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

August 9, 2022

- CLS-AX OASIS Phase 1/2a Trial Data from Cohorts 3 & 4 Expected in November 2022 -

- Non-Dilutive Financing Agreement with HealthCare Royalty Supports Progression of CLS-AX Clinical Program -

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

ALPHARETTA, Ga., Aug. 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 second quarter ended June 30, 2022 and provided a corporate update.

"We are building significant momentum through our internal and partnered programs leveraging our proprietary SCS platform technology," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "We have created a new paradigm in retinal drug delivery with XIPERE® for suprachoroidal use. It is the first product approved by the U.S. FDA for suprachoroidal injection and is now being used by physicians across the U.S. to treat patients with macular edema associated with uveitis."

Dr. Lasezkay continued, "There are multiple upcoming anticipated catalysts related to our internal CLS-AX program and from our development and commercialization partners. We successfully completed dosing in Cohorts 3 and 4 of OASIS, our Phase 1/2a clinical trial of CLS-AX in patients with neovascular age-related macular degeneration (wet AMD). We expect to report the OASIS data for all four cohorts in November of this year, which we believe will provide more insight into the potential benefits of combining pan-VEGF inhibition from the highly potent tyrosine kinase inhibitor, axitinib, with targeted delivery to affected chorioretinal tissues utilizing our proprietary SCS Microinjector."

Key Highlights

- Completed dosing 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, which may provide Clearside 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 all royalties and milestone payments due to Clearside from XIPERE and certain SCS Microinjector license agreements, subject to a cap of 2.5 times the total purchase price paid by HealthCare Royalty under the agreement; the cap may be increased under certain circumstances.
- Clearside's commercialization partner, Bausch + Lomb, received XIPERE's permanent J-code, a reimbursement code used in the US by commercial insurers and government payers, which became effective for provider billing on July 1, 2022.
- Appointed Susan L. Coultas, Ph.D., as Chief Clinical Officer.
- Clearside's proprietary suprachoroidal space injection platform was highlighted in the July 2022 special edition of *Retinal Physician* and in multiple presentations and panels at global conferences, including the American Society of Retina Specialists (ASRS) Annual Meeting, the Ophthalmology Innovation Source (OIS) Retina Innovation Summit, and the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting.
- A data manuscript entitled, "Suprachoroidal CLS-TA for non-infectious uveitis: an open-label, safety trial (AZALEA)" was published in the *British Journal of Ophthalmology* in June 2022.
- A data manuscript entitled, "Optical Coherence Tomography Anatomic and Temporal Biomarkers in Uveitic Macular Edema" was published in the *American Journal of Ophthalmology* in May 2022.
- A data manuscript entitled, "Suprachoroidal Injection of Triamcinolone Acetonide Suspension: Ocular Pharmacokinetics and Distribution in Rabbits Demonstrates High and Durable Levels in the Chorioretina" was published in the *Journal of Ocular Pharmacology* in April 2022.

Second Quarter 2022 Financial Results

Clearside's license and other revenue for the second quarter of 2022 was $384,000, compared to $780,000 for the second quarter of 2021.

Research and development expenses for the second quarter of 2022 were $5.4 million, compared to $4.1 million for the second quarter of 2021. The $1.3 million increase was primarily attributable to CLS-AX Phase 1/2a clinical trial costs.

General and administrative expenses for the second quarter of 2022 were $2.8 million, compared to $2.8 million for the second quarter of 2021.

Net loss for the second quarter of 2022 was $7.8 million, or $0.13 per share of common stock, compared to a net loss of $6.1 million, or $0.11 per share of common stock, for the second quarter of 2021.

On August 8, 2022 (Closing Date), Clearside entered into a non-dilutive financing agreement with HealthCare Royalty Partners for up to $65 million. Under the terms of the agreement, Clearside will receive an initial payment of $32.5 million, less certain expenses, within 15 business days of the Closing Date. At the same time, an additional $12.5 million will be deposited in an escrow account to be released to Clearside upon attainment of a pre-specified sales milestone for XIPERE. The terms of the agreement also provide for an additional milestone payment of $20 million to Clearside upon attainment of a second pre-specified 2024 sales milestone for XIPERE.

As of June 30, 2022, Clearside's cash and cash equivalents totaled $29.0 million. The initial royalty agreement payment of $32.5 million combined with the second quarter-end cash balance is expected to provide financial runway into 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. The live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations. The Company suggests participants log in 15 minutes in advance of the event.

About XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide for administration to the suprachoroidal space for the treatment of macular edema associated with uveitis. Bausch + Lomb, a leading global eye health company dedicated to helping people see better to live better, has the exclusive license for the commercialization and development of XIPERE in the United States and Canada. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE, which they refer to as Arcatus™, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPERE was approved by the U.S. Food and Drug Administration in October 2021 and is commercially available in the U.S.

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, the potential benefits of CLS-AX and product candidates using Clearside's SCS Microinjector ®, the anticipated use of proceeds from the agreement with HealthCare Royalty Partners, 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, 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021

License and other revenue	$ 384	$ 780	$ 731	$ 814
Operating expenses:				
Research and development	5,430	4,060	9,966	9,550
General and administrative	2,791	2,816	6,248	5,709
Total operating expenses	8,221	6,876	16,214	15,259
Loss from operations	(7,837)	(6,096)	(15,483)	(14,445)
Other income	24	1	26	999
Net loss	$ (7,813)	$ (6,095)	$ (15,457)	$ (13,446)
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.11)	$ (0.26)	$ (0.23)
Weighted average shares outstanding — basic and diluted	60,150,348	57,745,465	60,107,517	57,394,017

Balance Sheet Data	**June 30, 2022**	**December 31, 2021**
Cash and cash equivalents	$ 29,033	$ 30,436
Accounts receivable	123	10,000
Total assets	30,746	42,903
Total liabilities	5,498	4,928
Total stockholders' equity	25,248	37,975