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): February 27, 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 February 27, 2024, Fulcrum Therapeutics, Inc., or Fulcrum, announced its financial results for the quarter and year ended December 31, 2023. 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, 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 February 27, 2024, announcing financial results for the quarter and year ended December 31, 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 thereunto duly authorized.

FULCRUM THERAPEUTICS, INC.

Date: February 27, 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 Fourth Quarter and Full Year 2023

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

— Restart of the Phase 1b PIONEER trial of pociredir in sickle cell disease (SCD) underway —

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

CAMBRIDGE, Mass., – February 27, 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 fourth quarter and full year of 2023 as well as an update to the business.

"In 2023, we took important steps to advance our two key clinical programs which included completing enrollment for the Phase 3 REACH trial of losmapimod in FSHD and resolving the clinical hold for our Phase 1b PIONEER trial of pociredir in SCD," said Alex C. Sapir, Fulcrum's president and chief executive officer. "We are on track to report topline data for REACH in the fourth quarter of 2024, which could position losmapimod as the first approved treatment for patients with FSHD. The clinical data generated to date demonstrates losmapimod has the potential to slow progression and address the debilitating effects of this disease. Additionally, for PIONEER, we are encouraged by the level of physician engagement, and we are working diligently to activate additional trial sites and resume enrollment. We believe pociredir has the potential to shift the current standard of care and offer a differentiated, oral treatment option for patients with SCD."

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 in the fourth quarter of 2024. The trial enrolled 260 patients across sites in the United States, Canada, and Europe. There are currently no approved treatments for FSHD.
- Clinical trial sites have been activated for the Phase 1b trial evaluating pociredir in patients with 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.

Fourth Quarter and Full Year 2023 Financial Results

- **Cash Position:** As of December 31, 2023, cash, cash equivalents, and marketable securities were $236.2 million, as compared to $202.9 million as of December 31, 2022. The increase in our cash position is primarily due to net proceeds from our equity offering completed in January 2023 of $117.3 million, partially offset by our net cash used in operating activities in 2023.
- **Collaboration Revenue:** Collaboration revenue was $0.9 million for the fourth quarter of 2023 as compared to $0.7 million for the fourth quarter of 2022. The increase of $0.2 million was attributable to an increase in revenues under our collaboration agreement with MyoKardia as we completed our research services during the fourth quarter of 2023.

  Collaboration revenue was $2.8 million for the year ended December 31, 2023, as compared to $6.3 million for the year ended December 31, 2022. The decrease of $3.5 million was attributable to the completion of activities under our collaboration agreement with Acceleron, which terminated in October 2022, and due to a decrease in revenues under our collaboration agreement with MyoKardia as we completed our research services during the fourth quarter of 2023.
- **R&D Expenses:** Research and development expenses were $19.0 million for the fourth quarter of 2023 as compared to $18.6 million for the fourth quarter of 2022. The increase of $0.4 million was primarily due to increased personnel costs.

  Research and development expenses were $71.8 million for the year ended December 31, 2023 as compared to $76.8 million for the year ended December 31, 2022. The decrease of $5.0 million was primarily due to a $5.0 million obligation to GSK incurred in the second quarter of 2022 upon initiation of the REACH clinical trial.
- **G&A Expenses:** General and administrative expenses were $9.9 million for the fourth quarter of 2023 as compared to $10.1 million for the fourth quarter of 2022. The decrease of $0.2 million was primarily due to decreased professional services costs.

  General and administrative expenses were $41.7 million for each of the years ended December 31, 2023 and 2022.
- **Net Loss:** Net loss was $24.8 million for the fourth quarter of 2023 as compared to $26.1 million for the fourth quarter of 2022.

  Net loss was $97.3 million for the year ended December 31, 2023 as compared to $109.9 million for the year ended December 31, 2022.

Cash Runway Guidance

Fulcrum continues to expect that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its operating requirements into 2026.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to review the fourth quarter and full year 2023 recent business highlights and financial results. Individuals may register for the conference call by clicking the link here . Once registered participants will receive dial-in details and a unique pin which will allow them to access the call. The webcast will be accessible through the Investor Relations section of Fulcrum's website at www.fulcrumtx.com or by clicking here. Following the live webcast, an archived replay will also be available for 90 days.

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 (formerly known as FTX-6058), 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 U.S. Food and Drug Administration (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 16,000 to 38,000 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 U.S. 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; reinitiation of the Phase 1b trial of pociredir and enrollees in each cohort; Fulcrum’s ability to deliver an FDA-approved therapy for FSHD patients; the potential for pociredir to shift the standard of care; and Fulcrum’s 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 CEO and CFO; 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)

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 236,221	$ 202,921
Working capital[(1)]	228,524	190,794
Total assets	257,694	226,685
Total stockholders' equity	235,193	198,942

(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 December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	$ 871	$ 685	$ 2,805	$ 6,342
Operating expenses:				
Research and development	18,999	18,566	71,801	76,782
General and administrative	9,864	10,130	41,668	41,694
Restructuring expenses	—	(38)	—	427
Total operating expenses	28,863	28,658	113,469	118,903
Loss from operations	(27,992)	(27,973)	(110,664)	(112,561)
Other income, net	3,236	1,838	13,329	2,690
Net loss	$ (24,756)	$ (26,135)	$ (97,335)	$ (109,871)
Net loss per share, basic and diluted	$ (0.40)	$ (0.50)	$ (1.59)	$ (2.44)
Weighted-average common shares outstanding, basic and diluted	61,871	52,077	61,310	44,991

Contact:

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