Fulcrum Therapeutics Announces Second Quarter 2022 Financial Results and Business Update

August 11, 2022

- *Presented initial data from Phase 1b trial in sickle cell disease (SCD), which demonstrate rapid and robust increases in hemoglobin F (HbF); supports proof-of-concept that FTX-6058 is a novel oral HbF inducer*
- *Announced enrollment of first patient in Phase 3 REACH trial of losmapimod in facioscapulohumeral muscular dystrophy (FSHD); first ever Phase 3 trial in this disease*
- *Announced strategic realignment to reduce operating expenses by $40-50M, prioritize clinical execution, and extend cash runway into mid-2024*
- *Conference call scheduled for 8:00 a.m. ET today*

CAMBRIDGE, Mass., Aug. 11, 2022 (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 reported financial results for the second quarter of 2022 and announced a strategic plan to realign internal resources to support the two clinical programs that are expected to be the key drivers of near-term value and extend cash runway.

“In the second quarter, we achieved major milestones in both of our clinical programs,” said Bryan Stuart, Chief Executive Officer of Fulcrum Therapeutics. “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.”

Key Business Updates

FTX-6058

- 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.
- Delaying initiation of Phase 1b trial in non-SCD hemoglobinopathies, including beta-thalassemia.

Losmapimod

- Enrolled first patient in REACH pivotal Phase 3 trial in FSHD.
- Registrational trial will include over 30 sites in the U.S., EU, U.K., and Canada.

Preclinical Pipeline

- Planning to submit next Investigational New Drug application (IND) in 2023.

Organizational Changes

- Announced strategic plan to realign internal investments and operations to prioritize the two clinical programs that are expected to be the key drivers of near-term value and extend cash runway into mid-2024.
- Business realignment will streamline research and discovery efforts, expected to result in savings of $40-50M into mid-2024.
- Announced workforce reduction of 25% of planned headcount, primarily in discovery, research, and general & administrative (G&A).
- Announced the promotion of Mel Hayes to the role of Chief Operating Officer. Mel will assume responsibility for corporate operations, in addition to his current commercial responsibilities. Mel joined Fulcrum in September 2021 as Chief Commercial Officer.
- Announced the promotion of Curt Oltmans to the role of Chief Legal Officer. Curt previously served as Fulcrum’s Senior Vice President and General Counsel. Curt joined Fulcrum in November 2020.

Second Quarter 2022 Financial Results

- **Cash Position:** As of June 30, 2022, cash, cash equivalents, and marketable securities were $169.0 million, as compared to $218.2 million as of December 31, 2021. Based on current operating plans, including successful implementation of the operational realignment, Fulcrum 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 mid-2024.

- **Collaboration Revenue:** Collaboration revenue was $1.9 million for the second quarter of 2022, as compared to $4.4 million for the second quarter of 2021. The decrease of $2.5 million was primarily due to the winding down of Fulcrum's collaboration agreement with Acceleron Pharma Inc., a wholly owned subsidiary of Merck & Co., Inc.

- **R&D Expenses:** R&D expenses were $25.0 million for the second quarter of 2022, as compared to $17.4 million for the second quarter of 2021. The increase of $7.6 million was primarily due to a $5.0 million milestone payable to GlaxoSmithKline plc, upon the initiation of the Phase 3 REACH trial under the pre-existing right of reference and license agreement.

- **G&A Expenses:** G&A expenses were $11.1 million for the second quarter of 2022, as compared to $6.7 million for the second quarter of 2021. The increase of $4.4 million was primarily due to increased employee-related costs to support the growth of the organization and increased professional services due to increased use of consulting services and preparatory commercial activities.

- **Net Loss:** Net loss was $34.1 million for the second quarter of 2022, as compared to a net loss of $19.6 million for the second quarter of 2021.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to discuss its second quarter 2022 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 for 90 days.

Dial-in Number

U.S./Canada Dial-in Number: 1-833-634-2546
International Dial-in Number: 1-412-902-4190
Conference ID: 7096297

Replay Dial-in Number: 1-877-344-7529
Replay International Dial-in Number: 1-412-317-0088
Conference ID: 7096297

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 two lead programs in clinical development are losmapimod, a small molecule for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and FTX-6058, a small molecule designed to increase expression of fetal hemoglobin for the treatment of sickle cell disease and other hemoglobinopathies, including beta-thalassemia. Fulcrum's proprietary product engine, FulcrumSeek™, identifies drug targets that can modulate gene expression to treat the known root cause of gene mis-expression. For more information, visit www.fulcrumtx.com and follow us on Twitter @FulcrumTx and LinkedIn.

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. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, including statements regarding the strategic operational realignment and impact on operating expenses, research and discovery efforts, cost savings, Fulcrum's cash runway, and ability to achieve near term objectives and deliver on its long-term vision; completion of enrollment in the Phase 1b SCD trial of FTX-6058, as well as enrollment in three dose cohorts; timing of registration trial of FTX-6058 in SCD as well as timing for Phase 1b trial in other hemoglobinopathies; the REACH trial; timing of submission of next IND; among others. 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 continue to advance its product candidates in clinical trials; initiate and enroll clinical trials on the timeline expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of losmapimod, FTX-6058 and its other product candidates; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; realize the anticipated benefits of the strategic realignment; 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 Fulcrum'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 Fulcrum's most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Fulcrum's views as of the date hereof and should not be relied upon as representing Fulcrum's views as of any date subsequent to the date hereof. Fulcrum anticipates that subsequent events and developments will cause Fulcrum's views to change. However, while Fulcrum may elect to update these forward-looking statements at some point in the future, Fulcrum specifically disclaims any obligation to do so.

Fulcrum Therapeutics, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

(Unaudited)

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 168,973	$ 218,162
Working capital[(1)]	152,126	206,799
Total assets	195,233	235,000
Total stockholders' equity	160,755	211,539

(1) Fulcrum defines working capital as current assets minus current liabilities.

Fulcrum Therapeutics, Inc.

Consolidated Statements of Operations

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 1,882	$ 4,381	$ 4,474	$ 9,170
Operating expenses:				
Research and development	25,019	17,378	42,850	33,712
General and administrative	11,098	6,685	21,857	12,183
Total operating expenses	36,117	24,063	64,707	45,895
Loss from operations	(34,235)	(19,682)	(60,233)	(36,725)
Other income, net	165	34	235	78
Net loss	$ (34,070)	$ (19,648)	$ (59,998)	$ (36,647)
Net loss per share, basic and diluted	$ (0.83)	$ (0.60)	$ (1.47)	$ (1.14)
Weighted-average common shares outstanding, basic and diluted	40,890	32,636	40,768	32,076

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