
**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 8, 2018

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.)

**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 November 8, 2018, Clearside Biomedical, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and nine months ended September 30, 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 November 8, 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

Charles A. Deignan Chief Financial Officer

Date: November 8, 2018



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

ALPHARETTA, GA, November 8, 2018 (GLOBE NEWSWIRE) – Clearside Biomedical, Inc. (NASDAQ: CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, today reported financial results for the quarter ended September 30, 2018 and provided an update on its development programs.

“We continue to attract an impressive group of connected and experienced people who are exceptionally well qualified to help us transform Clearside from a development-stage to a commercial-stage company,” said Daniel White, Chief Executive Officer and President of Clearside. “We believe awareness and acceptance of the clinical profile of XIPERE™ for the potential treatment of uveitic macular edema are building as we work to advance our commercial readiness. I am confident we will be ready for a successful launch of XIPERE in 2019, should we receive approval.”

Key Development Program Highlights and Upcoming Milestones

Macular Edema Associated with Non-Infectious Uveitis

- Rahul N. Khurana, M.D., presented additional analyses of data from the pivotal Phase 3 trial (“PEACHTREE”) of XIPERE (formerly “suprachoroidal CLS-TA”) in patients with uveitic macular edema at the American Academy of Ophthalmology 2018 Annual Meeting:
 - Signs of inflammation resolved (defined as achieving a score of zero) on the applicable Standardization of Uveitis Nomenclature (“SUN”) scale in more than two-thirds of PEACHTREE patients treated with XIPERE across three measures of inflammation in the eye, including vitreous haze in 68%, anterior chamber cell inflammation in 72% and anterior chamber flare in 74% of XIPERE-treated patients, compared to 23%, 17% and 20%, respectively, of patients in the control arm.
 - Of patients with baseline scores of 2+ in vitreous haze based on the SUN scale, 40.9% experienced resolution in the XIPERE arm, compared to 0% of patients in the sham control arm.
 - Patients with uveitis from each of the four anatomic subtypes (anterior, intermediate, posterior and panuveitis) treated with XIPERE achieved significant visual improvement.
 - Clearside expects to submit a New Drug Application (“NDA”) for suprachoroidal XIPERE to treat macular edema associated with non-infectious uveitis to the U.S. Food and Drug Administration (“FDA”) by the end of 2018.
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Diabetic Macular Edema (“DME”)

- Clearside has consulted with its scientific and medical advisors to evaluate a path forward in its DME program. Based on their advice, and in light of the results of the SAPHIRE trial in retinal vein occlusion (“RVO”), the company has decided to cease any clinical development of XIPERE in combination with an anti-VEGF therapy. Clearside believes there is a potential role for XIPERE as monotherapy in DME, RVO and other potential indications outside of uveitis, similar to the approval and use of other steroid products for these indications.

Nonclinical Pipeline and Collaborations

- Clearside continues nonclinical efforts, both internally and with multiple collaborators, in other ocular diseases and technologies, such as gene therapy, that may benefit from a suprachoroidal treatment approach, and plans to report additional results from preclinical studies next year.

Organizational Changes

Clearside has made several recent management appointments designed to increase its commercial readiness and further strengthen its ability to advance its late-stage pipeline, while, at the same time, working to select and prioritize potential new product candidates to treat sight threatening conditions that may benefit from its proprietary suprachoroidal treatment approach.

The following executives have joined Clearside with extensive experience at leading healthcare companies, including Genentech, Inc., Allergan, Inc. Novartis Pharma AG, Alcon Research Ltd., Merck & Co., Inc., Ciba Vision, Shionogi Pharma, Inc., Arbor Pharmaceuticals, Inc., Abbot Laboratories and Spark Therapeutics, Inc.:

- Thomas A. Ciulla, M.D., MBA - Chief Medical Officer
- Thomas Crawford, CSCP - Vice President, Supply Chain
- Carol Hoang, Pharm.D., MBA - Vice President, Medical Affairs
- Viral Kansara, Ph.D. - Vice President, Discovery
- Lester Rodriguez - Vice President, Quality
- Leslie Zacks, J.D. - General Counsel and Chief Compliance Officer

In addition, Clearside appointed Jeffrey Edwards to its Board of Directors, succeeding Evgeny Zaytsev, M.D., in September 2018.

Third Quarter 2018 Financial Results

Clearside’s research and development (“R&D”) expenses for the three months ended September 30, 2018 were \$20.1 million, compared to \$16.1 million for the third quarter of 2017. The increase was primarily attributable to an increase in costs related to Clearside’s clinical programs.

General and administrative expenses were \$3.9 million for the third quarter of 2018, compared to \$2.3 million for the same period last year. This increase was primarily attributable to an increase in employee-related costs and marketing-related expenses as Clearside prepares for the potential commercialization of XIPERE for the treatment of macular edema associated with non-infectious uveitis.

At September 30, 2018, Clearside had cash, cash equivalents and short-term investments totaling \$64.9 million. Based on that, Clearside's current research and development plans, including its planned discontinuation of its clinical development programs for combination therapy in RVO and DME, and its anticipated available borrowing capacity under its debt facility, Clearside believes it will have sufficient resources to fund its planned operations into the first quarter of 2020.

Net loss for the third quarter of 2018 was \$23.9 million, or \$0.75 per share of common stock, compared to \$18.3 million, or \$0.72 per share of common stock, for the third quarter of 2017. The increase in net loss and net loss per share was primarily attributable to higher R&D expenses in the third quarter of 2018 compared to the third quarter of 2017.

Conference Call & Webcast Details

Clearside is pleased to invite all interested parties to participate in a conference call this morning 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 463490, 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 February 10, 2019.

About XIPERE

XIPERE, Clearside's first investigational treatment, is a 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. Clearside's proprietary suprachoroidal treatment approach is designed to enable rapid dispersion of medicine to the back of the eye, so that adequate medicine reaches and stays at the site of disease and has potential to act longer. This approach has potential to provide efficacy advantages and require fewer treatments and doctor's office visits, while minimizing harm to the surrounding healthy parts of the eye in the case of a corticosteroid.

About Clearside

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform for eye disease treatments is inherently flexible and intended to work with established medicines, new formulations of medicines, as well as future innovations. Clearside's most advanced program is in non-infectious uveitis and it expects to submit an NDA to the FDA for XIPERE for the treatment of macular edema associated with non-infectious uveitis by the end of 2018. Clearside is headquartered in Alpharetta, GA. For more information, please visit <http://www.clearsidebio.com>. Follow @clearsidebio on Twitter and LinkedIn.

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 to the FDA and marketing authorization applications with regulatory agencies in Europe and other jurisdictions, and the potential commercialization of XIPERE, 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, Clearside’s Quarterly Report on Form 10-Q for the quarter ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
License and collaboration revenue	\$ —	\$ 155	\$ —	\$ 290
Operating expenses:				
Research and development	20,083	16,050	50,805	35,118
General and administrative	3,873	2,298	10,508	7,259
Total operating expenses	23,956	18,348	61,313	42,377
Loss from operations	(23,956)	(18,193)	(61,313)	(42,087)
Other income (expense), net	84	(143)	133	(395)
Net loss	\$ (23,872)	\$ (18,336)	\$ (61,180)	\$ (42,482)
Net loss per share of common stock — basic and diluted	\$ (0.75)	\$ (0.72)	\$ (2.02)	\$ (1.68)
Weighted average shares outstanding — basic and diluted	32,024,223	25,338,462	30,292,909	25,299,910

Balance Sheet Data

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 64,942	\$ 37,640
Restricted cash	360	360
Total assets	69,381	40,493
Long-term debt (including current portion)	9,911	8,009
Total liabilities	25,300	19,078
Total stockholders' equity	44,081	21,415

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