Fulcrum Therapeutics Announces Recent Business Highlights and Third Quarter 2022 Financial Results

November 8, 2022 at 7:18 AM EST

— Selected 12mg as the dose for next cohort in the Phase 1b trial of FTX-6058 in sickle cell disease (SCD) —

— Presented 96-week data from the Phase 2 ReDUX4 trial open label extension (OLE) study at World Muscle Society (WMS) conference —

— Completed equity raise of approximately $80.8 million in net proceeds; Updated cash runway guidance into late 2024 —

— Announced the appointments of Chief Medical Officer and Chief Scientific Officer —

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

CAMBRIDGE, Mass., Nov. 08, 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 third quarter of 2022.

“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.”

Key Business Updates

FTX-6058

- 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.

Losmapimod

- Presented 96-week OLE data from the Phase 2 ReDUX4 trial at the WMS conference in October:
    - 97 percent of participants in the initial 48-week study continued into the OLE.
    - Participants in the initial treatment-arm who continued to receive losmapimod demonstrated maintenance of effect through 96-weeks as measured by reachable workspace (RWS) mean change from baseline.
    - Participants who crossed over from placebo to losmapimod after the initial 48-week trial period showed improvement and slowing of disease progression as measured by RWS mean change from baseline.
    - Losmapimod continued to demonstrate a favorable safety profile and was generally well tolerated.
- Continuing to enroll patients in REACH Phase 3 pivotal trial at sites in the U.S., Canada, the U.K., and Europe.
- Plan to complete enrollment in 2023.

Preclinical Pipeline

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

Operational Changes

- Announced the appointment of Santiago Arroyo, MD., Ph.D. as chief medical officer. Dr. Arroyo joined Fulcrum on November 7th, 2022
- Announced the appointment of Jeff W. Jacobs, Ph.D. as chief scientific officer. Dr. Jacobs will join Fulcrum as of December 1st, 2022.

Third Quarter 2022 Financial Results

- **Cash Position:** As of September 30, 2022, cash, cash equivalents, and marketable securities were $221.8 million, as compared to $218.2 million as of December 31, 2021. The increase in cash is primarily tied to our equity offering in August 2022, partially offset by our net cash used in operating activities.
- **Collaboration Revenue:** Collaboration revenue was $1.2 million for the third quarter of 2022, as compared to $4.9 million for the third quarter of 2021. The decrease of $3.7 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.

- **Operating Expenses:** Total operating expenses were $25.5 million for the third quarter of 2022, as compared to $25.7 million for the third quarter of 2021. A decrease of $1.7 million in R&D expenses was primarily due to reduced discovery and external research and development costs. This was partially offset by an increase of $1.1 million in G&A expenses due to employee-related costs to support the growth of the organization.
- **Net Loss:** Net loss was $23.7 million for the third quarter of 2022, as compared to a net loss of $20.7 million for the third quarter of 2021.

Financial Guidance

Fulcrum expects that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into late 2024.

Conference Call and Webcast

Fulcrum Therapeutics, Inc. will host a conference call and webcast today at 8:00 a.m. ET to discuss its third 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. Dial-in Number: 833-634-2546
International Dial-in Number: +1-412-902-4190

Replay U.S. Dial-in Number: 877-344-7529
Replay Canada Dial-in Number: 855-669-9658
Replay International Dial-in Number: 412-317-0088
Replay Access Code: 2495296

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 (SCD) 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 Dr. Jacobs' role at Fulcrum, including start date; 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; the REACH trial; timing of and 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 integration of new employees; 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)

	September 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 221,789	$ 218,162
Working capital[(1)]	213,028	206,799
Total assets	247,805	235,000

Total stockholders' equity	221,414	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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ 1,183	$ 4,935	$ 5,657	$ 14,105
Operating expenses:				
Research and development	15,366	17,077	58,216	50,789
General and administrative	9,707	8,628	31,564	20,811
Restructuring expenses	465	—	465	—
Total operating expenses	25,538	25,705	90,245	71,600
Loss from operations	(24,355)	(20,770)	(84,588)	(57,495)
Other income, net	617	54	852	132
Net loss	$ (23,738)	$ (20,716)	$ (83,736)	$ (57,363)
Net loss per share, basic and diluted	$ (0.51)	$ (0.57)	$ (1.97)	$ (1.71)
Weighted-average common shares outstanding, basic and diluted	46,213	36,606	42,603	33,603

Contact:

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

Media:
Dee Smith
Executive Director, Corporate Communications
Fulcrum Therapeutics, Inc.
dsmith@fulcrumtx.com
202-746-1324