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 09, 2022

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

Not applicable
(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 9, 2022, Fulcrum Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2022. 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 (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 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 by the Company on May 9, 2022
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 9, 2022

By: /s/ Bryan Stuart
Name: Bryan Stuart
Title: President and Chief Executive Officer

Fulcrum Therapeutics Reports Recent Business Highlights and First Quarter 2022 Financial Results

– Initial data from Phase 1b trial of FTX-6058 in sickle cell disease to be presented at the EHA 2022 Congress –

– Phase 3 REACH trial of losmapimod in FSHD expected to begin in 2Q 2022 –

– Conference call scheduled for 8:00 a.m. ET today –

CAMBRIDGE, Mass. – May 9, 2022 – Fulcrum Therapeutics, Inc.® (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined rare diseases, today provided a business update and reported financial results for the first quarter of 2022.

"Our clinical programs continued to make significant progress in the first quarter," said Bryan Stuart, president and chief executive officer. "Looking ahead, we are sharing initial data from the ongoing 6 mg dose cohort in the Phase 1b trial of FTX-6058 in people with sickle cell disease at the EHA Congress, and we plan to open the next dose cohort in the trial in the second quarter. Additionally, we plan to begin dosing patients in REACH, our Phase 3 trial of losmapimod in FSHD, in the second quarter. We are in a strong financial position to continue to execute on these programs, both of which have the potential to be life-changing, while continuing to leverage our FulcrumSeek™ product engine to expand our pipeline and fuel our long-term growth."

Upcoming Milestones

FTX-6058

- Report initial data, including measures of HbF protein induction and safety, from the ongoing 6 mg dose cohort in the Phase 1b trial in people with sickle cell disease at the European Hematology Association (EHA) 2022 Hybrid Congress, taking place from June 9-12, 2022.
- Open next dose cohort in Phase 1b trial in people with sickle cell disease in the second quarter of 2022.
- Initiate registrational trial in sickle cell disease in early 2023.
- Initiation of Phase 1b trial in select other hemoglobinopathies, including beta-thalassemia, now expected in the second half of 2022.

Losmapimod

- Initiate REACH, a Phase 3 randomized, double-blind, placebo-controlled multi-national trial that will evaluate the efficacy and safety of losmapimod for Facioscapulohumeral Muscular Dystrophy (FSHD), in the second quarter of 2022. The trial is expected to enroll approximately 230 adults with FSHD. Patients will be randomized 1:1 to receive either losmapimod, administered orally as a 15 mg tablet twice a day, or placebo, and evaluated over a 48-week treatment period. The primary endpoint of the trial is the absolute change from baseline in Reachable Workspace (RWS). Secondary endpoints include muscle fat infiltration (MFI) measured by MRI, Patient Global Impression of Change (PGIC), and Quality of Life in Neurological Disorders of the upper extremity (Neuro QoL UE).

Preclinical Pipeline

- Nominate next development candidate by end of 2022 to support submission of Fulcrum's fourth Investigational New Drug (IND) by the end of the first quarter of 2023.

Recent Business Highlights

- Announced design of Phase 3 REACH trial, including alignment with US and EU regulatory agencies on key aspects of the trial design.
- Hosted a key opinion leader (KOL) event to discuss the unmet need in FSHD, key measures of disease progression and design of Phase 3 REACH trial.
- Together with the FSHD Society, hosted a webinar on REACH for the patient community.
- Presented supportive clinical data from the ReDUX4 Phase 2b trial and an open-label Phase 2 study of losmapimod at the 2022 Muscular Dystrophy Association (MDA) Clinical and Scientific Conference and American Academy of Neurology's Annual Meeting.

First Quarter 2022 Financial Results

- **Cash Position:** As of March 31, 2022, cash, cash equivalents, and marketable securities were $195.1 million, as compared to $218.2 million as of December 31, 2021. Based on current plans, the company expects that its existing cash, cash equivalents, and marketable securities will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into 2024.
- **Collaboration Revenue:** Collaboration revenue was $2.6 million for the first quarter of 2022, as compared to $4.8 million for the first quarter of 2021.
- **R&D Expenses:** Research and development expenses were $17.8 million for the first quarter of 2022, as compared to $16.3 million for the first quarter of 2021. The increase of $1.5 million was primarily due to increased employee-related costs to support the growth of our R&D organization.
- **G&A Expenses:** General and administrative expenses were $10.8 million for the first quarter of 2022, as compared to $5.5 million for the first quarter of 2021. The increase of $5.3 million was primarily due to increased employee-related costs to support the growth of the organization and increased professional services due to increased use of consulting services and preparatory commercial activities.
- **Net Loss:** Net loss was $25.9 million for the first quarter of 2022, as compared to a net loss of $17.0 million for the first quarter of 2021.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to discuss the Company's first quarter 2022 recent business highlights and financial results. The webcast will be accessible through the Investor Relations section of Fulcrum's website at www.fulcrumtx.com. Following the live webcast, an archived replay will also be available for 90 days.

Dial-in Number
U.S./Canada Dial-in Number: 800-527-6973
International Dial-in Number: 470-495-9162
Conference ID: 1129907

Replay Dial-in Number: 855-859-2056
Replay International Dial-in Number: 404-537-3406
Conference ID: 1129907

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 and other hemoglobinopathies, including beta-thalassemia. Fulcrum'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.

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 statements regarding the planned REACH trial including its expected start date and enrollment target, presentation of data from first dose cohort in Phase 1b trial of FTX-6058 and the second dose cohort, the clinical development plan for FTX-6058 as well as timing for expansion into other hemoglobinopathies and initiation of registrational trial for sickle cell disease, nomination of additional development candidates and timing of fourth IND, the sufficiency of Fulcrum’s cash resources, losmapimod’s potential as a therapy for FSHD and the ability of the selected endpoints of the REACH trial to support regulatory approval. 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; initiate and enroll clinical trials on the timeline expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of losmapimod, FTX-6058 and its other product candidates; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. 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, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 195,112	$ 218,162
Working capital[(1)]	181,776	206,799
Total assets	220,248	235,000
Total stockholders' equity	189,160	211,539

(1) We define 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,	
	2022	**2021**
Collaboration revenue	$ 2,592	$ 4,789
Operating expenses:		
Research and development	17,831	16,334
General and administrative	10,759	5,498
Total operating expenses	28,590	21,832
Loss from operations	(25,998)	(17,043)
Other income, net	70	44
Net loss	$ (25,928)	$ (16,999)
Net loss per share, basic and diluted	$ (0.64)	$ (0.54)
Weighted-average common shares outstanding, basic and diluted	40,644	31,510

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