

**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 11, 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 March 11, 2020, Clearside Biomedical, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter and year ended December 31, 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 March 11, 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: March 11, 2020

By: s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer



Clearside Biomedical Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

- *IND Submission for CLS-AX (axitinib injectable suspension) On Track for Mid-2020 -*
- *Greater China Licensing Partnership and Updated NDA Resubmission Timeline for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) -*
- *Partners Expected to Initiate Clinical Testing in 2020 for Treatment of Wet AMD, Diabetic Retinopathy and Ocular Cancer Using SCS Microinjector™ -*
- *Management to Host Webcast and Conference Call Today at 4:30 P.M. ET -*

ALPHARETTA, Ga., March 11, 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 fourth quarter and year ended December 31, 2019 and provided a corporate update.

“The momentum for Clearside is building as we increase awareness of our suprachoroidal space injection platform, develop our internal pipeline and work with our partners to advance multiple clinical programs,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “We have been encouraged by the medical community’s interest in our preclinical data on CLS-AX (axitinib injectable suspension), which we believe could support the potential for long-acting pan-VEGF inhibition in wet age-related macular degeneration. We expect to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for CLS-AX in mid-2020, which would potentially enable us to initiate a Phase 1/2a clinical trial before the end of this year. Our pipeline is also growing as our partners in gene therapy and ocular cancer are moving to initiate clinical testing of their compounds using our proprietary SCS Microinjector™. Based on our partners’ plans, we expect several IND submissions and the initiation of multiple clinical trials in 2020.”

Dr. Lasezkay continued, “As we continue to progress our XIPERE program and partnerships, we are working together with Bausch + Lomb and our commercial manufacturer to ensure the most thorough and highest quality New Drug Application (NDA) resubmission. We currently expect to resubmit our NDA for XIPERE by the end of August 2020 and believe the FDA will review the NDA within six months of receipt of the resubmission. We also signed a new development and commercialization partnership with Arctic Vision that expands the global reach of XIPERE to Greater China and South Korea. This collaboration adds \$4.0 million in an upfront payment to our balance sheet with the possibility of additional revenue through future milestone payments up to \$31.5 million and royalties on product sales.”

Key Highlights and Upcoming Milestones

- License agreement with upfront and milestone payments and royalties on product sales from Arctic Vision for the commercialization and development of XIPERE in Greater China and South Korea.
- George Lasezkay, Pharm.D., J.D. was appointed President and Chief Executive Officer, transitioning from the Interim CEO position.
- Adeno-associated virus (AAV) gene therapy partner, REGENXBIO, plans to initiate its Phase 2 clinical trial for suprachoroidal delivery of RGX-314 using the SCS Microinjector for treatment of wet age-related macular degeneration (wet AMD) in the first half of 2020, with interim data from the first cohort expected by the end of 2020.
- REGENXBIO expects to submit an IND application for a Phase 2 trial for treatment of diabetic retinopathy in the first half of 2020 using the SCS Microinjector to deliver RGX-314 to the suprachoroidal space. The trial is expected to begin in the second half of 2020 and enrollment of the first cohort is expected to be complete by the end of 2020, with interim data expected in 2021.
- Ocular oncology partner, Aura Biosciences, expects to initiate clinical testing during the second half of 2020 using suprachoroidal delivery for AU-011 for the potential treatment of certain ocular cancers, including choroidal melanoma.
- Preclinical data on Clearside's lead development asset, CLS-AX was presented at the 43rd Annual Meeting of The Macula Society.
- Multiple oral 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 of The Macula Society, the Annual Angiogenesis Meeting, the Annual American Uveitis Society Winter Symposium and the American Academy of Ophthalmology Annual Meeting.
- *Ophthalmology*, the peer-reviewed journal of the American Academy of Ophthalmology, published results from the Phase 3 clinical trial of XIPERE (the PEACHTREE trial).

Fourth Quarter 2019 Financial Results

Clearside's license revenue for the fourth quarter of 2019 was \$1.9 million, compared to \$30,000 for the fourth quarter of 2018. The \$1.9 million increase was associated with payments from partner licensing agreements.

Research and development expenses for the fourth quarter of 2019 were \$1.3 million, compared to \$17.5 million for the fourth quarter of 2018. The \$16.2 million decrease was primarily attributable to reduced expenses from two closed late-stage clinical trials and subsequent vendor credits of \$2.0 million upon reconciliation of final trial costs.

General and administrative expenses for the fourth quarter of 2019 were \$3.7 million, compared to \$4.2 million for the fourth quarter of 2018. The \$0.5 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 fourth quarter of 2019 was \$3.1 million, or \$0.07 per share of common stock, compared to a net loss of \$21.6 million, or \$0.68 per share of common stock, for the fourth quarter of 2018. The decrease in net loss was primarily attributable to lower research and development expenses in 2019.

Full Year 2019 Financial Results

Clearside's license and collaboration revenue for the year ended December 31, 2019 was \$2.2 million, compared to \$30,000 for the year ended December 31, 2018. The \$2.1 million increase was associated with payments from partner licensing agreements.

Research and development expenses for the year ended December 31, 2019 were \$15.7 million, compared to \$68.3 million for the year ended December 31, 2018. The \$52.6 million decrease was primarily attributable to reduced expenses from two closed late-stage clinical trials.

General and administrative expenses were \$16.8 million for the year ended December 31, 2019, compared to \$14.7 million for the year ended December 31, 2018. The \$2.1 million increase was primarily attributable to increased employee-related costs, including accrued expenses related to the resignation of Clearside's former CEO.

Net loss for the year ended December 31, 2019 was \$30.8 million, or \$0.81 per share of common stock, compared to a net loss of \$82.8 million, or \$2.69 per share of common stock, for the year ended December 31, 2018. The decrease in net loss was primarily attributable to lower research and development expenses in 2019.

Cash and cash equivalents totaled \$22.6 million as of December 31, 2019, which included partner licensing revenue and private placement funding received in the fourth quarter of 2019. The Company expects to have sufficient resources to fund planned operations into the first quarter of 2021.

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: 2462408. An archive of the webcast will be available for three months.

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 opportunities for expanding Clearside’s internal pipeline, the potential benefits of XIPERE and the SCS injection platform, the potential receipt of milestone payments, the timing for resubmitting the XIPERE NDA and the anticipated outcome of interactions with the FDA and the development and potential benefits of CLS-AX, including the timing for the IND submission for CLS-AX. 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, Clearside’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 8, 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		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
License revenue	\$ 1,942	\$ 30	\$ 2,173	\$ 30
Operating expenses:				
Research and development	1,305	17,486	15,658	68,291
General and administrative	3,650	4,176	16,819	14,684
Total operating expenses	4,955	21,662	32,477	82,975
Loss from operations	(3,013)	(21,632)	(30,304)	(82,945)
Other (expense) income, net	(83)	(6)	(466)	127
Net loss	\$ (3,096)	\$ (21,638)	\$ (30,770)	\$ (82,818)
Net loss per share of common stock — basic and diluted	\$ (0.07)	\$ (0.68)	\$ (0.81)	\$ (2.69)
Weighted average shares outstanding — basic and diluted	42,394,959	32,041,305	38,170,830	30,733,600

Balance Sheet Data

	December 31,	December 31,
	2019	2018
Cash, cash equivalents and short-term investments	\$ 22,595	\$ 40,878
Restricted cash	360	360
Total assets	26,776	44,120
Deferred revenue	5,000	—
Long-term debt (including current portion)	5,152	9,975
Total liabilities	15,619	20,500
Total stockholders' equity	11,157	23,620

Source: Clearside Biomedical, Inc.