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 7, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLSD	The Nasdaq Stock Market LLC

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 accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2019, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended June 30, 2019, 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 August 7, 2019

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 Deignan
Chief Financial Officer

Date: August 7, 2019

EXHIBIT 99.1

Clearside Biomedical Announces Second Quarter 2019 Financial Results and Provides Corporate Update

- Strategic Focus on Building Internal Pipeline and External Collaborations Based on Suprachoroidal Space Injection Platform -

- Clearside Plans to Out-License XIPERE™ -

- Management to Host Webcast and Conference Call Today at 4:30 P.M. ET -

ALPHARETTA, Ga., August 7, 2019 -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, today reported financial results for the second quarter of 2019 and provided a corporate update.

“We continue to make progress in leveraging Clearside’s proprietary suprachoroidal space (SCS) injection platform,” said George Lasezkay, Pharm.D., J.D., Clearside’s Chief Executive Officer. “We recently announced an agreement with Aura Biosciences, which broadens the potential use of our SCS Microinjector™ technology into ocular oncology, where there is a significant unmet medical need. With ongoing exposure at medical conferences and in ophthalmic publications highlighting our targeted drug delivery approach, we are exploring various opportunities to prudently build our internal pipeline and we are also attracting significant interest from other companies to partner our technology like we did with Aura Biosciences.”

Dr. Lasezkay continued, “I have been working with our team and Board of Directors to re-evaluate the Company’s overall strategy. We have concluded that the optimal path to maximize the value of XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) is to out-license rights to XIPERE rather than commercialize it on our own. The XIPERE New Drug Application is currently under review with the U.S. FDA. We believe that a partner, or partners, will be better positioned to bring XIPERE to market more effectively and to more markets than would be possible for Clearside, and we are currently in ongoing discussions with multiple interested parties. This change in strategy benefits Clearside in a number of ways in the near term: it lowers expenses and eliminates the inherent risks and investment related to creating and maintaining a commercial infrastructure; it also has the potential to provide access to non-dilutive funding via potential upfront and milestone-based payments, and future royalties, which could be used to fund our internal research and development (R&D) pipeline.”

“We are excited about this new strategic direction for the Company. We can now dedicate additional resources to advancing our two-prong development strategy centered on the use of our proprietary SCS injection platform. This includes (1) building an internal R&D pipeline in areas such as gene therapy and novel small molecules, and (2) creating

external collaborations with other companies, allowing them access to the SCS so their therapies can be delivered in a targeted, non-surgical manner. As a result of this strategic change, we believe we will now have sufficient resources to fund our planned operations into the third quarter of 2020, without relying on any partnership-related payments that we might gain through XIPERE out-licensing or external R&D collaboration agreements," concluded Dr. Lasezkay.

Key Highlights

- Worldwide licensing agreement with Aura Biosciences for the use of Clearside's SCS Microinjector to deliver Aura's proprietary drug candidates into the suprachoroidal space for the potential treatment of certain ocular cancers, including choroidal melanoma.
- Positive meeting with the Austrian Medicines and Medical Devices Agency supporting a path forward for XIPERE registration for uveitic macular edema in the European Union.
- Multiple oral presentations on Clearside's pipeline and proprietary SCS Microinjector were given by leading ophthalmology experts at the American Society of Retinal Specialists (ASRS) Annual Meeting.
- Thomas A. Ciulla, M.D., MBA, Chief Medical Officer of Clearside, served on a panel entitled, "Advancements in Genetic and Regenerative Therapies" at the Ophthalmology Innovation Summit event at ASRS.
- Opportunities for suprachoroidal delivery were recently featured in several professional journals including two articles in the official journal of the ASRS, *Retina Times*: "Suprachoroidal Drug Delivery for Uveitic Macular Edema"; "Gene Therapy: Predicting the Impact on Treating Rare and Chronic Diseases"; and a feature article in *Ophthalmology Management* titled "Introduction to Gene Therapy."

Second Quarter 2019 Financial Results

Clearside's research and development expenses for the quarter ended June 30, 2019 were $0.7 million, compared to $17.3 million for the quarter ended June 30, 2018. The $16.6 million decrease was primarily attributable to a $14.1 million decrease due to closing down two late-stage clinical trials, which included a one-time credit of $2.6 million upon reconciliation of final costs.

General and administrative expenses were $5.0 million for the quarter ended June 30, 2019, compared to $3.6 million for the quarter ended June 30, 2018. The $1.4 million increase was primarily attributable to an increase in employee-related costs, including expenses related to the resignation of Clearside's former CEO, and marketing-related expenses for XIPERE.

Net loss for the quarter ended June 30, 2019 was $5.7 million, or $0.15 per share of common stock, compared to $20.7 million for the quarter ended June 30, 2018, or $0.65 per share of common stock. The decrease in net loss was primarily related to lower clinical development costs.

Cash and cash equivalents totaled $26.2 million as of June 30, 2019.

Conference Call & Webcast Details

Clearside's management will host a webcast and conference call today at 4:30 p.m. Eastern Time to discuss the financial results and provide a corporate update. The live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations. The live call can be accessed by dialing (844) 263-8310 (domestic) or (213) 358-0959 (international) and entering conference code: 7657547 An archive of the webcast will be available for three months.

About XIPERE™

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile. A New Drug Application was submitted to the U.S. Food and Drug Administration in December 2018 for XIPERE, and, if approved, XIPERE will be the first therapy indicated for macular edema associated with uveitis.

About Uveitis and Macular Edema

Uveitis is a set of ocular inflammatory conditions and is one of the leading causes of vision loss, affecting approximately 350,000 patients in the United States and more than one million worldwide. Approximately one-third of these patients develop uveitic macular edema, a build-up of fluid in the macula, the area of the retina responsible for sharp, straight-ahead vision. Macular edema is the leading cause of vision loss and blindness in uveitis patients and can occur from uveitis affecting any anatomic location - anterior, intermediate, posterior or pan. The uveitis market is expected to grow by 2024 to nearly $550 million in the United States and over $1 billion globally.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside's proprietary SCS Microinjector™ targeting the suprachoroidal space (SCS) offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. The Company's SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications, as well as future therapeutic innovations such as gene therapy. For more information, please visit 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 statements regarding the potential out-licensing of XIPERE and the economic terms such a license might include, opportunities for expanding Clearside’s internal pipeline and entering into other licensing arrangements, the potential benefits of XIPERE and the SCS injection platform, the potential approval of XIPERE for the treatment of macular edema associated with uveitis in the United States and Europe and the period of time over which Clearside expects its current financial resources to be sufficient to fund its planned operations. 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, 2018, filed with the U.S. Securities and Exchange Commission (“SEC”) on March 15, 2019, 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.

Investor and Media Contacts:

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-Financial Tables Follow-

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

Statements of Operations Data	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 45	$ —	$ 90	$ —
Operating expenses:				
Research and development	658	17,343	11,625	30,722
General and administrative	5,004	3,561	9,388	6,635
Total operating expenses	5,662	20,904	21,013	37,357
Loss from operations	(5,617)	(20,904)	(21,923)	(37,357)
Other (expense) income, net	(117)	203	(215)	49
Net loss	$ (5,734)	$ (20,701)	$ (21,138)	$ (37,308)
Net loss per share of common stock — basic and diluted	$ (0.15)	$ (0.65)	$ (0.59)	$ (1.27)
Weighted average shares outstanding — basic and diluted	37,636,053	31,979,158	35,899,777	29,412,904

Balance Sheet Data	June 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 26,174	$ 40,878
Restricted cash	360	360
Total assets	29,854	44,120
Long-term debt (including current portion)	10,099	9,975
Total liabilities	16,953	20,500
Total stockholders' equity	12,901	23,620

Source: Clearside Biomedical, Inc.