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): **January 17, 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 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 8.01. Other Events

On January 17, 2023, Leap Therapeutics, Inc. (the "Company") and Flame Biosciences, Inc. ("Flame") issued a joint press release announcing that the Company had acquired Flame, pursuant to an Agreement and Plan of Merger, dated January 17, 2023, by and among the Company, Fire Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Flame Biosciences LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, Flame, and Shareholder Representative Services, LLC, solely in its capacity as Stockholder Representative.

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference; provided, however that information on or connected to our website referenced in the Company's press release is expressly not incorporated by reference into or intended to be filed as a part of this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report on Form 8-K 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 the Company 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 expected benefits of the merger, including estimations of anticipated cost savings and projected cash runway; the competitive ability and position of the combined company; the sufficiency of the combined company's cash, cash equivalents and short-term investments to fund operations; future product development plans; stockholder approval of the conversion rights of the Series X Non-Voting Convertible Preferred Stock; the potential, safety, efficacy, and regulatory and clinical progress of the combined company's product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and the expectations surrounding potential regulatory submissions, approvals and timing thereof; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from the Company's plans, estimates or expectations could include, but are not limited to: (i) the Company's ability to successfully integrate the Flame operations and realize the anticipated benefits of the acquisition of Flame; (ii) whether the Company's stockholders approve the conversion of the Series X Non-Voting Convertible Preferred Stock; (iii) whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the newly acquired Flame operations, including the liabilities of Flame incurred in connection with the completion of the merger; (iv) whether Flame's products will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; (v) whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (vi) the impact of legislative, regulatory, economic, competitive and technological changes; (vii) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of the Company's traded securities; (viii) 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, global conflict or supply chain related issues; (ix) the size and growth potential of the markets for the Company's drug product candidates; and (x) the Company's ability to comply with the continued listing requirements of the Nasdaq Global Market. 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. The Company 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 the Company'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 the Company, 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 the Company's views as of any date subsequent to the date hereof.

Additional Information

The Company plans to file with the SEC and mail or otherwise provide to its stockholders a proxy statement regarding the conversion of the Series X Non-Voting Convertible Preferred Stock (as amended or supplemented from time to time, the "Proxy Statement"). INVESTORS AND STOCKHOLDERS ARE URGED TO READ ANY SUCH PROXY STATEMENT IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY THE COMPANY WITH THE SEC OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Stockholders will be able to obtain a free copy of the Proxy Statement and other documents containing important information about the Company, once such documents are filed with the SEC, from the SEC's website at www.sec.gov. The Company makes available free of charge at www.leaptx.com (in the "Investors" section), copies of materials they file with, or furnish to, the SEC.

Participants in the Solicitation

The Company, its directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the merger. Securityholders may obtain information regarding the names, affiliations and interests of the Company's directors and executive officers in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the SEC on March 11, 2022, and its definitive proxy statement for the 2022 annual meeting of stockholders, which was filed with the SEC on April 28, 2022. Additional information regarding the interests of such individuals in the merger will be included in the Proxy Statement relating to the merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov and the Company's website at www.leaptx.com.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Joint Press Release dated January 17, 2023.
104	Cover Page Interactive Data File.

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: January 17, 2023

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

Exhibit 99.1

Leap Therapeutics Acquires Flame Biosciences

Adds FL-301, clinical stage anti-Claudin18.2 antibody,
and two preclinical antibody programs to Leap's pipeline

Combined cash balance of approximately $115 million
enhances runway to mid-2025, fully-funding advancement of DKN-01 and FL-301

Leap to host conference call at 9:00 a.m. ET today

Cambridge, MA – January 17, 2023 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, and Flame Biosciences, Inc., a privately-held biotechnology company, today announced that the companies have entered into a definitive merger agreement pursuant to which Leap has acquired Flame and its assets, including FL-301, its clinical stage anti-Claudin18.2 monoclonal antibody, FL-302, its preclinical anti-Claudin18.2/CD137 bispecific monoclonal antibody, FL-501, its preclinical anti-GDF15 monoclonal antibody, and net cash of approximately $50 million as of December 31, 2022.

The combined company will continue to trade on Nasdaq under the ticker symbol "LPTX," will be led by Leap's existing management team, and will also remain focused on advancing DKN-01, Leap's anti-DKK1 monoclonal antibody, in Phase 2 clinical trials in gastric cancer, endometrial cancer, and colorectal cancer patients. The total cash balance of the combined company as of December 31, 2022 was approximately $115 million, expected to be sufficient to fund Leap's planned operating expenses and development plans for DKN-01, FL-301, and the preclinical programs to mid-2025.

"This is a transformative transaction for Leap. Acquiring FL-301 is a perfect fit with our vision of developing novel biomarker-targeted therapies for cancer patients, that is represented by our DKN-01 program. We believe that DKK1 and Claudin18.2 will become important patient selection biomarkers in gastric cancer, alongside HER-2 and PD-L1 expression, with the potential for delivering personalized medicines to patients who currently have poor survival outcomes," said Douglas E. Onsi, President & CEO of Leap. "The additional pipeline strength is further enhanced by additional financial strength. With the combined company resources, Leap will focus on executing on the randomized controlled trial for DKN-01 in combination with BeiGene's tislelizumab and chemotherapy in first-line gastric cancer patients, the new study of DKN-01 in colorectal cancer patients, and the investigator-sponsored trial of DKN-01 in combination with Merck's pembrolizumab in endometrial cancer patients."

"Flame conducted an extensive strategic process. It was clear that the Leap development team, with its expertise in developing DKN-01, was the ideal partner for FL-301, our preclinical assets, and the Flame shareholders," said Patricia Martin, the Co-Chief Executive Officer of Flame.

"We share Leap's commitment to developing novel, biomarker-targeted therapies in cancers where there is a significant unmet need and look forward to joining them to bring DKN-01 and FL-301 to patients around the world," said Christian Richard, Head of Public Research of Samsara BioCapital.

Transaction Details

In the merger, Leap will issue approximately 19,794,373 shares of its common stock and approximately 136,833 shares of a newly designated Series X non-voting convertible preferred stock to Flame stockholders. Upon approval by the stockholders of Leap, each share of the Series X non-voting convertible preferred stock will be automatically converted into 1,000 shares of common stock. Flame's institutional shareholders include Rock Springs Capital, funds and accounts advised by T. Rowe Price Associates, Inc., Janus Henderson Investors, Samsara BioCapital, Adage Capital Management LP, Cormorant Asset Management LP, Surveyor Capital (a Citadel company), Terra Magnum Capital Partners, Logos Capital, and Acuta Capital Partners. In addition, Leap will pay the Flame shareholders 80% of the after-tax net proceeds, if any, from certain post-merger transactions to out-license or sell FL-101 or FL-103, Flame's anti-IL-1b antibodies.

Leap plans to hold a special meeting of stockholders to approve the conversion of the Series X non-voting convertible preferred stock into shares of common stock and related matters. The number of shares of Leap common stock issuable upon conversion of the Series X non-voting convertible preferred stock are subject to adjustment in the event of any corporate transactions or reverse stock split that may be effectuated by Leap. HealthCare Ventures, which holds 6,763,210 shares or 6.83% of Leap's outstanding common stock, has signed a support agreement to vote in favor of the proposals to be presented at the shareholder meeting. Assuming the approval by the Leap stockholders, on an as-converted basis, the Flame shareholders will in the aggregate own 58% of the outstanding shares including pre-funded warrants of Leap, and 47.4% on a fully-diluted basis assuming the exercise of all outstanding warrants, options and restricted stock units exercisable for Leap common stock and shares eligible for grant under Leap's equity incentive plans.

The securities sold in the merger have not been registered under the Securities Act of 1933, as amended ("Securities Act"), or any state or other applicable jurisdiction's securities laws, and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions' securities laws. Leap has agreed to file a registration statement with the U.S. Securities and Exchange Commission (the "SEC") to register the resale by the Flame stockholders of the shares of Leap common stock to be issued in connection with the merger.

Raymond James acted as exclusive financial advisor to Leap on the transaction.

Management and Organization

Effective as of the closing of the transactions, the Leap leadership team will continue to be responsible for all executive positions of the combined company. Leap has added two members nominated by Flame to its existing eight person Board of Directors: Patricia Martin and Christian Richard.

About DKN-01

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 and has an important role in promoting tumor proliferation, metastasis, angiogenesis, and in mediating an immune suppressive tumor microenvironment through enhancing the activity of myeloid-derived suppressor cells and downregulating NK cell ligands on tumor cells. The U.S. Food and Drug Administration has granted DKN-01 Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer and Fast Track Designation in combination with tislelizumab for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high DKK1 protein, following disease progression on or after prior fluoropyrimidine- and platinum- containing chemotherapy and if appropriate, human epidermal receptor growth factor (HER2)/neu-targeted therapy.

About FL-301

FL-301 is a fully human monoclonal antibody that binds to and blocks Claudin18.2. Claudin18.2 regulates barrier properties and contributes to cell-to-cell adhesion. Expression of Claudin18.2 is very limited in normal tissue, as it is typically buried in the tight junction complex of gastric mucosal cells. In the development of cancer, however, cells lose their polarity and structure. As a result, Claudin18.2 may be exposed and accessible as a target for cancer therapy and is highly expressed on gastric cancer and pancreatic cancer cells. The U.S. Food and Drug Administration has granted FL-301 Orphan Drug Designation for the treatment of gastric and gastroesophageal junction cancer and for the treatment of pancreatic cancer. FL-301 is being developed through an exclusive license from NovaRock Biotherapeutics for territories excluding China and is currently in a Phase 1 clinical trial in cancer patients in China.

Conference Call Information

Leap's management team will host a conference call today at 9:00 a.m. Eastern Time to discuss the transaction. The live presentation of the conference call can be accessed by registering here. A replay of the event will be available for a limited time and may be access on the Investors page of Leap's website at https://investors.leaptx.com.

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. 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. 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/.

About Flame Biosciences

Flame Biosciences is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics that address major unmet needs in diseases that are linked to chronic inflammation including cancer, atherosclerotic cardiovascular disease and arthritis. Flame has been funded by Rock Springs Capital, funds and accounts advised by T. Rowe Price Associates, Inc., Cormorant Asset Management LP, Janus Henderson Investors, Surveyor Capital (a Citadel company), Samsara BioCapital, Adage Capital Management LP, Terra Magnum Capital Partners, Logos Capital and Acuta Capital Partners.

FORWARD-LOOKING STATEMENTS

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Participants in the Solicitation

Leap, its directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Leap in connection with the merger. Securityholders may obtain information regarding the names, affiliations and interests of Leap's directors and executive officers in Leap's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the SEC on March 11, 2022, and its definitive proxy statement for the 2022 annual meeting of stockholders, which was filed with the SEC on April 28, 2022. Additional information regarding the interests of such individuals in the merger will be included in the Proxy Statement relating to the merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov and Leap's website at www.leaptx.com.

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