
**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, 2017

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 March 14, 2017, Clearside Biomedical, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the quarter and year ended December 31, 2016, as well as information regarding a conference call to discuss these financial results. 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 March 14, 2017, “Clearside Biomedical, Inc. Announces Fourth Quarter And Full Year 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: March 14, 2017

By: /s/ Charles A. Deignan

Charles A. Deignan
Chief Financial Officer

EXHIBIT INDEX

| Exhibit Number | Exhibit Description |
|---------------------------|---|
| 99.1 | Press Release, dated March 14, 2017, "Clearside Biomedical, Inc. Announces Fourth Quarter And Full Year 2016 Financial Results" |

Clearside Biomedical, Inc. Announces Fourth Quarter And Full Year 2016 Financial Results

ALPHARETTA, GA, March 14, 2017 (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 fourth quarter and full year ended December 31, 2016, and provided an update on its development programs.

“2016 was truly an historic year for Clearside in our pursuit of transformative, elegant, precise solutions to restore and preserve vision,” commented Daniel H. White, Chief Executive Officer and President of Clearside. “With the completion of our IPO this past summer and the follow-on offering in December 2016, we secured the financial resources required to achieve a number of pivotal accomplishments and to continue the development of drug therapies administered suprachoroidally for the treatment of sight-threatening diseases. These efforts have set us on a firm path as we entered multiple Phase 3 trials with our lead programs, and we look forward to updating our stakeholders on our continued progress in the months ahead.”

Update on Key Development Programs

Suprachoroidally administered CLS-TA (“suprachoroidal CLS-TA”), Clearside’s proprietary suspension formulation of triamcinolone acetonide, used either alone or together with an intravitreal anti-VEGF agent, is part of Clearside’s pipeline for the treatments of unmet or underserved blinding eye diseases where the pathologies manifest in the choroid and retina.

Macular Edema Associated with Non-Infectious Uveitis

Clearside continues to enroll patients in PEACHTREE, the Phase 3 trial of suprachoroidal CLS-TA in patients with 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 CLS-TA and approximately 60 patients being randomized into a control arm to receive a sham suprachoroidal procedure with no drug administered. Clearside currently expects to report preliminary results from PEACHTREE in early 2018.

Macular Edema Associated with Retinal Vein Occlusion (“RVO”)

On February 16, 2017, Clearside announced the enrollment of the first patient in a Phase 3 clinical trial, SAPPHIRE, of suprachoroidal CLS-TA used together with intravitreally administered EYLEA® (afibercept) (“intravitreal Eylea”) for the treatment of macular edema associated with RVO.

SAPPHIRE is a multicenter, randomized, masked, controlled trial designed to assess the safety and efficacy of suprachoroidal CLS-TA used together with intravitreal Eylea in subjects with RVO. The primary objective of this trial will be to determine the proportion of patients in each arm with best corrected visual acuity improvement of at least 15 letters from baseline at eight weeks after initial treatment. Several secondary efficacy and safety outcomes will also be evaluated.

Diabetic Macular Edema (“DME”)

On November 15, 2016, Clearside announced the enrollment of the first patient in a Phase 1/2 clinical trial, HULK, of suprachoroidal CLS-TA either with or without intravitreal Eylea for the treatment of DME. HULK is an exploratory, multicenter trial designed to assess the safety and efficacy of the administration of suprachoroidal CLS-TA both alone and in combination with intravitreal Eylea in patients with DME. We are targeting enrollment of approximately 20 patients in the trial. Safety and efficacy data will be collected at each monthly visit during the 6-month evaluation period. Clearside currently expects to report preliminary results from HULK in the second half of 2017.

Clearside is also planning a multicenter, randomized, masked, controlled Phase 2 trial to assess suprachoroidal CLS-TA together with intravitreal Eylea, compared to intravitreal Eylea monotherapy, in patients with DME over a 9-month evaluation period. Clearside expects to enroll the first patient in this trial in mid-2017.

Wet Age-Related Macular Degeneration (“wet AMD”)

On February 27, 2017, Clearside announced that it had initiated a strategic realignment of its research and development resources from its pre-clinical development program for axitinib for the treatment of wet AMD toward its ongoing clinical development program for the treatment of DME. Clearside will continue to explore potential opportunities for the use of pharmacological therapies via suprachoroidal injection for the treatment of wet AMD.

Collaborations

As Clearside’s development programs move further into the clinic, opportunities have been created to collaborate with third-party proprietary programs. In this regard, Clearside continues pre-clinical efforts with multiple collaborations in gene therapy, complement inhibition, and alternative mechanisms in the treatment complex retinal vascular diseases like wet AMD.

Fourth Quarter 2016 Financial Results

Clearside’s research and development expenses for the three months ended December 31, 2016 were \$7.0 million, compared to \$3.8 million for fourth quarter of 2015, an increase of \$3.2 million. This increase was primarily attributable to increased costs related to Clearside’s ongoing clinical development programs for CLS-TA and an increase in device manufacturing costs.

General and administrative expenses were \$2.4 million for the fourth quarter of 2016, compared to \$1.2 million for the same period last year, an increase of \$1.2 million. This year-over-year increase was primarily attributable to an increase of \$0.8 million in employee-related costs and a \$0.4 million increase for costs associated with operating as a public company, including an increase in director and officer insurance premiums, professional fees and non-employee director compensation in the three months ended December 31, 2016.

Net loss for the fourth quarter of 2016 was \$9.7 million, or \$0.45 per share of common stock, compared to \$5.2 million, or \$1.95 per share of common stock, for the fourth quarter of 2015. The increase in net loss is primarily attributable to higher research and development expenses, while the decrease in net

loss per share of common stock is primarily due to an increase in the number of shares of common stock outstanding resulting from Clearside's financing activities in 2016.

Full Year 2016 Financial Results

Clearside's research and development expenses for the year ended December 31, 2016 were \$19.5 million, compared to \$10.8 million for the year ended December 31, 2015, an increase of \$8.7 million. This increase was primarily attributable to increased costs related to Clearside's ongoing clinical development programs for CLS-TA and an increase in device manufacturing costs.

General and administrative expenses were \$6.3 million and \$6.6 million for the years ended December 31, 2016 and 2015, respectively. In 2015, Clearside recognized \$1.9 million of expenses related to the write-off of previously deferred offering costs, which did not recur in 2016. This year-over-year decrease in general and administrative expenses was primarily offset by an increase of \$1.0 million in employee-related costs and a \$0.5 million increase for costs associated with operating as a public company, including an increase in director and officer insurance premiums, professional fees and non-employee director compensation in the year ended December 31, 2016.

Net loss for the year ended December 31, 2016 was \$25.9 million, or \$1.97 per share of common stock, compared to \$17.6 million for the year ended December 31, 2015, or \$7.54 per share of common stock. The increase in net loss is primarily attributable to higher research and development expenses, while the decrease in net loss per share of common stock is primarily due to an increase in the number of shares of common stock outstanding resulting from Clearside's financing activities in 2016.

Cash, cash equivalents and short-term investments totaled \$83.6 million as of December 31, 2016. Clearside completed two public offerings of its common stock in 2016, an IPO in June and a follow-on public offering in December, yielding aggregate net proceeds of \$89.9 million to Clearside, inclusive of an additional \$5.1 million received in early January 2017 upon the underwriters' exercise of their option to purchase additional shares.

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 84209729, 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 April 13, 2017.

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 pre-clinical 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 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 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 September 30, 2016, filed with the U.S. Securities and Exchange Commission (“SEC”) on November 14, 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 | | Year Ended | |
|---|--------------------|------------|--------------|-------------|
| | December 31, | | December 31, | |
| | 2016 | 2015 | 2016 | 2015 |
| License revenue | \$ 5 | \$ — | \$ 520 | \$ — |
| Operating expenses: | | | | |
| Research and development | 6,971 | 3,798 | 19,455 | 10,762 |
| General and administrative | 2,391 | 1,218 | 6,263 | 6,555 |
| Total operating expenses | 9,362 | 5,016 | 25,718 | 17,317 |
| Loss from operations | (9,357) | (5,016) | (25,198) | (17,317) |
| Other expense | (329) | (154) | (684) | (322) |
| Net loss | \$ (9,686) | \$ (5,170) | \$ (25,882) | \$ (17,639) |
| Net loss per share of common stock — basic and diluted | \$ (0.45) | \$ (1.95) | \$ (1.97) | \$ (7.54) |
| Weighted average shares outstanding — basic and diluted | 21,349,748 | 2,656,754 | 13,111,067 | 2,338,950 |

Balance Sheet Data

| | December 31, | |
|---|--------------|-----------|
| | 2016 | 2015 |
| Cash, cash equivalents and short-term investments | \$ 83,631 | \$ 20,283 |
| Restricted cash | 360 | — |
| Total assets | 84,813 | 21,055 |
| Long-term debt (including current portion) | 7,586 | 5,976 |
| Total liabilities | 13,154 | 10,400 |
| Total stockholders' equity (deficit) | 71,659 | (36,659) |

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