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): August 22, 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 Items.

On August 22, 2019, Clearside Biomedical, Inc. (the "***Company***") issued a press release providing an update regarding the status of the Company's 505(b)(2) New Drug Application with the U.S. Food and Drug Administration for the Company's product candidate, XIPERE™, for the treatment of macular edema associated with uveitis. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated August 22, 2019, titled "Clearside Biomedical Provides New Drug Application Filing Update for XIPERE™"

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: August 22, 2019

Exhibit 99.1

Clearside Biomedical Provides New Drug Application Update for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)

ALPHARETTA, Ga., August 22, 2019 -- Clearside Biomedical, Inc. (Nasdaq:CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, announced today an update regarding the Company's 505(b)(2) New Drug Application (NDA) for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) with the U.S. Food and Drug Administration (FDA).

In a meeting this week, the FDA's Office of Pharmaceutical Quality (OPQ) requested that Clearside provide stability data for the triamcinolone acetonide (TA) suspension produced utilizing an enhanced manufacturing process implemented by the Company. The formulation of the TA suspension has not changed; however, OPQ requested the data to verify the comparability of the stability profiles of the batches made with the enhanced manufacturing process with that of the batches originally submitted as part of the NDA. The requested data does not relate to or affect the SCS Microinjector™ platform.

As a result of this request, Clearside expects to receive a Complete Response Letter from the FDA on or before its October 19, 2019 PDUFA (Prescription Drug User Fee Act) goal date. The Company plans to re-submit the NDA in the first quarter of 2020 with the requested stability data.

"After a productive meeting with the FDA, the Agency has provided clear guidance on the Chemistry, Manufacturing, and Controls (CMC) data to be included in the NDA resubmission," stated George Lasezkay, Pharm.D., J.D., Chief Executive Officer. "We believe this is primarily a timing issue since our stability data from previously manufactured batches have been consistent and predictable, and we have every reason to believe this will continue to be the case. We will complete these efforts as quickly as possible as we work towards approval of XIPERE as a potential treatment option for patients suffering from uveitic macular edema. Discussions with potential XIPERE out-licensing partners remain ongoing. We continue to expect that we will have sufficient resources to fund operations into the third quarter of 2020, without relying on any partnership-related payments that we might gain through XIPERE partnering or R&D collaboration agreements."

Dr. Lasezkay continued, "This request does not impact in any way the SCS Microinjector platform targeting the delivery of therapeutic agents to the suprachoroidal space. We continue to focus on building our internal R&D initiatives and advancing discussions with potential partners interested in accessing the suprachoroidal space."

Clearside believes the FDA will review the NDA within six months of the receipt of the resubmission. The above information is subject to the final meeting minutes and anticipated receipt of a Complete Response Letter from the FDA.

About XIPERE™

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside's proprietary SCS Microinjector™ targeting the suprachoroidal space (SCS) offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. The Company's SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications, as well as future therapeutic innovations such as gene therapy. For more information, please visit www.clearsidebio.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release 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 Clearside's current beliefs and expectations. These forward-looking statements include statements regarding the timing for resubmitting the XIPERE NDA, the receipt of a Complete Response Letter from the FDA, the potential out-licensing of XIPERE and the economic terms such a license might include, opportunities for expanding Clearside's internal pipeline and entering into other licensing arrangements, the potential benefits of XIPERE and the SCS injection platform and the period of time over which Clearside expects its current financial resources to be sufficient to fund its planned operations. 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, Clearside's reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in Clearside'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, Clearside’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019, and Clearside’s other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Clearside as of the date of this release, and Clearside 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.

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Source: Clearside Biomedical, Inc.