Clearside Biomedical Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 9, 2023

- Initiation of Phase 2b ODYSSEY Trial of CLS-AX in Wet AMD Expected in Q2 2023 -

- Medical Meeting Presentations Highlight Significant Potential of CLS-AX Based on Positive OASIS Phase 1/2a Safety Data, Durability, and Biologic Effect Over 6 Months -

- Continued Growth in Retinal Specialists Trained in Suprachoroidal Space (SCS®) Injection Procedure Using FDA-Approved XIPERE® -

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

ALPHARETTA, Ga., March 09, 2023 (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 fourth quarter and year ended December 31, 2022 and provided a corporate update.

"Over the past year, we have reinforced Clearside's leadership position in the delivery of therapeutics into the suprachoroidal space through our in-office, repeatable, non-surgical procedure utilizing our proprietary SCS Microinjector®," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "With the launch of XIPERE® in the United States in 2022 by our partner, Bausch + Lomb, we believe there is increasing acceptance of treating serious retinal diseases through the SCS. Importantly, we also made excellent progress with our internal CLS-AX (axitinib injectable suspension) wet AMD clinical program."

Dr. Lasezkay continued, "The positive data from our OASIS Phase 1/2a clinical trial reinforces our belief that CLS-AX has the potential to reduce treatment burden in patients with wet AMD while maintaining stable visual acuity. CLS-AX was well tolerated and demonstrated an excellent safety profile across all timepoints and doses in the trial. Importantly, the full extension data showed promising durability, with 67% of participants going at least six months without additional treatment."

"Given this favorable CLS-AX Phase 1/2a data, as previously announced, we will conduct a randomized, controlled, double-masked, Phase 2b clinical trial, called ODYSSEY, in wet AMD participants. Based on the draft guidance on wet AMD drug development released on February 24, 2023, by the U.S. Food & Drug Administration (FDA), we plan to adjust our trial design to use on-label aflibercept dosing in the comparator arm of ODYSSEY. We expect a seamless transition to this adjusted trial design and plan to open trial enrollment in the second quarter of 2023," concluded Dr. Lasezkay.

Key Highlights

- Favorable safety data, durability, and biologic effect were reported from OASIS, Clearside's U.S.-based, open-label, dose-escalation Phase 1/2a clinical trial of CLS-AX (axitinib injectable suspension) in patients with neovascular age-related macular degeneration (wet AMD).
- Clearside's XIPERE® (triamcinolone acetonide injectable suspension) commercialization partner, Bausch + Lomb, continues to expand outreach and training with over 1,000 retinal physicians trained to date in the use of the SCS Microinjector for suprachoroidal delivery.
- Clearside's licensing partner, Aura Biosciences, finalized its global Phase 3 clinical trial design in alignment with regulatory agencies and selected suprachoroidal route of administration to evaluate the efficacy and safety of belzupacap saratalocan (bel-sar) in early-stage choroidal melanoma, a life-threatening rare disease with no approved therapies.
- Former Chief Medical Officer and Chief Development Officer, Thomas A. Ciulla, M.D., M.B.A., transitioned to an external advisory role for Clearside as Chief Medical Advisor-Retina and Chair of the Scientific Advisory Board, continuing to share his medical expertise as a practicing retinal specialist and providing counsel on Clearside's suprachoroidal development programs.
- Promising data results were presented at major medical meetings on behalf of partners utilizing Clearside's proprietary SCS Microinjector to administer ocular gene therapy and oncology agents.
- Multiple presentations featuring Clearside's proprietary suprachoroidal space injection platform were highlighted at global conferences, including the Macula Society Annual Meeting; Angiogenesis, Exudation, and Degeneration Virtual Conference; American Academy of Ophthalmology; Retina Society Annual Scientific Meeting; and, OIS Retina Summit.

Fourth Quarter 2022 Financial Results

Clearside's license and other revenue for the fourth quarter of 2022 was $330,000, compared to $25.7 million for the fourth quarter of 2021. The $25.4 million decrease was primarily attributable to one-time milestone payments received from XIPERE licensing partners in the fourth quarter of 2021.

Cost of goods sold for the fourth quarter of 2022 was $204,000, compared to $0 for the fourth quarter of 2021. This increase was related to sales of Clearside's SCS Microinjector.

Research and development expenses for the fourth quarter of 2022 were $5.0 million, compared to $3.8 million for the fourth quarter of 2021. The $1.2 million increase was primarily attributable to preclinical research program costs.

General and administrative expenses for the fourth quarter of 2022 were $3.2 million, compared to $3.1 million for the fourth quarter of 2021.

Net loss for the fourth quarter of 2022 was $9.7 million, or $0.16 per share of common stock, compared to net income of $18.7 million, or $0.31 per share of common stock, for the fourth quarter of 2021. The decrease in net income was primarily attributable to higher license revenue in the fourth quarter of 2021.

Full Year 2022 Financial Results

Clearside's license and other revenue for the year ended December 31, 2022, was $1.3 million, compared to $29.6 million for the year ended December 31, 2021. The $28.2 million decrease was primarily attributable to one-time milestone payments received from XIPERE licensing partners in 2021.

Cost of goods sold for the year ended December 31, 2022, was $204,000, compared to $0 for the year ended December 31, 2021. This increase was related to sales of Clearside's SCS Microinjector.

Research and development expenses for the year ended December 31, 2022, were $19.6 million, compared to $18.5 million for the year ended December 31, 2021. The $1.1 million increase was primarily attributable to CLS-AX program costs.

General and administrative expenses for the year ended December 31, 2022, were $11.8 million, compared to $11.7 million for the year ended December 31, 2021.

Net loss for the year ended December 31, 2022, was $32.9 million, or $0.55 per share of common stock, compared to net income of $376,000, or $0.01 per share of common stock, for the year ended December 31, 2021. The decrease in net income was primarily attributable to higher license revenue in 2021.

As of December 31, 2022, Clearside's cash and cash equivalents totaled $48.3 million. The Company believes it will have sufficient resources to fund its planned operations into the second 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. Registration for the live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations. To participate via telephone, please register in advance using the link provided in the event listing. The Company suggests participants log in 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, utilizing the Company's proprietary 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 and strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. Clearside's first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit www.clearsidebio.com.

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, timeline for initiating the ODYSSEY Phase 2b clinical trial for CLS-AX, the potential benefits of CLS-AX and other product candidates using Clearside's SCS Microinjector ® and Clearside's ability to fund its operations into the second 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 9, 2022 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.

-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**	**Year Ended**

	December 31,		December 31,	
	2022	2021	2022	2021
License and other revenue	$ 330	$ 25,687	$ 1,327	$ 29,575
Operating expenses:				
Cost of goods sold	204	—	204	—
Research and development	5,027	3,840	19,630	18,537
General and administrative	3,169	3,140	11,770	11,665
Total operating expenses	8,400	6,980	31,604	30,202
(Loss) income from operations	(8,070)	18,707	(30,277)	(627)
Other income	449	2	669	1,003
Non-cash interest expense on liability related to the sales of future royalties	(2,042)	—	(3,339)	—
Net (loss) income	$ (9,663)	$ 18,709	$ (32,947)	$ 376
Net (loss) income per share of common stock — basic and diluted	$ (0.16)	$ 0.31	$ (0.55)	$ 0.01
Weighted average shares outstanding — basic	60,412,700	59,669,759	60,204,862	58,491,986
Weighted average shares outstanding — diluted	60,412,700	61,182,414	60,204,862	59,906,602

Balance Sheet Data	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 48,258	$ 30,436
Accounts receivable	—	10,000
Total assets	51,303	42,903
Liabilities related to the sales of future royalties, net	33,977	—
Total liabilities	40,696	4,928
Total stockholders' equity	10,607	37,975

Source: Clearside Biomedical, Inc.

Investor and Media Contacts: Jenny Kobin Remy Bernarda ir@clearsidebio.com (678) 430-8206