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): March 5, 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** **(Address of Principal Executive Offices)**	**02139** **(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 March 5, 2020, Fulcrum Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2019. 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 March 5, 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: March 5, 2020

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

Fulcrum Therapeutics Reports Recent Business Highlights and Fourth Quarter and Full Year 2019 Financial Results

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

CAMBRIDGE, Mass. – March 5, 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 fourth quarter and full year of 2019.

"We made important progress at a rapid pace in 2019 as we transitioned from a private, discovery company into a public, clinical-stage company," said Robert J. Gould, president and chief executive officer. "In our losmapimod program for patients with facioscapulohumeral muscular dystrophy (FSHD), we completed enrollment in our Phase 2 clinical trials, including ReDUX4, the randomized, double-blind placebo-controlled multicenter international Phase 2b clinical trial, and we continue to expect to announce topline data on the primary endpoint in the third quarter of 2020. We also plan to submit an IND for FTX-6058 for the treatment of sickle cell disease in the second half of this year. We look forward to building on this progress as we execute on our goal of advancing therapies focused on improving the lives of patients with genetically defined diseases."

Recent Business Highlights

- Evidence of dose-dependent target engagement observed in skeletal muscle with losmapimod in Phase 1.
  - Builds on previously announced dose-dependent pharmacokinetics and target engagement in blood.
- Completed patient enrollment in ReDUX4 Phase 2b trial of losmapimod, a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor.
  - Phase 2 Open Label Study also completed enrollment
  - ReDUX4 open label extension initiated
  - Remain on track to report topline data in the third quarter of 2020
- Received U.S. Orphan Drug Designation for losmapimod in FSHD.
- Presented Phase 1 clinical data at the World Muscle Society meeting highlighting the safety, tolerability, and target engagement of losmapimod for the treatment of FSHD.
- Plan to submit an investigational new drug application (IND) to the U.S. Food and Drug Administration for FTX-6058 in the second half 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 beta hemoglobin in sickle cell disease.
- Expanded patent portfolio.
  - U.S. patent 10,537,560 covers the use of other p38 kinase inhibitors for the treatment of FSHD. This is in addition to U.S. patent 10,342,786 which covers the method of using losmapimod for the treatment of FSHD. These two patents each provide protection through 2038.
- Executed a pulmonary research and discovery collaboration agreement with Acceleron Pharma, Inc.
- Multiple abstracts accepted at the Muscular Dystrophy Association and American Academy of Neurology Annual Meetings this Spring.
- Continued evolution of Fulcrum's proprietary product engine to identify drug targets, programs and clinical development candidates in a broad range of genetically defined diseases (FulcrumSeek).
- Appointed Katina Dorton to the Company's Board of Directors.

Fourth Quarter and Full Year 2019 Financial Results

- **Cash Position:** As of December 31, 2019, cash and cash equivalents were $96.7 million, as compared to $72.8 million as of December 31, 2018. Based on its current plans, the Company expects that its existing cash and cash equivalents will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2021.
- **R&D Expenses:** Research and development expenses were $12.1 million for the fourth quarter of 2019, as compared to $6.9 million for the fourth quarter of 2018. The increase of $5.2 million was primarily due to increased costs related to the advancement of losmapimod for the treatment of FSHD, including increased external costs to support Fulcrum's ongoing and planned clinical trials, as well as increased personnel-related costs due to additional headcount to support the growth of Fulcrum's research and development organization.

  Research and development expenses were $71.1 million for the year ended December 31, 2019, as compared to $25.2 million for the year ended December 31, 2018. The increase of $45.9 million was primarily due to a $28.1 million increase in one-time costs associated with the Company's license agreement with GSK, including $25.6 million of costs associated with the issuance of Series B convertible preferred stock to GSK during 2019 and a $2.5 million milestone paid to GSK during 2019, increased costs related to the advancement of losmapimod for the treatment of FSHD, including increased external costs to support Fulcrum's ongoing and planned clinical trials, as well as increased personnel-related costs associated with increased headcount to support the growth of Fulcrum's research and development organization.
- **G&A Expenses:** General and administrative expenses were $4.4 million for the fourth quarter of 2019, as compared to $2.4 million for the fourth quarter of 2018. The increase of $2.0 million was primarily due to increased personnel-related costs associated with increased headcount to support the growth of our organization, as well as increased consulting and professional fees associated with operating as a public company, including costs for insurance premiums, legal services, investor relations, and accounting.

  General and administrative expenses were $13.1 million for the year ended December 31, 2019, as compared to $8.3 million for the year ended December 31, 2018. The increase of $4.8 million was primarily due to increased personnel-related costs associated with increased headcount to support the growth of our organization, as well as increased consulting and professional fees associated with operating as a public company, including costs for insurance premiums, legal services, investor relations, and accounting.
- **Net Loss:** Net loss was $16.1 million for the fourth quarter of 2019, as compared to a net loss of $8.9 million for the fourth quarter of 2018.

  Net loss was $82.7 million for the year ended December 31, 2019, as compared to $32.6 million for the year ended December 31, 2018.

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 fourth quarter and full year 2019 financial results and recent developments. 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: 3683902

Replay Dial-in Number: 855-859-2056
Replay International Dial-in Number: 404-537-3406
Conference ID: 3683902

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. Although losmapimod has never previously been explored in muscular dystrophies, it has been evaluated in more than 3,500 subjects in clinical trials across multiple other indications, including in several Phase 2 trials and a Phase 3 trial. No safety signals were attributed to losmapimod in any of these trials. Fulcrum is currently conducting Phase 2 trials investigating the safety, tolerability, and efficacy of losmapimod to treat the root cause of FSHD.

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 has completed extensive pre-clinical research for FTX-6058 for the treatment of sickle cell disease and beta-thalassemia.

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 timing of 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; replicate in later clinical trials positive results found in preclinical studies and early-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)

	December 31, 2019	December 31, 2018
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 96,713	$ 72,797
Working capital[(1)]	87,943	69,866
Total assets	110,439	85,771
Convertible preferred stock	—	139,670
Total stockholders' equity (deficit)	87,153	(63,670)

(1) We define working capital as current assets minus current liabilities.

Fulcrum Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share data)

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	12,087	6,860	71,072	25,184
General and administrative	4,403	2,391	13,145	8,314
Total operating expenses	16,490	9,251	84,217	33,498
Loss from operations	(16,490)	(9,251)	(84,217)	(33,498)
Other income, net:				
Interest income, net	360	385	1,511	518
Other income	7	7	29	392
Net loss and comprehensive loss	$ (16,123)	$ (8,859)	$ (82,677)	$ (32,588)
Cumulative convertible preferred stock dividends	—	(2,823)	(7,128)	(6,559)
Net loss attributable to common stockholders	$ (16,123)	$ (11,682)	$ (89,805)	$ (39,147)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (7.82)	$ (8.13)	$ (31.14)
Weighted average number of common shares used in net loss per share attributable to common stockholders, basic and diluted	22,610	1,493	11,046	1,257

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