Clearside Biomedical Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

March 11, 2020

- IND Submission for CLS-AX (axitinib injectable suspension) On Track for Mid-2020 -
- Greater China Licensing Partnership and Updated NDA Resubmission Timeline for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) -
- Partners Expected to Initiate Clinical Testing in 2020 for Treatment of Wet AMD, Diabetic Retinopathy and Ocular Cancer Using SCS Microinjector ™ -
- Management to Host Webcast and Conference Call Today at 4:30 P.M. ET -

ALPHARETTA, Ga., March 11, 2020 (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, 2019 and provided a corporate update.

"The momentum for Clearside is building as we increase awareness of our suprachoroidal space injection platform, develop our internal pipeline and work with our partners to advance multiple clinical programs," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "We have been encouraged by the medical community's interest in our preclinical data on CLS-AX (axitinib injectable suspension), which we believe could support the potential for long-acting pan-VEGF inhibition in wet age-related macular degeneration. We expect to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for CLS-AX in mid-2020, which would potentially enable us to initiate a Phase 1/2a clinical trial before the end of this year. Our pipeline is also growing as our partners in gene therapy and ocular cancer are moving to initiate clinical testing of their compounds using our proprietary SCS Microinjector™. Based on our partners' plans, we expect several IND submissions and the initiation of multiple clinical trials in 2020."

Dr. Lasezkay continued, "As we continue to progress our XIPERE program and partnerships, we are working together with Bausch + Lomb and our commercial manufacturer to ensure the most thorough and highest quality New Drug Application (NDA) resubmission. We currently expect to resubmit our NDA for XIPERE by the end of August 2020 and believe the FDA will review the NDA within six months of receipt of the resubmission. We also signed a new development and commercialization partnership with Arctic Vision that expands the global reach of XIPERE to Greater China and South Korea. This collaboration adds $4.0 million in an upfront payment to our balance sheet with the possibility of additional revenue through future milestone payments up to $31.5 million and royalties on product sales."

Key Highlights and Upcoming Milestones

- License agreement with upfront and milestone payments and royalties on product sales from Arctic Vision for the commercialization and development of XIPERE in Greater China and South Korea.
- George Lasezkay, Pharm.D., J.D. was appointed President and Chief Executive Officer, transitioning from the Interim CEO position.
- Adeno-associated virus (AAV) gene therapy partner, REGENXBIO, plans to initiate its Phase 2 clinical trial for suprachoroidal delivery of RGX-314 using the SCS Microinjector for treatment of wet age-related macular degeneration (wet AMD) in the first half of 2020, with interim data from the first cohort expected by the end of 2020.
- REGENXBIO expects to submit an IND application for a Phase 2 trial for treatment of diabetic retinopathy in the first half of 2020 using the SCS Microinjector to deliver RGX-314 to the suprachoroidal space. The trial is expected to begin in the second half of 2020 and enrollment of the first cohort is expected to be complete by the end of 2020, with interim data expected in 2021.
- Ocular oncology partner, Aura Biosciences, expects to initiate clinical testing during the second half of 2020 using suprachoroidal delivery for AU-011 for the potential treatment of certain ocular cancers, including choroidal melanoma.
- Preclinical data on Clearside's lead development asset, CLS-AX was presented at the 43rd Annual Meeting of The Macula Society.
- Multiple oral 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 Annual Meeting of The Macula Society, the Annual Angiogenesis Meeting, the Annual American Uveitis Society Winter Symposium and the American Academy of Ophthalmology Annual Meeting.
- *Ophthalmology*, the peer-reviewed journal of the American Academy of Ophthalmology, published results from the Phase 3 clinical trial of XIPERE (the PEACHTREE trial).

Fourth Quarter 2019 Financial Results

Clearside's license revenue for the fourth quarter of 2019 was $1.9 million, compared to $30,000 for the fourth quarter of 2018. The $1.9 million increase was associated with payments from partner licensing agreements.

Research and development expenses for the fourth quarter of 2019 were $1.3 million, compared to $17.5 million for the fourth quarter of 2018. The $16.2 million decrease was primarily attributable to reduced expenses from two closed late-stage clinical trials and subsequent vendor credits of $2.0 million upon reconciliation of final trial costs.

General and administrative expenses for the fourth quarter of 2019 were $3.7 million, compared to $4.2 million for the fourth quarter of 2018. The $0.5 million decrease was primarily attributable to lower marketing and employee-related expenses due to Clearside's out-licensing of the commercialization of XIPERE.

Net loss for the fourth quarter of 2019 was $3.1 million, or $0.07 per share of common stock, compared to a net loss of $21.6 million, or $0.68 per share of common stock, for the fourth quarter of 2018. The decrease in net loss was primarily attributable to lower research and development expenses in 2019.

Full Year 2019 Financial Results

Clearside's license and collaboration revenue for the year ended December 31, 2019 was $2.2 million, compared to $30,000 for the year ended December 31, 2018. The $2.1 million increase was associated with payments from partner licensing agreements.

Research and development expenses for the year ended December 31, 2019 were $15.7 million, compared to $68.3 million for the year ended December 31, 2018. The $52.6 million decrease was primarily attributable to reduced expenses from two closed late-stage clinical trials.

General and administrative expenses were $16.8 million for the year ended December 31, 2019, compared to $14.7 million for the year ended December 31, 2018. The $2.1 million increase was primarily attributable to increased employee-related costs, including accrued expenses related to the resignation of Clearside's former CEO.

Net loss for the year ended December 31, 2019 was $30.8 million, or $0.81 per share of common stock, compared to a net loss of $82.8 million, or $2.69 per share of common stock, for the year ended December 31, 2018. The decrease in net loss was primarily attributable to lower research and development expenses in 2019.

Cash and cash equivalents totaled $22.6 million as of December 31, 2019, which included partner licensing revenue and private placement funding received in the fourth quarter of 2019. The Company expects to have sufficient resources to fund planned operations into the first quarter of 2021.

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: 2462408. 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 opportunities for expanding Clearside's internal pipeline, the potential benefits of XIPERE and the SCS injection platform, the potential receipt of milestone payments, the timing for resubmitting the XIPERE NDA and the anticipated outcome of interactions with the FDA and the development and potential benefits of CLS-AX, including the timing for the IND submission for CLS-AX. 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 September 30, 2019, filed with the SEC on November 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 December 31,**		**Year Ended December 31,**	
	2019	**2018**	**2019**	**2018**
License revenue	$ 1,942	$ 30	$ 2,173	$ 30
Operating expenses:				
Research and development	1,305	17,486	15,658	68,291
General and administrative	3,650	4,176	16,819	14,684
Total operating expenses	4,955	21,662	32,477	82,975
Loss from operations	(3,013)	(21,632)	(30,304)	(82,945)
Other (expense) income, net	(83)	(6)	(466)	127
Net loss	$ (3,096)	$ (21,638)	$ (30,770)	$ (82,818)
Net loss per share of common stock — basic and diluted	$ (0.07)	$ (0.68)	$ (0.81)	$ (2.69)
Weighted average shares outstanding — basic and diluted	42,394,959	32,041,305	38,170,830	30,733,600

Balance Sheet Data	**December 31, 2019**	**December 31, 2018**
Cash, cash equivalents and short-term investments	$ 22,595	$ 40,878
Restricted cash	360	360
Total assets	26,776	44,120
Deferred revenue	5,000	–
Long-term debt (including current portion)	5,152	9,975
Total liabilities	15,619	20,500
Total stockholders' equity	11,157	23,620

Source: Clearside Biomedical, Inc.

CLEARSIDE™ BIOMEDICAL

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