

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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): December 17, 2019

Clearside Biomedical, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37783

(Commission File Number)

45-2437375

(IRS Employer
Identification No.)

900 North Point Parkway, Suite 200

Alpharetta, GA 30005

(Address of principal executive offices, including zip code)

(678) 270-3631

(Registrant's telephone number, including area code)

N/A

(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.

Clearside Biomedical, Inc. (the “*Company*”) provided an update regarding the Company’s New Drug Application (“*NDA*”) for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) for the treatment of macular edema associated with uveitis.

As previously disclosed, the U.S. Food and Drug Administration (“*FDA*”) requested additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system in at least 30 patients. In response to that request, the Company proposed the submission of clinical use information in 160 subjects from its TOPAZ study for the treatment of macular edema associated with retinal vein occlusion. In recent meeting correspondence, the FDA agreed that it would be acceptable for the Company to submit such data in lieu of the requested clinical use assessment. As a result, the Company no longer plans to conduct an additional clinical use assessment with the SCS Microinjector. As previously disclosed, the Company plans to re-submit the XIPERE NDA in the second quarter of 2020.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this Current Report on Form 8-K that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on the Company’s current beliefs and expectations. These forward-looking statements include statements regarding the timing for resubmitting the XIPERE NDA and the anticipated outcome of interactions with the FDA. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, the Company’s reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission (“SEC”) on March 15, 2019, the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 8, 2019, and the Company’s other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this Current Report on Form 8-K and are based on information available to the Company as of the date of this Current Report on Form 8-K, and the Company assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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.

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles A. Deignan

Charles A. Deignan
Chief Financial Officer

Date: December 17, 2019