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

May 11, 2023

- Phase 2b ODYSSEY Trial of CLS-AX in Wet AMD Expected to Open Enrollment in Q2 2023 -

- Positive Safety Data, Duration and Biologic Effect of CLS-AX Over 6 Months in OASIS Phase 1/2a Extension Study Highlighted in Presentations at Recent Medical Meetings -

- Management to Host Webcast and Conference Call Today at 8:30 A.M. ET -

ALPHARETTA, Ga., May 11, 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 first quarter ended March 31, 2023 and provided a corporate update.

"We have delivered a productive start to 2023 as we continue executing on our near-term plan to advance CLS-AX (axitinib injectable suspension) for the treatment of wet AMD," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "In February, we announced positive data from the OASIS Phase 1/2a Extension Study demonstrating an excellent safety profile for CLS-AX with promising duration and biologic effect over 6 months in treatment-experienced, anti-VEGF sub-responder wet AMD participants. This data was recently presented at the ARVO Annual Meeting in New Orleans."

"We are now looking to build upon the OASIS results in ODYSSEY, our Phase 2b clinical trial of CLS-AX in wet AMD patients, which will open for enrollment this quarter, with topline results expected in Q3 2024. The recently announced ODYSSEY trial design was based on input from our enhanced Scientific Advisory Board and other experienced retinal physicians, while taking into account the recent FDA draft guidance for wet AMD drug development. In conducting the ODYSSEY trial, we believe that CLS-AX has the potential to demonstrate an important reduction in treatment burden while maintaining stable visual acuity in patients with wet AMD. Importantly, we also believe that the number of participants, the duration, and the outcome measures of the ODYSSEY trial will provide the necessary clinical data to inform the design of a CLS-AX Phase 3 program," concluded Dr. Lasezkay.

Key Highlights

- Clearside announced plans for ODYSSEY, its randomized, double-masked, parallel-group, active-controlled, multi-center Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD).
- Favorable safety data, duration and biologic effect over 6 months in treatment-experienced anti-VEGF sub-responders was reported from Cohorts 3 and 4 of the Extension Study of OASIS, Clearside's U.S.-based, open-label, dose-escalation Phase 1/2a clinical trial of CLS-AX in wet AMD.
- Clearside's Scientific Advisory Board (SAB) was enhanced with the additions of Thomas A. Ciulla, M.D., M.B.A. as Chair, Arshad M. Khanani, M.D., M.A. and Lejla Vajzovic, M.D. The SAB is comprised of industry leading retinal physicians who provide medical and scientific expertise and input on the Company's research and development programs.
- Clinical data was presented at The Association for Research in Vision and Ophthalmology (ARVO) 2023 Annual Meeting, which highlighted that SCS delivery of small molecule suspensions offered targeted, compartmentalized, and durable drug delivery to the chorioretina. In addition, a poster presentation based on OASIS Phase 1/2a trial data showed that CLS-AX had an excellent safety profile and that Extension Study participants with wet AMD maintained visual acuity while experiencing a meaningful reduction in treatment burden over 6 months.
- Presentations featuring Clearside's proprietary suprachoroidal space injection platform were highlighted at the Macula Society Annual Meeting and the Angiogenesis, Exudation, and Degeneration Virtual Conference.

First Quarter 2023 Financial Results

- License Revenue: Clearside's license and other revenue for the first quarter of 2023 was $4,000, compared to $347,000 for the first quarter of 2022.
- Research and Development (R&D) Expenses**:** R&D expenses for the first quarter of 2023 and the first quarter of 2002 were $4.5 million.
- General and Administrative (G&A) Expenses**:** G&A expenses for the first quarter of 2023 were $3.2 million, compared to $3.5 million for the first quarter of 2022.
- Other Income: Other income for the first quarter of 2023 was $492,000, compared to $2,000 for the first quarter of 2022. Other income in both periods was comprised of interest income from cash and cash equivalents.

- Other Expense**:** Non-cash interest expense for the first quarter of 2023 was $2.2 million, compared to $0 in the first 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 first quarter of 2023 was $9.3 million, or $0.15 per share of common stock, compared to net loss of $7.6 million, or $0.13 per share of common stock, for the first quarter of 2022.
- Cash Position**:** As of March 31, 2023, Clearside's cash and cash equivalents totaled $41.4 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 8:30 a.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. The Company's lead program, CLS-AX (axitinib injectable suspension), for the treatment of neovascular age-related macular degeneration (wet AMD), is in Phase 2 clinical testing. 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 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 expected timing of topline results from the ODYSSEY clinical trial, 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 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 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 March 31,**	
	2023	**2022**
License and other revenue	$ 4	$ 347
Operating expenses:		
Research and development	4,451	4,536
General and administrative	3,158	3,457
Total operating expenses	7,609	7,993
Loss from operations	(7,605)	(7,646)
Other income	492	2
Non-cash interest expense on liability related to the sales of future royalties	(2,167)	—

Net loss	$ (9,280)	$ (7,644)
Net loss per share of common stock — basic and diluted	$ (0.15)	$ (0.13)
Weighted average shares outstanding — basic and diluted	61,169,486	60,064,209

Balance Sheet Data	**March 31, 2023**	**December 31, 2022**
Cash and cash equivalents	$ 41,419	$ 48,258
Total assets	44,695	51,303
Liabilities related to the sales of future royalties, net	36,144	33,977
Total liabilities	41,995	40,696
Total stockholders' equity	2,700	10,607

Source: Clearside Biomedical, Inc.