
**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): August 11, 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 August 11, 2016, Clearside Biomedical, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the quarter ended June 30, 2016. 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 August 11, 2016, “Clearside Biomedical, Inc. Reports Second 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.

By: /s/ Charles A. Deignan

Charles A. Deignan
Chief Financial Officer

Date: August 11, 2016

EXHIBIT INDEX

**Exhibit
Number**

Exhibit Description

99.1 Press Release, dated August 11, 2016, "Clearside Biomedical, Inc. Reports Second Quarter 2016 Financial Results"



Clearside Biomedical, Inc. Reports Second Quarter 2016 Financial Results

Alpharetta, GA (August 11, 2016)— 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 a corporate update and financial results for the quarter ended June 30, 2016.

“Completing our IPO in June provided the financial resources to continue our clinical efforts in administering drug therapies through the suprachoroidal space for the treatment of patients suffering from sight-threatening diseases,” said Daniel H. White, Chief Executive Officer and President. “The team at Clearside achieved some very important milestones in the second quarter of 2016 with the completion of our Phase 2 trial using Zuprata™ to treat macular edema associated with retinal vein occlusion, a retinal vascular disease, when given in combination with anti-VEGF therapy. Building on our Phase 2 trial using Zuprata to treat macular edema associated with non-infectious uveitis, we believe Zuprata will have multiple opportunities to treat blinding conditions associated with the back of the eye,” continued Mr. White.

Clearside Business Highlights

- ***Announced Positive Topline Results for Phase 2 Clinical Trial (TANZANITE) in Macular Edema Associated with Retinal Vein Occlusion (RVO)***

Patients in the Phase 2 clinical trial (TANZANITE) “active arm” achieved 19 letters of improvement in Best Corrected Visual Acuity (BCVA) at the end of the three-month trial observation period as compared to 11 letters of improvement in the “control arm”. Seventy eight percent (78%, or 18/23) of patients in the active arm of the trial did not require additional intravitreal Eylea treatments during the three-month trial compared to 30% (7/23) in the control arm (p=0.003).

- ***Closed Initial Public Offering***

Clearside received net proceeds of approximately \$51.4 million from the issuance and sale of 8,148,843 shares of its common stock in its IPO, including shares issued from the exercise of the underwriters’ option to purchase additional shares. On June 2, 2016, Clearside’s shares began trading on the NASDAQ Global Market under the symbol “CLSD”.

- ***Wet Age-Related Macular Degeneration Program (wet AMD)***

Clearside selected axitinib as the lead compound for its development program for the treatment of wet AMD through suprachoroidal administration. Clearside is developing a proprietary suspension formulation of axitinib and plans to submit to the U.S. Food and Drug Administration (FDA) an Investigational New Drug (IND) application in the second half of 2016, with the subsequent commencement of a Phase 1/2 clinical trial.

Second Quarter 2016 Financial Results

Clearside's research and development expenses were \$4.2 million for the quarter ended June 30, 2016, compared to \$2.1 million for the same period in 2015. The increase was primarily due to ongoing costs of Clearside's Phase 3 clinical trial in macular edema associated with non-infectious uveitis and increased manufacturing costs associated with the commercialization of Zuprata.

General and administrative expenses were \$1.0 million for the quarter ended June 30, 2016, compared to \$3.0 million in the second quarter of 2015. The decrease is primarily due to recognizing \$1.9 million of deferred offering costs in the second quarter in 2015.

Cash and cash equivalents totaled \$55.3 million as of June 30, 2016, compared to \$20.3 as of December 31, 2015. The increase reflects net proceeds of \$45.3 million received from Clearside's IPO after deducting underwriter discounts and commissions and offering expenses. Subsequent to the end of the second quarter, an additional \$6.1 million of net proceeds was received from the exercise of the underwriter's option to purchase additional shares.

Net losses attributable to common stockholders for the quarter ended June 30, 2016 were \$5.1 million, or \$0.62 per share, compared to \$5.2 million and \$2.36 per share for the same period in 2015.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a publicly-traded, late-stage clinical biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye using Clearside's proprietary suprachoroidal space microinjector to reach diseased tissue through the suprachoroidal space. Clearside holds intellectual property protecting the delivery of drugs of any type through the suprachoroidal space to reach the back of the eye. Clearside has a portfolio of clinical and pre-clinical programs using drug administration through the suprachoroidal space to provide a route of access to treat diseases of the back-of-the-eye such as RVO, uveitis, wet AMD and diabetic macular edema (DME). Clearside is currently enrolling patients in a Phase 3 clinical trial (PEACHTREE) for the treatment of patients with macular edema associated with non-infectious uveitis and has initiated IND-enabling studies for the treatment of wet AMD. Visit www.clearsidebio.com for more information.

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 the Risk Factors section of Clearside’s Registration Statement on Form S-1 (File No. 333-208916) declared effective by the Securities and Exchange Commission (SEC) on June 1, 2016, and Clearside’s other Periodic Reports filed with the SEC. These documents are available under the “Investor Relations” section of Clearside’s website at <http://www.clearsidebio.com>. 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.

Financials

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

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|------------|------------------|------------|
| | June 30, | | June 30, | |
| | 2016 | 2015 | 2016 | 2015 |
| Statements of Operations Data | | | | |
| License revenue | \$ 5 | \$ — | \$ 510 | \$ — |
| Operating expenses: | | | | |
| Research and development | 4,213 | 2,147 | 8,802 | 4,655 |
| General and administrative | 970 | 3,023 | 2,243 | 4,272 |
| Total operating expenses | 5,183 | 5,170 | 11,045 | 8,927 |
| Loss from operations | (5,178) | (5,170) | (10,535) | (8,927) |
| Other income (expense) | 76 | (67) | (16) | (67) |
| Net loss | \$ (5,102) | \$ (5,237) | \$ (10,551) | \$ (8,994) |
| Net loss per share of common stock — basic and diluted | \$ (0.62) | \$ (2.36) | \$ (1.94) | \$ (4.46) |
| Weighted average shares outstanding — basic and diluted | 8,243,864 | 2,216,755 | 5,452,105 | 2,018,325 |

| | June 30, | December 31, |
|--|-----------|--------------|
| | 2016 | 2015 |
| Balance Sheet Data | | |
| Cash and cash equivalents | \$ 55,279 | \$ 20,283 |
| Total assets | 56,164 | 21,055 |
| Deferred revenue | 190 | 700 |
| Long-term debt (including current portion) | 5,686 | 5,976 |
| Total liabilities | 10,268 | 10,400 |
| Accumulated deficit | (49,914) | (39,363) |
| Total stockholders' equity (deficit) | 45,896 | (36,659) |

Contacts

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