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): May 11, 2023

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 May 15, 2023, Fulcrum Therapeutics, Inc., or Fulcrum, announced its financial results for the quarter ended March 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 5.02 Departure of Director or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 11, 2023, in recognition of the duties he is performing and the vacancy in the chief financial officer position, Fulcrum's board of directors, or the Board, appointed Robert E. Gould, current interim president and chief executive officer, as principal financial officer, with immediate effect. On May 11, 2023, the Board also appointed Alex C. Sapir as Fulcrum's president and chief executive officer, and as a class II director, effective July 1, 2023. Accordingly, Mr. Sapir will succeed Dr. Gould as principal executive officer and as principal financial officer effective July 1, 2023. Dr. Gould will remain on the Board as a class III director.

On May 12, 2023, Mr. Sapir joined Fulcrum in a part-time capacity as special advisor to Dr. Gould, and will be employed in this part-capacity through June 30, 2023 before assuming the role of president and chief executive officer and joining the Board.

Mr. Sapir, 56, served as chief executive officer and a member of the board of directors of ReViral Ltd. (acquired by Pfizer Inc.), from June 2019 until June 2022. ReViral was a a privately held, clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel antiviral therapeutics that target respiratory syncytial virus. From January 2017 to December 2018 he served as the president and chief executive officer of Dova Pharmaceuticals Inc., or Dova (acquired by Sobi, Inc.), and as a member of Dova's board of directors from March 2017 to April 2019. Prior to its acquisition, Dova was a pharmaceutical company focused on acquiring, developing and commercializing drug candidates for diseases that are treated by specialist physicians, with an initial focus on addressing thrombocytopenia, Earlier in his career Mr. Sapir was the Executive Vice President for Marketing and Sales at United Therapeutics Corporation, a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions and prior to that, Mr. Sapir held commercial positions of increasing responsibility at GlaxoSmithKline and other smaller healthcare companies. Mr. Sapir currently serves as a member of the board of directors of PhaseBio Pharmaceuticals, Inc., a biotechnology company. Mr. Sapir received a B.A. in economics from Franklin and Marshall College and an M.B.A. from Harvard Business School.

Mr. Sapir entered into an employment agreement with Fulcrum effective May 12, 2023 that governs his services both during the initial advisory period, as well as his full-time employment beginning on July 1, 2023. During the initial advisory period, Mr. Sapir is entitled to salary at a monthly rate of $27,000 per month. Effective July 1, 2023, when he becomes president and chief executive officer, Mr. Sapir will be entitled to an annual base salary of $650,000 and an annual target performance bonus of up to 50% of his then annual base salary (both subject to pro-ration based on his start date). The employment agreement also provides for up to $100,000 annual cash allowance for housing and commuting expenses, grossed up, which amount shall be subject to the Board's review each year after the first year (and subject to pro-ration based on his start date).

In addition, and as contemplated by his employment agreement, effective May 12, 2023, the Board granted Mr. Sapir a nonstatutory option to purchase 2,430,400 shares of Fulcrum's common stock. The option was granted pursuant to Fulcrum's 2022 Inducement Stock Incentive Plan as an inducement material to Mr. Sapir's entry into employment with Fulcrum in accordance with Nasdaq Listing Rule 5635(c)(4), and has an exercise price of $3.27 per share (the fair market value on the grant date). The stock option will vest as to 25% of the underlying shares on the first anniversary of the grant date and as to an additional 6.25% of the shares in equal quarterly installments over the 12 successive quarters thereafter subject to Mr. Sapir's continues to be an "eligible participant" (as defined in such plan) through each applicable vesting date.

Mr. Sapir's employment agreement also provides for severance benefits. In the event of the termination of Mr. Sapir's employment by Fulcrum without cause, or by him for good reason, prior to or more than 18 months following a "change in control" (as such terms are is defined in his employment agreement), Mr. Sapir would be entitled to his base salary that has accrued and to which he is entitled as of the termination date and other accrued benefits. In addition, he is entitled to (1) continued payment of his then-current base salary, in accordance with Fulcrum's regular payroll procedures, for a period of 18 months, (2) a lump sum payment equal to Mr. Sapir's then-current "target bonus" (as such term is defined in his employment agreement) multiplied by 1.5, (3) provided he is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by Fulcrum of the portion of health coverage premiums it pays for similarly situated, active employees who receive the same type of coverage, for a period of up to 18 months following his date of

termination, and (iv) accelerated vesting of his then-unvested equity awards that would otherwise vest during the 18 month period following his date of termination.

In the event of the termination of Mr. Sapir's employment by Fulcrum without cause, or by him for good reason, within 18 months following a "change in control" (as such terms are is defined in his employment agreement) and such termination occurs after Mr. Sapir has completed at least 12 months of employment for Fulcrum, Mr. Sapir is entitled to his base salary that has accrued and to which he is entitled as of the termination date and other accrued benefits. In addition, he is entitled to (1) continued payment of his then-current base salary, in accordance with Fulcrum's regular payroll procedures, for a period of 27 months, (2) a lump sum payment equal to Mr. Sapir's "target bonus" (as such term is defined in his employment agreement) multiplied by 2.25, (3) provided he is eligible for and timely elects to continue receiving group medical insurance under COBRA and the payments would not result in the violation of nondiscrimination requirements of applicable law, payment by Fulcrum of the portion of health coverage premiums it pays for similarly situated, active employees who receive the same type of coverage, for a period of up to 18 months following his date of termination, and (iv) accelerated vesting of his then-unvested equity awards that vest based on the passage of time.

Mr. Sapir will also enter into Fulcrum's standard for indemnification agreement in connection with his July 2023 appointment as a director and executive officer.

The foregoing description of Mr. Sapir's employment agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such agreement, a copy of which Fulcrum intends to file as an exhibit to its Quarterly Report on Form 10-Q for the three months ending June 30, 2023.

Other than his employment agreement, there are no arrangements or understandings between Mr. Sapir and any other persons pursuant to which Mr. Sapir was appointed as a member of the Board. There are also no family relationships between Mr. Sapir and any director or executive officer of Fulcrum. Other than his employment agreement, Mr. Sapir has no direct or indirect interest in any transaction or proposed transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Dr. Gould, 68, has served as a member of the Board since July 2016, served as Fulcrum's president and chief executive officer from July 2016 to March 2021, and was appointed interim president and chief executive officer in January 2023. Dr. Gould has served as an operating partner of Khosla Ventures since September 2021. Dr. Gould previously served as president and chief executive officer of Epizyme, Inc., or Epizyme, a biopharmaceutical company, from March 2010 to September 2015. Prior to joining Epizyme, he served as director of novel therapeutics at the Broad Institute of Massachusetts Institute of Technology, or MIT, and Harvard, a research institute, from December 2006 to March 2010. Dr. Gould spent 23 years at Merck, a healthcare company, where he held a variety of leadership positions, culminating in the role of vice president, licensing and external research. Dr. Gould currently is on the board of directors of Hemoshear Therapeutics, Inc., a biotechnology company, Turnstone Biologics Corp, a biotechnology company, Faeth Therapeutics, Inc., a biotechnology company, and Rubido Life Sciences, a biotechnology company. Dr. Gould served as a member of the board of directors of Epizyme from March 2010 to March 2016. Dr. Gould received a B.A. from Spring Arbor University and a Ph.D. from the University of Iowa and completed postdoctoral studies at the Johns Hopkins University.

Dr. Gould is not receiving any additional compensation in connection with his appointment as principal financial officer.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished herewith:

99.1	Press Release issued May 15, 2023, announcing financial results for the three months ended March 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: May 15, 2023

By: /s/ Robert J. Gould

Name: Robert J. Gould
Title: Interim President and Chief Executive Officer

Fulcrum Therapeutics Announces Recent Business Highlights and Financial Results for the First Quarter 2023

— Appointed Alex C. Sapir CEO & President, effective July 1st, 2023 —

— On track to complete enrollment in Phase 3 REACH trial of losmapimod in facioscapulohumeral muscular dystrophy (FSHD) during 2H'23 —

— Active discussions continue with the U.S. Food and Drug Administration (FDA) to resolve clinical hold for FTX-6058 in sickle cell disease (SCD) —

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

CAMBRIDGE, Mass., – May 15, 2023 – Fulcrum Therapeutics, Inc.® (the "Company") (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined rare diseases, today reported financial results for the first quarter 2023 and provided a business update.

"With today's announcement of Alex as our next CEO and President, Fulcrum has ended the first quarter of 2023 in a position of strength and with great promise for the future," said Robert J. Gould, Ph.D., Fulcrum's interim president and chief executive officer. "We continue to engage in productive dialogue with the FDA, as we work diligently to address the clinical hold for FTX-6058. Additionally, we remain on track to complete enrollment in the Phase 3 REACH trial in the second half of 2023, which will bring us one step closer to potentially delivering the first FDA-approved therapy for FSHD patients."

Key Business Updates

FTX-6058

- On February 23, 2023, the FDA placed the investigational new drug (IND) application for FTX-6058 for the potential treatment of SCD on full clinical hold.
  - In its communication, the Agency noted preclinical data previously submitted in April, October and December 2022, a response to an early February 2023 information request from the FDA about data that we submitted in mid-February 2023, and non-clinical and clinical evidence of hematological malignancies observed with other inhibitors of polycomb repressive complex 2 (PRC2).
  - Active discussions with the Agency regarding the clinical hold of FTX-6058 are ongoing.
- Initial data reported in March 2023 but obtained prior to the clinical hold showed a 10.0% absolute fetal hemoglobin (HbF) increase from baseline in one subject in the 12 mg dose cohort of the Phase 1b clinical trial in SCD, resulting in a total HbF level of 24.9% after 42 days of treatment.
- FTX-6058 was generally well-tolerated, as of the March 2023 data cutoff date, with no drug-related treatment emergent serious adverse events and no discontinuations due to treatment emergent adverse events.

Losmapimod

- Enrollment is ongoing in the REACH Phase 3 pivotal trial evaluating losmapimod in FSHD at sites in the United States, Canada and Europe.
- On track to complete enrollment in the second half of 2023.

Corporate Updates

- Announced that Alex C. Sapir will join as president and CEO, and member of the Fulcrum board of directors, effective July 1, 2023. Prior to assuming his new role, Mr. Sapir will serve as Special Advisor to the interim president and CEO, effective May 12, 2023.

- Completed underwritten public offering of common stock in January 2023, raising approximately $117.3 million in net proceeds.
- Esther Rajavelu resigned as chief financial officer, effective April 21, 2023. Ms. Rajavelu is serving in a consulting role to ensure the continuity of Fulcrum's financial operations.

First Quarter 2023 Financial Results

- **Cash Position:** As of March 31, 2023, cash, cash equivalents, and marketable securities were $297.8 million, as compared to $202.9 million as of December 31, 2022.
- **Collaboration Revenue:** Collaboration revenue was $0.3 million for the first quarter of 2023 as compared to $2.6 million for the first quarter of 2022.
- **R&D Expenses:** Research and development expenses were $16.7 million for the first quarter of 2023 as compared to $17.8 million for the first quarter of 2022. The decrease of $1.1 million was primarily due to decreased research and development headcount, partially offset by increased costs associated with the advancement of REACH.
- **G&A Expenses:** General and administrative expenses were $11.5 million for the first quarter of 2023 as compared to $10.8 million for the first quarter of 2022. The increase of $0.7 million was primarily due to increased stock-based compensation expense.
- **Net Loss:** Net loss was $24.8 million for the first quarter of 2023 as compared to $25.9 million for the first quarter of 2022.

Financial Guidance

Fulcrum expects that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into mid-2025.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to review the first quarter and 2023 recent business highlights and financial results. Individuals may register for the conference call by clicking the link here. Once registered participants will receive dials 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 improving 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 for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease (SCD) and other hemoglobinopathies, which is currently under a full clinical hold issued by the U.S. Food and Drug Administration. The company's proprietary product engine, FulcrumSeek™, identifies 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 **@FulcrumTx** and **LinkedIn**.

About FTX-6058

FTX-6058 is an investigational oral small-molecule inhibitor of Embryonic Ectoderm Development (EED) that was discovered using FulcrumSeek™, Fulcrum's proprietary discovery engine. Inhibition of EED leads to potent downregulation of key fetal globin repressors, including BCL11A, thereby causing an increase in fetal hemoglobin (HbF). FTX-6058 is being developed for the treatment of sickle cell disease (SCD) and other hemoglobinopathies. Initial data in SCD demonstrated proof-of-concept and achieved absolute levels of HbF increases associated with potential overall patient benefit. Through the March 2023 data cutoff date, FTX-6058 has been generally well-tolerated in people with SCD with up to three months of exposure, with no serious treatment-emergent adverse events reported. FTX-6058 has been granted U.S. Food and Drug Administration (FDA) Fast Track designation and Orphan Drug Designation for the treatment of SCD. FTX-6058 is currently under a full clinical hold issued by the FDA.

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.

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 slowed 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 profound decreases in the 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.

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 completion of enrollment in REACH; the clinical hold on FTX-6058, including Fulcrum’s ability to resolve such hold; Fulcrum’s cash runway; and Fulcrum’s ability to deliver an FDA-approved therapy for FSHD patients ;; 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 resolving the clinical hold on FTX-6058 and responding to FDA’s requests; 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, FTX-6058 (if resumed) and any other product candidates; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; realizing the anticipated benefits of the strategic realignment; managing executive and employee turnover, including integrating a new CEO; 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)

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 297,840	$ 202,921
Working capital[(1)]	288,423	190,794
Total assets	321,120	226,685
Total stockholders' equity	296,256	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 March 31,	
	2023	**2022**
Collaboration revenue	$ 295	$ 2,592
Operating expenses:		
Research and development	16,715	17,831
General and administrative	11,520	10,759
Total operating expenses	28,235	28,590
Loss from operations	(27,940)	(25,998)
Other income, net	3,161	70
Net loss	$ (24,779)	$ (25,928)
Net loss per share, basic and diluted	$ (0.41)	$ (0.64)
Weighted-average common shares outstanding, basic and diluted	59,722	40,644

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