

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): May 09, 2024

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, Georgia
(Address of Principal Executive Offices)

30005
(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 May 9, 2024, Clearside Biomedical, Inc. (the “**Registrant**”) issued a press release announcing its financial results for the quarter ended March 31, 2024, 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 May 9, 2024
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: May 9, 2024

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



Clearside Biomedical Announces First Quarter 2024 Financial Results and Provides Corporate Update

*- Phase 2b ODYSSEY Trial in Wet AMD Remains on Track
with Topline Data Expected Q3 2024 -*

- Strengthened Management Team and Board of Directors with Two Key Additions -

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

ALPHARETTA, Ga., May 9, 2024 -- 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 first quarter ended March 31, 2024, and provided a corporate update.

“As we near the midpoint of 2024, I am excited to highlight key aspects of our program and the steps we have taken to position Clearside for an important year,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “Our lead clinical program, CLS-AX (axitinib injectable suspension), is focused on the multi-billion-dollar market for wet AMD. Our target profile for CLS-AX is to maintain visual acuity without the need for retreatment for potentially up to 6 months. The data readout from our Phase 2b ODYSSEY clinical trial remains on track for the end of the third quarter of this year. Importantly, ODYSSEY is a 36-week study designed to re-dose patients with CLS-AX at 6 months, or earlier if needed. This will provide valuable data in a chronic disease for patients treated with more than one dose of CLS-AX, as we begin planning our CLS-AX Phase 3 clinical development program.”

Dr. Lasezkay continued, “We have an outstanding team at Clearside that has been strategically expanded over the past several months. We added Dr. Victor Chong, a well-respected, board-certified retinal specialist, as our Chief Medical Officer. Victor’s extensive major pharmaceutical company experience, most recently at Johnson & Johnson, is extremely valuable as he spearheads our product development activities led by the upcoming ODYSSEY data analysis and the planning for our Phase 3 program. In addition, we appointed Tony Gibney, a seasoned biotechnology executive, to our Board of Directors. Tony has broad expertise in business strategy, collaborations, finance, and M&A, including recent and relevant ophthalmology experience at Iveric Bio. We look

forward to their contributions as we advance our pipeline and continue our efforts to increase the adoption of suprachoroidal delivery.”

Key Highlights

- Topline data expected in the third quarter of 2024 from Phase 2b ODYSSEY clinical trial of CLS-AX using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD).
- Victor Chong, M.D., MBA joined Clearside in March 2024 as Chief Medical Officer. Dr. Chong has more than 25 years of experience advancing drug candidates through all stages of development, including serving as Vice President, Global Head of Retina DAS at Johnson & Johnson, and Global Head of Medicine, Retinal Health at Boehringer Ingelheim.
- Appointed Tony Gibney to Clearside’s Board of Directors in April 2024. Mr. Gibney is an experienced biotechnology executive and former investment banker who brings over 25 years of experience dedicated to advising biotechnology companies on business strategy, collaborations, financings, and mergers and acquisitions.
- Completed a registered direct offering in February 2024, which generated \$15.0 million in gross proceeds to Clearside.
- On January 1, 2024, a new permanent Category 1 Current Procedural Terminology (CPT) code for XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use became available for physician use.
- Multiple data presentations on the use of Clearside’s suprachoroidal delivery platform were featured at prominent medical meetings, including the Association for Research in Vision and Ophthalmology (ARVO), the Macula Society and Hawaiian Eye and Retina.
 - Presentations included positive data on the extended treatment duration of XIPERE utilizing suprachoroidal delivery. Real-world data showed excellent durability in which more than 75% of eyes did not require retreatment for 6 months after a single dose of XIPERE, supporting Clearside’s approach to extended drug release and reduced treatment burden for patients by delivering drug directly to the back of the eye via the SCS Microinjector.

First Quarter 2024 Financial Results

- License and other revenue for the first quarter of 2024 was \$230,000, compared to \$4,000 for the first quarter of 2023.
 - Research and development expenses for the first quarter of 2024 were \$5.6 million, compared to \$4.5 million for the first quarter of 2023. The increase was primarily due to ODYSSEY clinical trial expenses.
-

- General and administrative expenses for the first quarter of 2024 were \$2.8 million, compared to \$3.2 million for the first quarter of 2023.
- Other expense for the first quarter of 2024 was \$1.5 million, compared to \$0 for the first quarter of 2023. Other expense was comprised of issuance costs for the warrants and shares of common stock issued in the February 2024 registered direct offering and the change in fair value related to warrant liabilities.
- Non-cash interest expense for the first quarter of 2024 was \$2.4 million, compared to \$2.2 million in the first quarter of 2023. 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 for the first quarter of 2024 was \$11.8 million, or \$0.17 per share of common stock, compared to net loss of \$9.3 million, or \$0.15 per share of common stock, for the first quarter of 2023.
- As of March 31, 2024, Clearside's cash and cash equivalents totaled \$35.4 million. The Company believes it will have sufficient resources to fund its planned operations into the third quarter of 2025.

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 888-645-4404 (U.S.) or 862-298-0702 (international) and requesting the Clearside call. 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 patented 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 2b 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 clearsidebio.com and follow us on LinkedIn and X.

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 benefits of CLS-AX, Clearside’s suprachoroidal delivery technology and Clearside’s SCS Microinjector® and Clearside’s ability to fund its operations into the third quarter of 2025. 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, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on March 12, 2024 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:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

-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,	
	2024	2023
License and other revenue	\$ 230	\$ 4
Operating expenses:		
Research and development	5,615	4,451
General and administrative	2,824	3,158
Total operating expenses	8,439	7,609
Loss from operations	(8,209)	(7,605)
Interest income	348	492
Other expense	(1,499)	—
Non-cash interest expense on liability related to the sales of future royalties	(2,403)	(2,167)
Net loss	\$ (11,763)	\$ (9,280)
Net loss per share of common stock — basic and diluted	\$ (0.17)	\$ (0.15)
Weighted average shares outstanding — basic and diluted	69,853,227	61,169,486

Balance Sheet Data	March 31,	December 31,
	2024	2023
Cash and cash equivalents	\$ 35,355	\$ 28,920
Total assets	40,142	34,018
Liabilities related to the sales of future royalties, net	44,391	41,988
Warrant liabilities	11,039	—
Total liabilities	61,952	49,930
Total stockholders' deficit	(21,810)	(15,912)

