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): November 13, 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 November 13, 2023, Clearside Biomedical, Inc. (the "***Registrant***") issued a press release announcing its financial results for the quarter ended September 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 November 13, 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: November 13, 2023

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

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

- New Licensing Partnership with BioCryst Pharmaceuticals Expands Clearside's Proprietary Suprachoroidal Injection Platform to Plasma Kallikrein Inhibitor -

- BioCryst Collaboration Provides $5 Million Upfront, the Potential for Additional $77.5 Million in Clinical, Regulatory, and Sales Based Milestone Payments, Plus Royalties -

- Recruitment Completed in CLS-AX Phase 2b ODYSSEY Wet AMD Trial with Topline Data Expected in Q3 2024 -

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

ALPHARETTA, Ga., November 13, 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 third quarter ended September 30, 2023, and provided a corporate update.

"We are successfully delivering on our two-pronged strategy of advancing our internal pipeline and expanding the use of our SCS delivery platform through external collaborations," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "With the completion of recruitment in our ODYSSEY Phase 2b wet AMD trial, we expect to report topline data in the third quarter of 2024. In addition, we signed a promising new licensing partnership with BioCryst Pharmaceuticals, which enhances our external development pipeline, and expands the utility and versatility of our proprietary SCS injection platform with a new molecule specifically targeting diabetic macular edema (DME)."

Dr. Lasezkay continued, "We are partnering with BioCryst to develop their proprietary plasma kallikrein inhibitor, avoralstat, in combination with our patented SCS Microinjector® for patients with DME, the most common cause of vision loss in individuals with diabetes. Avoralstat has high potency and low solubility, characteristics that are ideal for suprachoroidal administration and important to achieving potential efficacy with reduced dosing frequency. Delivering avoralstat into the SCS and behind the visual field could allow avoralstat to inhibit plasma kallikrein directly at the site of edema formation. We believe there is a significant market opportunity in DME utilizing suprachoroidal administration."

“We are excited about the progress all of our partners have reported over the last few weeks utilizing our SCS Microinjector. Bausch + Lomb announced that XIPERE® has been granted a new CPT code to help facilitate better access and adoption of the product, and Arctic Vision completed enrollment in their Phase 3 trial in uveitic macular edema. At AAO, REGENXBIO and AURA presented clinically meaningful data in diabetic retinopathy and choroidal melanoma, respectively. These results, combined with the internal progress on our CLS-AX program in wet AMD, reinforce our leadership in suprachoroidal delivery to treat multiple serious retinal diseases,” concluded Dr. Lasezkay.

Key Highlights

- Recruitment of participants was completed for 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) with topline data expected in Q3 2024.
- New exclusive, worldwide license with BioCryst Pharmaceuticals to use Clearside’s SCS Microinjector for the delivery of BioCryst’s proprietary plasma kallikrein inhibitor, avoralstat, for the treatment and prevention of DME. Under the terms of the agreement, Clearside will receive an upfront license fee of $5 million and is eligible to receive up to an aggregate of $77.5 million in clinical, regulatory and post-approval sales-based milestone payments. BioCryst will pay Clearside tiered mid-single digit royalties on annual global net product sales.
- XIPERE® commercial partners provided important updates:
  - Arctic Vision completed enrollment in China in its Phase 3 randomized, double-blind, placebo-controlled clinical trial in uveitic macular edema (UME). XIPERE is referred to as ARCATUS® (ARVN001) in China.
  - Bausch + Lomb announced that the American Medical Association has granted a new permanent Category 1 Current Procedural Terminology (CPT) code for XIPERE to help facilitate better access and adoption of the product.
  - Bausch + Lomb presented survey data on positive physician experience using XIPERE in the treatment of UME indicating that physicians found the XIPERE suprachoroidal injection easy to learn, with patient outcomes consistent with clinical trial data.
- Development partners presented promising clinical data using Clearside’s proprietary SCS Microinjector technology at the recent American Academy of Ophthalmology (AAO) annual meeting:

- REGENXBIO reported ABBV-RGX-314 gene therapy continues to be well tolerated and that dose level 2 prevented disease progression and reduced vision-threatening events in non-proliferative diabetic retinopathy at one year.
- Aura Biosciences reported positive clinical safety and efficacy updates of bel-sar for early-stage choroidal melanoma from its ongoing Phase 2 clinical trial with suprachoroidal administration. The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6 and who match the criteria for the planned global Phase 3 trial, showed a tumor control rate of 80% and the visual acuity preservation rate was 90%.

- Data from Clearside's OASIS Phase 1/2a clinical trial of CLS-AX in wet AMD were presented at several prominent medical meetings: AAO, American Society of Retina Specialists, and at The Retina Society. These presentations highlighted the excellent safety profile, stable vision and reduced frequency of injections observed for up to 6-months in the OASIS trial and Extension Study.
- Clearside's SCS Microinjector technology was featured in the peer-reviewed *Pharmaceuticals* journal, in an article titled *Suprachoroidal Injection: A Novel Approach for Targeted Drug Delivery (Wu, Kevin Y., et al., September 2023)*. Based on a comprehensive review of the recent literature on suprachoroidal injections, the authors concluded that suprachoroidal injections present a significant advancement over conventional administration routes, such as eye drops and intravitreal injections, and offer increased drug bioavailability, extended duration of action, and a marked reduction in off-target adverse effects. The full article is available on Clearside's website.

Third Quarter 2023 Financial Results

- License Revenue: License and other revenue for the third quarter of 2023 was $0.9 million, compared to $0.3 million for the third quarter of 2022.
- Research and Development (R&D) Expenses**:** R&D expenses for the third quarter of 2023 were $5.1 million, compared to $4.6 million for the third quarter of 2022. The increase was primarily due to ODYSSEY clinical trial costs.
- General and Administrative (G&A) Expenses**:** G&A expenses for the third quarter of 2023 were $2.6 million, compared to $2.4 million for the third quarter of 2022.
- Other Income: Other income for the third quarter of 2023 was $0.4 million, compared to $0.2 million for the third 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 third quarter of 2023 was $2.6 million, compared to $1.3 million in the third 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 third quarter of 2023 was $9.3 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 third quarter of 2022.
- Cash Position: As of September 30, 2023, Clearside's cash and cash equivalents totaled $28.8 million. Subsequent to the quarter end, Clearside entered into a new licensing agreement which includes a $5 million upfront license fee from BioCryst. The Company believes it will have sufficient resources to fund its planned operations into the fourth 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 888-506-0062 (U.S.) or 973-528-0011 (international) and entering conference code: 971200. 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 utilizes its patented SCS Microinjector®, the first and only FDA-approved way to access the suprachoroidal space. Clearside's 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 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 is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector. Clearside's lead suprachoroidal development program, CLS-AX (axitinib injectable suspension), is in Phase 2b clinical testing for the treatment of neovascular age-related macular degeneration (wet AMD). 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 TwitterX.

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 fourth 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, Clearside’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 13, 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.

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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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
License and other revenue	$ 859	$ 266	$ 1,881	$ 997
Operating expenses:				
Cost of goods sold	142	—	355	—
Research and development	5,134	4,637	14,533	14,603
General and administrative	2,637	2,353	8,922	8,601
Total operating expenses	7,913	6,990	23,810	23,204
Loss from operations	(7,054)	(6,724)	(21,929)	(22,207)
Other income	409	194	1,359	220
Non-cash interest expense on liability related to the sales of future royalties	(2,622)	(1,297)	(7,083)	(1,297)
Net loss	$ (9,267)	$ (7,827)	$ (27,653)	$ (23,284)
Net loss per share of common stock — basic and diluted	$ (0.15)	$ (0.13)	$ (0.45)	$ (0.39)
Weighted average shares outstanding — basic and diluted	61,983,987	60,188,541	61,605,648	60,134,821

Balance Sheet Data	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 28,802	$ 48,258
Accounts receivable	882	91
Total assets	34,420	51,303
Liabilities related to the sales of future royalties, net	40,710	33,977
Total liabilities	47,269	40,696
Total stockholders' (deficit) equity	(12,849)	10,607

Source: Clearside Biomedical, Inc.