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

May 8, 2019

- Scientific Presentations Support Broad Applicability of Clearside Delivery Platform -
- XIPERE ™under review for October 19, 2019 PDUFA Date -
- Management to Host Webcast and Conference Call Today at 8:30 A.M. ET -

ALPHARETTA, Ga., May 08, 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 first quarter of 2019 and provided a corporate update.

“Clearside has a compelling opportunity to leverage our innovative, non-surgical suprachoroidal space (SCS) delivery platform to make a difference for patients with sight-threatening diseases in the U.S. and around the world,” said George Lasezkay, Pharm.D., J.D., Clearside’s Interim Chief Executive Officer. “We believe our proprietary approach and strong intellectual property in the suprachoroidal space are broadly applicable across a range of serious ophthalmic diseases.”

Dr. Lasezkay continued, “We are validating our platform with the potential approval of our first product candidate, XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection for the treatment of macular edema associated with uveitis, a condition that currently has no approved therapies. Uveitis is a leading cause of vision impairment and blindness in the developed world, and treating the associated macular edema is particularly important as it is an underserved patient population often affecting younger people and can result in numerous years of lost visual function.”

“We have a highly experienced team that developed XIPERE, submitted our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), and is now focused on achieving the successful approval and launch of our first commercial product. We are also committed to maximizing our SCS injection platform to expand our product pipeline and create future value through select strategic partnerships. As indicated in recent medical meeting presentations, the potential of our SCS injection platform includes small molecule therapeutics and may extend to gene-based therapies for inherited retinal diseases,” concluded Dr. Lasezkay.

Key Highlights

- 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 (Prescription Drug User Fee Act) goal date of October 19, 2019.
- Biopharmaceutical executive and current Clearside Board member, George Lasezkay, Pharm.D., J.D., was appointed to the position of Interim Chief Executive Officer.
- Use of Clearside’s SCS injection platform in uveitis patients and with gene therapy was highlighted at the Association for Research in Vision and Ophthalmology (ARVO) 2019 Conference.
- Clearside’s SCS injection platform was featured at the 42nd Annual Meeting of The Macula Society in multiple oral presentations, including release of new, non-clinical data on suprachoroidal administration of gene-based therapies.

First Quarter 2019 Financial Results

Clearside’s research and development expenses for the quarter ended March 31, 2019 were $11.0 million, compared to $13.4 million for the quarter ended March 31, 2018. The $2.4 million decrease was primarily related to lower clinical development costs for XIPERE.

General and administrative expenses were $4.4 million for the quarter ended March 31, 2019, compared to $3.1 million for the quarter ended March 31, 2018. The $1.3 million increase was mostly attributable to increased employee-related costs and expenses related to the potential commercialization of XIPERE.

Net loss for the quarter ended March 31, 2019 was $15.4 million, or $0.45 per share of common stock, compared to $16.6 million for the quarter ended March 31, 2018, or $0.62 per share of common stock. The decrease in net loss was primarily related to lower clinical development costs.

Cash, cash equivalents and short-term investments totaled $34.9 million as of March 31, 2019, which includes $6.6 million in net proceeds from sales of common stock under the company’s at-the-market facility during the quarter.

Conference Call & Webcast Details

Clearside’s management will host a webcast and conference call today at 8:30 a.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: 7816049. An archive of the webcast will be available for three months.

About Clearside’s SCS Injection Platform

Clearside’s proprietary suprachoroidal space (SCS) 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 non-surgically 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 to minimize side effects and harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile. An NDA was submitted to the FDA in December 2018 for XIPERE, and, if approved, XIPERE will be the first therapy indicated for macular edema associated with uveitis.

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 SCS platform for eye disease treatments is an inherently flexible and non-surgical procedure, intended to work with established medications, new formulations of medicines, as well as future therapeutic 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 potential benefits of the SCS injection platform and the potential approval and commercialization 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, 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)

Statement of Operations Data	**Three Months Ended March 31,**	
	2019	**2018**
Collaboration revenue	$ 45	$ —
Operating expenses:		
Research and development	10,967	13,379
General and administrative	4,384	3,074
Total operating expenses	15,351	16,453
Loss from operations	(15,306)	(16,453)
Other expense, net	(98)	(154)
Net loss	$ (15,404)	$ (16,607)
Net loss per share of common stock — basic and diluted	$ (0.45)	$ (0.62)
Weighted average shares outstanding — basic and diluted	34,144,209	26,818,137

Balance Sheet Data	**March 31,**	**December 31,**

	2019	2018
Cash, cash equivalents and short-term investments	$ 34,938	$ 40,878
Restricted cash	360	360
Total assets	37,534	44,120
Long-term debt (including current portion)	10,036	9,975
Total liabilities	21,443	20,500
Total stockholders' equity	16,091	23,620

Source: Clearside Biomedical, Inc.

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