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

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** **(Address of principal executive offices)**		**02139** **(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 November 13, 2024, Fulcrum announced its financial results for the quarter ended September 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 November 13, 2024, announcing financial results for the quarter ended September 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: November 13, 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 Third Quarter 2024

— Patient enrollment and site activation progressing in Phase 1b PIONEER trial of pociredir in sickle cell disease (SCD) —

— Ended the third quarter of 2024 with $257.2 million in cash, cash equivalents, and marketable securities; cash runway into at least 2027 —

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

CAMBRIDGE, Mass., – November 13, 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 third quarter of 2024 as well as a business update.

"In the third quarter, we made progress enrolling patients and activating new sites in the Phase 1b PIONEER trial of pociredir in sickle cell disease and advancing our preclinical pipeline.," said Alex C. Sapir, Fulcrum's president and chief executive officer. "The need for effective therapeutic options for patients with sickle cell disease has become even more urgent due to the recent withdrawal of OXBRYTA® globally. Based on the initial data generated in the Phase 1b trial, we believe that pociredir has the potential to increase fetal hemoglobin to levels that could ameliorate symptoms of sickle cell disease. While we were disappointed with the results of the Phase 3 REACH trial announced in September, we remain committed to improving the lives of patients with genetically defined diseases in areas of high unmet medical need like sickle cell disease. We are focused on progressing the development of pociredir as expeditiously as possible and remain on track to provide data from the PIONEER trial in 2025."

Recent Business Highlights

- Patient enrollment and site activations continue to progress in the Phase 1b PIONEER trial evaluating pociredir in patients with SCD. Cohort 3 of the Phase 1b trial is evaluating pociredir at the 12 mg once daily dose, which will be followed by Cohort 4 at the 20 mg once daily dose. Each cohort is expected to enroll up to 10 patients. Fulcrum plans to share clinical data from the PIONEER trial in 2025.
- Following recent interactions with the FDA, Fulcrum plans to initiate Phase 1 clinical studies in healthy volunteers in support of the overall pociredir development program.
- Following the REACH trial results disclosed in September 2024, Fulcrum suspended development of losmapimod and has focused its research and development activities on advancing pociredir for the treatment of SCD, as well as advancing novel therapeutic agents for the potential treatment of inherited aplastic anemias, such as Diamond-Blackfan anemia, Shwachman-Diamond syndrome, and Fanconi anemia, and its early discovery programs.

Third Quarter 2024 Financial Results

- **Cash Position:** As of September 30, 2024, cash, cash equivalents, and marketable securities were $257.2 million, as compared to $236.2 million as of December 31, 2023. The increase 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 operating activities in 2024.
- **Collaboration Revenue:** Collaboration revenue was zero for the three months ended September 30, 2024, as compared to $0.8 million for the three months ended September 30, 2023. The decrease of $0.8 million was due to the completion of research services under the collaboration agreement with MyoKardia during the fourth quarter of 2023.
- **R&D Expenses:** Research and development expenses were $14.6 million for the three months ended September 30, 2024, as compared to $18.2 million for the three months ended September 30, 2023. The decrease of $3.6 million was primarily due to the reimbursement from the global development cost sharing under the collaboration with Sanofi for losmapimod, partially offset by increased costs related to the advancement of the Phase 1b PIONEER trial.
- **G&A Expenses:** General and administrative expenses were $8.4 million for the three months ended September 30, 2024, as compared to $10.0 million for three months ended September 30, 2023. The decrease of $1.6 million was primarily due to decreased employee compensation costs as a result of the reduction in workforce implemented in the third quarter of 2024.
- **Net Loss:** Net loss was $21.7 million for the three months ended September 30, 2024, as compared to a net loss of $24.0 million for the three months ended September 30, 2023.

Cash Guidance

Based on its current operating plans, Fulcrum expects to end 2024 with approximately $240.0 million of cash, cash equivalents, and marketable securities, and expects its cash burn for the full year 2025 will be approximately $55.0 million to $65.0 million. Fulcrum also expects that its cash, cash equivalents, and marketable securities as of September 30, 2024 will be sufficient to fund its current operating requirements into at least 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 third 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 Fulcrum'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 lead program in clinical development is pociredir, a small molecule designed to increase expression of fetal hemoglobin and in development for the treatment of 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 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 Phase 1b PIONEER clinical trial of pociredir, including status of enrollment, number of patients per cohort and planned data announcement for such trial; the potential of pociredir to increase fetal hemoglobin to levels that could ameliorate symptoms of SCD; resumption of Phase 1 clinical studies in healthy volunteers ; Fulcrum’s ability to progress its early stage development programs; the effects of the reduction in workforce; and its projected year end cash position, cash runway and cash burn for 2025, 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; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; realize the anticipated benefits of the workforce reduction and strategic realignment and managing risks associated therewith; 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)

	September 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 257,234	$ 236,221
Working capital[(1)]	252,980	228,524
Total assets	279,008	257,694
Total stockholders' equity	257,291	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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ —	$ 759	$ 80,000	$ 1,934
Operating expenses:				
Research and development	14,639	18,238	51,673	52,802
General and administrative	8,424	9,961	28,732	31,804
Restructuring expenses	2,063	—	2,063	—
Total operating expenses	25,126	28,199	82,468	84,606
Loss from operations	(25,126)	(27,440)	(2,468)	(82,672)
Other income, net	3,430	3,423	9,311	10,093
Net (loss) income	$ (21,696)	$ (24,017)	$ 6,843	$ (72,579)
Net (loss) income per share, basic	$ (0.35)	$ (0.39)	$ 0.11	$ (1.19)
Net (loss) income per share, diluted	$ (0.35)	$ (0.39)	$ 0.11	$ (1.19)
Weighted-average common shares outstanding, basic	62,409	61,823	62,200	61,121
Weighted-average common shares outstanding, diluted	62,409	61,823	63,688	61,121

Contact:

Chris Calabrese
LifeSci Advisors, LLC
ccalabrese@lifesciadvisors.com
917-680-5608