Clearside Biomedical Announces Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

March 27, 2025

- Successful End-of-Phase 2 Meeting with FDA Results in Alignment on Phase 3 Plans for CLS-AX in Wet AMD -

- Asia-Pacific Partner's New Drug Application for ARCATUS ® (XIPERE®) for Uveitic Macular Edema Accepted for Regulatory Review in China -

- Multiple Medical Meeting Presentations Highlight Potential Advantages and Key Differentiators of Suprachoroidal Drug Delivery Utilizing Clearside's SCS Microinjector® -

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

ALPHARETTA, Ga., March 27, 2025 (GLOBE NEWSWIRE) -- 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 fourth quarter and year ended December 31, 2024, and provided a corporate update.

"We are redefining the delivery of therapeutics to the retina through the suprachoroidal space with the proven reliability and broad applicability of our innovative SCS Microinjector®," said George Lasezkay, PharmD, JD, President and Chief Executive Officer. "Over the past six months, we announced positive Phase 2b data, conducted a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), designed the CLS-AX (axitinib injectable suspension) Phase 3 program to maximize commercial potential in wet AMD, and supported several of our SCS Microinjector partners as they advance their suprachoroidal drug candidates into Phase 3 clinical trials."

"Clearside has developed a differentiated platform of early and later stage SCS assets, has entered into multiple validating SCS collaborations, and has the potential for pipeline expansion opportunities in geographic atrophy, diabetic retinopathy, and diabetic macular edema," concluded Dr. Lasezkay.

Key Recent Highlights

- Completion of an End-of-Phase 2 meeting with the FDA and alignment on Phase 3 plans for suprachoroidal CLS-AX in wet AMD. The meeting and formal minutes confirmed key elements of the proposed pivotal Phase 3 program, including agreement on the protocol design of two non-inferiority trials, patient population, primary and secondary endpoints, and use of sham injections.
- CLS-AX Phase 3 plans are based on positive results from the ODYSSEY Phase 2b clinical trial that achieved its primary and secondary endpoints, demonstrated extended duration, stable vision and anatomic measures and a well-tolerated safety profile.
- Clearside's Asia-Pacific partner, Arctic Vision, announced that its New Drug Application (NDA) for ARCATUS ® (known as XIPERE® in the U.S.) for the treatment of uveitic macular edema (UME) was formally accepted for review by the Center for Drug Evaluation of China National Medical Products Administration.
- 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.
- Arctic Vision signed a new commercial collaboration with Santen Pharmaceutical Co., Ltd. for commercial rights in China to ARVN001 (ARCATUS) in the treatment of UME and certain other ophthalmic indications under development.
- Clearside's gene therapy partner, REGENXBIO, in collaboration with AbbVie, announced in January 2025 that they will plan a Phase 3 clinical program for sura-vec (ABBV-RGX-314) using suprachoroidal delivery for the treatment of diabetic retinopathy. Their Phase 2 ALTITUDE® trial is enrolling a cohort of patients with center-involved diabetic macular edema (DME). Their Phase 2 AAVIATE® trial continues enrolling a new cohort to evaluate sura-vec at dose level 4 with a short course of prophylactic steroid eye drops.
- Clearside's ocular oncology partner, Aura Biosciences, is enrolling patients in its global Phase 3 CoMpass trial evaluating belzupacap sarotalocan (bel-sar) for the first-line treatment of adult patients with small choroidal melanoma or indeterminate lesions.
- Clearside's partner, BioCryst Pharmaceuticals, highlighted plans to initiate clinical testing in 2025 of avoralstat, its plasma kallikrein inhibitor, for the potential treatment of DME.
- Multiple medical meeting presentations were delivered on transforming retinal disease treatments using suprachoroidal delivery, including Hawaiian Eye & Retina 2025, 3rd Annual Ophthalmic Drug Delivery Summit, Angiogenesis, Exudation,

and Degeneration 2025, Macula Society 48th Annual Meeting, Asia-Pacific Vitreo-Retina Society (APVRS), and the Academy of Ophthalmology (AAO).

- The Royal College of Ophthalmologists, *Eye* and *Nature.com*, published a summary of critical insights into drug development and regulatory processes based on a presentation at the prestigious annual Edridge Green Lecture by Clearside's Chief Medical Officer and Executive Vice President, Head of Research and Development, Dr. Victor Chong. The article provides a comprehensive overview of the intricate processes involved in clinical trial design and regulatory pathways for drug development, with a special focus on retinal diseases.
- Tony Gibney was appointed Chair of Clearside's Board of Directors, effective November 1, 2024, succeeding Clay Thorp, who continues serving as a member of the Board. Mr. Gibney joined Clearside's Board as an independent director in April 2024 and is an experienced biotechnology executive and former investment banker, most recently serving as Executive Vice President, Chief Business & Strategy Officer, of Iveric Bio, Inc. until the company's acquisition by Astellas Pharma Inc. in July 2023.

Fourth Quarter 2024 Financial Results

- License and other revenue for the fourth quarter of 2024 was $0.3 million, compared to $6.3 million for the fourth quarter of 2023. The decrease was primarily attributable to the receipt of license fees and milestone payments from partners in the fourth quarter of 2023.
- Research and development (R&D) expenses for the fourth quarter of 2024 were $4.2 million, compared to $6.3 million for the fourth quarter of 2023. The decrease was primarily due to lower clinical trial costs following completion of the ODYSSEY Phase 2b trial.
- General and administrative (G&A) expenses for the fourth quarter of 2024 were $3.1 million, compared to $2.9 million for the fourth quarter of 2023. The increase was primarily due to higher patent-related expenses and consulting fees.
- Net loss for the fourth quarter of 2024 was $7.3 million, or $0.10 per share of common stock, compared to net loss of $4.8 million, or $0.08 per share of common stock, for the fourth quarter of 2023. The increase in net loss was primarily attributable to the receipt of license fees and milestone payments from partners in the fourth quarter of 2023.
- As of December 31, 2024, Clearside's cash and cash equivalents totaled $20.0 million. The Company believes it will have sufficient resources to fund its planned operations into the fourth quarter of 2025.

Full Year 2024 Financial Results

- License and other revenue for the year ended December 31, 2024 was $1.7 million, compared to $8.2 million for the year ended December 31, 2023. The $6.6 million decrease was primarily attributable to the receipt of license fees and milestone payments from partners in the fourth quarter of 2023.
- R&D expenses for the year ended December 31, 2024 were $18.6 million, compared to $20.8 million for the year ended December 31, 2023. The decrease was primarily due to lower clinical trial costs following completion of the ODYSSEY Phase 2b trial.
- G&A expenses for the year ended December 31, 2024 were $11.8 million, compared to $11.9 million for the year ended December 31, 2023.
- Net loss for the year ended December 31, 2024 was $34.4 million, or $0.47 per share of common stock, compared to net loss of $32.5 million, or $0.53 per share of common stock, for the year ended December 31, 2023.

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 (domestic) or 973-528-0011 (international) and entering conference code: 733956. 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®) 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, 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 ®, pipeline expansion opportunities, 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.

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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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
License and other revenue	$ 306	$ 6,345	$ 1,664	$ 8,226
Operating expenses:				
Cost of goods sold	149	—	149	355
Research and development	4,244	6,313	18,590	20,846
General and administrative	3,062	2,947	11,807	11,869
Total operating expenses	7,455	9,260	30,546	33,070
Loss from operations	(7,149)	(2,915)	(28,882)	(24,844)
Interest income	358	360	1,462	1,719
Other income, net	2,064	—	2,847	—
Non-cash interest expense on liability related to the sales of future royalties	(2,579)	(2,277)	(9,779)	(9,360)
Net loss	$ (7,306)	$ (4,832)	$ (34,352)	$ (32,485)
Net loss per share of common stock — basic and diluted	$ (0.10)	$ (0.08)	$ (0.47)	$ (0.53)
Weighted average shares outstanding — basic and diluted	75,850,759	62,404,329	73,803,348	61,806,959

Balance Sheet Data	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 20,020	$ 28,920
Total assets	25,126	34,018
Liabilities related to the sales of future royalties, net	51,767	41,988
Warrant liabilities	6,692	—
Total liabilities	63,981	49,930
Total stockholders’ deficit	(38,855)	(15,912)

Source: Clearside Biomedical, Inc.