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 14, 2023**

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:

☐ 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 August 14, 2023, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2023. 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 14, 2023.
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: August 14, 2023

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

Exhibit 99.1

Leap Therapeutics Reports Second Quarter 2023 Financial Results

Cambridge, MA – August 14, 2023 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today reported financial results for second quarter ended June 30, 2023.

Leap Highlights:

- Announced that initial data from Part A of the Phase 2 DeFianCe study of DKN-01 in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer (CRC) exceeded a twenty percent (20%) overall response rate (ORR) with a high disease control rate, leading to the initiation of the 130-patient randomized controlled Part B of the study

- Presented new long-term follow-up data from Part A of the Phase 2 DisTinGuish study of DKN-01 plus tislelizumab and chemotherapy demonstrating 19.5 months median overall survival (OS) in first-line patients with advanced gastroesophageal adenocarcinoma (GEA) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

"The Company made important progress on our DKN-01 program during the second quarter. Based on Part A of the DeFianCe study exceeding our threshold of a 20% ORR, all of which are now confirmed responses, we initiated Part B, our second randomized controlled trial," said Douglas E. Onsi, President and Chief Executive Officer of Leap. "We also presented new long-term follow-up data from Part A of the DisTinGuish study at ASCO, demonstrating 19.5 months median overall survival which exceeds current benchmarks. Additionally, enrollment continues to be strong in the 160 patient randomized controlled Part C of the DisTinGuish study, and we expect to complete enrollment in the fourth quarter of this year."

DKN-01 Development Update

- ***Announced initial results from Part A of the DeFianCe Study of DKN-01 for the treatment of colorectal cancer patients and initiation of the randomized controlled Part B of the study.*** The DeFianCe study (NCT05480306) is a Phase 2, randomized, open-label, multicenter 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 for advanced disease. The study began with an initial Part A cohort that enrolled 33 patients, including significant numbers of patients who had early progression on first-line therapy, previous exposure to bevacizumab, tumors with Ras mutations, or liver metastases. Initial results indicated an ORR above twenty percent (20%) with a high disease control rate, which exceeds the benchmarks expected for this population. The study has expanded into a 130-patient Part B randomized controlled trial. The primary endpoint of the randomized study is progression free survival. Secondary objectives include overall response rate, duration of response, and overall survival. Leap expects to be able to enroll Part B in approximately 12 months.

- ***Presented updated data from Part A of the DisTinGuish Study of DKN-01 plus tislelizumab and chemotherapy in gastric cancer patients at the 2023 ASCO Annual Meeting.*** The Company presented new long-term follow-up data in first-line patients with advanced GEA from Part A of the DisTinGuish study (NCT0436380), a Phase 2 clinical trial evaluating Leap's anti-Dickkopf-1 (DKK1) antibody, DKN-01, in combination with tislelizumab and chemotherapy. Highlights from the data include:

    - At two years follow up, DKN-01 plus tislelizumab and chemotherapy demonstrated an ORR of 73% in the modified intent-to-treat (mITT) population and 86% in the PD-L1 low-subgroup

- Median OS of 19.5 months and median progression-free survival (PFS) of 11.3 months exceeds benchmark results in the overall population

- Combination was well tolerated with manageable toxicity, with most adverse events related to DKN-01 being low-grade

Selected Second Quarter 2023 Financial Results

Net Loss was $13.4 million for the second quarter 2023, compared to $17.0 million for the same period in 2022. The decrease was primarily due to decreased research and development expenses and increased interest income.

Research and development expenses were $11.1 million for the second quarter 2023, compared to $14.0 million for the same period in 2022. The decrease in research and development expenses was primarily due to a decrease of $4.5 million in manufacturing costs related to clinical trial material, partially offset by an increase of $0.8 million in clinical trial costs and an increase of $0.8 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 $3.6 million for the second quarter 2023, compared to $2.9 million for the same period in 2022. The increase in general and administrative expenses was primarily due to an increase of $0.6 million in professional fees due to higher finance and legal costs associated with our business development activities and a $0.3 million increase in payroll and other related expenses due to an increase in headcount of our general and administrative full-time employees, partially offset by a decrease of $0.2 million in insurance costs.

Interest income was $1.2 million for the second quarter 2023, compared to an immaterial amount for the same period in 2022. The increase reflects the increased interest rate environment applicable to the Company's cash balance.

Cash and cash equivalents totaled $91.4 million at June 30, 2023. Research and development incentive receivables totaled $2.6 million at June 30, 2023.

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, gynecologic, and colorectal cancers. FL-301, is a humanized monoclonal antibody targeting Claudin18.2, being developed in patients with gastric and pancreatic cancer. Leap also has preclinical antibody programs targeting Claudin18.2/CD137 and GDF15. 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 outcomes of patients in Part A of the DeFianCe study, the anticipated timing for initiation of or success of enrollment in Part B of the DeFianCe study, Part C of the DisTinGuish study, and other clinical trials and release of clinical data, and any outcomes of such trials; the potential, safety, efficacy, and regulatory and clinical progress of Leap's product candidates; our future preclinical and clinical development plans in connection with our programs; the ability to enter into a new strategic partnership for DKN-01 or any of Leap's other programs; the continuation over time of the clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the ability of NovaRock Biotherapeutics to conduct the FL-301 clinical trial in China; 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; (iv) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (v) the effect of inflation and currency rate fluctuations on Leap's future expenses; (vi) fluctuations in the market price of Leap's traded securities; (vii) that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by global conflict or supply chain related issues; and (viii) whether Leap's cash resources will be sufficient to fund Leap's continuing operations and planned studies. 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 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.
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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 11,104	$ 14,045	$ 50,046	$ 21,829
General and administrative	3,558	2,855	7,342	5,703
Total operating expenses	14,662	16,900	57,388	27,532
Loss from operations	(14,662)	(16,900)	(57,388)	(27,532)
Interest income	1,157	39	2,005	44
Interest expense	-	(17)	-	(38)
Australian research and development incentives	298	587	570	624
Foreign currency loss	(145)	(733)	(452)	(498)
Change in fair value of Series X preferred stock warrant liability	(38)	-	12	-
Net loss attributable to common stockholders	$ (13,390)	$ (17,024)	$ (55,253)	$ (27,400)
Net loss per share				
Basic & diluted	$ (0.91)	$ (1.50)	$ (4.01)	$ (2.42)
Weighted average common shares outstanding				
Basic & diluted	14,710,375	11,324,893	13,794,605	11,324,893

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

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 91,415	$ 65,500
Research and development incentive receivable	2,046	2,099
Prepaid expenses and other current assets	419	351
Total current assets	93,880	67,950
Property and equipment, net	13	20
Right of use assets, net	467	669
Research and development incentive receivable, net of current portion	563	-
Deferred costs	-	576
Other long term assets	-	30
Deposits	934	1,108
Total assets	$ 95,857	$ 70,353
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,500	$ 5,657
Accrued expenses	4,826	5,152
Lease liability - current portion	436	416
Total current liabilities	11,762	11,225
Non current liabilities:		
Lease liability, net of current portion	38	262
Total liabilities	11,800	11,487
Stockholders' equity:		
Common stock, $0.001 par value; 240,000,000 shares authorized; 25,565,414 and 9,902,137 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	26	10
Additional paid-in capital	457,038	376,896
Accumulated other comprehensive income	414	128
Accumulated deficit	(373,421)	(318,168)
Total stockholders’ equity	84,057	58,866
Total liabilities and stockholders' equity	$ 95,857	$ 70,353

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

	(Unaudited) Three Months Ended June 30		(Unaudited) Six Months Ended June 30	
	2023	**2022**	**2023**	**2022**
Cash used in operating activities	$ (10,185)	$ (12,259)	$ (22,885)	$ (23,777)
Cash provided by (used in) investing activities	(348)	-	48,969	-
Cash used in financing activities	-	-	(29)	(210)
Effect of exchange rate changes on cash and cash equivalents	(90)	(78)	(140)	(46)
Net increase (decrease) in cash and cash equivalents	(10,623)	(12,337)	25,915	(24,033)
Cash and cash equivalents at beginning of period	102,038	103,220	65,500	114,916
Cash and cash equivalents at end of period	$ 91,415	$ 90,883	$ 91,415	$ 90,883