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): October 18, 2019

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, 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.

On December 19, 2018, Clearside Biomedical, Inc. (the "Company") submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for the Company's product candidate, XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) for the treatment of macular edema associated with uveitis. On February 20, 2019, the Company announced that it had received notification that the FDA had accepted the NDA and assigned a Prescription Drug User Fee Act ("PDUFA") goal date for completion of its review by October 19, 2019.

On August 22, 2019, the Company announced that the FDA requested Chemistry, Manufacturing and Controls ("CMC") related items, including that the Company provide stability data for the triamcinolone acetonide suspension produced utilizing an enhanced manufacturing process implemented by the Company, and as a result, the Company expected to receive a Complete Response Letter ("CRL") from the FDA.

On October 18, 2019, the Company received a CRL from the FDA regarding its NDA for XIPERE. As part of the complete NDA review, the FDA did not identify any efficacy issues, and there were no requests for further clinical efficacy studies. As anticipated, the CRL included the FDA's request for additional stability data and reinspection of the drug product manufacturer. The CRL included one new request for additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system. The Company currently expects that this device use assessment will be conducted by at least three physicians in 30 patients, per the FDA's request.

The Company currently believes that these recommendations cited in the CRL can be addressed in a timely manner that will enable the Company to resubmit the NDA in the first quarter of 2020. The Company will be requesting a meeting with the FDA to discuss and confirm its plans for addressing the recommendations contained in the CRL. In addition, the Company continues to have advanced discussions with potential out-licensing partners for XIPERE.

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. 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 June 30, 2019, filed with the SEC on August 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: October 21, 2019