Clearside Biomedical Announces Second Quarter 2021 Financial Results and Provides Corporate Update

August 10, 2021

- Enrollment Underway in Cohort 2 of OASIS Wet AMD Phase 1/2a Trial with Data Expected by the End of 2021 –

- Upcoming FDA PDUFA Action Date in October 2021 for XIPERE™(triamcinolone acetonide suprachoroidal injectable suspension) -

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

ALPHARETTA, Ga., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, today reported financial results for second quarter ended June 30, 2021.

“We continue to demonstrate our position as the leader in the suprachoroidal space with numerous clinical trials in multiple indications, a New Drug Application (NDA) for XIPERE™ under regulatory review and recent positive results from our CLS-AX clinical trial,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “We are the first company to develop a clinically tested, non-surgical, repeatable micro-injection technology designed to unlock the potential clinical benefits of administering drugs into the suprachoroidal space. We are encouraged by the Cohort 1 results of our OASIS Phase 1/2a trial in wet AMD patients, which achieved its safety and tolerability endpoints. We believe the Cohort 1 data supports our hypothesis that the combination of targeted and compartmentalized suprachoroidal delivery and the potent pan-VEGF attributes of axitinib may facilitate an effective treatment option for patients suffering from wet AMD. We have begun enrollment in Cohort 2 with more than triple the dose used in Cohort 1 and look forward to reporting results by the end of 2021.”

“Following our NDA resubmission for XIPERE for the treatment of macular edema associated with uveitis, the U.S. Food and Drug Administration (FDA) assigned a Prescription Drug User Fee Act (PDUFA) action date of October 30, 2021. If approved, XIPERE would represent the first therapy for macular edema associated with uveitis, the first approved therapeutic delivered into the suprachoroidal space and the first commercial product developed by Clearside. In addition to progressing our internal development initiatives, we continue to work closely with our commercial and drug development partners, and expect data from their ongoing clinical trials using our SCS Microinjector® later this year,” concluded Dr. Lasezkay.

Key Highlights

- Patient enrollment is underway in Cohort 2 of OASIS, Clearside’s U.S. based, open-label, dose-escalation Phase 1/2a trial in wet AMD patients, to assess the safety and tolerability of a 0.1 mg dose of CLS-AX administered by suprachoroidal injection via Clearside’s SCS Microinjector ®.
- Clearside reported positive results from Cohort 1 of OASIS in six patients (n=6) with neovascular age-related macular degeneration (wet AMD). The primary endpoints were achieved in Cohort 1, as the initial lowest planned dose of 0.03 mg CLS-AX was well tolerated with no serious adverse events and no drug related treatment emergent adverse events observed throughout the study period.
- FDA accepted the XIPERE NDA resubmission and assigned a PDUFA action date of October 30, 2021.
- Multiple presentations featuring the use of Clearside’s proprietary suprachoroidal space (SCS ®) delivery platform to administer small molecules and gene therapy were highlighted at global conferences, including the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and the Wet AMD & DME Drug Development Summit.
- Data was published in *Translational Vision Science & Technology* titled “Evaluation of Long-Lasting Potential of Suprachoroidal Axitinib Suspension Via Ocular and Systemic Disposition in Rabbits” in June 2021.

Second Quarter 2021 Financial Results

Clearside’s license and other revenue for the second quarter of 2021 was $0.8 million, compared to $0.4 million for the second quarter of 2020. This increase was primarily attributable to higher revenue from partner licensing agreements in the second quarter of 2021.

Research and development expenses for the second quarter of 2021 were $4.1 million, compared to $3.3 million for the second quarter of 2020. This increase was primarily attributable to increased costs for continued development of pipeline programs and employee-related expenses.

General and administrative expenses for the second quarter of 2021 were $2.8 million, compared to $2.6 million for the second quarter of 2020. This increase was primarily attributable to an increase in employee-related expenses.

Net loss for the second quarter of 2021 was $6.1 million, or $0.11 per share of common stock, compared to a net loss of $5.8 million, or $0.13 per share of common stock, for the second quarter of 2020. This increase in net loss was primarily attributable to higher research and development expenses in the second quarter of 2021. The change in net loss per share was related to the increase in shares outstanding.

As of June 30, 2021, Clearside’s cash and cash equivalents totaled $26.4 million. The Company believes it will have sufficient resources to fund its

planned operations into the second quarter of 2022, not including receipt of potential partner milestone payments.

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: 7785213. An archive of the webcast will be available for three months.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside's proprietary SCS Microinjector ® targets the suprachoroidal space (SCS®) and offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. The Company's SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications. 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 resubmitted NDA for and anticipated regulatory approval of XIPERE and Clearside's ability to fund its operations into the second quarter of 2022. 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
License and other revenue	$ 780	$ 354	$ 814	$ 4,451
Operating expenses:				
Research and development	4,060	3,300	9,550	7,111
General and administrative	2,816	2,611	5,709	5,733
Total operating expenses	6,876	5,911	15,259	12,844
Loss from operations	(6,096)	(5,557)	(14,445)	(8,393)
Other income	1	—	999	—
Other expense	—	(197)	—	(272)
Net loss	$ (6,095)	$ (5,754)	$ (13,446)	$ (8,665)
Net loss per share of common stock — basic and diluted	$ (0.11)	$ (0.13)	$ (0.23)	$ (0.19)
Weighted average shares outstanding — basic and diluted	57,745,465	45,214,500	57,394,017	44,984,005

Balance Sheet Data	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 26,414	$ 17,287

Total assets	28,592	19,322
Deferred revenue	5,000	5,000
Long-term debt (including current portion)	—	991
Total liabilities	9,254	10,559
Total stockholders' equity	19,338	8,763

Source: Clearside Biomedical, Inc.