Clearside Biomedical Announces Third Quarter 2022 Financial Results and Provides Corporate Update

November 9, 2022

- Favorable Safety Results, Durability and Biologic Effect Observed in Cohorts 3 and 4 of CLS-AX OASIS Phase 1/2a Trial -

- Recent Positive Data Presentations Highlight the Potential Safety, Efficacy and Durability Benefits of Suprachoroidal Administration of Small Molecule Suspensions -

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

ALPHARETTA, Ga., Nov. 09, 2022 (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, 2022 and provided a corporate update.

"Based on the encouraging data we reported today from our OASIS study, we are now positioned to advance our suprachoroidal CLS-AX program into a larger randomized, controlled Phase 2 trial," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "We see significant opportunity across the retinal disease spectrum for CLS-AX, which combines pan-VEGF inhibition from the highly potent tyrosine kinase inhibitor, axitinib, with targeted SCS delivery using our SCS Microinjector®. In addition, the growing level of awareness and acceptance of SCS delivery in the retinal medical community is further validating our SCS delivery platform, with recent positive clinical data presented from four other suprachoroidal trials of three different novel therapies each delivered with our proprietary SCS Microinjector."

Key Highlights

- Reported favorable results of safety, durability and biologic effect observed in the higher doses administered in Cohorts 3 and 4 of OASIS, Clearside's U.S. based, open-label, dose-escalation Phase 1/2a clinical trial of CLS-AX in patients with wet AMD.
- Entered into a Royalty Interest Purchase and Sale Agreement with HealthCare Royalty Partners, in which Clearside received an initial payment of $32.5 million, less certain expenses, with the potential to receive up to $65 million in non-dilutive funding to support ongoing clinical development of Clearside's pipeline, and pursuant to which HealthCare Royalty Partners will receive certain royalties and milestone payments due to Clearside from XIPERE® (triamcinolone acetonide injectable suspension) and certain SCS Microinjector license agreements.
- Clearside's commercialization partner, Bausch + Lomb, received XIPERE's permanent J-code, a reimbursement code used in the U.S. by commercial insurers and government payers, which became effective for provider billing on July 1, 2022.
- XIPERE was nominated for the 2022 Prix Galien USA Award, which recognizes outstanding achievements in improving the global human condition through the development of innovative drugs, technologies, and other treatments.
- Clearside's proprietary SCS delivery platform was highlighted in multiple presentations and panels at global conferences, including the American Academy of Ophthalmology (AAO) 2022 Annual Meeting, the Retina Society, the Ophthalmology Futures Retina Forum 2022, the American Society of Retina Specialists (ASRS) Annual Meeting, and the Ophthalmology Innovation Source (OIS) Retina Innovation Summit.

Third Quarter 2022 Financial Results

Clearside's license and other revenue for the third quarter of 2022 was $0.3 million, compared to $3.1 million for the third quarter of 2021. This decrease was primarily attributable to higher revenue from partner licensing agreements in the third quarter of 2021.

Research and development expenses for the third quarter of 2022 were $4.6 million, compared to $5.1 million for the third quarter of 2021. This decrease was primarily attributable to a decrease in costs in the XIPERE program following approval in October 2021.

General and administrative expenses for the third quarter of 2022 were $2.4 million, compared to $2.8 million for the third quarter of 2021. This decrease was primarily attributable to a $0.3 million decrease in employee related costs related for share-based compensation.

Net loss for the third quarter of 2022 was $7.8 million, or $0.13 per share of common stock, compared to a net loss of $4.9 million, or $0.08 per share of common stock, for the third quarter of 2021. This decrease was primarily attributable to higher revenue from partner licensing agreements in the third quarter of 2021.

As of September 30, 2022, Clearside's cash and cash equivalents totaled $53.4 million. The Company believes this cash balance will provide financial runway into 2024.

Conference Call & Webcast Details

Clearside's management will host a webcast and conference call at 8:30 a.m. Eastern Time to provide a corporate update and to discuss results from the OASIS trial. 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: 111701. An archive of the webcast will be available for three months.

About Clearside Biomedical

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 delivery 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, including the initiation of the Phase 2 clinical trial, the potential benefits of CLS-AX and product candidates using Clearside's SCS Microinjector ®, potential future payments under the agreement with HealthCare Royalty Partners and Clearside's ability to fund its operations into 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, 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,	
	2022	2021	2022	2021
License and other revenue	$ 266	$ 3,074	$ 997	$ 3,888
Operating expenses:				
Research and development	4,637	5,147	14,603	14,697
General and administrative	2,353	2,816	8,601	8,525
Total operating expenses	6,990	7,963	23,204	23,222
Loss from operations	(6,724)	(4,889)	(22,207)	(19,334)
Other income	194	2	220	1,001
Non-cash interest expense on liability related the sales of future royalties	(1,297)	—	(1,297)	—
Net loss	$ (7,827)	$ (4,887)	$ (23,284)	$ (18,333)
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.08)	$ (0.39)	$ (0.32)
Weighted average shares outstanding — basic and diluted	60,188,541	59,474,346	60,134,821	58,095,080

Balance Sheet Data	September 30, 2022	December 31, 2021

Cash and cash equivalents	$	53,381	$	30,436
Accounts receivable		123		10,000
Total assets		55,685		42,903
Liability related to the sales of future royalties, net		31,935		—
Total liabilities		37,139		4,928
Total stockholders’ equity		18,546		37,975

Source: Clearside Biomedical, Inc.