# Clearside Biomedical Announces Third Quarter 2021 Financial Results and Provides Corporate Update

November 10, 2021

*- XIPERE™ is First FDA-Approved Product for Injection into the Suprachoroidal Space -*

*- Approval-Related Milestones to Provide $19 Million in Non-Dilutive Funding -*

*- Continued Progress in CLS-AX Wet AMD Phase 1/2a Trial -*

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

ALPHARETTA, Ga., Nov. 10, 2021 (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, 2021.

"The approval of XIPERE™ marks a significant milestone for Clearside as we enter a new era in delivering therapies to the back of the eye via the suprachoroidal space using our proprietary platform," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "It is always an exciting moment when you are able to develop a truly innovative pharmaceutical treatment option for patients that addresses an important unmet medical need. XIPERE is now the first product approved for injection into the suprachoroidal space, and the first therapy approved for macular edema associated with uveitis. By utilizing our SCS Microinjector®, retina physicians will now have a differentiated route of administration that provides a targeted treatment for their patients suffering from this sight-threatening disease."

Dr. Lasezkay continued, "I am proud of the work completed by our team to advance our first clinical product, XIPERE, to final FDA approval, validating our ability to successfully develop ophthalmic therapies for suprachoroidal administration. We also continue to work closely and cooperatively with Bausch + Lomb as they prepare to launch XIPERE in the U.S. in the first quarter of 2022."

"With the approval of XIPERE, we expect to receive a total of $19 million in non-dilutive funding for approval and pre-launch milestones from our commercialization partners. This additional capital will be utilized to advance our clinical development pipeline led by CLS-AX (axitinib injectable suspension) for suprachoroidal administration. In September 2021, we completed dosing in Cohort 2 of OASIS, our ongoing Phase 1/2a clinical trial of CLS-AX in patients with neovascular age-related macular degeneration (wet AMD). We look forward to reporting the safety and tolerability results from Cohort 2 by the end of this year," concluded Dr. Lasezkay.

**Key Highlights**

- XIPERE (triamcinolone acetonide injectable suspension) for suprachoroidal use for the treatment of macular edema associated with uveitis was approved by the U.S. Food and Drug Administration in October 2021.
- Enrollment and dosing were completed in Cohort 2 of 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 a 0.1 mg dose of CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside's SCS Microinjector.
- Exclusive XIPERE license agreement with Arctic Vision, a China-based biotechnology company focused on innovative ophthalmic therapies, was expanded from Greater China and South Korea to also include Australia, New Zealand, India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam).
- REGENXBIO presented positive initial data from two Phase 2 clinical trials testing RGX-314 using suprachoroidal delivery. In the AAVIATE® trial for the treatment of wet AMD, RGX-314 was well tolerated in 50 patients in Cohorts 1-3, with no drug-related serious adverse events, and a treatment effect observed in Cohort 1 patients at six months after one-time treatment. In the ALTITUDE™ trial for the treatment of diabetic retinopathy, RGX-314 was well tolerated in 15 patients in Cohort 1, with no drug-related serious adverse events, no intraocular inflammation observed, and positive interim data from Cohort 1 at three months after one-time treatment.
- Aura Biosciences presented interim Phase 2 safety data evaluating suprachoroidal administration of AU-011 in patients with choroidal melanoma, reporting that there have been no related serious adverse events, dose limiting toxicities, or grade 3 adverse events observed during the trial and that suprachoroidal administration may improve the therapeutic index and optimize treatment parameters.
- Multiple presentations featuring the use of Clearside's proprietary suprachoroidal space injection platform were highlighted at global conferences, including the American Society of Retina Specialists Annual Meeting, the Retina Society 54th Annual Scientific Meeting, the OIS Retina Summit and the Ophthalmology Futures European 2021 Virtual Retina Forum.
- A data manuscript entitled, "Suprachoroidal CLS-TA with and without Systemic Corticosteroid and/or Steroid-Sparing

Therapy: A Post-Hoc Analysis of the Phase 3 PEACHTREE Clinical Trial", was published in *Ocular Immunology & Inflammation* in August 2021.

**Third Quarter 2021 Financial Results**

Clearside's license and other revenue for the third quarter of 2021 was $3.1 million, compared to $3.4 million for the third quarter of 2020. This decrease was primarily attributable to higher revenue from partner licensing agreements in the third quarter of 2020.

Research and development expenses for the third quarter of 2021 were $5.1 million, compared to $3.5 million for the third quarter of 2020. This increase was primarily attributable to increased costs for continued development of CLS-AX and other pipeline programs and employee-related expenses.

General and administrative expenses for the third quarter of 2021 were $2.8 million, compared to $2.4 million for the third quarter of 2020. This increase was primarily attributable to an increase in employee-related expenses.

Net loss for the third quarter of 2021 was $4.9 million, or $0.08 per share of common stock, compared to a net loss of $2.4 million, or $0.05 per share of common stock, for the third quarter of 2020. This increase in net loss was primarily attributable to higher research and development expenses in the third quarter of 2021.

As of September 30, 2021, Clearside's cash and cash equivalents totaled $25.2 million. With the anticipated XIPERE approval related milestone payments of $19 million from Clearside's commercialization partners, the Company believes it will have sufficient resources to fund its planned operations into 2023.

**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: 1698586. An archive of the webcast will be available for three months.

**Important Safety Information about XIPERE™**

**Indication**
XIPERE ™ (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

**IMPORTANT SAFETY INFORMATION**
Patients should be monitored following injection for elevated intraocular pressure. See Dosage and Administration instructions in full Prescribing Information.

- XIPERE is contraindicated in patients with **active or suspected ocular or periocular infections** including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
- XIPERE ™ is contraindicated in patients with known **hypersensitivity to triamcinolone acetonide** or any other components of this product.
- Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses, and should be used cautiously in patients with a history of ocular herpes simplex.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use.
- In controlled studies, the most common ocular adverse reactions were increased ocular pressure, non-acute (14%), eye pain, non-acute (12%), cataract (7%); increased intraocular pressure, acute (6%), cataract (7%), vitreous detachment (5%), injection site pain (4%) conjunctival hemorrhage (4%), visual acuity reduced (4%), dry eye (3%), eye pain, acute (3%), photophobia (3%), and vitreous floaters (3%), and in 2% of patients: uveitis, conjunctival hyperaemia, punctate keratitis, conjunctival oedema, meibomianitis, anterior capsule contraction, chalazion, eye irritation, eye pruritus, eyelid ptosis, photopsia, and vision blurred.

  The most common non-ocular adverse event was headache (5%).

- Corticosteroids should be used during pregnancy or nursing only if the potential benefit justifies the potential risk to the fetus or nursing infant.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

Please click here for full Prescribing Information.

**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, was approved by the U.S. Food and Drug Administration in October 2021. 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, including the timing of data from the OASIS clinical trial, the potential benefits of XIPERE, CLS-AX and therapies using Clearside's SCS Microinjector ®, the timing of commercial launch of XIPERE by Bausch + Lomb and Clearside's ability to fund its operations into 2023. 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, 2020, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2021, 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,** | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| License and other revenue | $ 3,074 | $ 3,432 | $ 3,888 | $ 7,883 |
| Operating expenses: | | | | |
| Research and development | 5,147 | 3,490 | 14,697 | 10,601 |
| General and administrative | 2,816 | 2,374 | 8,525 | 8,107 |
| Total operating expenses | 7,963 | 5,864 | 23,222 | 18,708 |
| Loss from operations | (4,889) | (2,432) | (19,334) | (10,825) |
| Other income | 2 | — | 1,001 | — |
| Other expense | — | (1) | — | (273) |
| Net loss | $ (4,887) | $ (2,433) | $ (18,333) | $ (11,098) |
| Net loss per share of common stock — basic and diluted | $ (0.08) | $ (0.05) | $ (0.32) | $ (0.24) |
| Weighted average shares outstanding — basic and diluted | 59,474,346 | 46,976,649 | 58,095,080 | 45,653,068 |

| **Balance Sheet Data** | **September 30, 2021** | **December 31, 2020** |
|---|---|---|
| Cash and cash equivalents | $ 25,217 | $ 17,287 |
| Total assets | 27,378 | 19,322 |
| Deferred revenue | 5,000 | 5,000 |
| Long-term debt (including current portion) | — | 991 |
| Total liabilities | 9,530 | 10,559 |
| Total stockholders' equity | 17,848 | 8,763 |

Source: Clearside Biomedical, Inc.