

**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

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

License Agreement

On October 22, 2019, Clearside Biomedical, Inc. (the “Company”) entered into a License Agreement (the “License Agreement”) with Bausch Health Ireland Limited (“Bausch”). Pursuant to the License Agreement, the Company has granted an exclusive license to Bausch to develop, manufacture, distribute, promote, market and commercialize XIPERE™, the Company’s proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye using the Company’s proprietary microneedle (the “Device”), as well as specified other steroids, corticosteroids and NSAIDs in combination with the Device (“Other Products”), subject to specified exceptions, in the United States and Canada for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the License Agreement, Bausch has agreed to pay the Company an upfront payment of \$5.0 million (the “Upfront Payment”), which is subject to a refund if the License Agreement is terminated in specified circumstances. In addition, Bausch has agreed to make additional payments of up to \$15.0 million upon the achievement of specified pre-launch development and regulatory milestones (the “Pre-Launch Milestone Payments”) and up to an aggregate of \$56.0 million in additional milestone payments upon the achievement of (i) specified regulatory approvals for specified additional indications of XIPERE and (ii) specified levels of annual net sales (as defined in the License Agreement). Further, during the applicable royalty term, the Company will also be entitled to receive tiered royalties at increasing percentages, from the high-teens to twenty percent, based on XIPERE achieving certain annual net sales thresholds in the United States and Canada, as well as a lower royalty on annual net sales of Other Products, in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first \$30.0 million of cumulative net sales of all products.

The Company is responsible for all development expenses for XIPERE until the Company’s New Drug Application (“NDA”) for XIPERE is approved by the U.S. Food and Drug Administration (the “FDA”), subject to specified exceptions, as well as manufacturing costs in connection with the NDA. The Company is also responsible for all clinical and development expenses conducted to satisfy the FDA’s requests in the complete response letter issued on October 18, 2019 related to the NDA and any subsequent complete response letter related to the NDA (the “CRL-related expenses”). If XIPERE is approved by the FDA, Bausch will be responsible for all expenses following such approval; provided that the Company will be responsible for the CRL-related expenses and for half of the costs of any post-approval clinical trials required by the FDA, up to a specified maximum amount.

During the term of the License Agreement, and in the United States and Canada, the Company has agreed not to (i) develop or commercialize XIPERE alone or in combination with an Other Device (as defined in the License Agreement) in the licensed field, (ii) develop or commercialize any corticosteroid with the Device or an Other Device in the licensed field, (iii) develop or commercialize the Device or an Other Device with any active pharmaceutical ingredient for non-infectious uveitis or macular edema associated with non-infectious uveitis, including with any Other Drug (as defined in the License Agreement), (iv) develop or commercialize any Other Drug in combination with the Device and (v) commercialize any Other Device for achieving non-surgical access to the suprachoroidal space where such device is sold as a stand-alone product, subject to specified exceptions. The License Agreement will expire on the later of (i) the date that all of the licensed patent rights have expired in the United States and Canada, (ii) the date of the loss of regulatory exclusivity of XIPERE and any Other Products in the United States and Canada, or (iii) ten years from the later of the first sale of XIPERE or any Other Products in the United States or Canada. Bausch may terminate the License Agreement immediately and have the Upfront Payment refunded if the FDA has not approved the XIPERE NDA by February 28, 2021. Following the payment of the Pre-Launch Milestone Payments, Bausch may also terminate the License Agreement for convenience upon 180 days’ written notice. In addition, the Company can terminate the License Agreement if Bausch commences a legal action challenging the validity, enforceability or scope of any of the licensed patents. If the FDA requires an additional clinical trial prior to approving the NDA for XIPERE and the Company notifies Bausch that the Company will not conduct the trial at the Company’s expense, then Bausch may terminate the License Agreement and have the Upfront Payment refunded within 60 days of the receipt of such notice from the Company. Both parties may terminate the License Agreement (i) upon a material breach of the License Agreement, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency. Upon termination (other than for a material breach by or bankruptcy or insolvency event of the Company), all licenses and other rights granted by the Company to Bausch pursuant to the License Agreement would revert to the Company.

The foregoing is a summary description of certain terms of the License Agreement, is not complete and is qualified in its entirety by reference to the text of the License Agreement, which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2019.

Amendments to Loan and Security Agreement

In connection with the entry by the Company into the License Agreement, on October 18, 2019, the Company entered in a Third Amendment to Second Amended and Restated Loan and Security Agreement (the “Third Amendment”) with Silicon Valley Bank (“SVB”). Pursuant to the Third Amendment, among other things, the Company has repaid \$5.0 million of the outstanding principal balance of its \$10.0 million term loan on October 18, 2019. The Company did not pay any final payment or termination fees in connection with the \$5.0 million prepayment. In addition, the Company and SVB agreed to modify the repayment schedule. As amended, the term loan repayment schedule provides for interest only payments through April 30, 2020, or if the Company completes a specified financial milestone, October 31, 2020, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. In addition, the Company agreed that if the Company’s cash and cash equivalents balance with SVB becomes less than \$10.0 million, then the Company will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus an amount for a final payment fee equal to \$340,441.

In addition, on October 22, 2019, the Company entered in a Consent and Fourth Amendment to Second Amended and Restated Loan and Security Agreement (the “Fourth Amendment”) with SVB. Pursuant to the Fourth Amendment, among other things, the SVB consented to the Company’s entry into the License Agreement.

Except as modified by the Third Amendment and the Fourth Amendment, all terms and conditions of the Second Amended and Restated Loan and Security Agreement remain in full force and effect.

The foregoing summary descriptions of certain terms of the Third Amendment and the Fourth Amendment are not complete and are qualified in their entirety by reference to the text of the Third Amendment and the Fourth Amendment, which the Company expects to file as exhibits to the Company’s Annual Report on Form 10-K for the year ending December 31, 2019.

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 23, 2019