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 13, 2024**

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:

☐ 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 Capital 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 13, 2024, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2024. 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 13, 2024.
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 13, 2024

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

Exhibit 99.1

Leap Therapeutics Reports Third Quarter 2024 Financial Results

Cambridge, MA – November 13, 2024 – 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, 2024.

Leap Highlights:

- Completed enrollment in the expanded randomized controlled Part B of the Phase 2 DeFianCe study evaluating DKN-01, Leap's anti-DKK1 monoclonal antibody, in combination with standard of care bevacizumab and chemotherapy in second-line patients with advanced colorectal cancer (CRC); data expected in mid-2025

- Patient follow-up continuing in the randomized controlled Part C of the Phase 2 DisTinGuish study evaluating DKN-01 in combination with tislelizumab and chemotherapy in first-line patients with advanced gastroesophageal junction (GEJ) and gastric cancer; data expected in late 2024 or early 2025

- Initiated development of FL-501, Leap's anti-GDF-15 monoclonal antibody

"We have made significant progress advancing our pipeline this quarter, including the completion of enrollment in the expanded Part B of the Phase 2 DeFianCe study of DKN-01 in patients with advanced colorectal cancer," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We look forward to sharing initial randomized controlled data from the DisTinGuish study and the DeFianCe study in the coming months. In addition, based on positive preclinical data, we are enthusiastically moving FL-501 into development. With a strong cash position that is expected to fund operations into Q2 2026, Leap is well positioned for continued success and long-term growth to deliver personalized medicines to patients fighting against cancer."

DKN-01 Development Update

- ***Enrollment completed in the expanded randomized controlled Part B of the DeFianCe study evaluating DKN-01 in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced CRC.*** Part B of the DeFianCe study (NCT05480306) is a Phase 2, randomized, controlled, open-label study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy. Part B of the study enrolled 188 patients. The Company expects to report initial data in mid-2025.

- ***Patient follow-up continuing in the randomized controlled Part C of the DisTinGuish study evaluating DKN-01 in combination with tislelizumab and chemotherapy in patients with GEJ and gastric cancer, with initial data expected in late 2024 or early 2025***. Part C of the DisTinGuish study (NCT0436380) is a Phase 2, randomized, controlled, open-label study of DKN-01 in combination with tislelizumab and chemotherapy in first-line, HER-2 negative patients with GEJ and gastric cancer. Part C of the study enrolled 170 patients. The Company expects to report initial data in late 2024 or early 2025.

Pipeline Update:

- ***Advancing FL-501 into development as a potential best-in-class anti-GDF-15 antibody with promising preclinical data.*** FL-501 is a potential best-in-class monoclonal antibody designed to neutralize GDF-15 to treat patients with cachexia and other GDF-15-driven diseases. FL-501 may also enhance the activity of the immune system in the tumor micro-environment. FL-501 was engineered for higher target affinity and a longer plasma half-life compared to competing therapies. In preclinical cachexia models, FL-501 increased body weight and restored muscle mass.

Selected Third Quarter 2024 Financial Results

Net Loss was $18.2 million for the third quarter 2024, compared to $13.7 million for the same period in 2023. The increase was primarily due to an increase in research and development expenses.

Research and development expenses were $14.9 million for the third quarter 2024, compared to $11.5 million for the same period in 2023. The increase of $3.4 million was primarily due to an increase of $1.7 million in manufacturing costs related to clinical trial material and manufacturing campaigns, and an increase of $0.8 million in clinical trial costs due to patient enrollment, the duration of patients on study, the enhancement of correlative studies, increase in site activity associated with Part C of the DisTinGuish study, and the expansion of the size of Part B of the DeFianCe study. There was also an increase of $0.5 million in consulting fees associated with research and development activities and an increase of $0.4 million in payroll and other related expenses due to an increase in headcount of our research and development full-time employees.

General and administrative expenses were $2.9 million for the third quarter 2024, compared to $3.3 million for the same period in 2023. The decrease of $0.4 million in general and administrative expenses during the three months ended September 30, 2024 as compared to the same period in 2023, was due to a $0.4 million decrease in professional fees.

Cash and cash equivalents totaled $62.8 million at September 30, 2024.

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 being developed in patients with esophagogastric, colorectal, and gynecological cancers. Leap’s pipeline also includes FL-501, a humanized monoclonal antibody targeting the growth and differentiation factor 15 (GDF-15) protein, in preclinical development. 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 the federal securities laws. Such statements are based upon current plans, estimates and expectations of the management of Leap that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements.

All statements, other than historical facts, including statements regarding the potential safety, efficacy, and regulatory and clinical progress of Leap's product candidates; the anticipated timing for initiation or completion of clinical trials and release of clinical trial data and the expectations surrounding the outcomes thereof; Leap's future clinical or preclinical product development plans for any of Leap's product candidates; Leap's estimations of projected cash runway; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from Leap's plans, estimates or expectations could include, but are not limited to: (i) Leap's ability to successfully execute its clinical trials and the timing of enrollment in and cost of such clinical trials; (ii) the results of Leap's clinical trials and pre-clinical studies; (iii) Leap's ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs and to maintain its ongoing collaborations with BeiGene and Adimab; (iv) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; and (v) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap's traded securities. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Leap may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Leap's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Leap, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Leap's views as of any date subsequent to the date hereof.

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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,		(Unaudited) Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 14,915	$ 11,503	$ 44,099	$ 61,549
General and administrative	2,940	3,330	9,833	10,672
Total operating expenses	17,855	14,833	53,932	72,221
Loss from operations	(17,855)	(14,833)	(53,932)	(72,221)
Interest income	894	1,084	2,534	3,089
Australian research and development incentives	(499)	554	-	1,124
Foreign currency loss	(8)	(501)	(18)	(953)
Change in fair value of Series X preferred stock warrant liability	-	-	-	12
Loss before income taxes	(17,468)	(13,696)	(51,416)	(68,949)
Provision for income taxes	(708)	-	(708)	-
Net loss	(18,176)	(13,696)	(52,124)	(68,949)
Dividend attributable to down round feature of warrants	-	-	(234)	-
Net loss attributable to common stockholders	$ (18,176)	$ (13,696)	$ (52,358)	$ (68,949)
Net loss per share				
Basic & diluted	$ (0.44)	$ (0.51)	$ (1.44)	$ (3.78)
Weighted average common shares outstanding				
Basic & diluted	41,209,639	26,987,182	36,307,890	18,240,455

Leap Therapeutics, Inc
Consolidated Balance Sheet

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 62,823	$ 70,643
Research and development incentive receivable	780	771
Prepaid expenses and other current assets	209	183
Total current assets	63,812	71,597
Property and equipment, net	-	5
Right of use assets, net	370	257
Deposits	865	966
Total assets	$ 65,047	$ 72,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,946	$ 6,465
Accrued expenses	9,049	5,957
Income tax payable	722	-
Lease liability - current portion	376	262
Total current liabilities	16,093	12,684
Total liabilities	16,093	12,684
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 240,000,000 shares authorized; 38,264,464 and 25,565,414 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	38	26
Additional paid-in capital	500,850	459,591
Accumulated other comprehensive income	6	106
Accumulated deficit	(451,940)	(399,582)
Total stockholders’ equity	48,954	60,141
Total liabilities and stockholders' equity	$ 65,047	$ 72,825

Leap Therapeutics, Inc
Consolidated Statement of Cash Flows

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

	(Unaudited) Three Months Ended September 30		(Unaudited) Nine Months Ended September 30	
	2024	**2023**	**2024**	**2023**
Cash used in operating activities	$ (15,600)	$ (10,488)	$ (44,787)	$ (33,373)
Cash provided by investing activities	-	-	-	48,969
Cash provided by (used in) financing activities	(66)	(1)	37,080	(30)
Effect of exchange rate changes on cash and cash equivalents	10	(183)	(113)	(323)
Net increase (decrease) in cash and cash equivalents	(15,656)	(10,672)	(7,820)	15,243
Cash and cash equivalents at beginning of period	78,479	91,415	70,643	65,500
Cash and cash equivalents at end of period	$ 62,823	$ 80,743	$ 62,823	$ 80,743