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): March 5, 2018

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))

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 account standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2018, Clearside Biomedical, Inc. (the "***Company***") filed a preliminary prospectus supplement with the U.S. Securities and Exchange Commission in connection with a proposed registered underwritten public offering of common stock (the "***Offering***"), which included the following disclosure:

> "As of December 31, 2017, we had approximately $37.6 million of cash, cash equivalents and short-term investments. This amount is an unaudited and preliminary estimate that (i) represents the most current information available to management as of the date of this prospectus supplement, (ii) is subject to completion of financial closing and auditing procedures that could result in significant changes to the estimated amounts, and (iii) does not present all information necessary for an understanding of our financial condition as of, and our results of operations for the year ended, December 31, 2017. Accordingly, you should not place undue reliance on this preliminary estimate."

Item 8.01 Other Events.

On March 5, 2018, the Company issued a press release announcing positive topline results from a pivotal Phase 3 clinical trial of CLS-TA in macular edema associated with non-infectious uveitis. On March 6, the Company issued a press release announcing an update on its two Phase 3 clinical trials CLS-TA in retinal vein occlusion. Also on March 6, 2018, the Company issued a press release announcing the Offering. Copies of the press releases are filed as Exhibits 99.1, 99.2 and 99.3, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21 E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. These forward-looking statements include statements about the Company's anticipated public offering, anticipated use of proceeds, clinical development of the Company's product candidates, expectations regarding future clinical trials, the preliminary financial results as of December 31, 2017 and future expectations and plans and prospects for the Company. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, and uncertainties inherent in the initiation of future clinical trials. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2017, the Company's preliminary prospectus supplement filed with the Securities and Exchange Commission on March 6, 2018 and in the Company's other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company is under no obligation to (and expressly disclaims any such obligation to) update or alter its 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 March 5, 2018, titled "Clearside Biomedical Announces Positive Topline Results from Pivotal Phase 3 Clinical Trial of CLS-TA in Macular Edema Associated with Non-Infectious Uveitis"
99.2	Press Release, dated March 6, 2018, titled "Clearside Biomedical Provides Update on Two Phase 3 Clinical Trials of CLS-TA in Retinal Vein Occlusion"
99.3	Press Release, dated March 6, 2018, titled "Clearside Announces Proposed Offering of Common Stock"

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: March 6, 2018

Clearside Biomedical Announces Positive Topline Results from Pivotal Phase 3 Clinical Trial of CLS-TA in Macular Edema Associated with Non-Infectious Uveitis

Primary Endpoint Achieved – Statistically Significant Improvement in Proportion of Patients Gaining 15 or More Letters in Visual Acuity

All Key Secondary Endpoints Achieved

Clearside to Host Conference Call Today at 8:30 AM Eastern Time

ALPHARETTA, Ga., March 5, 2018 – Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today announced positive topline results from its pivotal Phase 3 clinical trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis.

Suprachoroidal CLS-TA is Clearside's proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via the suprachoroidal space, or SCS™, which is the space located between the choroid and the outer protective layer of the eye known as the sclera.

Clearside enrolled 160 patients in this randomized, controlled, masked Phase 3 pivotal clinical ("PEACHTREE") trial. Of the 160 patients enrolled, 96 patients were randomized to the treatment arm to receive two 4.0 mg doses of suprachoroidal CLS-TA 12 weeks apart, and 64 patients were randomized to undergo sham procedures at the same 12-week interval. Patients were evaluated every four weeks for a total of 24 weeks, and a total of 155 patients, or 97% of those enrolled, completed the full evaluation period of the trial.

In the PEACHTREE trial, 47% of patients who received suprachoroidal CLS-TA every 12 weeks gained at least 15 letters in best corrected visual acuity ("BCVA"), as measured using the Early Treatment of Diabetic Retinopathy Study ("ETDRS") scale, from baseline at week 24, compared to 16% of patients who underwent a sham procedure. This improvement, which was the primary endpoint of the trial, was statistically significant ($p < 0.001$). Further, in terms of improvements in BCVA, the mean change from baseline was better in the treatment arm than the sham arm at each monthly evaluation. The mean improvement from baseline was maintained throughout the evaluation period, with 9.6 letters gained at week 4 and 13.7 letters at week 24 in the active arm, compared to 1.2 letters at week 4 and 2.9 letters at week 24 in the control arm, respectively.

The following tables summarize the topline BCVA improvement data observed in the PEACHTREE trial:

Subjects Gaining ³ 15 ETDRS Letters at Week 24 from Baseline

	CLS-TA (N=96)	Control (Sham) (N=64)
Proportion (n) of Subjects Gaining ³ 15 ETDRS Letters at Week 24 from Baseline	46.9% (45)	15.6% (10)
p-value	<0.001	

Mean Change from Baseline

Change from Baseline in Each Arm	CLS-TA Arm [ETDRS Letters]	Control Arm (Sham) [ETDRS Letters]
Week 4	9.6	1.2
Week 24	13.7	2.9

For the other key secondary endpoint, administration of suprachoroidal CLS-TA resulted in a mean reduction from baseline of 157 microns in central subfield thickness at week 24 in the active arm compared to a 19 micron mean reduction in the sham arm, a result that was also statistically significant ($p < 0.001$).

Suprachoroidal CLS-TA was generally well tolerated, with no treatment-related serious adverse events reported in the trial. Through 24 weeks, corticosteroid-related elevated intraocular pressure adverse events were reported for approximately 11.5% of patients in the CLS-TA treatment group, compared to no patients in the sham group.

Detailed results from PEACHTREE will be presented at an upcoming medical conference.

“These positive topline data from PEACHTREE are very encouraging for this population with macular edema as a complication due to their uveitis,” said Rahul N. Khurana, MD, an investigator for PEACHTREE, Partner at Northern California Retina Vitreous Associates, and Clinical Associate Professor in Ophthalmology at UCSF Medical Center. “The PEACHTREE study was the first pivotal phase 3 clinical trial of a drug candidate for patients with uveitic macular edema in which a BCVA measure was the primary efficacy endpoint, potentially raising the bar for future trials in this population. Typically, uveitic macular edema may persist despite adequate control of uveitis itself, and it is challenging to treat and may persist despite multiple interventions. Also, while corticosteroids are the most common treatment for all complications of uveitis, including the associated macular edema, systematic controlled studies of this kind are rare. I believe that based on these positive results, and if marketing authorization is obtained from the FDA, suprachoroidal CLS-TA has the potential to become a new paradigm for the treatment of visual impairment associated with macular edema associated with non-infectious uveitis.”

“Having nearly 50% of the PEACHTREE trial patients treated with suprachoroidal CLS-TA gain 15 or more letters in vision is highly compelling. It represents a huge step forward in advancing suprachoroidal administration of CLS-TA towards becoming a powerful new approach in potentially treating blinding eye diseases,” said Daniel H. White, Clearside’s Chief Executive Officer and President. “We currently expect to submit a new drug application for suprachoroidal CLS-TA in patients with macular edema associated with uveitis to the FDA in the fourth quarter of 2018, and we are also evaluating a number of options for submissions to regulatory agencies in additional territories outside of the United States.”

Suprachoroidal CLS-TA, used either alone or together with an intravitreal anti-VEGF agent, is being studied as part of Clearside’s pipeline of treatments for unmet or underserved blinding eye diseases where the pathologies manifest in the retina and the choroid.

Conference Call & Webcast Details

Clearside is pleased to invite all interested parties to participate in a conference call today at 8:30 a.m. Eastern Time, during which the PEACHTREE topline results will be discussed. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID

5799948, approximately 10 minutes prior to the start time. A live, listen-only audio webcast of the conference call can be accessed by visiting the “Investor Relations” section at www.clearsidebio.com. An archive of the webcast will be available until June 5, 2018.

About PEACHTREE

PEACHTREE, a randomized, masked, sham-controlled Phase 3 trial, enrolled 160 patients with macular edema associated with non-infectious uveitis. Patients were randomized to receive two unilateral suprachoroidal CLS-TA injections or two unilateral suprachoroidal sham procedures approximately 12 weeks apart. The primary efficacy outcome measure in the trial was the proportion of patients with a change from baseline of at least 15 letters in BCVA using the ETDRS scale at 24 weeks. Safety was assessed by analyzing the occurrence of adverse events and changes in key safety parameters over the course of the trial. Additional efficacy and safety endpoints were also evaluated.

About Uveitis

Uveitis, a set of inflammatory conditions affecting the eye, is one the world’s leading causes of blindness. Uveitis occurs in about 350,000 patients in the United States and is typically found in both eyes. Macular edema is the build-up of fluid in the macula, an area in the center of the retina responsible for sharp, straight-ahead vision. Fluid buildup causes the macula to swell and thicken, which distorts vision. Macular edema occurs in approximately one-third of all non-infectious uveitis cases and is a major contributor to vision loss in these patients.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage clinical ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and preclinical product candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the SCS. This offers potentially meaningful treatment benefit to patients suffering from sight threatening diseases like uveitis, retinal vein occlusion, diabetic macular edema and wet age-related macular degeneration, where macular edema is a common complication.

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 expectations regarding the clinical development of Clearside’s product candidates, the potential attributes and benefits of Clearside’s product candidates and the timing of Clearside’s submission of a new drug application to the U.S. Food and Drug Administration for suprachoroidal CLS-TA for the treatment of macular edema associated with non-infectious uveitis. 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, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2017, 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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Exhibit 99.2

Clearside Biomedical Provides Update on Two Phase 3 Clinical Trials of CLS-TA in Retinal Vein Occlusion

ALPHARETTA, GA, March 6, 2018 (GLOBE NEWSWIRE) – Clearside Biomedical, Inc. (NASDAQ:CLSD), a late- stage biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today announced the enrollment of the first patient in a Phase 3 clinical trial ("TOPAZ") of suprachoroidal CLS-TA used with an intravitreally administered anti-VEGF agent ("intravitreal anti-VEGF agent") for the treatment of macular edema associated with Retinal Vein Occlusion ("RVO").

Suprachoroidal CLS-TA is Clearside's proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via the suprachoroidal space, or SCS™, which is the space located between the choroid and the outer protective layer of the eye known as the sclera.

TOPAZ is a multicenter, randomized, masked, controlled trial to assess the safety and efficacy of suprachoroidal CLS-TA used together with one of two intravitreal anti-VEGF agents, Lucentis® (ranibizumab) or Avastin® (bevacizumab) in treatment naïve patients with RVO. Patients in the combination arm of the trial will receive suprachoroidal CLS-TA together with an intravitreal anti-VEGF agent at the beginning of the trial, an intravitreal anti-VEGF agent alone at week 4, and suprachoroidal CLS-TA together with an intravitreal anti-VEGF agent at weeks 12 and 24. Patients in the control arm will receive an intravitreal anti-VEGF agent alone at the beginning of the trial and every four weeks thereafter through week 24. After 24 weeks, patients in both arms will be followed for approximately an additional six months. The primary objective of this trial will be to determine the proportion of patients in each arm with a best corrected visual acuity improvement of at least 15 letters from baseline at eight weeks after initial treatment. Several secondary efficacy and safety endpoints will also be evaluated. Clearside anticipates total enrollment of approximately 460 patients in this Phase 3 trial.

"TOPAZ is our second Phase 3 trial of suprachoroidal CLS-TA with an intravitreal anti-VEGF agent in patients with RVO," said Daniel H. White, Chief Executive Officer and President of Clearside. "Our first Phase 3 RVO study, called SAPPHIRE, is evaluating suprachoroidal CLS-TA in combination with intravitreal Eylea. Accordingly, if the primary endpoints are met in both the TOPAZ and SAPPHIRE trials, we expect to seek an agnostic label in the United States, where suprachoroidal CLS-TA can be used together with any anti-VEGF agent for the treatment of RVO."

Clearside also announced today that, based on patient enrollment progress, it now expects to report preliminary data from the SAPPHIRE trial in the fourth quarter of 2018 instead of the first quarter of 2019.

Suprachoroidal CLS-TA, used either alone or together with an intravitreal anti-VEGF agent, is being studied as part of Clearside's pipeline of treatments for unmet or underserved blinding eye diseases where the pathologies manifest in the retina and the choroid.

About Retinal Vein Occlusion

RVO is a sight-threatening disorder resulting from a blockage of one or more of the veins carrying blood out of the retina. This blockage can lead to bleeding within the retina and the additional fluid can cause swelling resulting in macular edema. This bleeding and macular edema can affect central vision.

According to a 2010 study published in the journal *Ophthalmology*, RVO is estimated to affect more than 16 million adults worldwide. Of those, Clearside estimates approximately 2.2 million reside in the United States.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage clinical ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and preclinical product candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the SCS. This offers potentially meaningful treatment benefit to patients suffering from sight-threatening diseases like uveitis, retinal vein occlusion, diabetic macular edema and wet age-related macular degeneration, where macular edema is a common complication.

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 expectations regarding the clinical development of Clearside’s product candidates, including the timing of preliminary data from the SAPPHIRE trial, and the potential attributes and benefits of Clearside’s product candidates. 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, 2016, filed with the U.S. Securities and Exchange Commission (“SEC”) on March 16, 2017, 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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CLEARSIDE ANNOUNCES PROPOSED PUBLIC OFFERING OF COMMON STOCK

ALPHARETTA, GA, March 6, 2018 – Clearside Biomedical, Inc. (NASDAQ: CLSD), a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today announced that it intends to offer and sell, subject to market conditions, $75 million of shares of its common stock in an underwritten public offering. All of the shares of common stock to be sold in the offering will be offered by Clearside. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or the actual size or terms of the offering.

Clearside intends to use the net proceeds of the offering to prepare and submit an NDA for suprachoroidal CLS-TA for the treatment of patients with macular edema associated with non-infectious uveitis and to invest in commercialization and marketing of suprachoroidal CLS-TA, if approved. In addition, Clearside intends to use the net proceeds to continue its Phase 3 SAPPHIRE clinical trial for its RVO program, complete its Phase 2 TYBEE clinical trial for its DME program and initiate its second Phase 3 TOPAZ clinical trial for its RVO program, as well as for continued research and development of its earlier-stage programs, working capital and general corporate purposes.

J.P. Morgan Securities LLC and Cowen and Company, LLC are acting as joint book-running managers for the offering. Stifel, Nicolaus & Company, Incorporated is acting as a passive book-running manager and Needham & Company, LLC and Wedbush Securities Inc. are acting as co-managers for the offering. Clearside intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of its common stock offered in the public offering.

A shelf registration statement relating to the shares of common stock offered in the public offering described above was filed with the Securities and Exchange Commission (SEC) on July 3, 2017 and declared effective by the SEC on July 13, 2017. The offering will be made only by means of a written prospectus and prospectus supplement that form a part of the registration statement. A preliminary prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available on the SEC's website at www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus, when available, may also be obtained by contacting J.P. Morgan Securities LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, New York 11717, or by email at prospectus-eq_fi@jpmchase.com, or by phone at (866) 803-9204; or Cowen and Company, LLC, c/o Broadridge Financial Services, 1155 Long Island Avenue, Edgewood, NY 11717, Attention: Prospectus Department, or by phone at (631) 274-2806, or by fax at (631) 254-7140.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities being offered, nor shall there be any sale of the securities being offered in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a publicly traded, ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and nonclinical candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the suprachoroidal space (SCS™). This offers potentially meaningful treatment benefits to patients suffering from sight threatening diseases like uveitis, retinal vein occlusion, diabetic macular edema and wet age-related macular degeneration.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Clearside, including statements about the Clearside's anticipated public offering, anticipated use of proceeds and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, uncertainties inherent in the initiation of future clinical trials and such other factors as are set forth in the risk factors detailed in Clearside's Annual Report on Form 10-K filed with the SEC on March 16, 2017 and other filings with the SEC under the heading "Risk Factors." In addition, the forward-looking statements included in this press release represent Clearside's views as of the date hereof. Clearside anticipates that subsequent events and developments will cause Clearside's views to change. However, while Clearside may elect to update these forward-looking statements at some point in the future, Clearside specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Clearside's views as of any date subsequent to the date hereof.

# # #

Source: Clearside Biomedical, Inc.

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