

**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): May 8, 2020

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))

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 May 8, 2020, Clearside Biomedical, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 May 8, 2020

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: May 8, 2020

By: s/ Charles A. Deignan

Charles A. Deignan
Chief Financial Officer



Clearside Biomedical Announces First Quarter 2020 Financial Results

ALPHARETTA, Ga., May 8, 2020 -- 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 first quarter ended March 31, 2020.

“Our team remains focused on progressing our programs as we navigate the evolving business and regulatory environment,” said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. “We are committed to advancing our first product candidate, XIPERE™, to the U.S. regulatory finish line as quickly as possible to maximize its commercial potential. Our Investigational New Drug application remains on track for submission in mid-2020 for CLS-AX (axitinib injectable suspension) in wet age-related macular degeneration, which would potentially enable us to initiate a Phase 1/2a clinical trial before the end of this year. Additionally, we continue to support our clinical development partners in gene therapy and ocular cancer as they move their programs forward using our SCS Microinjector®.”

Key Highlights

- Clearside and Bausch Health Companies Inc. and its leading global eye health business, Bausch + Lomb, amended their licensing agreement for the commercialization and development of XIPERE in the U.S. and Canada. Clearside granted Bausch + Lomb an exclusive option for the right to commercialize and develop XIPERE in (i) Europe and the United Kingdom, (ii) Australia and New Zealand, and/or (iii) South America and Mexico; and Bausch + Lomb extended the time allowed for Clearside to obtain regulatory approval for XIPERE in the U.S.
 - NDA resubmission timeline for XIPERE (triamcinolone acetonide suprachoroidal injectable suspension) is currently targeted for the fourth quarter of 2020 based on recent manufacturing updates.
 - Clearside received an upfront payment of \$4.0 million from Arctic Vision pursuant to a license agreement for the commercialization and development of XIPERE in China, Hong Kong, Macau, Taiwan and South Korea.
 - Experienced research and development executive, Nancy J. Hutson, Ph.D., was appointed to Clearside’s Board of Directors.
 - Clearside established a Scientific Advisory Board with highly experienced retinal physicians who will provide input on program and clinical development.
 - Multiple presentations featuring Clearside’s suprachoroidal injection platform in a range of indications, including wet AMD, uveitis, diabetic macular edema and ocular gene therapy, were highlighted at global conferences, including the Annual Meeting
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of the Macula Society, the Annual Angiogenesis Meeting, and the Annual American Uveitis Society Winter Symposium.

- *Ophthalmology*, the peer-reviewed journal of the American Academy of Ophthalmology, published results from the Phase 3 clinical trial of XIPERE (the PEACHTREE trial).

First Quarter 2020 Financial Results

Clearside's license revenue for the first quarter of 2020 was \$4.1 million, compared to \$45,000 for the first quarter of 2019. The \$4.0 million increase was related to the receipt of the upfront payment from Arctic Vision.

Research and development expenses for the first quarter of 2020 were \$3.8 million, compared to \$11.0 million for the first quarter of 2019. The \$7.2 million decrease was primarily attributable to reduced expenses from two closed late-stage clinical trials.

General and administrative expenses for the first quarter of 2020 were \$3.1 million, compared to \$4.4 million for the first quarter of 2019. The \$1.3 million decrease was primarily attributable to lower marketing and employee-related expenses due to Clearside's out-licensing of the commercialization of XIPERE.

Net loss for the first quarter of 2020 was \$2.9 million, or \$0.07 per share of common stock, compared to a net loss of \$15.4 million, or \$0.45 per share of common stock, for the first quarter of 2019. The decrease in net loss was primarily attributable to lower research and development expenses in 2020.

As of March 31, 2020, Clearside's cash and cash equivalents totaled \$20.9 million. Based on Clearside's current research and development plans and expected near-term partnership milestone payments, Clearside believes it will have sufficient resources to fund its planned operations into the second quarter of 2021.

Clearside will not be hosting a conference call in conjunction with this release. The Company conducted a corporate update call on April 28, 2020, which is accessible on the Clearside website under the Investors section: [Events and Presentations](#).

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 timelines for resubmitting the NDA for XIPERE and submitting the IND for CLS-AX, as well as Clearside’s ability to fund its operations into the second quarter of 2021, including the receipt of potential milestone payments. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside’s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission (“SEC”) on March 13, 2020, 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	
	March 31,	
	2020	2019
License and other revenue	\$ 4,097	\$ 45
Operating expenses:		
Research and development	3,811	10,967
General and administrative	3,122	4,384
Total operating expenses	6,933	15,351
Loss from operations	(2,836)	(15,306)
Other expense	(75)	(98)
Net loss	\$ (2,911)	\$ (15,404)
Net loss per share of common stock — basic and diluted	\$ (0.07)	\$ (0.45)
Weighted average shares outstanding — basic and diluted	44,753,510	34,144,209

Balance Sheet Data

	March 31,	December 31,
	2020	2019
Cash and cash equivalents	\$ 20,930	\$ 22,595
Restricted cash	360	360
Total assets	25,043	26,776
Deferred revenue	5,100	5,000
Debt (including current portion)	5,183	5,152
Total liabilities	14,603	15,619
Total stockholders' equity	10,440	11,157

Source: Clearside Biomedical, Inc.