Clearside Biomedical Announces Third Quarter 2019 Financial Results and Provides Corporate Update

November 6, 2019

– Recent Partnerships Support the Broad Applicability of Suprachoroidal Space Injection Platform to Potentially Treat Multiple Ocular Diseases –

– Suprachoroidal Axitinib IND Submission Targeted for Mid-2020 –

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

ALPHARETTA, Ga., Nov. 06, 2019 (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 third quarter of 2019 and provided a corporate update.

"With three recent partnerships and plans to expand our internal development pipeline, we have made meaningful progress on our overall strategy to broaden the reach of our suprachoroidal space injection platform," said George Lasezkay, Pharm.D., J.D., Clearside's Chief Executive Officer. "Last quarter, we announced our plans to out-license rights to XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) rather than commercialize it on our own, to create external collaborations with other companies enabling access to our platform, and to build an internal pipeline in areas such as gene therapy and small molecules."

"We have now signed deals with Bausch Health, REGENXBIO and Aura Biosciences that will benefit Clearside in a number of ways: 1) we have eliminated the inherent risks and investment related to building and maintaining a commercial infrastructure for XIPERE ourselves; 2) we are entitled to receive $7 million of non-dilutive capital in upfront payments and are eligible to receive over $200 million in potential future development and sales milestones and royalty payments; and 3) we have expanded the use of our platform to other indications including choroidal melanoma, wet age-related macular degeneration (AMD), and diabetic retinopathy. We look forward to completing the next steps on XIPERE and continuing to expand our pipeline through partner collaborations and planned internal research and development efforts," concluded Dr. Lasezkay.

Thomas A. Ciulla, M.D., MBA, Chief Medical Officer of Clearside, commented, "With a renewed focus on research and development, our team has spent the last several months performing additional analysis on our proprietary suspension of axitinib (CLS-AX) for suprachoroidal injection and we are now planning to advance this as our next internal development program. Axitinib directly inhibits receptor tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors-1, -2, and -3 with high potency and specificity, and pan-VEGF inhibition may benefit patients who sub-optimally respond to current anti-VEGF therapy. Further, our preclinical testing of CLS-AX using our proprietary microinjector demonstrated reduced growth of experimental neovascularization with decreased fluorescein leakage, and delivered the compound directly to affected tissues with durable drug levels, suggesting the potential to maintain visual gains and reduce clinical treatment burden in patients with angiogenic retinal diseases. Based on our current and planned non-clinical research, we are targeting submission of an Investigational New Drug (IND) application for CLS-AX in mid-2020."

Clearside is working to address the issues raised by the U.S. Food and Drug Administration (FDA) in the complete response letter received last month regarding XIPERE. The Company currently expects to resubmit its New Drug Application (NDA) in the first quarter of 2020 and believes the FDA will review the NDA within six months of receipt of the resubmission.

Key Highlights

- Bausch Health acquired an exclusive license for the commercialization and development of XIPERE in the United States and Canada.
- REGENXBIO Inc. exercised its option to license Clearside's proprietary, in-office SCS Microinjector for the delivery of adeno-associated virus (AAV)-based therapeutics to the suprachoroidal space to potentially treat wet AMD, diabetic retinopathy, and other conditions for which chronic anti-VEGF treatment is currently the standard of care.
- Aura Biosciences entered a worldwide licensing agreement for the use of Clearside's SCS Microinjector to deliver Aura's proprietary drug candidates into the suprachoroidal space for the potential treatment of certain ocular cancers, including choroidal melanoma.
- Multiple oral presentations at the American Academy of Ophthalmology (AAO) 2019 Annual Meeting featured Clearside's suprachoroidal injection platform and potential value of XIPERE in uveitis patients.
- Presentations were made related to Clearside on gene therapy delivery, additional analysis of XIPERE clinical programs, and the unmet need in diabetic macular edema at global conferences including The Retina Society 52nd Scientific Program in London, UK, the Ophthalmology Futures Forum in Paris, France and the European Society of Retina Specialists EURETINA 2019 Congress in Paris, France.

Third Quarter 2019 Financial Results

Clearside's research and development expenses for the quarter ended September 30, 2019 were $2.7 million, compared to $20.1 million for the quarter ended September 30, 2018. The $17.4 million decrease was primarily attributable to closing down two late-stage clinical trials in early 2019. General and administrative expenses were $3.8 million for the quarter ended September 30, 2019, compared to $3.9 million for the quarter ended

September 30, 2018.

Net loss for the quarter ended September 30, 2019 was $6.5 million, or $0.17 per share of common stock, compared to $23.9 million for the quarter ended September 30, 2018, or $0.75 per share of common stock. The decrease in net loss was primarily related to lower clinical development costs.

Cash and cash equivalents totaled $22.6 million as of September 30, 2019.

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: 1137365. 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™ targeting the suprachoroidal space (SCS) 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, as well as future therapeutic innovations such as gene therapy. 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 timing for resubmitting the XIPERE NDA and submitting the IND for CLS-AX, plans to expand Clearside's internal pipeline and enter into other licensing arrangements, the potential benefits of CLS-AX and the SCS injection platform and the potential approval of XIPERE for the treatment of macular edema associated with uveitis. 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, and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2019, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019 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,**	
	2019	**2018**	**2019**	**2018**
Collaboration revenue	$ 141	$ —	$ 231	$ —
Operating expenses:				
Research and development	2,728	20,083	14,353	50,805
General and administrative	3,781	3,873	13,169	10,508
Total operating expenses	6,509	23,956	27,522	61,313
Loss from operations	(6,368)	(23,956)	(27,291)	(61,313)
Other (expense) income, net	(168)	84	(383)	133
Net loss	$ (6,536)	$ (23,872)	$ (27,674)	$ (61,180)
Net loss per share of common stock — basic and diluted	$ (0.17)	$ (0.75)	$ (0.75)	$ (2.02)
Weighted average shares outstanding — basic and diluted	38,414,751	32,024,223	36,747,314	30,292,909

Balance Sheet Data	**September 30, 2019**	**December 31, 2018**

Cash, cash equivalents and short-term investments	$ 22,551	$ 40,878
Restricted cash	360	360
Total assets	25,867	44,120
Long-term debt (including current portion)	10,162	9,975
Total liabilities	16,108	20,500
Total stockholders' equity	9,759	23,620

Source: Clearside Biomedical, Inc.

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