Clearside Biomedical Announces Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

March 12, 2019

- Novel Retinal Treatment Demonstrates Potential of Proprietary Therapeutic Platform -
- XIPERE ™NDA Accepted and On Track for October 19, 2019 PDUFA Date -
- Management to Host Webcast and Conference Call Today at 5:00 PM ET -

ALPHARETTA, Ga., March 12, 2019 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, today reported financial results for the fourth quarter and year ended December 31, 2018 and provided a corporate update.

“Clearside is focused on treating blinding diseases by combining our innovative technology with a proprietary drug formulation to deliver pharmacotherapy to the part of the eye that requires treatment,” said Daniel H. White, President and Chief Executive Officer. “The recent acceptance of our New Drug Application (NDA) for XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection for the treatment of macular edema associated with uveitis marks a significant milestone for Clearside and our unique, therapeutic platform. We believe this targeted drug delivery approach has broad applicability utilizing proven compounds, like triamcinolone, novel small molecules, and gene therapy.”

“As we look forward, our plan is to expand our expertise in macular edema associated with uveitis to broader indications, prudently build our ophthalmic pipeline, and work with potential partners to leverage our platform and provide international reach. We are looking forward to our October 19, 2019 PDUFA (Prescription Drug User Fee Act) goal date to receive a response from the U.S. Food and Drug Administration (FDA). Our team is working diligently on launch preparations to make XIPERE available to uveitis patients with macular edema, the most common cause of uveitis-related blindness and where there is no approved therapy. Given the timing of our October 19th PDUFA date, if approved, we expect to formally launch XIPERE in the first quarter of 2020,” Mr. White concluded.

Charlie Deignan, Chief Financial Officer, commented, “We are prudently allocating funds to our near-term priorities and have reduced research & development (R&D) expenses by closing down the two large Phase 3 studies in retinal vein occlusion (RVO). Based on our current plans for commercializing XIPERE, R&D activities, and anticipated available funding facilities, we believe we will have sufficient resources to fund our planned operations into the first quarter of 2020, including the potential launch of XIPERE for the treatment of macular edema associated with uveitis.”

Key Highlights and Upcoming Milestones

- Clearside’s NDA for XIPERE for the treatment of macular edema associated with uveitis was accepted for review by the FDA and assigned a PDUFA goal date of October 19, 2019.
- Clearside’s suprachoroidal injection platform was featured at the 42nd Annual Meeting of The Macula Society in multiple oral presentations, including release of new, nonclinical data on suprachoroidal administration of gene-based therapies.
- Data was presented at the American Uveitis Society’s Winter Symposium based on Clearside’s Phase 3 extension study (MAGNOLIA) demonstrating that XIPERE maintained efficacy outcomes through 48-weeks in uveitic macular edema patients.
- Clearside discontinued development of combination therapy in retinal vein occlusion based on results of its Phase 3 study (SAPPHIRE).
- Additional data from Clearside’s pivotal Phase 3 study of XIPERE (PEACHTREE) were presented at the American Academy of Ophthalmology 2018 Annual Meeting, highlighting efficacy data resolving non-infectious uveitic inflammation and clinically significant vitreous haze in patients with non-infectious uveitic macular edema.

Fourth Quarter 2018 Financial Results

Clearside’s research and development expenses for the fourth quarter of 2018 were $17.5 million, compared to $13.9 million for the fourth quarter of 2017. The $3.6 million increase was primarily attributable to increased costs related to Clearside’s clinical development programs, including costs related to closing down the two Phase 3 clinical trials in RVO.

General and administrative expenses for the fourth quarter of 2018 were $4.2 million, compared to $2.4 million for the fourth quarter of 2017. The $1.8 million increase was primarily attributable to increased employee-related costs and marketing expenses related to the potential commercialization of XIPERE.

Net loss for the fourth quarter of 2018 was $21.6 million, or $0.68 per share of common stock, compared to $16.5 million, or $0.65 per share of common stock, for the fourth quarter of 2017. The increase in net loss was primarily attributable to higher research and development expenses in 2018.

Full Year 2018 Financial Results

Clearside’s research and development expenses for the year ended December 31, 2018 were $68.3 million, compared to $49.1 million for the year ended December 31, 2017. The $19.2 million increase was primarily attributable to increased costs related to Clearside’s clinical development

programs.

General and administrative expenses were $14.7 million for the year ended December 31, 2018, compared to $9.7 million for the year ended December 31, 2017. The $5.0 million increase was primarily attributable to increased employee-related costs and marketing expenses related to the potential commercialization of XIPERE.

Net loss for the year ended December 31, 2018 was $82.8 million, or $2.69 per share of common stock, compared to $59.0 million for the year ended December 31, 2017, or $2.33 per share of common stock. The increase in net loss was primarily attributable to higher research and development expenses in 2018.

Cash, cash equivalents and short-term investments totaled $40.9 million as of December 31, 2018. Since then, Clearside has augmented its year-end 2018 cash balance with $5.6 million of net proceeds from sales of common stock under its at-the-market facility.

Conference Call & Webcast Details

Clearside's management will host a webcast and conference call today at 5:00 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: 1855758. An archive of the webcast will be available for three months.

About Suprachoroidal Injection Platform

Clearside's proprietary suprachoroidal injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform is inherently flexible and intended to work with established medications, new formulations of medicines, as well as future innovations such as gene therapy.

About XIPERE

XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection, formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via suprachoroidal injection for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The Company's unique platform for eye disease treatments is inherently flexible and intended to work with established medications, new formulations of medicines, as well as future innovations such as gene therapy. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://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 expectations regarding the clinical development of Clearside's product candidates, the potential attributes and benefits of Clearside's product candidates, and the potential approval and commercialization of XIPERE in the United States. 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, 2017, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2018, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 2018, 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,**	**Year Ended December 31,**

	2018	2017	2018	2017
License and collaboration revenue	$ 30	$ 55	$ 30	$ 345
Operating expenses:				
Research and development	17,486	13,935	68,291	49,053
General and administrative	4,176	2,441	14,684	9,700
Total operating expenses	21,662	16,376	82,975	58,753
Loss from operations	(21,632)	(16,321)	(82,945)	(58,408)
Other (expense) income, net	(6)	(172)	127	(567)
Net loss	$ (21,638)	$ (16,493)	$ (82,818)	$ (58,975)
Net loss per share of common stock — basic and diluted	$ (0.68)	$ (0.65)	$ (2.69)	$ (2.33)
Weighted average shares outstanding — basic and diluted	32,041,305	25,346,345	30,733,600	25,311,614

Balance Sheet Data	**December 31, 2018**	**December 31, 2017**
Cash, cash equivalents and short-term investments	$ 40,878	$ 37,640
Restricted cash	360	360
Total assets	44,120	40,493
Long-term debt (including current portion)	9,975	8,009
Total liabilities	20,500	19,078
Total stockholders’ equity	23,620	21,415

Source: Clearside Biomedical, Inc.

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