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): May 9, 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 May 9, 2018, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended March 31, 2018, as well as information regarding a conference call to discuss these financial results and the Registrant's recent corporate highlights. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated May 9, 2018

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

Date: May 9, 2018

Charles A. DeignanChief Financial Officer

Exhibit 99.1

Clearside Biomedical Announces First Quarter 2018 Financial Results and Provides Corporate Update

ALPHARETTA, GA, May 9, 2018 (GLOBE NEWSWIRE) – Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat blinding diseases of the eye, today reported financial results for the quarter ended March 31, 2018, and provided an update on its development programs.

"Coming on the heels of the recent release of positive topline results from our pivotal Phase 3 PEACHTREE trial in uveitis, and as we have continued to accumulate additional data from the trial around the resolution of signs and symptoms, our confidence in the potential of suprachoroidal CLS-TA to become a powerful new treatment option for this sight-threatening disease, both at home and abroad, continues to build," said Daniel H. White, Chief Executive Officer and President. "To that end, we are working to submit an NDA for suprachoroidal CLS-TA in patients with macular edema associated with uveitis to the FDA before the end of the year, and we are also evaluating our regulatory submission strategy for territories outside of the United States."

Update on Key Development Programs

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

Macular Edema Associated with Non-Infectious Uveitis

In March 2018, Clearside announced positive topline results from PEACHTREE, its pivotal Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis.

In the PEACHTREE trial, 47% of patients in the treatment arm 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 in the control arm 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 in the control arm at each monthly evaluation. The mean improvement from baseline seen at the first evaluation at week 4 was maintained throughout the trial, with 9.6 letters gained at week 4 and 13.7 letters at week 24 in the treatment arm, compared to 1.2 letters at week 4 and 2.9 letters at week 24 in the control arm. 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 treatment arm, compared to a 19 micron mean reduction in the control arm, a result that was also statistically significant ($p < 0.001$).

In addition, based on further analysis performed subsequent to the March 2018 data release, we observed that signs of inflammation resolved in more than two-thirds of patients treated with suprachoroidal CLS-TA across three commonly used measures of inflammation in the eye: vitreous haze, anterior chamber cells and anterior chamber flare. The following table summarizes these changes:

Resolution of Signs of Uveitis

Subjects Displaying Reduction to Zero at Week 24	CLS-TA Treatment Arm (%)	Control Arm (%)
Anterior Chamber Cells	72.0	17.0
Anterior Chamber Flare	74.3	22.0
Vitreous Haze	68.9	6.9

With respect to durability of effect, over 85% of the patients in the treatment arm did not receive rescue therapy, remaining on suprachoroidal CLS-TA over the 24 weeks of the trial, compared to between 30% and 35% of patients in the control arm who did not receive rescue therapy.

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, or IOP, adverse events were reported for approximately 11.5% of patients in the treatment arm, compared to no patients in the control arm. Both the treatment and control arms reported similar cataract adverse events, with approximately 8.3% of patients in the treatment arm and 7.8% of patients in the control arm developing cataracts. No patients underwent surgeries associated with these adverse events.

Clearside expects to submit a new drug application ("NDA") for suprachoroidal CLS-TA to treat macular edema associated with non-infectious uveitis to the U.S. Food and Drug Administration in the fourth quarter of 2018, and is also evaluating options for potential submissions to regulatory agencies in additional territories outside of the United States.

Macular Edema Associated with Retinal Vein Occlusion ("RVO")

Clearside expects to complete patient enrollment in SAPPHIRE, its first Phase 3 clinical trial of suprachoroidal CLS-TA used in combination with the intravitreal anti-VEGF agent, EYLEA® (aflibercept) ("intravitreal Eylea") in treatment naïve patients with RVO, in the second quarter of 2018. SAPPHIRE is a randomized, masked, multi-center, controlled trial with evaluations every 4 weeks. After 24 weeks, patients will be followed for approximately an additional six months. The primary objective of this trial is to determine the proportion of patients in the combination treatment arm, compared to the intravitreal Eylea alone control arm, with BCVA improvement of at least 15 ETDRS letters from baseline at eight weeks after initial treatment. Several secondary efficacy and safety endpoints will also be evaluated. Based on patient enrollment progress, Clearside expects to report preliminary 8-week data from the SAPPHIRE trial in the fourth quarter of 2018.

In March 2018, Clearside announced the enrollment of the first patient in TOPAZ, a second Phase 3 clinical trial of suprachoroidal CLS-TA with one of two intravitreal anti-VEGF agents, LUCENTIS® (ranibizumab) or

AVASTIN® (bevacizumab), in treatment naïve patients with RVO. The primary objective of this trial is to determine the proportion of patients in the combination treatment arm who achieve a BCVA improvement of at least 15 ETDRS letters from baseline at eight weeks, compared to the monotherapy intravitreal anti-VEGF in the control arm. Several secondary efficacy and safety endpoints will also be evaluated. Clearside anticipates total enrollment of approximately 460 patients in the TOPAZ trial.

If the primary endpoints are met in both the TOPAZ and SAPPHIRE trials, Clearside intends to seek a class label in the United States, which would allow suprachoroidal CLS-TA to be used together with any anti-VEGF agent for the treatment of RVO.

Diabetic Macular Edema ("DME")

In October 2017, Clearside announced the completion of patient enrollment in TYBEE, its multicenter, randomized, masked, controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of suprachoroidal CLS-TA used in combination with intravitreal Eylea in patients with DME who are naïve to treatment. In this trial, 71 patients were randomized to receive either suprachoroidal CLS-TA together with intravitreal Eylea or intravitreal Eylea alone. The primary outcome measure in each of the two trial arms is mean change from baseline in BCVA measured using the ETDRS scale at 6 months. An additional analysis will compare the number of injections required between the two trial arms. Clearside expects to announce preliminary data from TYBEE in the second quarter of 2018.

Pipeline and Collaborations

Clearside continues nonclinical efforts, both internally and with multiple collaborators, in development areas such as gene therapy, wet age-related macular degeneration ("wet AMD"), and other ocular diseases that may benefit from a suprachoroidal treatment approach.

First Quarter 2018 Financial Results

Clearside's research and development expenses for the three months ended March 31, 2018 were $13.4 million, compared to $7.6 million for the first quarter of 2017, an increase of $5.8 million. This was primarily attributable to an increase in costs related to Clearside's clinical programs. Costs for Clearside's RVO program increased $5.4 million and costs for its DME program increased $1.0 million. In addition, Clearside incurred a $0.1 million increase in regulatory costs in preparation for an NDA submission for CLS-TA in Clearside's uveitis program, a $0.2 million increase in other research and development expenses, and a $0.2 million increase in employee-related costs due to an increase in headcount to support the increased clinical trial activities. These increases were partially offset by a $0.6 million decrease in clinical costs for Clearside's uveitis program, as the PEACHTREE trial was completed during the first quarter of 2018, and a $0.4 million decrease in costs related to device and drug manufacturing.

General and administrative expenses were $3.1 million for the first quarter of 2018, compared to $2.7 million for the same period last year, an increase of $0.4 million. This increase was primarily attributable to an increase of $0.4 million in employee-related costs and of $0.2 million in marketing-related expenses as Clearside prepares for the potential commercialization of CLS-TA, partially offset by a decrease of $0.2 million in patent-related expenses.

Cash, cash equivalents and short-term investments totaled $101.1 million as of March 31, 2018, compared to $37.6 million as of December 31, 2017. Clearside received net proceeds of $79.6 million from a public offering of its common stock that closed in March 2018.

Net loss for the first quarter of 2018 was $16.6 million, or $0.62 per share of common stock, compared to $10.4 million, or $0.41 per share of common stock, for the first quarter of 2017. The increase in net loss and net loss per share was primarily attributable to higher research and development expenses in the first quarter of 2018 compared to the first quarter of 2017.

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 management will discuss the financial results and provide an update on Clearside's corporate developments. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID 5796507, approximately 10 minutes prior to the start time. A live, listen-only audio webcast of the conference call can accessed by visiting the "Investor Relations" section at www.clearsidebio.com. An archive of the webcast will be available until June 10, 2018.

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 has the potential to offer meaningful treatment benefit to patients suffering from sight-threatening diseases like uveitis, RVO, DME and wet AMD. To learn more about how Clearside is changing ophthalmology, please visit us at 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 expectations regarding the potential clinical development of Clearside's product candidates, the availability of data from Clearside's clinical trials, the timing of a potential submission of an NDA with the FDA, and the potential commercialization of CLS-TA, both in the United States and internationally. 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, 2017, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2018, 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.

CLEARSIDE BIOMEDICAL, INC.
Selected Financial Data
(in thousands, except share and per share data)
(unaudited)

Statements of Operations Data	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
License revenue	$ —	$ 5
Operating expenses:		
Research and development	13,379	7,590
General and administrative	3,074	2,671
Total operating expenses	16,453	10,261
Loss from operations	(16,453)	(10,256)
Other expense, net	(154)	(117)
Net loss	$ (16,607)	$ (10,373)
Net loss per share of common stock — basic and diluted	$ (0.62)	$ (0.41)
Weighted average shares outstanding — basic and diluted	26,818,137	25,250,333

Balance Sheet Data	March 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 101,055	$ 37,640
Restricted cash	360	360
Total assets	104,462	40,493
Long-term debt (including current portion)	7,307	8,009
Total liabilities	18,531	19,078
Total stockholders' equity	85,931	21,415

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