UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 14, 2023

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, Georgia	**30005**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 678 270-3631

(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 14, 2023, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended June 30, 2023, 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 14, 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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: August 14, 2023

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

Clearside Biomedical Announces Second Quarter 2023 Financial Results and Provides Corporate Update

- Phase 2b ODYSSEY Trial of CLS-AX in Wet AMD Progressing as Planned with Nearly 30 Sites Now Open -

- Proprietary Suprachoroidal Injection Platform Featured in Peer-Reviewed Publication and at ARVO, ASRS and OIS Scientific Meetings -

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

ALPHARETTA, Ga., August 14, 2023 -- Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), today reported financial results for the second quarter ended June 30, 2023 and provided a corporate update.

“The last several months have been very productive for Clearside with the initiation of ODYSSEY, our Phase 2b clinical trial with CLS-AX, which we believe has the potential to be up to a twice-a-year treatment for wet AMD,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “We are enrolling patients through a broad network of U.S. clinical sites, and we now have nearly all of our planned 30 sites currently open to enroll participants in the trial. We expect to report topline data in the third quarter of 2024. Our differentiated treatment approach utilizes our SCS Microinjector®, a proven, non-surgical, non-implant way to deliver our proprietary formulation of axitinib, the most potent tyrosine kinase inhibitor in development for patients with wet AMD.”

“We continue to be encouraged by the acceptance of suprachoroidal administration as an innovative and safe form of ophthalmic drug delivery. With an approved product in the U.S., our Asia-Pacific partner’s recent NDA submission in Australia, the continued clinical progress by REGENXBIO/AbbVie and Aura Biosciences using our SCS Microinjector, and multiple presentations at prominent medical meetings, including ARVO and ASRS, Clearside is the leader in suprachoroidal delivery of therapeutic agents to the back of the eye,” concluded Dr. Lasezkay.

Key Highlights

- Enrollment and dosing of participants is underway in ODYSSEY, Clearside's randomized, multi-center Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD).
- Clearside's Asia-Pacific partner, Arctic Vision, announced the acceptance in Australia of its New Drug Application for suprachoroidal use of Arcatus® (known as XIPERE® in the U.S.) for the treatment of uveitic macular edema.
- Clearside's SCS Microinjector technology was featured in the peer-reviewed *Nature* portfolio journal, *Experimental & Molecular Medicine*, in an article titled *Genome editing in the treatment of ocular diseases (Choi, E.H., et al., August 2023)*. The article highlighted suprachoroidal injection as a novel modality for delivering genome-editing tools to the retinal pigment epithelium and retina and concluded that it is reasonable that therapeutics for neovascular and non-neovascular AMD delivered to the SCS might reach the retinal-RPE interface more readily than those delivered via intravitreal injection. The full article is available on Clearside's website.
- Safety and tolerability data from Clearside's OASIS Phase 1/2a clinical trial of CLS-AX in wet AMD were presented at the American Society of Retina Specialists (ASRS) 41st Annual Scientific Meeting by Rahul N. Khurana, MD, FACRS, highlighting the excellent safety profile and potential benefits of CLS-AX, a proprietary suspension formulation of the tyrosine kinase inhibitor (TKI) axitinib, delivered via Clearside's proprietary SCS Microinjector® to provide high potency pan-VEGF inhibition.
- Clinical data was presented at The Association for Research in Vision and Ophthalmology (ARVO) 2023 Annual Meeting, which highlighted that SCS delivery of small molecule suspensions offered targeted, compartmentalized, and durable drug delivery to the chorioretina. In addition, a poster presentation based on the OASIS Phase 1/2a trial data showed that CLS-AX had an excellent safety profile and that Extension Study participants with wet AMD maintained visual acuity while experiencing a meaningful reduction in treatment burden over 6 months.
- Partner presentations featuring clinical data from programs using Clearside's proprietary SCS Microinjector technology were highlighted at the ASRS and ARVO meetings. In addition, Clearside's commercial partner presented data on the adoption of XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, which continues to garner broad acceptance by the retinal community.
- Clearside received the International Organization for Standardization (ISO) Certification EN ISO 13485:2016 for "*The design, development, and manufacture of sterile piston syringes, needles, and associated accessories for the area of ophthalmology*".

- In June 2023, Clay B. Thorp, General Partner, Hatteras Venture Partners, was named Chair of Clearside's Board of Directors. Mr. Thorp has served as a director of Clearside since 2012. He succeeds William D. Humphries, CEO, Alcami Corporation, who continues to serve as a director. Mr. Humphries has served as a director of Clearside since 2012 and served as Board Chair from 2018 to 2023.
- Clearside's Scientific Advisory Board (SAB) was enhanced with the additions of Thomas A. Ciulla, M.D., M.B.A. as Chair, Arshad M. Khanani, M.D., M.A. and Lejla Vajzovic, M.D. The SAB is comprised of industry leading retinal physicians who provide medical and scientific expertise and input on the Company's research and development programs.

Second Quarter 2023 Financial Results

- License Revenue: License and other revenue for the second quarter of 2023 was $1.0 million, compared to $0.4 million for the second quarter of 2022.
- Cost of Goods Sold: Cost of Goods Sold for the second quarter of 2023 was $0.2 million, compared to $0 for the second quarter of 2022. The increase was related to sales of Clearside's SCS Microinjector to licensees.
- Research and Development (R&D) Expenses**:** R&D expenses for the second quarter of 2023 were $4.9 million, compared to $5.4 million for the second quarter of 2022.
- General and Administrative (G&A) Expenses**:** G&A expenses for the second quarter of 2023 were $3.1 million, compared to $2.8 million for the second quarter of 2022.
- Other Income: Other income for the second quarter of 2023 was $0.5 million, compared to $24,000 for the second quarter of 2022. The increase was due to higher interest rates earned on cash and cash equivalents.
- Other Expense**:** Non-cash interest expense for the second quarter of 2023 was $2.3 million, compared to $0 in the second quarter of 2022. Non-cash interest expense was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.
- Net Loss: Net loss for the second quarter of 2023 was $9.1 million, or $0.15 per share of common stock, compared to net loss of $7.8 million, or $0.13 per share of common stock, for the second quarter of 2022.
- Cash Position**:** As of June 30, 2023, Clearside's cash and cash equivalents totaled $35.0 million. The Company believes it will have sufficient resources to fund its planned operations into the third quarter of 2024.

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 (877) 545-0320 (U.S.) or 973-528-0002 (international) and entering conference code: 895559. The Company suggests participants join 15 minutes in advance of the event.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector®, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector. The Company's lead program, CLS-AX (axitinib injectable suspension), for the treatment of neovascular age-related macular degeneration (wet AMD), is in Phase 2 clinical testing. Clearside developed and gained approval for its first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, which is available in the U.S. through a commercial partner. Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. 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 clinical development of CLS-AX, the expected timing of topline results from the ODYSSEY clinical trial, the potential for CLS-AX to be a twice-a-year treatment for wet AMD and other potential benefits of CLS-AX and other product candidates using Clearside's SCS Microinjector® and Clearside's ability to fund its operations into the third quarter of 2024. 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, 2022, filed with the U.S. Securities and Exchange Commission (SEC) on March 14, 2023 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,	
	2023	2022	2023	2022
License and other revenue	$ 1,018	$ 384	$ 1,022	$ 731
Operating expenses:				
Cost of goods sold	213	—	213	—
Research and development	4,948	5,430	9,399	9,966
General and administrative	3,127	2,791	6,285	6,248
Total operating expenses	8,288	8,221	15,897	16,214
Loss from operations	(7,270)	(7,837)	(14,875)	(15,483)
Other income	458	24	950	26
Non-cash interest expense on liability related to the sales of future royalties	(2,294)	—	(4,461)	—
Net loss	$ (9,106)	$ (7,813)	$ (18,386)	$ (15,457)
Net loss per share of common stock — basic and diluted	$ (0.15)	$ (0.13)	$ (0.30)	$ (0.26)
Weighted average shares outstanding — basic and diluted	61,654,520	60,150,348	61,413,343	60,107,517

Balance Sheet Data	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 35,005	$ 48,258
Accounts receivable	255	—
Total assets	39,185	51,303
Liabilities related to the sales of future royalties, net	38,088	33,977
Total liabilities	44,158	40,696
Total stockholders' (deficit) equity	(4,973)	10,607

Source: Clearside Biomedical, Inc.