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): July 31, 2024

Fulcrum Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38978**	**47-4839948**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
26 Landsdowne Street Cambridge, Massachusetts		**02139**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (617) 651-8851

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 per share	FULC	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 Jule 31, 2024, Fulcrum announced its financial results for the quarter ended June 30, 2024. The full text of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or 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 expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits
The following exhibit is furnished herewith:

99.1	Press Release issued July 31, 2024, announcing financial results for the quarter ended June 30, 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.

FULCRUM THERAPEUTICS, INC.

Date: July 31, 2024

By: /s/ Alex C. Sapir
Name: Alex C. Sapir
Title: President and Chief Executive Officer

Exhibit 99.1

Fulcrum Therapeutics Announces Recent Business Highlights and Financial Results for Second Quarter 2024

— On track to report topline data for Phase 3 REACH trial of losmapimod in facioscapulohumeral muscular dystrophy (FSHD) by the end of October 2024 —

— Entered into a collaboration and ex-U.S. license agreement with Sanofi for the development and commercialization of losmapimod —

— Conference call and webcast scheduled for 8:00 a.m. ET today —

CAMBRIDGE, Mass., – July 31, 2024 – Fulcrum Therapeutics, Inc.® (Fulcrum) (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases, today reported financial results for the second quarter of 2024 as well as a business update.

"We are on track to report topline results for the Phase 3 REACH trial by the end of October 2024, and as we advance towards this important inflection point, we continue to prepare for the potential NDA filing and the U.S. launch of losmapimod. In parallel, we are working with Sanofi in preparation for regulatory filings and the launch of losmapimod outside of the U.S.," said Alex C. Sapir, Fulcrum's president and chief executive officer. "Our Phase 1b PIONEER trial of pociredir, currently in development as a highly differentiated oral treatment option for sickle cell disease, continues to make progress. Our excitement for this program is based on the initial data generated in the Phase 1b trial, which suggests that pociredir has potential to raise HbF to levels that could ameliorate symptoms of the disease."

Recent Business Highlights

- REACH, the Phase 3 clinical trial evaluating losmapimod in patients with FSHD, continues to progress, and Fulcrum expects to report topline data by the end of October 2024. The trial enrolled 260 patients across sites in the United States, Canada, and Europe. There are currently no approved treatments for FSHD.
  - As of June 30, 2024, 234 patients had completed the Part A 48-week treatment phase of the clinical trial, of which 232 chose to enroll in the Part B Open Label Extension phase.
  - Fulcrum is on track to complete the activities agreed-upon with the U.S. Food and Drug Administration (FDA) to define the clinical meaningfulness of RWS, the primary endpoint of the REACH trial, at the time of reporting topline data.
  - Presented multiple abstracts at the 31st Annual FSHD Society International Research Congress held June 13-14, 2024, in Denver, Colorado, including one outlining the baseline characteristics of patients enrolled in the Phase 3 REACH trial of losmapimod. The presentations and posters are available on the publications page of the Fulcrum website here.
- Continue to make progress in the Phase 1b trial evaluating pociredir in patients with sickle cell disease (SCD). Cohort 3 of the Phase 1b trial will evaluate pociredir at the 12 mg once daily dose, followed by Cohort 4 at the 20 mg once daily dose. Each cohort is expected to enroll approximately 10 patients.
- Presented interim results of the Phase 1b trial at the European Hematology Association 2024 (EHA24) Hybrid Congress, on June 14, 2024. The presentation is available on the publications page of the Fulcrum website here.

Second Quarter 2024 Financial Results

- **Cash Position:** As of June 30, 2024, cash, cash equivalents, and marketable securities were $273.8 million, as compared to $236.2 million as of December 31, 2023. The increase in our cash position is due to the $80.0 million upfront payment received from Sanofi in the second quarter of 2024, partially offset by cash used to fund our operating activities in 2024.
- **Collaboration Revenue:** Collaboration revenue was $80.0 million for the three months ended June 30, 2024, as compared to $0.9 million for the three months ended June 30, 2023. The increase of $79.1 million was primarily due to the recognition of the $80.0 million upfront license payment received from Sanofi during the second quarter of 2024.
- **R&D Expenses:** Research and development expenses were $17.3 million for the three months ended June 30, 2024, as compared to $17.8 million for the three months ended June 30, 2023. The decrease of $0.5 million was primarily due to the reimbursement from the global development cost sharing under our collaboration with Sanofi for losmapimod, partially offset by increased costs related to the advancement of REACH.
- **G&A Expenses:** General and administrative expenses were $10.2 million for the three months ended June 30, 2024, as compared to $10.3 million for three months ended June 30, 2023. The decrease of $0.1 million was primarily due to decreased employee compensation costs.
- **Net Income (Loss):** Net income was $55.4 million for the three months ended June 30, 2024, as compared to a net loss of $23.8 million for the three months ended June 30, 2023. The net income during the quarter was primarily attributable to the upfront payment of $80.0 million from Sanofi. Excluding the potential for future milestone payments under our Sanofi collaboration, Fulcrum expects to be in a loss position for the foreseeable future, including for the year ended December 31, 2024.

Cash Runway Guidance

Based on its current operating plans, Fulcrum continues to expect that its cash, cash equivalents, and marketable securities as of June 30, 2024 will be sufficient to fund its operating requirements into 2027.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to review the second quarter 2024 financial results and recent business highlights. Individuals may register for the conference call by clicking the link here. Once registered, participants will receive dial-in details and unique PIN which will allow them to access the call. An audio webcast will be accessible through the Investor Relations section of the company's website at www.fulcrumtx.com or by clicking here. Following the live webcast, an archived replay will also be available.

About Fulcrum Therapeutics
Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases in areas of high unmet medical need. Fulcrum's two lead programs in clinical development are losmapimod, a small molecule in development for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and pociredir, a small molecule designed to increase expression of fetal hemoglobin and in development for the treatment of sickle cell disease (SCD). Fulcrum uses proprietary technology to identify drug targets that can modulate gene expression to treat the known root cause of gene mis-expression. For more information, visit www.fulcrumtx.com and follow us on Twitter/X (@FulcrumTx) and LinkedIn.

About Losmapimod
Losmapimod is a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor. Fulcrum exclusively in-licensed losmapimod from GSK following Fulcrum's discovery of the role of p38α/β inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Results reported from the Phase 2b ReDUX4 trial demonstrated slower disease progression and improved function, including positive impacts on upper extremity strength and functional measures supporting losmapimod's potential to be a transformative therapy for the treatment of FSHD. Although losmapimod had never previously been explored in muscular dystrophies, it had been evaluated in more than 3,600 subjects in clinical trials across multiple other indications with no safety signals attributed to losmapimod. Losmapimod has been granted FDA Fast Track designation and Orphan Drug Designation for the treatment of FSHD. Losmapimod is currently being evaluated in a Phase 3 multi-center randomized, double-blind, placebo-controlled, 48-week parallel-group study in people with FSHD (NCT05397470).

About FSHD
FSHD is a serious, rare, progressive, and debilitating disease for which there are no approved treatments. It is characterized by fat infiltration of skeletal muscle leading to muscular atrophy involving primarily the face, scapula and shoulders, upper arms, and abdomen. Impact on patients includes relentless and accumulating muscle and functional loss impacting their ability to perform activities of daily living, loss of upper limb function, loss of mobility and independence, and chronic pain. FSHD is one of the most common forms of muscular dystrophy and has an estimated patient population of 30,000 in the United States alone.

About Pociredir
Pociredir is an investigational oral small-molecule inhibitor of Embryonic Ectoderm Development (EED) that was discovered using Fulcrum's proprietary discovery technology. Inhibition of EED leads to potent downregulation of key fetal globin repressors, including BCL11A, thereby causing an increase in fetal hemoglobin (HbF). Pociredir is being developed for the treatment of SCD. Initial data in SCD demonstrated proof-of-concept and achieved absolute levels of HbF increases associated with potential overall patient benefit. In clinical trials conducted prior to the clinical hold, which was lifted by the FDA in August 2023, pociredir was generally well-tolerated in people with SCD with up to three months of exposure, with no serious treatment-related adverse events reported. Pociredir has been granted FDA Fast Track designation and Orphan Drug Designation for the treatment of SCD. To learn more about these trials please visit ClinicalTrials.gov.

About Sickle Cell Disease
Sickle cell disease (SCD) is a genetic disorder of the red blood cells caused by a mutation in the HBB gene. This gene encodes a protein that is a key component of hemoglobin, a protein complex whose function is to transport oxygen in the body. The result of the mutation is less efficient oxygen transport and the formation of red blood cells that have a sickle shape. These sickle shaped cells are much less flexible than healthy cells and can block blood vessels or rupture cells. People with SCD typically suffer from serious clinical consequences, which may include anemia, pain, infections, stroke, heart disease, pulmonary hypertension, kidney failure, liver disease, and reduced life expectancy.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, including express or implied statements regarding Fulcrum’s clinical trials, including timing of topline data for the Phase 3 REACH trial of losmapimod, definition of the clinical relevance of RWS and ability to complete activities in connection therewith; Fulcrum’s collaboration and license agreement with Sanofi; its ability to receive the milestone and royalty payments thereunder and achieve benefits therefrom; reinitiation of the Phase 1b trial of pociredir and number of enrollees in each cohort; and Fulcrum’s ability to deliver an FDA-approved therapy for FSHD patients; and its cash runway, among others. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Fulcrum’s ability to continue to advance its product candidates in clinical trials; initiating and enrolling clinical trials on the timeline expected or at all; obtaining and maintaining necessary approvals from the FDA and other regulatory authorities; replicating in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of losmapimod, pociredir and any other product candidates; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; managing executive and employee turnover, including integrating a new CMO; and raising the substantial additional capital needed to achieve its business objectives, among others. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Fulcrum’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties, and other important factors, in Fulcrum’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Fulcrum’s views as of the date hereof and should not be relied upon as representing Fulcrum’s views as of any date subsequent to the date hereof. Fulcrum anticipates that subsequent events and developments will cause Fulcrum’s views to change. However, while Fulcrum may elect to update these forward-looking statements at some point in the future, Fulcrum specifically disclaims any obligation to do so.

Fulcrum Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

(Unaudited)

	June 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 273,778	$ 236,221
Working capital[(1)]	267,587	228,524
Total assets	294,256	257,694
Total stockholders' equity	273,790	235,193

(1) Fulcrum defines working capital as current assets minus current liabilities.

Fulcrum Therapeutics, Inc.

Consolidated Statements of Operations

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 80,000	$ 880	$ 80,000	$ 1,175
Operating expenses:				
Research and development	17,261	17,849	37,034	34,564
General and administrative	10,247	10,323	20,308	21,843
Total operating expenses	27,508	28,172	57,342	56,407
Income (loss) from operations	52,492	(27,292)	22,658	(55,232)
Other income, net	2,917	3,509	5,881	6,670
Net income (loss)	$ 55,409	$ (23,783)	$ 28,539	$ (48,562)
Net income (loss) per share, basic	$ 0.89	$ (0.38)	$ 0.46	$ (0.80)
Net income (loss) per share, diluted	$ 0.87	$ (0.38)	$ 0.45	$ (0.80)
Weighted-average common shares outstanding, basic	62,205	61,794	62,095	60,764
Weighted-average common shares outstanding, diluted	63,587	61,794	63,684	60,764

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