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

May 11, 2022

- First Approved Suprachoroidal Product, XIPERE®, Now Commercially Available in U.S. -

- Cohort 4 Enrolling at 1.0 mg Dose in CLS-AX OASIS Wet AMD Phase 1/2a Trial -

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

ALPHARETTA, Ga., May 11, 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 first quarter ended March 31, 2022 and provided a corporate update.

"The approval and recent commercial launch of XIPERE® in the U.S. validates delivery into the suprachoroidal space by our proprietary SCS Microinjector®, and supports our strategic approach focused on small molecule suspensions," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "As part of the launch process, hundreds of retinal specialists throughout the country have been trained on the use of our SCS Microinjector. This vast experience and technical knowledge using our Microinjector establishes a strong base for our platform as we expand our internal and externally partnered therapeutic candidates."

Dr. Lasezkay continued, "Our lead internal suprachoroidal pipeline product candidate, CLS-AX, combines our proprietary small molecule suspension of the tyrosine kinase inhibitor axitinib with delivery by our SCS Microinjector. We are progressing OASIS, our Phase 1/2a single dose escalating clinical trial targeting patients with wet AMD. We are encouraged by the growing interest in this trial, and as a result, we have recently doubled the number of clinical trial sites to ten. Our Safety Monitoring Committee reviewed one-month initial safety data from Cohort 3 and we are pleased to report that there were no dose limiting toxicities observed at the 0.5 mg dose. As a result, we are now enrolling patients in Cohort 4 at the higher dose of 1.0 mg while simultaneously continuing our Cohort 3 enrollment. We are targeting up to 25 patients in total from all four OASIS cohorts."

"This expanded enrollment of Cohort 3 and the addition of Cohort 4 will allow us to collect more CLS-AX patient data in order to help guide our selection of the most appropriate dosing protocol for our planned Phase 2b clinical trial. We now expect to report safety and tolerability data from both Cohorts 3 and 4 in the fourth quarter of this year. This will allow us to report a more comprehensive set of patient data as we will be able to include the complete analysis from all four dosing cohorts of the OASIS trial, in addition to the detailed individual patient data from the final two cohorts," concluded Dr. Lasezkay.

Key Highlights

- XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use for the treatment of macular edema associated with uveitis was commercially launched for sale in the U.S. by Bausch + Lomb.
- Continued progress made in OASIS, Clearside's U.S. based, open-label, dose-escalation Phase 1/2a trial in patients with wet AMD, to assess the safety and tolerability of CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside's SCS Microinjector.
- Benjamin R. Yerxa, Ph.D., Chief Executive Officer of the Foundation Fighting Blindness, the world's leading private funding source for retinal degenerative disease research, was appointed to Clearside's Board of Directors.
- Multiple presentations and panels featuring the use of Clearside's proprietary suprachoroidal space injection platform were highlighted at global conferences, including Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting, the American Society of Cataract and Refractive Surgery (ASCRS) Meeting, Vit Buckle Society Annual Meeting, Sonoma Eye Meeting, Wet AMD & DME Drug Development Summit and Angiogenesis, Exudation, and Degeneration Virtual Conference.
- Several posters were presented at ARVO related to XIPERE® for suprachoroidal use.
- Two presentations were delivered on REGENXBIO asset RGX-314 administered via Clearside's SCS Microinjector at ARVO.

First Quarter 2022 Financial Results

Clearside's license and other revenue for the first quarter of 2022 was $347,000, compared to $34,000 for the first quarter of 2021.

Research and development expenses for the first quarter of 2022 were $4.5 million, compared to $5.5 million for the first quarter of 2021. The $1.0 million decrease was primarily attributable to reduced XIPERE-related expenses which offset CLS-AX Phase 1/2a clinical trial costs.

General and administrative expenses for the first quarter of 2022 were $3.5 million, compared to $2.9 million for the first quarter of 2021. The $0.6 million increase was primarily attributable to share-based compensation and higher salary costs.

Net loss for the first quarter of 2022 was $7.6 million, or $0.13 per share of common stock, compared to a net loss of $7.4 million, or $0.13 per share of common stock, for the first quarter of 2021.

As of March 31, 2022, Clearside's cash and cash equivalents totaled $34.4 million. The Company believes it will have sufficient resources to fund its planned operations for at least the next twelve months.

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 (844) 263-8310 (domestic) or (213) 358-0959 (international) and entering conference code: 3749780. 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 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, including the expected timing of data from the OASIS clinical trial and plans for the Phase 2b trial, the potential benefits of CLS-AX and product candidates using Clearside's SCS Microinjector ® and Clearside's ability to fund its operations for at least the next twelve months. 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, 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,**	
	2022	2021
License and other revenue	$ 347	$ 34
Operating expenses:		
Research and development	4,536	5,490
General and administrative	3,457	2,893
Total operating expenses	7,993	8,383
Loss from operations	(7,646)	(8,349)
Other income	2	998
Net loss	$ (7,644)	$ (7,351)
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.13)
Weighted average shares outstanding — basic and diluted	60,064,209	57,038,664

Balance Sheet Data	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 34,372	$ 30,436
Accounts receivable	–	10,000
Total assets	36,059	42,903
Total liabilities	4,356	4,928
Total stockholders' equity	31,703	37,975

Source: Clearside Biomedical, Inc.