESMO) Congress

- Presented clinical data from Part B of the DisTinGuish study of DKN-01 plus tislelizumab in GEA cancer patients whose tumors express high levels of DKK1 (DKK1-high), and preclinical data supporting further evaluation of DNK-01 in colorectal cancer (CRC), at the Society for Immunotherapy of Cancer (SITC) Annual Meeting

- Enrolled first patient into Part C of the DisTinGuish study, the randomized controlled trial of DKN-01 plus tislelizumab and chemotherapy in first-line G/GEJ patients

- Enrolled first patient into the Phase 2 DeFianCe study of DKN-01 in second-line CRC patients

"This past quarter saw incredible progress across our DKN-01 program as we continue to focus on execution in our clinical, preclinical, biomarker, and manufacturing activities, and advance into the next stages of development," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "Results from Parts A and B of the DisTinGuish trial have been compelling with updated data presented at both ESMO and SITC. We were also delighted to announce the enrollment of the first patients into both Part C of the DisTinGuish gastric cancer study and the newly-initiated DeFianCe colorectal cancer trial, as we explore the broad therapeutic potential of DKN-01."

DKN-01 Development Update

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 natural killer (NK) cell ligands on tumor cells.

- ***Updated Clinical Data from Part A of DisTinGuish Study of DKN-01 Plus Tislelizumab in First-Line Patients with Advanced GEA at the ESMO Congress.*** The DisTinGuish study (NCT04363801) is a Phase 2 study of DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy in patients with inoperable, locally advanced GEA.

    - Overall median progression-free survival (PFS) was 11.3 months, exceeding benchmark results in unselected patients and in all four important biomarker-directed subgroups (DKK1-high, DKK1-low, PD-L1-low, and PD-L-1-high).

    - Median overall survival was not yet reached.

    - Overall response rate (ORR) was high and durable in unselected and aggressive subgroups (DKK1-high and PD-L1-low); 68% ORR in modified intent-to-treat (mITT) population overall (1 complete response, 14 partial responses).

    - DKN-01 and tislelizumab plus CAPOX was well tolerated in first-line treatment for advanced GEA patients, with a safety profile consistent with previous reports.

- ***New Clinical Data from WAKING Study of DKN-01 Plus Tecentriq® at the ESMO Congress.*** The WaKING study (NCT04166721) is an investigator-sponsored study of DKN-01 in combination with atezolizumab, Roche's anti-PD-L1 antibody, in patients with microsatellite stable esophago gastric cancer who have progressed following chemotherapy. This study is being sponsored by The Royal Marsden Hospital in the United Kingdom and being funded by Roche as part of its imCORE network.

- ***Updated Data from Part B of DisTinGuish Study of DKN-01 Plus Tislelizumab in Second-Line Patients with Advanced GEA Cancer Whose Tumors Exress High Levels of DKK1-High at the SITC Annual Meeting.***

    - DKN-01 and tislelizumab were well tolerated at both 300mg and 600mg DKN-01 doses with no Grade 5 treatment-emergent AEs (TEAE) and no TEAEs leading to study drug discontinuation or dose reduction

    - In evaluable anti-PD-1/PD-L1 naïve mITT population (n=43), 27% ORR and 43% disease control rate (DCR), exceeding the benchmark studies for anti-PD-1 monotherapy

        - In DKK1-high/PD-L1-high CPS ≥ 10 patients: 55% ORR, 73% DCR, and 7.7 months PFS

        - In DKK1-high/PD-L1-negative CPS < 1 patients: 27% ORR

- ***New Preclinical Data in Colorectal Cancer (CRC) Models at the SITC Annual Meeting***.

    - DKN-01 additive activity with 5-fluorouracil (5FU) and can overcome 5FU-resistance in two xenograft models, resulting in tumor regressions. 5FU-resistant models are reflective of a second-line CRC population currently being recruited in the DeFianCe study.

    - Treatment with DKN-01 as monotherapy or in combination with anti-PD-1 resulted in tumor regression in a CT26 synergenic CRC model.

- ***Leap Announced First Patient Enrolled in Part C of Phase 2 DisTinGuish Study of DKN-01 in Combination with Tislelizumab and Chemotherapy Compared to a Tislelizumab and Chemotherapy Control Arm, in Patients with G/GEJ.*** The DisTinGuish study (NCT04363801) is a Phase 2 study of DKN-01 in combination with tislelizumab and standard of care (SOC) chemotherapy in patients with inoperable, locally advanced, G/GEJ adenocarcinoma. Part C of the DisTinGuish study will enroll approximately 160 first-line, HER2-negative patients who have had no prior therapy for unresectable locally advanced or metastatic G/GEJ adenocarcinoma.

- ***Leap Announced First Patient Enrolled in DeFianCe Study of DKN-01 in Combination with Standard of Care Bevacizumab and in Chemotherapy in Second-Line Patients for the Treatment of CRC.*** The DeFianCe study (NCT05480306) is a Phase 2 study of DKN-01 in combination with bevacizumab and SOC chemotherapy in patients with advanced CRC who have received one prior systemic therapy. The study is designed with an initial 20 patient cohort and to then expand into a 130 patient randomized controlled trial against bevacizumab and SOC chemotherapy.

Selected Third Quarter 2022 Financial Results

Net Loss was $15.1 million for the third quarter 2022, compared to $11.1 million for the three months ended September 30, 2021.

Research and development expenses were $12.1 million for the three months ended September 30, 2022, compared to $10.1 million for the three months ended September 30, 2021. The increase of $2.0 million in research and development expenses was due to an increase of $1.4 million in clinical trial costs due to patient enrollment and the duration of patients on study, an increase of $0.4 million in payroll and other related expenses due to increased headcount, and an increase of $0.2 million in stock-based compensation expense.

General and administrative expenses were $3.2 million for the three months ended September 30, 2022, compared to $2.4 million for the three months ended September 30, 2021. The increase of $0.8 million in general and administrative expenses were due to an increase of $0.5 million in professional fees due to higher recruiting costs and an increase of $0.2 million in payroll and other related expenses due to an increase in headcount.

Cash and cash equivalents totaled $78.3 million at September 30, 2022. Additionally, short-term research and development incentive receivable totaled $1.3 million.

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, colorectal, and gynecologic 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 clinical studies, potential for the receipt of future option exercise, milestone, or royalty payments from BeiGene, financial runway, 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 the ongoing COVID-19 related issues, global conflict or supply chain related issues; unstable global market and economic conditions; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to maintain compliance with the listing requirements of the Nasdaq Global Market; 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, 2021, as filed with the SEC on March 11, 2022 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.

CONTACT:

Douglas E. Onsi
President & Chief Executive Officer
Leap Therapeutics, Inc.
617-714-0360
donsi@leaptx.com

Matthew DeYoung
Investor Relations
Argot Partners
212-600-1902
leap@argotpartners.com

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,	
	2022	**2021**	**2022**	**2021**
License revenue	$ -	$ 375	$ -	$ 1,125
Operating expenses:				
Research and development	12,102	10,077	33,931	24,090
General and administrative	3,186	2,438	8,889	7,973
Total operating expenses	15,288	12,515	42,820	32,063
Loss from operations	(15,288)	(12,140)	(42,820)	(30,938)
Interest income	360	1	404	4
Interest expense	(11)	(9)	(49)	(39)
Australian research and development incentives	652	1,269	1,276	1,584
Foreign currency loss	(807)	(260)	(1,305)	(410)
Net loss attributable to common stockholders	$ (15,094)	$ (11,139)	$ (42,494)	$ (29,799)
Net loss per share				
Basic & diluted	$ (0.13)	$ (0.14)	$ (0.38)	$ (0.39)
Weighted average common shares outstanding				
Basic & diluted	113,239,092	78,218,774	113,239,092	76,631,172

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 78,308	$ 114,916
Research and development incentive receivable	1,256	1,189
Prepaid expenses and other current assets	374	769
Total current assets	79,938	116,874
Property and equipment, net	24	36
Right of use assets, net	767	459
Deferred tax assets	142	159
Other long term assets	45	90
Deposits	1,249	293
Total assets	$ 82,165	$ 117,911
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,276	$ 4,189
Accrued expenses	5,042	5,366
Lease liability - current portion	405	432
Total current liabilities	11,723	9,987
Non current liabilities:		
Lease liability, net of current portion	369	37
Total liabilities	12,092	10,024
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 99,021,376 and 88,318,454 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	99	88
Additional paid-in capital	375,350	371,638
Accumulated other comprehensive income (loss)	690	(267)
Accumulated deficit	(306,066)	(263,572)
Total stockholders’ equity	70,073	107,887
Total liabilities and stockholders' equity	$ 82,165	$ 117,911

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

	(Unaudited) Three Months Ended September 30		(Unaudited) Nine Months Ended September 30	
	2022	**2021**	**2022**	**2021**
Cash used in operating activities	$ (12,253)	$ (8,102)	$ (36,030)	$ (24,441)
Cash provided by (used in) financing activities	-	97,262	(210)	97,280
Effect of exchange rate changes on cash and cash equivalents	(322)	(123)	(368)	(139)
Net increase (decrease) in cash and cash equivalents	(12,575)	89,037	(36,608)	72,700
Cash and cash equivalents at beginning of period	90,883	35,734	114,916	52,071
Cash and cash equivalents at end of period	$ 78,308	$ 124,771	$ 78,308	$ 124,771