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 26, 2019

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 26, 2019, Fulcrum Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 August 26, 2019

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 26, 2019

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

Fulcrum Therapeutics Reports Second Quarter 2019 Financial Results and Recent Business Highlights

– Completed initial public offering, raising $72.0 million in gross proceeds –

– Initiated ReDUX4, a Phase 2b clinical trial of losmapimod in FSHD –

– Initiated a Phase 2 open label clinical trial of losmapimod in FSHD –

CAMBRIDGE, Mass. – Aug. 26, 2019 (GLOBE NEWSWIRE) – 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 2019.

“Over the second quarter we continued to make strides in advancing our pipeline, positioning us well for the completion of our initial public offering in July,” said Robert J. Gould, Ph.D., Fulcrum’s president and chief executive officer. “The capital raised will enable the continued execution of our strategy to discover, develop, and commercialize small molecule therapies to treat the root cause of genetically defined rare diseases. We are pleased to have announced the initiation of the Phase 2b ReDUX4 clinical trial and to announce today the initiation of the Phase 2 open label clinical trial of our lead product candidate, losmapimod, for the treatment of patients with facioscapulohumeral muscular dystrophy (FSHD). FSHD is a progressive disease for which there are currently no approved treatments. We look forward to sharing results from our Phase 1 clinical trial of losmapimod in FSHD patients and healthy volunteers at the Annual Congress of the World Muscle Society to be held in Copenhagen, Denmark October 1st – 5th, 2019.”

Second Quarter 2019 and Recent Business Highlights

- In August 2019, Fulcrum announced that it initiated ReDUX4, its Phase 2b clinical trial evaluating losmapimod for the treatment of FSHD.
- In August 2019, Fulcrum announced that it initiated a Phase 2 open label clinical trial evaluating losmapimod for the treatment of FSHD.
- In July 2019, Fulcrum completed its initial public offering of common stock, raising $72.0 million in gross proceeds.

Second Quarter 2019 Financial Results

- **Cash Position:** As of June 30, 2019, cash and cash equivalents were $49.6 million, as compared to $72.8 million as of December 31, 2018. Cash and cash equivalents as of June 30, 2019 do not include the proceeds from the Company’s initial public offering of common stock, which closed in July 2019. Based on its current plans, the Company expects that its existing cash and cash equivalents, including the proceeds from its July 2019 initial public offering, 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 $10.9 million for the second quarter of 2019, as compared to $5.8 million for the second quarter of 2018. The increase of $5.1 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.

- **G&A Expenses:** General and administrative expenses were $2.6 million for the second quarter of 2019, as compared to $2.1 million for the second quarter of 2018. The increase of $0.5 million was primarily due to increased personnel-related costs due to additional headcount, as well as increased consulting and professional fees.
- **Net Loss:** Net loss was $13.2 million for the second quarter of 2019, as compared to a net loss of $7.8 million for the same period in 2018.

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/ß mitogen activated protein kinase (MAPK) inhibitor that was exclusively in-licensed by Fulcrum Therapeutics following Fulcrum’s discovery of the role of p38α/ß 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/ß 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.

About Fulcrum Therapeutics

Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined diseases in areas of high unmet medical need, with an initial focus on rare diseases. Fulcrum’s proprietary product engine identifies drug targets which can modulate gene expression to treat the known root cause of gene mis-expression. 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, except per share data)

(Unaudited)

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 49,628	$ 72,797
Working capital(1)	45,023	69,866
Total assets	65,151	85,771
Convertible preferred stock	165,136	139,670
Total stockholders’ deficit	(111,681)	(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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 10,860	$ 5,788	$ 45,489	$ 11,361
General and administrative	2,634	2,061	5,232	3,798
Total operating expenses	$ 13,494	$ 7,849	$ 50,721	$ 15,159
Loss from operations	(13,494)	(7,849)	(50,721)	(15,159)
Other income, net:				
Interest income (expense), net	317	(5)	694	(5)
Other income	8	8	15	378
Net loss and comprehensive loss	$(13,169)	$(7,846)	$(50,012)	$(14,786)
Cumulative convertible preferred stock dividends	(3,291)	(1,050)	(6,332)	(1,878)
Net loss attributable to common stockholders	$(16,460)	$(8,896)	$(56,344)	$(16,664)
Net loss per share attributable to common stockholders, basic and diluted	$ (9.21)	$ (7.50)	$ (32.85)	$ (15.14)
Weighted average number of common shares used in net loss per share attributable to common stockholders, basic and diluted	1,787	1,186	1,715	1,101

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