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 14, 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 14, 2018, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter and year ended December 31, 2017, 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 March 14, 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
Charlies A. Deignan
Chief Financial Officer

Date: March 14, 2018

Clearside Biomedical Announces Fourth Quarter 2017 Financial Results and Provides Corporate Update

ALPHARETTA, GA, March 14, 2018 (GLOBE NEWSWIRE) – 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 reported financial results for the fourth quarter and full year ended December 31, 2017, and provided an update on its development programs.

“Last week’s release of positive topline data from our pivotal Phase 3 PEACHTREE trial represents the achievement of a major milestone for Clearside, and a critical inflection point, providing us with the requisite clinical information to begin the process of filing an NDA and the potential opportunity to transition from a clinical-stage to a commercial-stage company,” said Daniel H. White, Chief Executive Officer and President. “Armed with our proprietary suprachoroidal approach to treatment, a focused pipeline of product candidates for multiple blinding eye diseases, extensive safety and efficacy data from our completed clinical trials, and a management team with a strong track record in both R&D and commercialization, we have never been more confident in Clearside’s ability to do great things in ophthalmology. We have a number of additional key milestones coming up over the course of 2018, and look forward to updating you as we continue to progress.”

Update on Key Development Programs

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. 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 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 CLS-TA (“active”) arm than in the sham (“control”) arm at each monthly evaluation. The mean improvement from baseline seen at the first evaluation timepoint 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 active 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 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 ("IOP") adverse events were reported for approximately 11.5% of patients in the CLS-TA arm, compared to no patients in the sham group.

Detailed results from PEACHTREE will be presented at an upcoming medical conference. 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 a number of options for potential submissions to regulatory agencies in additional territories outside of the United States.

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

Clearside continues to enroll patients in SAPPHIRE, a multicenter, multi-country, randomized, masked, controlled Phase 3 clinical trial designed to assess the safety and efficacy of suprachoroidal CLS-TA used in combination with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") in patients with RVO. 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 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 data from the SAPPHIRE trial in the fourth quarter of 2018.

In March 2018, Clearside announced the enrollment of the first patient in a second Phase 3 clinical trial ("TOPAZ") of suprachoroidal CLS-TA used with an intravitreal anti-VEGF agent in patients with RVO. 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. The primary objective of this trial is to determine the proportion of patients in in the combination treatment arm, compared to the intravitreal anti-VEGF agent alone control arm, with a BCVA 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 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 November 2017, during the Retina Subspecialty Day of the American Academy of Ophthalmology 2017 Annual Meeting, Charles C. Wykoff , MD, PhD, presented preliminary results from HULK, Clearside's open-label, multicenter Phase 1/2 clinical trial designed to assess the safety and efficacy of suprachoroidal CLS-TA in combination with intravitreal Eylea in 10 patients with DME who are naïve to treatment. The trial also assessed the safety and efficacy of suprachoroidal CLS-TA alone in 10 patients with DME who had previously been treated with intravitreal anti-VEGF agents or intravitreal corticosteroids and still required

further treatment. The HULK trial data presented by Dr. Wykoff showed a visual benefit for patients receiving CLS-TA, with a greater benefit in treatment naïve eyes. Anatomic improvement was observed in all treated eyes, with more than two-thirds of those eyes achieving a greater than 50% reduction in excess central retinal thickness based on monthly measurements through 6 months after initial treatment. In the treatment naïve group, 40% of patients did not require retreatment over the entire 6 months, with an additional 20% requiring only one retreatment. Suprachoroidal CLS-TA, including in patients who received as many as five injections, was well tolerated, with a low incidence of ocular side effects, including adverse events related to elevated IOP.

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 into either a combination arm to receive suprachoroidal CLS-TA together with intravitreal Eylea or a control arm to receive only intravitreal Eylea. The primary outcome measure in each of the two trial arms is mean change at 6 months from baseline in BCVA. 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.

U.S. Patent Protecting CLS-TA Used Together with an Anti-VEGF in Patients with Macular Edema

Clearside has recently received a Notice of Allowance from the U.S. Patent and Trademark Office for U.S. Patent Application Number 15/673,073 entitled, “Methods and Devices for the Treatment of Ocular Diseases in Human Subjects.”

Once the administrative process is complete, the U.S. patent that issues from this application will provide intellectual property protection for a method for treating macular edema associated with eye diseases by non-surgical delivery of an anti-inflammatory drug to the SCS in combination with non-surgical administration of a VEGF modulator.

This patent represents one in a series of Clearside filings protecting the use of the SCS as a location in the eye to dose drug that provides for higher bioavailability to target retinal and choroidal diseases and substantially spares drug exposure to the anterior segment where side effects may occur in the case of drugs like corticosteroids, regardless of the method of administration. This particular allowance relates specifically to the proprietary treatment approach that Clearside is employing in its clinical development programs for suprachoroidal CLS-TA in RVO and DME.

Pipeline and Collaborations

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

Fourth Quarter 2017 Financial Results

Clearside’s research and development expenses for the three months ended December 31, 2017 were $14.0 million, compared to $7.0 million for the fourth quarter of 2016. The $7.0 million increase was primarily attributable to increased costs related to Clearside’s ongoing clinical development programs for CLS-TA.

General and administrative expenses were $2.4 million for each of the fourth quarters of 2017 and 2016.

Net loss for the fourth quarter of 2017 was $16.5 million, or $0.65 per share of common stock, compared to $9.7 million, or $0.45 per share of common stock, for the fourth quarter of 2016. The increase in net loss is primarily attributable to the higher research and development expenses in the fourth quarter of 2017.

Full Year 2017 Financial Results

Clearside's research and development expenses for the year ended December 31, 2017 were $49.1 million, compared to $19.5 million for the year ended December 31, 2016. The $29.6 million increase was primarily attributable to increased costs related to Clearside's ongoing clinical development programs for CLS-TA.

General and administrative expenses were $9.7 million for the year ended December 31, 2017, compared to $6.3 million for the year ended December 31, 2016. The $3.4 million increase was primarily attributable to higher employee-related costs, patent and trademark costs and costs related to operating as a public company for a full year.

Net loss for the year ended December 31, 2017 was $59.0 million, or $2.33 per share of common stock, compared to $25.9 million for the year ended December 31, 2016, or $1.97 per share of common stock. The increase in net loss was primarily attributable to higher research and development expenses in 2017.

Cash, cash equivalents and short-term investments totaled $37.6 million as of December 31, 2017. Clearside completed a public offering of its common stock in March 2018, yielding gross proceeds to Clearside of $85.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by Clearside. Clearside has granted the underwriters of the offering an option, exercisable through April 6, 2018, to purchase up to an additional 980,769 shares of common stock at the public offering price.

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 7097276, 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 April 13, 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 suprachoroidal space (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 Clearside transitioning from a clinical-stage company to a commercial-stage company, the potential clinical development of Clearside’s product candidates, the availability of data from Clearside’s clinical trials, the timing of a potential filing of an NDA with the FDA, and the potential commercialization of CLS-TA. 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, to be filed with the U.S. Securities and Exchange Commission (“SEC”) on or about 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 December 31,**		**Year Ended December 31,**	
	2017	**2016**	**2017**	**2016**
License and collaboration revenue	$ 55	$ 5	$ 345	$ 520
Operating expenses:				
Research and development	13,935	6,971	49,053	19,455
General and administrative	2,441	2,391	9,700	6,263
Total operating expenses	16,376	9,362	58,753	25,718
Loss from operations	(16,321)	(9,357)	(58,408)	(25,198)
Other expense	(172)	(329)	(567)	(684)
Net loss	$ (16,493)	$ (9,686)	$ (58,975)	$ (25,882)
Net loss per share of common stock — basic and diluted	$ (0.65)	$ (0.45)	$ (2.33)	$ (1.97)
Weighted average shares outstanding — basic and diluted	25,346,345	21,349,748	25,311,614	13,111,067

Balance Sheet Data	December 31,	
	2017	2016
Cash, cash equivalents and short-term investments	$ 37,640	$ 83,631
Restricted cash	360	360
Total assets	40,493	84,813
Long-term debt (including current portion)	8,009	7,586
Total liabilities	19,078	13,154
Total stockholders’ equity	21,415	71,659

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