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): November 10, 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 November 10, 2020, Fulcrum Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 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 November 10, 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: November 10, 2020

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

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

– ReDUX4 trial progressing; full data with losmapimod in facioscapulohumeral muscular dystrophy (FSHD) expected in 2Q 2021 –

– On track to begin dosing Phase 1 trial with FTX-6058 for sickle cell disease before YE 2020 –

– Cash runway into 2Q 2022 –

– Key appointments to management team –

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

CAMBRIDGE, Mass. – November 10, 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 third quarter of 2020.

"We've made significant progress in 2020, which will lead to a number of key data readouts as we move into 2021," said Robert J. Gould, Ph.D., president and chief executive officer. "We plan to announce full data from our ReDUX4 trial with losmapimod in facioscapulohumeral muscular dystrophy (FSHD), including the primary endpoint in the second quarter of 2021. We are encouraged by the interim analysis from ReDUX4, which assessed reductions in DUX4-driven gene expression, the root cause of the disease, via muscle biopsy. The full data will also contain a number of validated and novel endpoints and we look forward to presenting a comprehensive assessment of the data in its entirety. Our select hemoglobinopathy program, FTX-6058, a highly potent small molecule EED inhibitor, has made important progress as well, and we are currently screening healthy volunteers in our Phase 1 trial. We believe FTX-6058 has the potential to offer a transformative small molecule treatment option that could represent a significant development for sickle cell patients."

"I am also pleased to report that Curtis Oltmans will be joining Fulcrum as Senior Vice President, General Counsel and Kim Hazen has been promoted to Senior Vice President, Human Resources," continued Dr. Gould. "In addition, Alan Ezekowitz, MBChB, D.Phil will take on the responsibility of clinical advisor as Diego Cadavid, MD is leaving his position as Senior Vice President, Clinical Development. Curt has an extensive record of legal and corporate development accomplishments. Kim has made important contributions since joining Fulcrum in 2017 and Alan has served on our Board of Directors since 2016. We are thrilled to have them on our leadership team. We thank Diego for his many contributions to Fulcrum."

Third Quarter and 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 FSHD.
    - Encouraging data suggest that muscles with the highest DUX4-driven gene expression in pre-treatment biopsies showed large reductions in DUX4-driven gene expression following treatment with losmapimod compared to placebo.
    - Remain on track to report full data in the second quarter of 2021. Data will include the primary endpoint, reduction from baseline of DUX4-driven gene expression, as well as a pre-specified sensitivity analysis assessing biopsies with the highest pre-treatment level of DUX4-driven gene expression, in addition to secondary and exploratory endpoints.
    - Continued evaluation of the Open Label Study and ReSOLVE Natural History Study
- On track to begin dosing healthy volunteers in a Phase 1 trial for sickle cell disease with FTX-6058 before year-end 2020.
    - FTX-6058, a highly potent small molecule EED inhibitor, is designed to induce expression of fetal hemoglobin (HbF) in red blood cells to compensate for the mutated adult hemoglobin for the potential treatment of hemoglobinopathies, including sickle cell disease and beta-thalassemia.

- Preclinical data with FTX-6058 showed an increase in HbF levels up to approximately 30% of total hemoglobin showing the potential to have a significant impact on the sickle cell patient population.
- Fulcrum's non-provisional composition of matter patent application covering FTX-6058 and related structures published.

- Enrolling patients in the international, multicenter Phase 3 trial with losmapimod for hospitalized subjects 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.
  - Progress in opening trial sites has been slower than anticipated. Based on assessments of enrollment thus far we anticipate providing an update on the LOSVID trial in the first quarter of 2021.
- Announced multiple scientific meeting presentations
  - Presented target engagement and good tolerability with FTX-6058 in multiple preclinical rodent models with once-a-day oral dosing at the 14th Annual Sickle Cell Disease Research & Educational Symposium and 43rd National Sickle Cell Disease Scientific Meeting, September 25, 2020.
  - Presented multiple posters demonstrating Fulcrum's integrated approach to the evaluation of FSHD patients during the 25th International Congress of the World Muscle Society (WMS), October 1, 2020.
  - Announced multiple posters demonstrating the potential of FTX-6058 accepted at the 62nd American Society of Hematology (ASH) annual meeting, December 5-8, 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.
- Key appointments to management team
  - Curtis Oltmans will join Fulcrum as Senior Vice President, General Counsel and Corporate Secretary, effective November 30, 2020.
    - Most recently, Mr. Oltmans served as Vice President, Head of Litigation for DaVita, Inc. where he was responsible for strategy and initiatives in the areas of law, including litigation, employee safety and insurance. Prior to DaVita, he served as General Counsel for Array BioPharma (acquired by Pfizer). Prior to Array BioPharma, Mr. Oltmans served as the US General Counsel for Novo Nordisk. Mr. Oltmans earned his undergraduate degree in political science at the University of Nebraska and his Juris Doctorate Degree at the University of Nebraska College of Law.
  - Alan Ezekowitz, MBChB, D.Phil will take on the responsibility of clinical advisor.
    - Dr. Ezekowitz has served on our board of directors since December 2016 and has served as a venture partner at Third Rock Ventures, LLC since December 2019. Prior to Third Rock Ventures, Dr. Ezekowitz served as the president and chief executive officer of Abide Therapeutics, Inc. (acquired by H. Lundbeck A/S). Prior to founding Abide, Dr. Ezekowitz was the senior vice president and franchise head for disease areas including bone, respiratory, immunology, muscle, dermatology and urology at Merck. Dr. Ezekowitz received his medical training at the University of Cape Town in South Africa and received a Doctor of Philosophy degree from Oxford University.
  - Kim Hazen promoted to Senior Vice President, Human Resources.
    - Ms. Hazen has over 25 years of experience in human resources and has been an invaluable member of the leadership team since she joined Fulcrum in September 2017.

Third Quarter 2020 Financial Results

- **Cash Position:** As of September 30, 2020, cash, cash equivalents, and marketable securities were $127.0 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 will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the second quarter of 2022.
- **R&D Expenses:** Research and development expenses were $15.6 million for the third quarter of 2020, as compared to $13.5 million for the third quarter of 2019. The increase of $2.1 million was primarily due to increased costs to support our ongoing and planned clinical trials and increased personnel-related costs to support the growth of Fulcrum's research and development organization, including increased stock-based compensation expense. Research and development expenses for the third quarter of 2019 include $2.5 million of one-time costs incurred associated with the achievement of a milestone under the Company's license agreement with GSK for losmapimod.
- **G&A Expenses:** General and administrative expenses were $5.3 million for the third quarter of 2020, as compared to $3.5 million for the third quarter of 2019. The increase of $1.8 million was primarily due to increased costs associated with operating as a public company and increased personnel-related costs to support the growth of our organization, including increased stock-based compensation expense.
- **Net Loss:** Net loss was $19.0 million for the third quarter of 2020, as compared to a net loss of $16.5 million for the third 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 third quarter 2020 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.

Dial-in Number
U.S./Canada Dial-in Number: 800-527-6973
International Dial-in Number: 470-495-9162
Conference ID: 2408316

Replay Dial-in Number: 855-859-2056
Replay International Dial-in Number: 404-537-3406
Conference ID: 2408316

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 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 FTX-6058

FTX-6058 is a highly potent small molecule inhibitor of Embryonic Ectoderm Development (EED) capable of inducing robust HbF protein expression in cell and murine models. Fulcrum believes the pharmacokinetics and human dose simulations support that FTX-6058 may be given as a once daily oral compound. The validation of EED as a target for sickle cell disease and the discovery of FTX-6058 as a novel HbF-inducing small molecule were conducted using Fulcrum’s proprietary Product Engine. Preclinical data with FTX-6058 showed an increase in HbF levels up to approximately 30% of total hemoglobin. Fulcrum has initiated a Phase 1 trial with FTX-6058 in healthy volunteers.

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 Phase 3 for the treatment of COVID-19. Fulcrum has also advanced FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease and beta thalassemia into Phase 1 clinical development.

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, 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)

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and marketable securities	$ 127,025	$ 96,713
Working capital(1)	105,657	87,943
Total assets	142,215	110,439
Total stockholders' equity	104,985	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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 1,848	$ —	$ 4,598	$ —
Operating expenses:				
Research and development	15,640	13,496	42,897	58,985
General and administrative	5,312	3,510	15,525	8,742
Total operating expenses	20,952	17,006	58,422	67,727
Loss from operations	(19,104)	(17,006)	(53,824)	(67,727)
Other income, net	142	464	725	1,173
Net loss	$ (18,962)	$ (16,542)	$ (53,099)	$ (66,554)
Cumulative convertible preferred stock dividends	—	(796)	—	(7,128)
Net loss attributable to common stockholders	$ (18,962)	$ (17,338)	$ (53,099)	$ (73,682)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.97)	$ (2.16)	$ (10.33)
Weighted average number of common shares used in net loss per share attributable to common stockholders, basic and diluted	27,261	17,785	24,621	7,133

Contact:

Investors:
Christi Waarich
Director, Investor Relations and
Corporate Communications
cwaarich@fulcrumtx.com
617-651-8664

Stephanie Ascher
Stern Investor Relations, Inc.
stephanie.ascher@sternir.com
212-362-1200

Media:
Kaitlin Gallagher
Berry & Company Public Relations
kgallagher@berrypr.com
212-253-8881