
**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): November 9, 2016

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.)

**1220 Old Alpharetta Road, Suite 300
Alpharetta, Georgia 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))
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Item 2.02 Results of Operations and Financial Condition.

On November 9, 2016, Clearside Biomedical, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the quarter ended September 30, 2016, as well as information regarding a conference call to discuss these financial results and the Registrant’s recent corporate highlights and outlook. 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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release, dated November 9, 2016, “Clearside Biomedical, Inc. Reports Third Quarter 2016 Financial Results”

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.

Date: November 9, 2016

By: /s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	Press Release, dated November 9, 2016, "Clearside Biomedical, Inc. Reports Third Quarter 2016 Financial Results"

Clearside Biomedical, Inc. Announces Third Quarter 2016 Financial Results and Provides Corporate Update

Phase 3 Program of Zuprata™ for Macular Edema Associated with Retinal Vein Occlusion to be Initiated in the First Half of 2017

Phase 1/2 Trial for Diabetic Macular Edema to be Initiated by the End of 2016

ALPHARETTA, GA, Nov. 9, 2016 (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 reported financial results for the quarter ended September 30, 2016 and provided an update on its development programs.

“At Clearside, we are relentlessly pursuing transformative, elegant, precise solutions to restore and preserve vision,” said Daniel H. White, Chief Executive Officer and President. “That pursuit has resulted in the achievement of a number of important milestones again in the third quarter of 2016. Noteworthy among those was the report of encouraging additional top-line data from our Phase 2 clinical trial of Zuprata™, our proprietary form of the corticosteroid triamcinolone acetonide, in patients with macular edema associated with retinal vein occlusion. We believe that an injection of Zuprata administered to the suprachoroidal space along with an intravitreal injection of an anti-VEGF agent like aflibercept, has the potential to improve visual outcomes relatively rapidly as compared to treatment with anti-VEGF monotherapy.”

Update on Key Development Programs

Macular Edema Associated with Non-Infectious Uveitis

At the American Society of Retina Specialists annual meeting in August 2016, Clearside presented findings from a Phase 2 clinical trial of suprachoroidally administered Zuprata (“suprachoroidal Zuprata”) for the treatment of macular edema associated with non-infectious uveitis. As previously reported, this trial met its primary endpoint, with a statistically significant mean reduction from baseline in retinal thickness of 164 microns at eight weeks following dosing ($p=0.002$). There was also a statistically significant mean 9 letter improvement in best corrected visual acuity at eight weeks following dosing ($p=0.0004$).

Clearside is continuing to enroll patients in PEACHTREE, its Phase 3 trial of suprachoroidal Zuprata in macular edema associated with non-infectious uveitis. This 6-month pivotal trial is expected to enroll approximately 150 patients, with approximately 90 patients being randomized into an active treatment arm to receive suprachoroidal Zuprata and approximately 60 patients being randomized into a control arm to receive a sham suprachoroidal procedure with no drug administered.

Macular Edema Associated with Retinal Vein Occlusion

During the 2016 Retina Sub-Specialty Day at the American Academy of Ophthalmology annual meeting in October, Dr. David M. Brown presented results from Clearside's Phase 2 TANZANITE trial of suprachoroidal Zuprata in patients with macular edema associated with retinal vein occlusion ("RVO"). In this controlled, masked, randomized trial, researchers compared the administration of an intravitreal injection of an anti-VEGF agent, aflibercept, in combination with suprachoroidal Zuprata to the administration of intravitreal aflibercept alone. Patients received additional intravitreal aflibercept treatments as needed. In this trial, Clearside observed both visual acuity improvements and macular edema reductions over a 3-month period following initial dosing, with 60% fewer additional intravitreal aflibercept injections in the aflibercept in combination with Zuprata arm than in the control monotherapy aflibercept arm.

Based on feedback from a recent End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"), Clearside intends to initiate Phase 3 trials of suprachoroidal Zuprata in treating RVO. While Clearside plans to announce detailed information about these Phase 3 trials at a later date, these trials are being designed to assess whether suprachoroidal Zuprata in combination with intravitreal aflibercept show superior visual acuity outcomes as compared to monthly injections of intravitreal aflibercept alone. Clearside anticipates dosing of the first patient in an RVO Phase 3 trial in the first half of 2017.

Diabetic Macular Edema ("DME")

In the Phase 2 TANZANITE trial, suprachoroidal Zuprata met the primary endpoint and Clearside observed encouraging visual acuity and macular edema improvements in patients with RVO. Accordingly, Clearside intends to expand its Zuprata clinical development programs to include another retinal vascular condition, DME. To that end, Clearside is planning a multi-center, open-label Phase 1/2 trial to evaluate a combination therapy of aflibercept and Zuprata, as well as Zuprata monotherapy, in patients with DME over a 6-month evaluation period. Clearside expects to enroll the first patient in this trial before the end of 2016.

Wet Age-Related Macular Degeneration ("wet AMD")

Earlier this year, Clearside selected axitinib as the lead compound for its development program for the treatment of wet AMD through suprachoroidal administration due to its potency in targeting the VEGF and PDGF receptors, and because of its long half-life when injected suprachoroidally. Clearside is developing a proprietary suspension formulation of axitinib and has scheduled a pre-Investigational New Drug ("IND") meeting with the FDA prior to the end of 2016. Following this meeting, Clearside expects to submit an IND application for axitinib for the treatment of wet AMD.

Third Quarter 2016 Financial Results

Clearside's research and development expenses were \$3.7 million for the quarter ended September 30, 2016, compared to \$2.3 million for the same period in 2015. The increase was primarily due to ongoing costs of the PEACHTREE Phase 3 clinical trial and increased manufacturing costs associated with the potential commercialization of suprachoroidal Zuprata. Clearside expects research and development expenses to continue to increase as additional clinical trials are conducted.

General and administrative expenses were \$1.6 million for the quarter ended September 30, 2016, compared to \$1.1 million in the third quarter of 2015. The increase was primarily due to higher employee-related expenses and costs related to being a public company, including increased directors and officers insurance, professional fees and non-employee director compensation.

Cash, cash equivalents and short-term investments totaled \$56.9 million as of September 30, 2016, compared to \$20.3 million as of December 31, 2015. The increase reflects total net proceeds of \$51.4 million received from Clearside's initial public offering in June 2016, including the exercise of the underwriters' option to purchase additional shares, partially offset by increased total operating expenses.

Net loss for the quarter ended September 30, 2016 was \$5.6 million, or \$0.28 per share, compared to \$3.5 million, or \$1.31 per share, for the same period in 2015.

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 results will be discussed. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID 12007881, 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 November 30, 2016.

About Clearside

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 pre-clinical product candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the suprachoroidal space (SCS™). This offers potentially significant treatment benefit to patients suffering from sight threatening diseases like uveitis, RVO, wet AMD and DME. 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 clinical development 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on August 12, 2016 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
License revenue	\$ 5	\$ —	\$ 515	\$ —
Operating expenses:				
Research and development	3,682	2,309	12,484	6,964
General and administrative	1,629	1,065	3,872	5,337
Total operating expenses	5,311	3,374	16,356	12,301
Loss from operations	(5,306)	(3,374)	(15,841)	(12,301)
Other expense	(339)	(101)	(355)	(168)
Net loss	\$ (5,645)	\$ (3,475)	\$ (16,196)	\$ (12,469)
Net loss per share of common stock — basic and diluted	\$ (0.28)	\$ (1.31)	\$ (1.54)	\$ (5.59)
Weighted average shares outstanding — basic and diluted	20,493,377	2,651,877	10,502,459	2,231,830

Balance Sheet Data

	September 30, 2016	December 31, 2015
Cash, cash equivalents and short-term investments	\$ 56,919	\$ 20,283
Total assets	57,771	21,055
Deferred revenue	185	700
Long-term debt (including current portion)	7,489	5,976
Total liabilities	10,833	10,400
Accumulated deficit	(55,599)	(39,363)
Total stockholders' equity (deficit)	46,938	(36,659)

Contacts

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