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): August 11, 2020

Fulcrum Therapeutics, Inc.

(Exact Name of Registrant as Specified in 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 (*see* General Instruction A.2. below):

☐ 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 August 11, 2020, Fulcrum Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2020. 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 August 11, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FULCRUM THERAPEUTICS, INC.

Date: August 11, 2020

By: /s/ Robert J. Gould
Name: Robert J. Gould
Title: President and Chief Executive Officer

Fulcrum Therapeutics Reports Recent Business Highlights and Second Quarter 2020 Financial Results

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

CAMBRIDGE, Mass. – August 11, 2020 – 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 second quarter of 2020.

"The team at Fulcrum not only delivered key progress across our pipeline this quarter, but also expanded our work into additional areas of critical unmet need," said Robert J. Gould, Ph.D., president and chief executive officer. "We are encouraged by the data from the ReDUX4 interim analysis announced earlier today, suggesting that muscles with the highest DUX4-driven gene expression in pre-treatment biopsies show greater reduction in DUX4-driven gene expression following treatment with losmapimod compared to placebo. Progress continues with FTX-6058 where we have seen an increase in HbF levels up to approximately 30% of total hemoglobin in preclinical assessment. Additionally, our recent collaboration with MyoKardia has expanded our research efforts into genetic cardiomyopathies following our previously announced collaboration with Acceleron. And while our focus remains steadfast on improving the lives of patients with genetically defined rare diseases in areas of high unmet medical need, our scientific team saw a compelling rationale to use losmapimod for the treatment of hospitalized patients with COVID-19, and we recently initiated a Phase 3 international trial, with topline data expected in the first quarter of 2021. In the midst of all this activity, we further strengthened our cash position through a private placement to support our expanding pipeline."

Recent Business Highlights

- Announced interim data for ReDUX4, a Phase 2b trial of losmapimod, a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor, in facioscapulohumeral muscular dystrophy (FSHD)
    - Results from the interim analysis in the first 29 randomized subjects indicated that DUX4-driven gene expression did not separate from placebo at 16 weeks.
    - In a pre-specified sensitivity analysis assessing biopsies with the highest pre-treatment level of DUX4-driven gene expression, treatment with losmapimod resulted in a 38-fold reduction in DUX4-driven gene expression as compared to the 5.4-fold reduction seen in the placebo arm.
    - Results indicate that muscle biopsies within the higher range of DUX4-driven gene expression may be needed to observe a reduction from baseline.
    - Secondary and exploratory endpoints were not assessed as part of this analysis.
    - Remain on track to share topline results on the primary endpoint in the first quarter of 2021 and full data, including all secondary and exploratory endpoints, in the second quarter of 2021.
- Initiated international, multicenter Phase 3 trial with losmapimod for hospitalized patients with COVID-19 (LOSVID). The trial is designed to assess the safety and efficacy of losmapimod compared to placebo for 14 days on top of standard of care in approximately 400 patients who are at risk of progression to critical illness based on older age and elevated systemic inflammation
    - Primary endpoint is the proportion of patients treated with losmapimod as compared to placebo who progress to death or respiratory failure by day 28, and additional secondary endpoints include clinical status on days seven and 14 as measured on the nine point WHO ordinal scale of COVID-19 severity, total number of study days free of oxygen supplementation, all-cause mortality, length of hospitalization and ICU stay, adverse events and viral clearance.
    - Trial site activation underway in the United States, Mexico and South America.
    - Expect to report topline data in the first quarter of 2021.
- On track to initiate Phase 1 trial of FTX-6058 in the fourth quarter of 2020.
    - FTX-6058 is an oral small molecule therapeutic discovered by Fulcrum and designed to induce expression of fetal hemoglobin (HbF) in red blood cells to compensate for the mutated adult hemoglobin in sickle cell disease.

    - Preclinical data with FTX-6058 showed an increase in HbF levels up to approximately 30% of total hemoglobin.
    - On-track to submit investigational new drug (IND) application in Q3 2020.
- Executed strategic collaboration and license agreement in July 2020 with MyoKardia to identify therapeutics that control the expression of genes that are known to be underlying drivers of genetic cardiomyopathies.
    - Fulcrum is eligible to receive preclinical milestone payments, development milestone payments and sales milestone payments of up to $298.5 million for a first product to progress through development and commercialization and may be eligible for up to $150.0 million in milestone payments for additional targets, as well as reimbursement for the costs of the research activities.
    - Fulcrum may also be eligible to receive tiered royalty payments in the mid-single-digit to low double-digit range on net sales for any products under the collaboration that are commercialized.
- Presented multiple posters at the 2020 American Academy of Neurology (AAN) Science on losmapimod data
    - Identified a set of stable DUX4-regulated gene transcripts that provide a pharmacodynamic biomarker endpoint to measure the treatment effect of losmapimod in FSHD.
    - Created a standardized whole-body magnetic resonance imaging (MRI) protocol to evaluate skeletal muscle composition in FSHD patients in collaboration with AMRA Medical.
- Completed $68.5 million private placement in June 2020, with a mix of new and existing investors, including EcoR1 Capital, LLC, Alyeska Investment Group, L.P., Boxer Capital, Casdin Capital LLC, Perceptive Advisors LLC, Samsara BioCapital, Monashee Investment Management LLC and Foresite Capital, to fund research and development expenses and other general corporate purposes.

Second Quarter 2020 Financial Results

- **Cash Position:** As of June 30, 2020, cash, cash equivalents, and marketable securities were $131.7 million, as compared to $96.7 million as of December 31, 2019. Based on its current plans, the Company expects that its existing cash, cash equivalents, and marketable securities, including the $12.5 million received from MyoKardia in July 2020, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2022.
- **R&D Expenses:** Research and development expenses were $12.8 million for the second quarter of 2020, as compared to $10.9 million for the second quarter of 2020. The increase of $1.9 million was primarily due to increased personnel-related costs to support the growth of Fulcrum's research and development organization, as well as increased costs related to the advancement of losmapimod for the treatment of FSHD.
- **G&A Expenses:** General and administrative expenses were $5.1 million for the second quarter of 2020, as compared to $2.6 million for the second quarter of 2019. The increase of $2.5 million was primarily due to increased costs associated with operating as a public company, as well as increased personnel-related costs to support the growth of our organization.
- **Net Loss:** Net loss was $15.7 million for the second quarter of 2020, as compared to a net loss of $13.2 million for the second quarter of 2019.

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 second quarter 2020 recent business highlights and financial results, as well as the ReDUX4 interim analysis. 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.

Dial-in Number
U.S./Canada Dial-in Number: 800-527-6973
International Dial-in Number: 470-495-9162
Conference ID: 9625789

Replay Dial-in Number: 855-859-2056
Replay International Dial-in Number: 404-537-3406
Conference ID: 9625789

About FSHD

FSHD is characterized by progressive skeletal muscle loss that initially causes weakness in muscles in the face, shoulders, arms and trunk, and progresses to weakness throughout the lower body. Skeletal muscle weakness results in significant physical limitations, including an inability to smile and difficulty using arms for activities, with many patients ultimately becoming dependent upon the use of a wheelchair for daily mobility.

FSHD is caused by mis-expression of DUX4 in skeletal muscle, resulting in the presence of DUX4 proteins that are toxic to muscle tissue. Normally, DUX4-driven gene expression is limited to early embryonic development, after which time the DUX4 gene is silenced. In people with FSHD, the DUX4 gene is turned “on” as a result of a genetic mutation. The result is death of muscle and its replacement by fat, leading to skeletal muscle weakness and progressive disability. There are no approved therapies for FSHD, one of the most common forms of muscular dystrophy, with an estimated patient population of 16,000 to 38,000 in the United States alone.

About Losmapimod

Losmapimod is a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor that was exclusively in-licensed from GSK by Fulcrum Therapeutics following Fulcrum’s discovery of the role of p38α/β inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Utilizing its internal product engine, Fulcrum discovered that inhibition of p38α/β reduced expression of the DUX4 gene in muscle cells derived from patients with FSHD. Researchers at Fulcrum also believe that losmapimod has the potential to treat COVID-19 by reducing the acute exaggerated pro-inflammatory responses to SARS-CoV-2 infection and restoring the antigen-specific immune responses needed for viral clearance, potentially leading to improved clinical outcomes. Losmapimod has been evaluated in more than 3,600 subjects in clinical research across multiple indications, including in several Phase 2 trials and a large Phase 3 trial in acute myocardial infarction. No safety signals were attributed to losmapimod in any of these trials. In 2020, the Company received U.S. and European Orphan Drug Designation for losmapimod for the treatment of FSHD. Fulcrum is currently conducting Phase 2 trials investigating the safety, tolerability, and efficacy of losmapimod to treat the root cause of FSHD and initiating a Phase 3 trial investigating the safety, tolerability, and efficacy of losmapimod to treat hospitalized patients with COVID-19.

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. SCD patients 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 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 proprietary product engine identifies drug targets which can modulate gene expression to treat the known root cause of gene mis-expression. The company has advanced losmapimod to Phase 2 clinical development for the treatment of facioscapulohumeral muscular dystrophy (FSHD) and is advancing losmapimod to Phase 3 for the treatment of COVID-19. Fulcrum also anticipates filing an IND in the third quarter with initiation of a clinical trial in the fourth quarter of 2020 with FTX-6058 for the treatment of sickle cell disease.

Please visit www.fulcrumtx.com.

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, including statements regarding the development status of the Company’s product candidates, the potential advantages and therapeutic potential of our product candidates, the timing of regulatory filings, initiation and enrollment of clinical trials and availability of clinical trial data, and the Company’s ability to fund its operations with cash on hand. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company’s strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. 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 obtain and maintain necessary approvals from the FDA and other regulatory authorities; continue to advance its product candidates in clinical trials; initiate and enroll clinical trials on the timeline expected or at all; correctly estimate the potential patient population and/or market for the Company’s product candidates; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of losmapimod and its other product candidates; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; 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 the Company’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 the Company’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

Fulcrum Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

(Unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents, and marketable securities	$ 131,738	$ 96,713
Working capital(1)	120,841	87,943
Total assets	144,862	110,439
Total stockholders' equity	122,131	87,153

(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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 2,000	$ —	$ 2,750	$ —
Operating expenses:				
Research and development	12,775	10,860	27,257	45,489
General and administrative	5,149	2,634	10,213	5,232
Total operating expenses	17,924	13,494	37,470	50,721
Loss from operations	(15,924)	(13,494)	(34,720)	(50,721)
Other income, net	239	325	583	709
Net loss	$ (15,685)	$ (13,169)	$ (34,137)	$ (50,012)
Cumulative convertible preferred stock dividends	—	(3,291)	—	(6,332)
Net loss attributable to common stockholders	$ (15,685)	$ (16,460)	$ (34,137)	$ (56,344)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (9.21)	$ (1.47)	$ (32.85)
Weighted average number of common shares used in net loss per share attributable to common stockholders, basic and diluted	23,854	1,787	$ 23,287	$ 1,715

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