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

November 12, 2024

- Recent ODYSSEY Phase 2b Trial of Suprachoroidal CLS-AX in Wet AMD Achieved All Primary and Secondary Outcomes -

- Positive Topline Results Support Advancing CLS-AX to Phase 3 Targeting a Differentiated Flexible Dosing Approach Similar to a Biologic with the Potential Extended Duration of a Tyrosine Kinase Inhibitor (TKI) -

- Recent Commercial Licensing Agreement for China by a Global Ophthalmic Pharmaceutical Company Provides Strategic Validation of Clearside's Suprachoroidal Platform -

- Compelling Data Presentations at AAO Demonstrated Potential Safety and Efficacy Benefits of Suprachoroidal Delivery Using Clearside's Proprietary SCS Microinjector® in Multiple Clinical Programs -

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

ALPHARETTA, Ga., Nov. 12, 2024 (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 reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

"We are making outstanding progress advancing our differentiated suprachoroidal delivery pipeline," said George Lasezkay, PharmD, JD, President and Chief Executive Officer. "The recent positive results from our ODYSSEY trial establish CLS-AX as a Phase 3 ready asset in the large and growing wet AMD market. We are positioning CLS-AX for real-world success by focusing on a Phase 3 program in wet AMD designed to evaluate extended efficacy duration compared to current standard of care intravitreal products and produce data supportive of a prescribing label that enables physicians to take advantage of flexible maintenance dosing between 3 and 6 months. We look forward to conducting an End-of-Phase 2 meeting with the FDA in early 2025 to align on the essential components of our Phase 3 program."

"As we work to expand the overall value of our suprachoroidal drug delivery platform, we are seeing significant interest among the retinal specialist community and from leading biopharmaceutical companies in applying our innovative approach to treating serious retinal diseases. The recent commercial collaboration announced by Santen Pharmaceutical Co. and our Asia-Pacific partner, Arctic Vision, is a compelling validation of our suprachoroidal platform from a well-respected leader in the global ophthalmic industry. The licensing of ARVN001, branded as XIPERE® in the U.S., is part of Santen's commitment to bringing innovative eyecare solutions to patients in China," concluded Dr. Lasezkay.

Victor Chong, M.D., MBA, Chief Medical Officer and EVP, Head of Research & Development, added, "In addition to our partners' promising programs, our research team is currently evaluating various small molecules through in vivo models for the potential treatment of geographic atrophy (GA), with a market size valued at over $20 billion in sales. We believe that GA is primarily a choroidal disease. Delivery of small molecules via suprachoroidal injection enables comprehensive drug coverage of both the retina and choroid, while potentially minimizing systemic and anterior segment side effects."

Key Highlights

- The ODYSSEY Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) for the treatment of neovascular age-related macular degeneration (wet AMD) achieved its primary and secondary outcomes, demonstrated extended duration, stable vision and anatomic measures and a well-tolerated safety profile.
- Clearside's Asia-Pacific partner, Arctic Vision, signed a new commercial collaboration with Santen Pharmaceutical Co., Ltd. for commercial rights in China to ARVN001, Arctic Vision's triamcinolone acetonide injectable suspension for suprachoroidal use, in the treatment of uveitic macular edema (UME) and certain other ophthalmic indications under development. ARVN001 is branded as XIPERE in the U.S. and ARCATUS® in China.
- Arctic Vision reported positive topline results from its Phase 3 clinical trial of ARCATUS for the treatment of UME in China and announced that New Drug Applications for ARCATUS are under review by regulators in Australia and Singapore.
- Tony Gibney was appointed Chair of Clearside's Board of Directors, effective November 1, 2024, succeeding Clay Thorp, who will continue 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.
- Glenn Yiu, MD, PhD, Professor of Ophthalmology at the University of California, Davis, was appointed to Clearside's Scientific Advisory Board 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 a focus on ocular imaging technologies, gene editing

and delivery, and animal models of retinal disease.

- An article was published titled “Early Adoption of Triamcinolone Acetonide Suprachoroidal Injection for UME: A Physician Survey” by Christopher R. Henry et al. that summarizes physicians’ “real-world” perspectives on early experiences with XIPERE for the treatment of patients with UME. Findings from this survey indicate that the suprachoroidal injection technique was easy to learn (92% found the injection procedure relatively easy post-training) and resulted in favorable patient outcomes consistent with clinical trial data. The full publication can be accessed here.
- Clearside’s gene therapy partner, REGENXBIO, reported on both of their programs administering ABBV-RGX-314 via Clearside’s SCS Microinjector. Based on positive interim results to date from the Phase 2 ALTITUDE ® trial in diabetic retinopathy (DR), AbbVie and REGENXBIO announced that they have accelerated a planned End-of-Phase 2 meeting with the FDA expected this quarter. REGENXBIO expects to initiate the first global pivotal trial in DR in the first half of 2025. In addition, the ALTITUDE trial is enrolling a new cohort of patients with center-involved diabetic macular edema. In wet AMD, based on a favorable safety profile and to evaluate dose levels for a planned pivotal program, the Phase 2 AAVIATE® trial is enrolling a new cohort.
- In September 2024, Clearside’s ocular oncology partner, Aura Biosciences, presented positive Phase 2 end-of-study results evaluating bel-sar (AU-011) for the first-line treatment of early-stage choroidal melanoma at The Retina Society Annual Meeting. Bel-sar is being administered via Clearside’s SCS Microinjector.
- Multiple presentations were delivered at the 2024 Annual Meeting of the American Academy of Ophthalmology (AAO) and preceding events that highlighted encouraging safety and efficacy data from clinical trials of therapies utilizing Clearside’s SCS Microinjector to deliver drugs into the suprachoroidal space to treat a variety of retinal diseases.

Third Quarter 2024 Financial Results

- License and other revenue for the third quarter of 2024 was $1.0 million, compared to $0.9 million for the third 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 third quarter of 2024 were $4.1 million, compared to $5.1 million for the third quarter of 2023. This decrease was primarily due to a $1.9 million decrease in costs related to the CLS-AX program, which was partially offset by increases in employee-related costs and device development and a research and development tax credit received in the prior year.
- General and administrative expenses were $2.8 million for the third quarter of 2024, compared to $2.6 million for the third quarter of 2023. This increase was primarily due to an increase in patent-related expenses and consulting fees.
- Net loss for the third quarter of 2024 was $7.7 million, or $0.10 per share of common stock, compared to net loss of $9.3 million, or $0.15 per share of common stock, for the third quarter of 2023.
- As of September 30, 2024, Clearside’s cash, cash equivalents and short-term investments totaled $23.6 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 (877) 545-0523 (domestic) or (973) 528-0016 (international) and entering conference code: 756568. 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), for the treatment of neovascular age-related macular degeneration (wet AMD), recently completed a Phase 2b clinical trial, and planning for a Phase 3 program is underway. 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, 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, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 filed with the SEC on August 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.

*References

- 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.
- Source: IMARC Geographic Atrophy Market: Epidemiology, Industry Trends, Share, Size, Growth, Opportunity, and Forecast 2024-2034
- ALTITUDE® and AAVIATE® are registered trademarks of REGENXBIO, Inc.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
License and other revenue	$ 1,038	$ 859	$ 1,358	$ 1,881
Operating expenses:				
Cost of goods sold	—	142	—	355
Research and development	4,128	5,134	14,346	14,533
General and administrative	2,844	2,637	8,745	8,922
Total operating expenses	6,972	7,913	23,091	23,810
Loss from operations	(5,934)	(7,054)	(21,733)	(21,929)
Interest income	338	409	1,104	1,359
Other income, net	365	—	783	—
Non-cash interest expense on liability related to the sales of future royalties	(2,457)	(2,622)	(7,200)	(7,083)
Net loss	$ (7,688)	$ (9,267)	$ (27,046)	$ (27,653)
Net loss per share of common stock — basic and diluted	$ (0.10)	$ (0.15)	$ (0.37)	$ (0.45)
Weighted average shares outstanding — basic and diluted	74,745,415	61,983,987	73,115,896	61,605,648

Balance Sheet Data	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 13,888	$ 28,920
Short-term investments	9,703	—
Total assets	29,161	34,018
Liabilities related to the sales of future royalties, net	49,188	41,988
Warrant liabilities	8,757	—
Total liabilities	63,950	49,930

Total stockholders’ deficit	(34,789)	(15,912)

Source: Clearside Biomedical, Inc.