Clearside Biomedical Announces Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

March 10, 2021

- OASIS Wet AMD Phase 1/2a Trial Initiated and Cohort 1 Dosing Completed -

- Initial Safety Data from OASIS Trial Expected Mid-2021 -

- Four Ongoing Internal & Partner Clinical Trials Using Clearside's SCS Microinjector ® -

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

ALPHARETTA, Ga., March 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 the fourth quarter and year ended December 31, 2020 and provided a corporate update.

"Over the past year, our team has executed on our key initiatives with purpose and focus," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "As the pioneers in treating back of the eye diseases through the suprachoroidal space, we expanded the use of our first in class, proprietary SCS Microinjector® into four clinical programs in the U.S. based on our internal product pipeline and our collaborators' efforts."

"We advanced our high-potential CLS-AX program with suprachoroidally-administered axitinib into the clinic and have fully enrolled and completed dosing in Cohort 1 of OASIS, our Phase 1/2a trial in patients with neovascular age-related macular degeneration (wet AMD). We expect to report initial safety data from Cohort 1 in mid-2021. In addition, we remain on track to resubmit our New Drug Application for XIPERE™ in the second quarter of 2021, which is in line with our prior guidance. With our recently completed financings, we are well-funded to reach multiple potential value-creating events over the next 12 months," concluded Dr. Lasezkay.

Key Highlights and Anticipated Milestones

- Initiation 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 single dose of CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector®.
- Completion of patient dosing in Cohort 1 of the OASIS trial with initial safety data expected mid-2021.
- Completion of registered direct offering of 4.2 million shares in January 2021, resulting in total gross proceeds of approximately $12.0 million.
- Clearside's adeno-associated virus (AAV)-based gene therapy partner, REGENXBIO, expects to: report interim efficacy data in the third quarter of 2021 from Cohort 1 and complete enrollment in Cohort 2 in the second quarter of 2021 in AAVIATE™, a Phase 2 trial for treatment of wet AMD; and report initial data from ALTITUDE, a Phase 2 trial for treatment of diabetic retinopathy, in 2021.
- Multiple presentations featuring Clearside's suprachoroidal injection platform in a range of indications, including wet AMD, uveitis, diabetic macular edema and ocular gene therapy, were highlighted at global conferences, including the American Academy of Ophthalmology Annual Meeting, the 44th Annual Meeting of The Macula Society and the Angiogenesis, Exudation, and Degeneration 2021 Meeting.
- Data was published in the *British Journal of Ophthalmology* in February 2021 titled "Suprachoroidal CLS-TA for Non-infectious Uveitis: an Open-label, Safety Trial (AZALEA)".
- Data was published in *Expert Opinion on Drug Delivery* in January 2021 titled "Biomechanics of Suprachoroidal Drug Delivery: From Benchtop to Clinical Investigation in Ocular Therapies".
- Data was published in *Translational Vision Science & Technology,* a journal of the Association for Research in Vision and Ophthalmology, in December 2020 titled "Suprachoroidally Delivered DNA Nanoparticles Transfect Retina and Retinal Pigment Epithelium/Choroid in Rabbits".

Fourth Quarter 2020 Financial Results

Clearside's license and other revenue for the fourth quarter of 2020 was $11,000, compared to $1.9 million for the fourth quarter of 2019. The $1.9 million decrease was primarily attributable to lower revenue from partner licensing agreements in the fourth quarter of 2020.

Research and development expenses for the fourth quarter of 2020 were $4.5 million, compared to $1.3 million for the fourth quarter of 2019. The $3.2 million increase was primarily attributable to increased expenses related to preparation for initiation of the CLS-AX Phase 1/2a clinical trial and costs

related to drug manufacturing activities for XIPERE.

General and administrative expenses for the fourth quarter of 2020 were $2.6 million, compared to $3.7 million for the fourth quarter of 2019. The $1.0 million decrease was primarily attributable to reduced marketing-related expenses resulting from the out-licensing of XIPERE commercialization.

Net loss for the fourth quarter of 2020 was $7.1 million, or $0.14 per share of common stock, compared to a net loss of $3.1 million, or $0.07 per share of common stock, for the fourth quarter of 2019. The increase in net loss was primarily attributable to higher research and development expenses in the fourth quarter of 2020.

Full Year 2020 Financial Results

Clearside's license and other revenue for the year ended December 31, 2020 was $7.9 million, compared to $2.2 million for the year ended December 31, 2019. The $5.7 million increase was primarily attributable to higher revenue from partner licensing agreements in 2020.

Research and development expenses for the year ended December 31, 2020 were $15.1 million, compared to $15.7 million for the year ended December 31, 2019.

General and administrative expenses for the year ended December 31, 2020 were $10.8 million, compared to $16.8 million for the year ended December 31, 2019. The $6.1 million decrease was primarily attributable to reduced marketing-related expenses resulting from the out-licensing of XIPERE commercialization.

Net loss for the year ended December 31, 2020 was $18.2 million, or $0.39 per share of common stock, compared to a net loss of $30.8 million, or $0.81 per share of common stock, for the year ended December 31, 2019. The decrease in net loss was primarily attributable to higher revenue from partner licensing agreements and lower general and administrative expenses in 2020.

As of December 31, 2020, Clearside's cash and cash equivalents totaled $17.3 million. In January 2021, aggregate net proceeds of $14.4 million were raised from a registered direct offering of 4.2 million shares and issuances of 1.2 million shares through an at-the-market agreement. The Company believes it will have sufficient resources to fund its planned operations into the first 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: 5286349. 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 safety data from the OASIS clinical trial, and the potential benefits, of CLS-AX and therapies using Clearside's SCS Microinjector ®, the timeline for resubmitting the NDA for XIPERE and Clearside's ability to fund its operations into the first 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, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2020, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 10, 2020 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 December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
License and other revenue	$ 11	$ 1,942	$ 7,894	$ 2,173
Operating expenses:				
Research and development	4,472	1,305	15,073	15,658
General and administrative	2,649	3,650	10,756	16,819
Total operating expenses	7,121	4,955	25,829	32,477
Loss from operations	(7,110)	(3,013)	(17,935)	(30,304)
Other expense	(2)	(83)	(275)	(466)
Net loss	$ (7,112)	$ (3,096)	$ (18,210)	$ (30,770)
Net loss per share of common stock — basic and diluted	$ (0.14)	$ (0.07)	$ (0.39)	$ (0.81)
Weighted average shares outstanding — basic and diluted	49,048,402	42,394,959	46,506,540	38,170,830

Balance Sheet Data	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 17,287	$ 22,595
Total assets	19,322	26,776
Deferred revenue	5,000	5,000
Long-term debt (including current portion)	991	5,152
Total liabilities	10,559	15,619
Total stockholders' equity	8,763	11,157

Source: Clearside Biomedical, Inc.