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): April 18, 2023

Clearside Biomedical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37783**	**45-2437375**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

900 North Point Parkway Suite 200 Alpharetta, Georgia	**30005**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 678 270-3631

(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:

☐ 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	CLSD	The Nasdaq Stock Market LLC

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 8.01 Other Events.

On April 18, 2023, Clearside Biomedical, Inc. (the "Company") announced its plans for ODYSSEY, a randomized, double-masked, parallel-group, active-controlled, multi-center Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) using suprachoroidal delivery in neovascular age-related macular degeneration ("wet AMD"). The 36-week trial design is summarized below:

- Number of Participants: 60 total participants with 2:1 randomization.
  - 40 participants in CLS-AX arm and 20 participants in aflibercept arm.
- Key inclusion criteria:
  - Diagnosed with wet AMD within 36 months of screening.
  - History of 2 to 4 anti-VEGF treatments in the 6 months before screening.
  - History of response to anti-VEGF treatment for wet AMD.
  - Reading center confirmation of persistent active disease.
  - Best corrected visual acuity ("BCVA") of 20 to 80 letters
- Loading Doses:Participants in both arms will receive 3 aflibercept (2 mg) loading doses. In the CLS-AX arm, participants will receive one dose of CLS-AX (1.0 mg) at the same visit as the second loading dose of aflibercept ("Baseline").
- Treatments:
  - In the CLS-AX arm, following the 3 loading doses of aflibercept and the initial dose of CLS-AX at Baseline, participants will receive CLS-AX at least every 24 weeks unless more frequently required based on disease activity.
  - In the aflibercept arm, following the 3 loading doses, participants will receive aflibercept on a fixed dosing regimen every 8 weeks.
- Monthly disease activity assessments: Will be conducted in both arms at Weeks 12 through 32 to determine if there is a need for supplemental treatment.
- Supplemental treatment criteria (based on measurement changes due to wet AMD):
  - BCVA reduction of >10 letters from Baseline.
  - Increase in central subfield thickness ("CST") of >100 microns on SD-OCT from Baseline.
  - BCVA reduction of > 5 letters from Baseline AND increase in CST of >75 microns on SD-OCT from Baseline.
  - Presence of new or worsening vision-threatening hemorrhage.
- Primary outcome measure: Mean change in BCVA from Baseline to Week 36.
- Secondary outcome measures:
  - Other changes in visual function and ocular anatomy, such as CST.
  - Need for supplemental treatment.
  - Treatment burden as measured by total injections over trial duration.

The Company plans to open the trial for enrollment during the second quarter of 2023 and expects topline results in the third quarter of 2024.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by the words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" or other similar terms or expressions that concern the Company's expectations, strategy, plans or intentions. Forward-looking statements include, without limitation, statements related to the clinical development of CLS-AX, the timeline for initiating the ODYSSEY Phase 2b clinical trial for CLS-AX and the expected timing of topline results from the ODYSSEY clinical trial. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs. Actual events or results may differ materially from those expressed or implied by any forward-looking statements contained herein, including, without limitation, the risks and uncertainties described in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "***SEC***") on March 14, 2023 and in subsequent filings the Company makes with the SEC from time to time. The Company undertakes no obligation to update the information contained in this Current Report on Form 8-K to reflect new events or circumstances, except as required by law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 18, 2023

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles A. Deignan
Name: Charles A. Deignan
Title: Chief Financial Officer