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 14, 2025

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 May 14, 2025, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended March 31, 2025. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report.

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 14, 2025
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 14, 2025

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

Exhibit 99.1

Clearside Biomedical Announces First Quarter 2025 Financial Results and Provides Corporate Update

- Successful End-of-Phase 2 Meeting with FDA Led to Alignment on Phase 3 Program Design for CLS-AX in Wet AMD -

- CLS-AX Targets Commercially Attractive Product Profile with Three-to-Six Month Flexible Maintenance Dosing -

- Multiple Milestones Achieved by Commercial and Development Partners -

- Use of Suprachoroidal Drug Delivery Featured in Over 15 Presentations at Major Ophthalmic Medical Meetings This Year -

ALPHARETTA, Ga., May 14, 2025 -- 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 announced financial results for the first quarter ended March 31, 2025, and provided a corporate update.

“Tremendous progress has been made thus far in 2025 to advance our proprietary suprachoroidal delivery platform both internally and globally by our partners,” said George Lasezkay, PharmD, JD, President and Chief Executive Officer. “Our interactions with the FDA related to CLS-AX have been very productive and we were pleased to report a positive outcome from our End-of-Phase 2 meeting with the Agency that led to alignment on our proposed Phase 3 program in wet AMD. We are targeting a flexible three-to-six-month dosing label for CLS-AX, which we believe offers a potential best-in-class product profile that may fit seamlessly into physician practices and be commercially compelling, if approved.”

Dr. Lasezkay added, “In addition, our partners are making significant progress in advancing their programs. ARCATUS® (XIPERE® in the U.S.) is now approved in both Australia and Singapore, and an NDA is under review in China. We are also very encouraged by new preclinical data from BioCryst Pharmaceuticals’ diabetic macula edema program demonstrating that the plasma kallikrein pathway may reduce vascular leakage and that there are high drug concentrations out to six months after a single dose of avoralstat delivered by suprachoroidal injection.”

“We strongly believe that our proprietary suprachoroidal delivery platform provides an effective and reliable way to target challenging retinal diseases that need longer lasting treatments. We continue to evaluate partnerships and other options to fund and maximize the value of our programs,” concluded Dr. Lasezkay.

Key Recent Highlights

- Successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) with alignment on the Phase 3 program design for CLS-AX in wet AMD.
- Clearside’s development partner, BioCryst Pharmaceuticals, announced it has been granted authorization to initiate its first clinical trial in Australia with avoralstat, its investigational plasma kallikrein inhibitor for the treatment of diabetic macular edema (DME) delivered with Clearside’s SCS Microinjector®. BioCryst expects initial data from DME patients in 2025.
- Clearside’s Asia-Pacific collaboration partner, Arctic Vision, announced that its New Drug Application (NDA) for ARCATUS® (known as XIPERE® in the U.S.) was formally accepted for review by the Center for Drug Evaluation of China National Medical Products Administration for the treatment of uveitic macular edema (UME).
- Arctic Vision’s NDAs for ARCATUS were approved by the Therapeutic Goods Administration of Australia and the Health Sciences Authority in Singapore for the treatment of UME.
- Multiple medical meeting presentations were delivered on transforming retinal disease treatments using suprachoroidal delivery, including six presentations at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Meeting; additional presentations were made at Retina Unplugged, Wet AMD & Diabetic Eye Disease Summit, Macula Society Annual Meeting, Angiogenesis Exudation and Degeneration, Ophthalmic Drug Delivery Summit, and Hawaiian Eye & Retina.

First Quarter 2025 Financial Results

- License and other revenue for the first quarter of 2025 was $2.3 million, compared to $0.2 million for the first quarter of 2024. The increase was primarily attributable to license fees from partners in the first quarter of 2025, including $1.5 million in milestones from Arctic Vision and $0.8 million in other revenue for training, services and the sales of SCS Microinjector kits to licensees.
- Research and development (R&D) expenses for the first quarter of 2025 were $4.5 million, compared to $5.6 million for the first quarter of 2024. The decrease was primarily due to lower clinical trial costs following completion of the ODYSSEY Phase 2b trial.
- General and administrative (G&A) expenses remained constant at $2.8 million in the first quarter of 2025 and 2024.

- Net loss for the first quarter of 2025 was $8.2 million, or $0.11 per share of common stock, compared to net loss of $11.8 million, or $0.17 per share of common stock, for the first quarter of 2024. The decrease in net loss was primarily attributable to license fees from partners and lower R&D expenses in the first quarter of 2025.
- As of March 31, 2025, Clearside's cash and cash equivalents totaled $13.6 million. The Company believes it will have sufficient resources to fund its planned operations into the fourth quarter of 2025.

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®) to improve patient outcomes. 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), is in development for the treatment of neovascular age-related macular degeneration (wet AMD). Planning for a Phase 3 program is underway. In addition, Clearside is evaluating various small molecules for the potential long-acting treatment of geographic atrophy (GA). 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 or 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, including the planned Phase 3 trial design and the timing of initiating additional trials and reporting data from our or our partners' clinical trials, the potential for our product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, CLS-AX's potential impact on the wet AMD market, 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 fourth 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, Clearside's ability to raise additional capital, and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the U.S. Securities and Exchange Commission (SEC) on March 27, 2025 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.

Reference:
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 is approved by the U.S. Food and Drug Administration and is commercially available in the U.S. A link to the full prescribing information is available at https://www.xipere.com/hcp/#isi.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com

-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,**	
	2025	**2024**
License and other revenue	$ 2,330	$ 230
Operating expenses:		
Cost of goods sold	248	—
Research and development	4,463	5,615
General and administrative	2,824	2,824
Total operating expenses	7,535	8,439
Loss from operations	(5,205)	(8,209)
Interest income	163	348
Other income, net	207	(1,499)
Non-cash interest expense on liability related to the sales of future royalties	(2,673)	(2,403)
Loss before income taxes	(7,508)	(11,763)
Income tax expense	715	—
Net loss	$ (8,223)	$ (11,763)
Net loss per share of common stock — basic and diluted	$ (0.11)	$ (0.17)
Weighted average shares outstanding — basic and diluted	76,921,843	69,853,227

Balance Sheet Data	**March 31, 2025**	**December 31, 2024**
Cash and cash equivalents	$ 13,628	$ 20,020
Total assets	19,668	25,126
Liability related to the sales of future royalties, net	53,440	51,767
Total liabilities	65,578	63,981
Total stockholders' deficit	(45,910)	(38,855)

Source: Clearside Biomedical, Inc.