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 12, 2024

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** **(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 August 12, 2024, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended June 30, 2024. 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 12, 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: August 12, 2024

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

Exhibit 99.1

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

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

- ODYSSEY Safety Review Committee Recommends Trial Continue as Planned with no Serious Adverse Events Observed -

- Recent Key Opinion Leader Webinar Highlighted the Broad Applicability and Real-World Experience of Suprachoroidal Drug Delivery -

ALPHARETTA, Ga., August 12, 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 second quarter ended June 30, 2024, and provided a corporate update.

“Our Phase 2b ODYSSEY clinical trial utilizing CLS-AX (axitinib injectable suspension) in patients with wet AMD continues to advance on track and on time with topline data expected in late Q3 2024,” said George Lasezkay, PharmD, JD, President and Chief Executive Officer. “In July, the Safety Review Committee reviewed masked safety data and noted that there have been no drug-related Serious Adverse Events (SAEs), including no endophthalmitis or retinal vasculitis, and recommended the trial continue as planned without modifying the protocol. Both arms of the ODYSSEY trial have completed six months of treatment, with CLS-AX being re-dosed per protocol in the CLS-AX arm. Re-dosing with CLS-AX is an important and differentiating feature of the ODYSSEY trial, and the re-dosing data will be valuable as we evaluate the effects of CLS-AX in this chronic disease and plan our Phase 3 clinical development program.”

Dr. Lasezkay continued, “Several noteworthy events have also occurred featuring our commercial product, XIPERE®[1], for the treatment of patients with macular edema associated with uveitis. Most importantly, our Asia-Pacific partner, Arctic Vision, reported positive results from their Phase 3 trial for XIPERE, known as ARCATUS in China, and announced that new drug applications (NDAs) for ARCATUS have been accepted for review in Australia and Singapore. In addition, data presented on the real-world use of XIPERE in the United States has shown the product has excellent durability as 87.7% of eyes did not require an injected or implanted corticosteroid for 6 months after a single dose of XIPERE[2].”

“In May 2024, consensus guidelines for drug delivery by suprachoroidal administration, co-authored by 16 practicing retinal physicians, were published in the prominent journal, *RETINA®.* The article describes the physicians’ best practices for injection into the suprachoroidal space. These valuable guidelines, combined with our progress with CLS-AX and the promising real-world and Phase 3 data from XIPERE continue to demonstrate the advantages of suprachoroidal administration utilizing our proprietary SCS Microinjector® to deliver therapies to the back of the eye for the treatment of a variety of retinal diseases,” concluded, Dr. Lasezkay,

Key Highlights

- Topline data expected in late third quarter of 2024 from Phase 2b ODYSSEY clinical trial of CLS-AX using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD).
- Clearside’s Asia-Pacific partner, Arctic Vision, reported positive topline results from its Phase 3 clinical trial of ARCATUS® for the treatment of uveitic macular edema in China and announced that NDAs for ARCATUS have been officially accepted in Australia and Singapore.
- Clearside hosted its Suprachoroidal Delivery Key Opinion Leader webinar highlighting broad applicability and real-world experience with suprachoroidal drug delivery and SCS development opportunities, including wet AMD and geographic atrophy. The replay of this event is available on the Clearside website under the Investors section: Events and Presentations.
- *Ophthalmology Science* published an article summarizing safety and tolerability data from OASIS, Clearside’s Phase 1/2a Open-Label, Dose-Escalation trial of CLS-AX (axitinib injectable suspension) in wet AMD. The full publication can be accessed here.
- *RETINA®, The Journal of Retinal and Vitreous Diseases* published consensus guidelines for drug delivery via Suprachoroidal Space (SCS®) injection. The full publication can be accessed here.
- Clearside’s gene therapy partner, REGENXBIO, reported progress on their ABBV-RGX-314 programs delivered via suprachoroidal injection with Clearside’s SCS Microinjector®. REGENEXBIO announced that they expect to initiate a global pivotal trial in the first half of 2025 for the treatment of diabetic retinopathy, and that their Phase 2 ALTITUDE® trial is now enrolling a new cohort of patients with center-involved diabetic macular edema (DME). In addition, REGENEXBIO announced their AAVIATE® Phase 2 trial in wet AMD is initiating enrollment in a new cohort at dose level 4.
- 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), Clinical Trials at the Summit and Retinal Imaging Biomarkers and Endpoints Summit.

- Glenn Yiu, MD, PhD, Professor of Ophthalmology at the University of California, Davis, was appointed to Clearside's Scientific Advisory Board (SAB) in July 2024. Dr. Yiu, a board-certified vitreoretinal surgeon, leads the translational research program at UC Davis studying AMD and other retinal diseases, with focus on ocular imaging technologies, gene editing and delivery, and animal models of retinal disease.
- Tony Gibney was appointed 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.

Second Quarter 2024 Financial Results

- License and other revenue for the second quarter of 2024 was $90,000, compared to $1.0 million for the second quarter of 2023. The revenue primarily related to payments pursuant to Clearside's license agreements and revenue for services and the sales of SCS Microinjector kits to licensees.
- Research and development expenses for the second quarter of 2024 were $4.6 million, compared to $4.9 million for the second quarter of 2023. The decrease was primarily related to the CLS-AX program ($0.2 million), development of the SCS Microinjector ($0.2 million), and preclinical work ($0.1 million). This was partially offset by a $0.2 million increase in employee related costs.
- General and administrative expenses remained constant at $3.1 million in the second quarter of 2024 and 2023.
- Interest income for the second quarter of 2024 was $0.4 million compared to $0.5 million for the second quarter of 2023. The decrease was due to the lower balance of cash, cash equivalents and short-term investments.
- Other income for the second quarter of 2024 was $1.9 million, compared to $0 for the second quarter of 2023. Other income for the second quarter of 2024 was due to the change in fair value of the warrant liabilities from the prior March 31, 2024 valuation date.
- Non-cash interest expense remained constant at $2.3 million in the second quarter of 2024 and 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 second quarter of 2024 was $7.6 million, or $0.10 per share of common stock, compared to net loss of $9.1 million, or $0.15 per share of common stock, for the second quarter of 2023.

- As of June 30, 2024, Clearside's cash, cash equivalents and short-term investments totaled $29.4 million. The Company believes it will have sufficient resources to fund its planned operations into the third quarter of 2025.

Additional Information

In lieu of a second quarter 2024 conference call, the Company hosted a Suprachoroidal Delivery Key Opinion Leader Webinar on Wednesday, July 24, 2024. The replay of this event is available on the Clearside website under the Investors section: Events and Presentations. Quarterly earnings conference calls are expected to resume with the third quarter 2024 financial results.

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.

[1]XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is being commercialized by Bausch + Lomb who has the exclusive license for the commercialization and development of XIPERE in the United States and Canada. Arctic Vision has the exclusive license for the commercialization and development of XIPERE, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPERE was approved by the U.S. Food and Drug Administration in October 2021 and is commercially available in the U.S. A link to the full prescribing information is available at https://www.xipere.com/hcp/#isi.

[2]Yiu, Glen, "*Suprachoroidal Drug Delivery in the Real World"*, Clinical Trials at the Summit Meeting, June 2024

[3]ALTITUDE® and AAVIATE® are registered trademarks of REGENXBIO, Inc.

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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,	
	2024	2023	2024	2023
License and other revenue	$ 90	$ 1,018	$ 320	$ 1,022
Operating expenses:				
Cost of goods sold	—	213	—	213
Research and development	4,603	4,948	10,218	9,399
General and administrative	3,077	3,127	5,901	6,285
Total operating expenses	7,680	8,288	16,119	15,897
Loss from operations	(7,590)	(7,270)	(15,799)	(14,875)
Interest income	419	458	767	950
Other income, net	1,917	—	418	—
Non-cash interest expense on liability related to the sales of future royalties	(2,340)	(2,294)	(4,743)	(4,461)
Net loss	$ (7,594)	$ (9,106)	$ (19,357)	$ (18,386)
Net loss per share of common stock — basic and diluted	$ (0.10)	$ (0.15)	$ (0.27)	$ (0.30)
Weighted average shares outstanding — basic and diluted	74,731,139	61,654,520	72,292,183	61,413,343

Balance Sheet Data	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 18,238	$ 28,920
Short-term investments	11,122	—
Total assets	33,934	34,018
Liabilities related to the sales of future royalties, net	46,731	41,988
Warrant liabilities	9,121	—
Total liabilities	62,219	49,930
Total stockholders' deficit	(28,285)	(15,912)

Source: Clearside Biomedical, Inc.