UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. FULCRUM THERAPEUTICS, INC., BRYAN STUART, ROBERT J. GOULD, and ESTHER RAJAVELU, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Fulcrum Therapeutics, Inc. ("Fulcrum" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Fulcrum securities between March 3, 2022 and March 8, 2023, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b)

and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Fulcrum 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. One of the Company's lead product candidates is FTX-6058, an investigational oral fetal hemoglobin inducer for the treatment of sickle cell disease and other hemoglobinopathies. Over the course of 2022, Fulcrum submitted preclinical data to the U.S. Food and Drug Administration ("FDA") in connection with the Company's intention to file an Investigational New Drug ("IND") application for FTX-6058 for the potential treatment of sickle-cell disease ("SCD").

3. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the preclinical data submitted in support of FTX-6058 showed safety concerns regarding potential hematological malignancies; (ii) the foregoing safety concerns increased the likelihood that the FDA would place a clinical hold on preclinical studies of FTX-6058; (iii) accordingly, the Company had overstated FTX-6058's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

4. On February 24, 2023, Fulcrum issued a press release "announc[ing] that on February 23, 2023, the U.S. Food and Drug Administration (FDA) verbally informed the company that it has issued a full clinical hold regarding the Investigational New Drug (IND) application for FTX-6058 for the potential treatment of sickle-cell disease. The Agency indicated that it would provide a formal Clinical Hold Letter to the company within 30 days." Fulcrum further disclosed that "[t]he clinical hold was initiated by the Agency due to previously reported preclinical data. Fulcrum will suspend dosing in the Phase 1b trial of FTX-6058 and intends to work diligently with the Agency to resolve the hold as soon as possible."

5. On this news, Fulcrum's stock price fell $7.23 per share, or 56.09%, to close at $5.66 per share on February 24, 2023.

6. Then, on March 9, 2023, before the market opened, Fulcrum issued a press release announcing recent business highlights and the Company's Q4 and full year 2022 financial results. The press release provided that in the clinical hold letter the Company received on February 24, 2023, the FDA referenced "preclinical data previously submitted in April, October and December 2022, and non-clinical and clinical evidence of hematological malignancies observed with other inhibitors of polycomb repressive complex 2 (PRC2)," and noted that "the profile of hematological malignancies observed in the non-clinical studies of FTX-6058 is similar to that observed with other inhibitors of PRC2, and that hematological

malignancies have been reported clinically with other PRC2 inhibitors." Finally, the FDA requested that Fulcrum "further define the population where the potential benefit of continued treatment with FTX-6058 outweighs potential risk."

7. On this news, Fulcrum's stock price fell $1.44, or 23%, to close at $4.82 per share on March 9, 2023.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Pursuant to Fulcrum's most recent annual report on Form 10-K, as of March 2, 2023, there were 61,758,994 shares of the Company's common stock outstanding. Fulcrum's securities trade on the Nasdaq Global Market ("NASDAQ"). Accordingly, there are presumably

hundreds, if not thousands, of investors in Fulcrum's securities located within the U.S., some of whom undoubtedly reside in this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Fulcrum securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Fulcrum is a Delaware corporation with principal executive offices located at 26 Landsdowne Street, Cambridge, Massachusetts. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "FULC."

15. Defendant Bryan Stuart ("Stuart") served as Fulcrum's Chief Executive Officer ("CEO") from before the start of the Class Period until January 2023.

16. Defendant Robert J. Gould ("Gould") has served as Fulcrum's CEO since January 2023.

17. Defendant Esther Rajavelu ("Rajavelu") has served as Fulcrum's Chief Financial Officer at all relevant times.

18. Defendants Stuart, Gould, and Rajavelu are sometimes referred to herein as the "Individual Defendants."

19. The Individual Defendants possessed the power and authority to control the contents of Fulcrum's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Fulcrum's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Fulcrum, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

20. Fulcrum and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

21. Fulcrum 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. One of the Company's lead product candidates is FTX-6058, an investigational oral fetal hemoglobin inducer for the treatment of sickle cell disease and other hemoglobinopathies. Over the course of 2022, Fulcrum submitted preclinical data to the FDA in connection with the Company's intention to file an IND for FTX-6058 for the potential treatment of sickle-cell disease.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on begins on March 3, 2022, when Fulcrum issued a press release announcing recent business highlights and the Company's Q4 and full year 2021 financial results. The press release quoted, in relevant part:

> "Our progress in 2021 has set us up for a tremendous 2022 with meaningful catalysts across our key programs," said [Defendant Stuart]. We are also on track to report initial data from our Phase 1b with FTX-6058 in people with sickle cell disease. We believe a once-daily well-tolerated oral [fetal hemoglobin ("HbF")] inducer that can deliver robust increases in HbF over baseline could be life-changing. We are also on track to initiate a Phase 1b trial with FTX-6058 in other hemoglobinopathies, including beta thalassemia. With our cash runway into 2024, we are focused on delivering key data to support our goal of bringing therapies to people with rare genetic diseases."
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> **Upcoming Milestones**
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> **FTX-6058**
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> - Report initial data, including measures of HbF protein induction and safety, from the Phase 1b trial in people with sickle cell disease in the second quarter of 2022.

- Initiate Phase 1b trial in select other hemoglobinopathies, including beta-thalassemia, in the second quarter of 2022.

- Initiate registrational trial in sickle cell disease in early 2023.

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Recent Business Highlights

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- Received Orphan Drug Designation from the FDA for FTX-6058 in sickle cell disease.

- Dosed first patient with sickle cell disease in the Phase 1b clinical trial of FTX-6058, an oral fetal hemoglobin (HbF) inducer.

23. That same day, Fulcrum filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2021 (the "2021 10-K"). In providing an overview of the Company's business, the 2021 10-K stated, in relevant part:

> [. . .] FTX-6058 [] is an investigational oral fetal hemoglobin, or HbF, inducer that is in development for [sickle cell disease] ["SCD"] and select other hemoglobinopathies, including ß-thalassemia. FTX-6058 is designed to bind to embryonic ectoderm development, or EED, and inhibit the transcriptional silencing activity of the polycomb repressive complex 2, or PRC2. By doing so, preclinical studies have shown that FTX-6058 downregulates key HbF repressors, including BCL11A and MYB, and upregulates HbF.
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> SCD is a genetic blood disorder caused by a mutation in the ß-subunit gene, or HBB gene. This mutation results in the formation of abnormal hemoglobin, or HbS, which causes red blood cells, or RBCs, to change from a round shape into a sickle shape that significantly

impairs their function. ß-thalassemia is a rare blood disorder caused by various genetic mutations in the HBB gene that can significantly impair the production of hemoglobin and RBCs. We designed FTX-6058 to compensate for the root cause of these hemoglobinopathies by inducing the expression of the two γ-globin genes, HBG1/2, whose expression is normally silenced shortly after birth. The HBG1/2 genes encode for γ-globin, a component of HbF, which is known to repair the abnormal RBC shape in SCD and to compensate for the presence of HbS in SCD and ß-thalassemia. We have observed in vitro and in vivo activation of the HBG1/2 genes in preclinical studies with FTX-6058. We have also observed that FTX-6058 demonstrated robust levels of HbF elevation with no adverse effects on important cellular health markers. We conducted additional pre-clinical profiling in CD34+ derived cells and observed that treatment with FTX-6058 increased HbF levels to approximately 30% of total hemoglobin, as measured by mass spectrometry, high performance liquid chromatography, and fast protein liquid chromatography techniques. The elevation of HbF was significantly greater than we observed with hydroxyurea in the cell models.

In the fourth quarter of 2020, we initiated a Phase 1 clinical trial of FTX-6058 in healthy adult volunteers. The Phase 1 randomized, double-blind, placebo-controlled trial was designed to evaluate the safety, tolerability, and PK of ascending doses of FTX-6058. In the single-ascending dose, or SAD, cohorts, healthy volunteers received one dose of either placebo or 2, 4, 10, 20, 30, 40 or 60mg of FTX-6058. In the multiple-ascending dose, or MAD, cohorts, healthy volunteers received a once-daily dose of placebo or 2, 6, 10, 20 or 30mg of FTX-6058 for 14 consecutive days. Each MAD cohort had six subjects on drug and two on placebo. Food effect was also studied in a separate 20mg dose cohort. Exploratory measures were included in the MAD cohorts to assess target engagement, changes in HBG mRNA and HbF-containing reticulocytes, or F-reticulocytes. A 6mg dose cohort in people with SCD was later added to this trial to further inform PK and pharmacodynamic, or PD, modeling for future dose selections.

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FTX-6058 was generally well-tolerated with no serious adverse events reported and no discontinuations due to treatment-emergent

adverse events, or TEAEs, across all SAD and MAD cohorts. Data continued to show dose-proportional PK, with a mean half-life of approximately 6-7 hours in the MAD cohorts, supporting once-daily dosing, and no food effect was observed with FTX-6058. Data from the MAD cohorts continued to show robust target engagement, as evidenced by an approximately 75-95% reduction from baseline in H3K27me3 after 14 days of treatment.

24. Further, in discussing the Company's strategy, the 2021 10-K stated, in relevant part:

> We are leveraging the broad applicability of our proprietary product engine to discover and develop small molecule therapies that modulate gene expression to address the known root cause of genetically defined rare diseases in areas of high unmet medical need. We believe that our initial product candidates for the treatment of FSHD, SCD and ß-thalassemia may have the potential to treat patients with these debilitating and, in some cases, life-threatening illnesses. The key components of our strategy include:
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> - ***Rapidly develop FTX-6058 for the treatment of select hemoglobinopathies***. We have initiated a Phase 1b clinical trial of FTX-6058 in people with SCD and expect to report initial data from the trial in the second quarter of 2022. We submitted an IND to the FDA in the fourth quarter of 2021 for FTX-6058 in other select hemoglobinopathies, including ß-thalassemia, and expect to initiate a Phase 1b study in the second quarter of 2022.
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> - ***Maximize the commercial potential of our product candidates***. We have retained all rights to our lead product candidates focused on rare genetically defined diseases, and plan to commercialize any approved product for such rare genetically defined diseases using a targeted sales infrastructure. We may in the future pursue commercialization partnerships for certain product candidates and/or markets outside the United States.

25. In addition, with respect to the Company's disclosure controls and procedures, the 2021 10-K stated, in relevant part, that "[b]ased on the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, ***our disclosure controls and procedures were effective at the reasonable assurance level***."[1]

26. Appended to the 2021 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Stuart and Rajavelu, attesting that "the information contained in the [2021 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

27. Also on March 3, 2022, Fulcrum hosted an earnings call with investors and analysts to discuss the Company's Q4 2021 results (the "Q4 2021 Earnings Call"). During the scripted portion of the Q4 2021 Earnings Call, Defendant Stuart stated, in relevant part:

> Our second clinical program, FTX-6058, an oral HbF inducer for sickle cell disease and other hemoglobinopathies shows great promise in addressing important unmet needs in these patient populations. The current treatment landscape in sickle cell disease consists of therapies that only target select symptoms.
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> HbF is the only mechanism that has been shown to broadly improve outcomes for key symptoms of sickle cell disease such as VOC events,

[1] All emphases included herein are added unless otherwise indicated.

> pain, fatigue, and acute chest syndrome. A robust body of genetic data shows that increases in HbF in every patient is meaningful. Emerging clinical data from gene editing further supports the benefit of HbF induction, but in the case of gene editing, it comes with a tremendous treatment burden making it most likely to be used as a salvage therapy.
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> Last year, we transitioned to the clinic and announced positive Phase 1 healthy volunteer data that demonstrated robust increases in HBG mRNA at multiple doses. These data gave us confidence to advance FTX-6058 into our ongoing Phase 1b study, where we will be dosing people with sickle cell disease long enough to observe protein increases.
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> We are highly encouraged that our robust preclinical data and Phase 1 healthy volunteer data, both predict that we can achieve these absolute increases that will be life changing for people with sickle cell disease.

28. Further, during the Q&A portion of the Q4 2021 Earnings Call, when asked to discuss feedback from patients and investigators "as to enrollment for your trial versus potentially others that may have somewhat overlapping timelines," Defendant Stuart responded, in relevant part:

> We have had nothing, but excitement from sites and feedback from patients about participating in this trial. And frankly, we have not felt any competition risk here. I think the excitement generates from the fact that we've generated now evidence that says that we are, in fact what we promised to be, which is an oral HbF inducer, and the mechanism behind HbF is well understood. It's impact on this disease have been well characterized and are well appreciated, not just by the patient community, but also by other physician community.

29. On May 9, 2022, Fulcrum issued a press release announcing recent business highlights and the Company's Q1 2022 financial results. The press release stated, in relevant part:

> "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.
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> **Upcoming Milestones**
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> **FTX-6058**
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> - 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.
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> - Open next dose cohort in Phase 1b trial in people with sickle cell disease in the second quarter of 2022.
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> - Initiate registrational trial in sickle cell disease in early 2023.

30. That same day, Fulcrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2022 results (the "Q1 2022 Earnings Call"). During the scripted portion of the Q1 2022 Earnings Call, Defendant Stuart stated, in relevant part:

> I'll start with an update on FTX-6058, our oral HbF inducer for sickle cell disease and other hemoglobinopathies. 6058 shows great promise

> in addressing critical unmet needs in these patient populations. The current treatment landscape consists of therapies that only target select symptoms of sickle cell disease. HbF is the only mechanism that has been shown to broadly improve clinical outcomes including anemia, VOC events, pain, fatigue, and acute chest syndrome. As the only agent in development with the potential to induce HbF, we believe that 6058 is uniquely positioned in the current and emerging landscape.
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> We also believe that 6058 could be a transformative therapy for other hemoglobinopathies, including beta-thalassemia and we are committed to developing 6058 in these patient populations as well.

31. Further, during the Q&A portion of the Q1 2022 Earnings Call, when asked to discuss how the Company determined an early 2023 timeline to transition into a registration trial for FTX-6058, Defendant Stuart responded, in relevant part, "[. . .] our goal and I think as we've stated all along that if we're able to see robust HbF increases, our goal is to transition into a registrational trial as early as possible in 2023," and "[w]e do believe that that is consistent with what we're hearing from the [key opinion leader] that this would be a drug because of the benefits of HbF that would be broadly utilized and has the potential to be standard of care."

32. On May 12, 2022, Fulcrum issued a press release entitled "Fulcrum Therapeutics to Present Initial Data from Phase 1b Trial of FTX-6058 in Adults Living with Sickle Cell Disease at the European Hematology Association (EHA) Hybrid Congress in Vienna, Austria." The press release stated, in relevant part:

> "HbF is the only mechanism that has shown the ability to broadly improve clinical outcomes for patients with SCD— including anemia,

> vaso-occlusive crises, pain, fatigue, and acute chest syndrome," said Judy Dunn, Ph.D., president of research and development at Fulcrum. "This Phase 1b study was designed to provide proof-of-concept that FTX-6058 produces increases in HbF and could potentially be the first oral HbF inducer to address critical unmet needs in this population."

33. On August 11, 2022, Fulcrum issued a press release announcing the Company's Q2 2022 financial results and business updates. The press release stated, in relevant part:

> "In the second quarter, we achieved major milestones in both of our clinical programs," said [Defendant Stuart]. "We demonstrated compelling proof of concept data for 6058 and initiated the first registrational trial for FSHD. Our strategic refocus will better position us to continue to advance our exciting pipeline and deliver on our unwavering commitment to patients with genetically defined rare diseases."
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> **Key Business Updates**
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> **FTX-6058**
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> - Announced data from initial patients in first cohort of Phase 1b trial of FTX-6058 in SCD; achieved HbF increases of up to 6.3% over baseline, showing proof-of-concept for FTX-6058 as an oral HbF inducer.
> - Enrolling new patients in 6mg and 2mg dose cohorts of Phase 1b SCD trial, including patients both on and off hydroxyurea.
> - Planning to initiate additional cohort at higher dose; expect to complete enrollment in three dose cohorts by end of 2022.
> - Planning to initiate registrational trial in 2023.

34. That same day, Fulcrum hosted an earnings call with investors and analysts to discuss the Company's Q2 2022 results (the "Q2 2022 Earnings Call").

During the scripted portion of the Q2 2022 Earnings Call, Defendant Stuart stated, in relevant part:

> I'll start with an update on FTX-6058. HbF induction is the only mechanism which has been shown to broadly improve outcomes and reduce both the frequency and severity of sickle cell disease symptoms such as [vaso-occlusive crises], anemia, pain, fatigue and acute chest syndrome. A wide-body of evidence has demonstrated that increasing HbF by 5% to 10% above baseline levels produces benefits that could be transformative for patients with sickle cell disease, an oral therapy that can produce robust increases in HbF has been a therapeutic goal in sickle cell disease for some time, which is why our initial data from our Phase Ib trial are so exciting.

35. Further, during the Q&A portion of the Q2 2022 Earnings Call, when asked to provide an update on the first patient exposed to FTX-6058, Defendant Stuart responded, in relevant part:

> I think Joe at this point, what we've guided to and I think one of the reasons that we chose to share the initial data at [European Hematology Association] is, we had made a commitment to do so. And we were very enthusiastic about the fact that we were seeing HbF increases. We were seeing them very quickly. We were already seeing robust increases. And that, obviously, gives us a lot of conviction for the program.
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> Moving forward, what we want to do now is to get all three dose cohorts enrolled and then be able to share a complete data set rather than on a piecemeal basis. We feel like we've certainly established proof of concept. And now moving forward we want to share the complete data set, which is really going to inform what dose we take into our registrational trial.

36. On November 8, 2022, Fulcrum issued a press release announcing recent business highlights and the Company's Q3 2022 financial results. The press release stated, in relevant part:

> "In the third quarter, we have continued our focus on strong clinical and operational execution. Now that we have established proof of concept for FTX-6058 as an oral HbF inducer and have initiated our Phase 3 registration-enabling trial in FSHD, the team is focused on progressing our clinical programs and developing high-quality, compelling data," said Bryan Stuart, president and chief executive officer. "We believe we are well positioned, with a strong cash runway to deliver on our upcoming catalysts as we prepare to have two registration-enabling trials in the next 18 months."
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> **Key Business Updates**
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> **FTX-6058**
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> - Selected 12mg as the dose for the third cohort in the Phase 1b SCD trial; plan to include participants both on and off hydroxyurea.
> - Continuing to enroll patients at both 6mg and 2mg doses.
> - The Phase 1b trial is expected to continue enrolling into 2023.

37. That same day, Fulcrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2022 results (the "Q3 2022 Earnings Call"). During the scripted portion of the Q3 2022 Earnings Call, Defendant Stuart stated, in relevant part:

> Currently, we have two clinical programs with the potential to dramatically transform the treatment paradigm in sickle cell disease and FSHD. We are committed to moving both programs through the development and regulatory process as rapidly as possible to address

the significant unmet needs that we know exist in these patient populations. We are also continuing to invest in our research engine and expect to file our next IND in 2023.

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FTX-6058 is an HbF-inducing agent that has the potential to address the unmet need in sickle cell disease, including symptoms not addressed by current therapies. Several independent lines of evidence, including human genetics and emerging gene editing data, support our therapeutic goal that a 5% to 10% increase in HbF above baseline can reduce both mortality and morbidity associated with SCD. An oral therapy that can produce robust increases in HbF has been a therapeutic goal in sickle cell disease for some time, which is why the initial data from our FTX-6058 Ib trial are so exciting. We have shown compelling proof of concept that FTX-6058 rapidly induces HbF protein in sickle cell disease patients and demonstrated that it is able to achieve absolute HbF increases within the range that clinicians have targeted for a potential future standard of care.

As our work on the Phase Ib trial continues, we will continue to focus on understanding the effect of 6058 across multiple dose cohorts and the consistency and response with 6058, both as monotherapy and in combination with hydroxyurea. In addition to our ongoing 6 milligram and 2 milligram dose cohorts, we have selected 12 milligrams as the dose for our next cohort and plan to continue enrollment into 2023. Our goal is to have high quality data across multiple cohorts to inform our plans for a registration enabling trial in 2023. We have been focused on clinical trial operations and trial conduct. During the second half of the year, we have increased the number of sites that are participating in the program and have targeted our recruitment efforts in areas with meaningful populations of people living with sickle cell disease. We are focused on building connections and partnerships with the SCD community because we understand that local community-based organizations have been on the front lines of the fight to treat sickle cell disease. The feedback that we have received from the community has been clear. The accessibility and ease of use of a new SCD therapy is extremely important. Our approach of developing an oral small molecule that can be taken once a day and deliver robust HbF induction

> has been met with very positive response from patients and health care providers.

38. Further, during the Q&A portion of the Q3 2022 Earnings Call, when asked to discuss dosing and trial execution of the FTX-6058 program, Defendant Stuart responded, in relevant part:

> In terms of trial execution, this has been a big focus of the company. One of the things that we mentioned at [European Hematology Association] is that we were transitioning towards observed dosing. We are now utilizing that. I think what we can say is we believe it is effective. And our goal from a trial execution perspective, as we've spoken to, is less about quantity of data and number of patients, but more about high quality data. Making sure that we are generating good data from patients that are adherent that will really help inform our next trial with our goal of that being a registrational trial. So I think that is proceeding well. We are going to be continuing enrollment into 2023, and that will be focused on all 3 dose cohorts. And we believe that, that is going to be able to provide sufficient data to transition into that registrational trial.

39. On January 4, 2023, Fulcrum issued a press release providing a business update and 2023 outlook. The press release stated, in relevant part:

> "We are entering 2023 with a tremendous amount of momentum and expect it to be a productive year for our two clinical programs: FTX-6058 for SCD, and losmapimod for FSHD," said [Defendant Gould]. "FTX-6058 is a potential best-in-class oral HbF inducer candidate that could address critical gaps in the SCD treatment landscape. We are excited by the levels of HbF induction in our initial doses and look forward to further broadening our understanding of its effect at a higher dose.["]
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> "We are encouraged by the new FTX-6058 data at 6 mg that show clinically relevant HbF increases, up to 9.5% from baseline with hemolysis and anemia improvement, suggesting its potential for best-

in-class therapy for people living with sickle cell disease," said Santiago Arroyo, M.D., Ph.D., Fulcrum's chief medical officer.

Key Business Updates and Upcoming Milestones

FTX-6058

- Received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the treatment of SCD in December 2022

- Phase 1b data from Cohort 1 subjects in the 6 mg cohort (n=10) showed up to 9.5% absolute HbF increases from baseline; data suggest no difference in response in subjects on (n=3) and off (n=7) background hydroxyurea

- Improved biomarkers of hemolysis in evaluable patients dosed at 6 mg

- In the Phase 1b trial, FTX-6058 appears to have dose dependent and clinically relevant increases in HbF; all subjects adherent to dosing regimen showed a response

- Generally well tolerated with no drug-related treatment emergent serious adverse events and no discontinuations due to treatment emergent adverse events to date

- Enrolling 12 mg dose cohort of the Phase 1b trial

40. The statements referenced in ¶¶ 22-39 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the preclinical data submitted in support

of FTX-6058 showed safety concerns regarding potential hematological malignancies; (ii) the foregoing safety concerns increased the likelihood that the FDA would place a clinical hold on preclinical studies of FTX-6058; (iii) accordingly, the Company had overstated FTX-6058's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

41. On February 24, 2023, Fulcrum issued a press release announcing that the FDA had placed a clinical hold on FTX-6058 in Sickle Cell Disease. The press release stated, in relevant part:

> Fulcrum Therapeutics [. . .] today announced that on February 23, 2023, the U.S. Food and Drug Administration (FDA) verbally informed the company that it has issued a full clinical hold regarding the Investigational New Drug (IND) application for FTX-6058 for the potential treatment of sickle-cell disease. The Agency indicated that it would provide a formal Clinical Hold Letter to the company within 30 days.
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> The clinical hold was initiated by the Agency due to previously reported preclinical data. Fulcrum will suspend dosing in the Phase 1b trial of FTX-6058 and intends to work diligently with the Agency to resolve the hold as soon as possible.
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> "Patient safety remains paramount to me. I am encouraged by the Agency's willingness to work with us to clarify the therapeutic potential of FTX-6058. Fulcrum intends to address questions related to modulation of the PRC2 complex and the preclinical data," said [Defendant Gould]. "We continue to have confidence in the benefit-risk profile of FTX-6058 and remain committed to our goal of providing a

differentiated therapeutic option for people living with sickle cell disease."

42. On this news, Fulcrum's stock price fell $7.23 per share, or 56.09%, to close at $5.66 per share on February 24, 2023.

43. Then, on March 9, 2023, before the market opened, Fulcrum issued a press release announcing recent business highlights and the Company's Q4 and full year 2022 financial results. The press release stated, in relevant part:

> Fulcrum [. . .] today reported financial results for the fourth quarter and full year 2022 and provided a business update, including on FTX-6058.
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> "We are confident that FTX-6058 has the potential to provide a differentiated therapeutic option for people living with sickle cell disease and that the clinical and preclinical data generated to date demonstrate a favorable benefit-risk profile. We are working diligently to address the clinical hold," said [Defendant Gould]. "Additionally, we remain on track to complete enrollment in the losmapimod Phase 3 REACH trial in the second half of 2023, and are excited about potentially being first to market with a treatment for FSHD patients who have no approved therapies."
>
> Key Business Updates
>
> **FTX-6058**
>
> - On February 23, 2023, the FDA placed the investigational new drug (IND) application for FTX-6058 for the potential treatment of sickle cell disease (SCD) on full clinical hold. In its communication, the Agency noted preclinical data previously submitted in April, October and December 2022, and non-clinical and clinical evidence of hematological malignancies observed with other inhibitors of polycomb repressive complex 2 (PRC2).

- The Company received a formal Clinical Hold Letter from the Agency on February 24, 2023. Enrollment has been paused and dosing suspended in the Phase 1b trial of FTX-6058.

- The clinical hold noted that the profile of hematological malignancies observed in the non-clinical studies of FTX-6058 is similar to that observed with other inhibitors of PRC2, and that hematological malignancies have been reported clinically with other PRC2 inhibitors. The Agency requested that Fulcrum further define the population where the potential benefit of continued treatment with FTX-6058 outweighs potential risk.

Preceding the FDA hold:

- The Company made submissions to the FDA in April, October and December 2022 that included non-clinical data.

- In December, the FDA granted FTX-6058 Fast Track Designation for the treatment of SCD.

- The Company previously disclosed Phase 1b data from Cohort 1 subjects in the 6 mg cohort (n=10): Primary endpoint showed up to 9.5% absolute fetal hemoglobin (HbF) increases from baseline, data suggest no difference in response in subjects on (n=3) and off (n=7) background hydroxyurea.
    - FTX-6058 treatment appears to result in dose dependent and clinically relevant increases in HbF; all subjects adherent to the dosing regimen showed a response.

    - Improved biomarkers of hemolysis were observed in evaluable patients.

    - FTX-6058 was generally well tolerated with no drug-related treatment emergent serious adverse events and no discontinuations due to treatment emergent adverse events to date.

    - Data from subjects in the 2 mg cohort (n=2) demonstrated continued absolute HbF increases up to 4.6% through the

end of treatment, suggesting 2 mg is a potentially minimally efficacious dose.

- Data from a subject in the 12 mg dose cohort (n=3), prior to the suspension of the trial, showed up to 10.0% absolute HbF increases from baseline after 42 days of treatment.

- On February 17, 2023, the Company responded to a request received on February 9, 2023, from the FDA about non-clinical data submitted in 2022.

44. On this news, Fulcrum's stock price fell $1.44, or 23%, to close at $4.82 per share on March 9, 2023.

45. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

46. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Fulcrum securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

47. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Fulcrum securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Fulcrum or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

48. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

49. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

50. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Fulcrum;

- whether the Individual Defendants caused Fulcrum to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Fulcrum securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

51. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

52. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Fulcrum securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Fulcrum securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

53. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

54. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

55. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

56. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

57. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Fulcrum securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Fulcrum securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

58. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or

issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Fulcrum securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Fulcrum's finances and business prospects.

59. By virtue of their positions at Fulcrum, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

60. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Fulcrum, the Individual Defendants had knowledge of the details of Fulcrum's internal affairs.

61. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Fulcrum. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Fulcrum's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Fulcrum securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Fulcrum's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Fulcrum securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

62. During the Class Period, Fulcrum securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Fulcrum securities at prices

artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Fulcrum securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Fulcrum securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

63. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

64. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

65. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

66. During the Class Period, the Individual Defendants participated in the operation and management of Fulcrum, and conducted and participated, directly and indirectly, in the conduct of Fulcrum's business affairs. Because of their senior positions, they knew the adverse non-public information about Fulcrum's misstatement of income and expenses and false financial statements.

67. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Fulcrum's financial condition and results of operations, and to correct promptly any public statements issued by Fulcrum which had become materially false or misleading.

68. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Fulcrum disseminated in the marketplace during the Class Period concerning Fulcrum's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Fulcrum to engage in the wrongful acts complained of herein. The

Individual Defendants, therefore, were "controlling persons" of Fulcrum within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Fulcrum securities.

69. Each of the Individual Defendants, therefore, acted as a controlling person of Fulcrum. By reason of their senior management positions and/or being directors of Fulcrum, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Fulcrum to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Fulcrum and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

70. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Fulcrum.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.