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): April 27 , 2020

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 com pany ☒

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 E xchange Act. ☒

Item 1.01 Entry into a Material Definitive Agreement.

On April 27, 2020, the Company and Bausch Health Ireland Limited ("Bausch") entered into an amendment (the "Amendment") to the Company's License Agreement with Bausch dated October 22, 2019 (as amended, the "License Agreement"). 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"; and together with XIPERE, "Products"), subject to specified exceptions, in the United States and Canada (the "Original Territory") fo r the treatment of ophthalmology indications, including non-infectious uveitis. In the Amendment, the Company has granted Bausch an exclusive option to develop, manufacture, distribute, promote, market and commercialize XIPERE in one or more of the following regions (the "Option"): (i) the European Union, including the United Kingdom, (ii) Australia and New Zealand and (iii) South America and Mexico (such regions, the "Additional Regions" and together with the Original Territory, the "Territory"). The Option may be exercised any time before the earlier of regulatory approval of XIPERE in the United States and August 31, 2021.

Pursuant to the License Agreement, Bausch paid 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 "P re-Launch Milestone Payments") and up to an aggregate of $57.3 million in additional milestone payments upon the achievement of (i) specified regulatory approvals for specified additional indications of XIPERE (including certain regulatory and commercial milestones if Bausch exercises its Option in the European Union) 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 Original Territory, as well as a lower royalty on annual net sales of Other Products in the Original Territory and on annual net sales of XIPERE in the Additional Regions if Bausch exercises its Option , in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first $45.0 million of cumulative net sales of all products in the Original Territory.

The Company is responsible for all development expenses for XIPERE in the Original Territory 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 Territory, 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 upon expiration of the royalty terms for all Products and countries in the Territory, with each royalty term for a given Product and country ending on the latest of (i) the date of expiration of the last-to-expire valid claim of any licensed patent rights covering such Product in such country in the Territory, (ii) the date of the loss of regulatory exclusivity for such Product in such country in the Territory, or (iii) ten years from the later of the first sale of such Product in such country in the Territory. For a specified period of time, Bausch may terminate the License Agreement immediately and have the Upfront Payment refunded if the FDA has not approved the XIPERE NDA by August 31, 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 tri al 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 o f 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 entiret y by reference to the text of the (i) License Agreement, which was filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2019 and (ii) Amendment, which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2020.

Item 2.02 Results of Operations and Financial Condition.

On April 28, 2020, the Company issued a press release (the "Press Release") announcing the Amendment and preliminary and unaudited financial information as of March 31, 2020. The Press Release has been furnished as 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

Item 7.01 Regulation FD Disclosure.

The information included in Item 2.02 is incorporated in this Item 7.01 by reference.

Item 8.01 Other Events.

On April 28, 2020, the Company provided an update regarding the timeline for resubmission of the NDA for XIPERE to the FDA in the Press Release. As previously disclosed, the FDA requested that the contract manufacturer for XIPERE (the "CMO") complete certain manufacturing activities within its facilities that were not specifically related to XIPERE. The CMO has advised the Company that, while progress has been made, the CMO will be delayed in completing the corrective actions needed. Based on this information, the Company currently expects to re-submit the NDA for XIPERE in the fourth 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. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission on March 13, 2020. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated April 28, 2020

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: April 28, 2020

Clearside Biomedical Revises NDA Resubmission Timeline and XIPERE™ Commercial Partnership with Bausch Health

- Management to Host Webcast and Conference Call Today at 8:30 A.M. ET -

ALPHARETTA, Ga., April 28, 2020 -- 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 to the XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) New Drug Application (NDA) resubmission timeline and to its commercialization and development partnership with Bausch Health Companies Inc. (“Bausch Health”) and Bausch + Lomb, its leading global eye health business .

As previously disclosed, the contract manufacturing organization (CMO) for XIPERE has been completing certain requalification activities within its facility. While these manufacturing activities are not specifically related to XIPERE, the CMO has advised Clearside that they continue to impact the timing of its production. Although extensive progress has been made, the CMO needs to resolve a final step affecting the proper functioning of its filling line equipment in order to produce the required stability batches to generate the data necessary for the XIPERE NDA resubmission. As a result, and due in part to COVID-19 related challenges that have impacted work schedules, the CMO has informed Clearside that there will be a delay in completing the necessary corrective action. Based on this current information, Clearside now expects to resubmit the XIPERE NDA in the fourth quarter of 2020.

In conjunction with this update, Clearside and Bausch Health have amended and revised their partnership for XIPERE. Bausch + Lomb acquired an exclusive license in October 2019 for the commercialization and development of XIPERE in the United States and Canada. Bausch + Lomb has now been granted exclusive options for the right to commercialize and develop XIPERE in (i) Europe and the United Kingdom, (ii) Australia and New Zealand, and (iii) South America and Mexico. In the amended agreement, Bausch + Lomb has extended the time allowed for Clearside to obtain XIPERE approval in the United States.

“We remain firmly committed to receiving approval from the U.S. Food and Drug Administration for XIPERE as a potential treatment option for patients suffering from macular edema associated with uveitis,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “ We have been working collaboratively with Bausch Health throughout this process and they have proven to be the ideal partner. We are pleased that their continued support of XIPERE and their interest in our suprachoroidal space (SCS ®) injection platform has resulted in an opportunity to expand

our relationship to maximize the commercial potential for XIPERE in additional important territories around the world . ”

“Our other pipeline programs and external collaborations are not impacted by this timing, as there are separate CMOs for the SCS Microinjector ® , CLS-AX (axitinib injectable suspension), and other compounds to be used in various clinical trials by our partners. We remain on track to submit an Investigational New Drug (IND) application in mid-2020 for CLS-AX in wet age-related macular degeneration, which would potentially enable us to initiate a Phase 1/2a clinical trial before the end of this year. We also expect a number of IND submissions in 2020 from our clinical development partners in gene therapy and ocular cancer utilizing our SCS Microinjector,” concluded Dr. Lasezkay.

As of March 31, 2020, Clearside’s cash and cash equivalents totaled $20.9 million. Based on Clearside’s current research and development plans and expected near-term partnership milestone payments, Clearside believes it will have sufficient resources to fund its planned operations into the second quarter of 2021. Detailed financial results for the quarter will be reported via a press release on May 8, 2020.

Management will host a webcast and conference call today at 8:30 a.m. Eastern Time to discuss this announcement and provide an update on the Company’s clinical development pipeline. The live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations . The live call can be accessed by dialing (844) 263-8310 (domestic) or (213) 358-0959 (international) and entering conference code : 5612638.

About XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)

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. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and an exclusive option for Europe and the United Kingdom, Australia and New Zealand, and South America and Mexico (through a license agreement between Clearside and Bausch Health’s affiliate). Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE in Greater China and South Korea.

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 timelines for resubmitting the NDA for XIPERE and submitting the IND for CLS-AX, as well as submissions of INDs by Clearside's partners. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2020, 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.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

Source: Clearside Biomedical, Inc.