Clearside Biomedical Announces Third Quarter 2020 Financial Results and Provides Corporate Update

November 10, 2020

- Initiation of Phase 1/2a Trial of CLS-AX (axitinib injectable suspension) for Wet Age-Related Macular Degeneration Expected by Year-End 2020 -
- Phase 2 Trials Using SCS Microinjector® Ongoing by Gene Therapy and Oncology Partners -
- Management to Host Webcast and Conference Call Today at 4:30 P.M. ET -

ALPHARETTA, Ga., Nov. 10, 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 third quarter ended September 30, 2020 and provided a corporate update on key initiatives.

"Over the last 15 months, we have been focused on implementing our strategy of building an internal research and development pipeline and establishing targeted external clinical development and commercial collaborations in the suprachoroidal space," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "We are making excellent progress on our internal and external programs and expect to have three novel therapeutic assets delivered via our SCS Microinjector® in four clinical trials by the end of this year. We expect this momentum to continue into 2021 with key catalyst events including the potential U.S. Food and Drug Administration approval of XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) and initial data from our Phase 1/2a CLS-AX clinical trial in wet age-related macular degeneration (wet AMD). We also plan to advance our preclinical programs and look forward to initial clinical data readouts from our collaboration partners."

Recent Key Highlights

- Clearside's adeno-associated virus (AAV)-based gene therapy partner, REGENXBIO, dosed the first patient in its Phase 2 clinical trial, entitled AAVIATE, to evaluate the suprachoroidal delivery of RGX-314, an AAV gene therapy, using Clearside's SCS Microinjector for the treatment of wet AMD. REGENXBIO expects to complete enrollment of the first cohort by the end of 2020, and report initial safety data from the first cohort in early 2021.
- REGENXBIO recently announced that its Phase 2 trial, ALTITUDE, to evaluate the targeted, in-office suprachoroidal delivery of RGX-314 in patients with diabetic retinopathy (DR), is active. REGENXBIO expects to begin enrolling patients by the end of 2020 and plans to report interim data from this trial in 2021.
- Clearside's ophthalmic oncology partner, Aura Biosciences, dosed the first patient in its Phase 2 clinical trial evaluating the safety and efficacy of suprachoroidal administration of AU-011 as a potential first-line treatment for patients with primary choroidal melanoma. Aura is using Clearside's SCS Microinjector to deliver AU-011 into the suprachoroidal space (SCS ®).
- Three new Clearside patents were issued in the United States and Europe, including a U.S. patent that covers Clearside's SCS Microinjector for the suprachoroidal administration of axitinib (CLS-AX), and two European patents related to suprachoroidal administration of any therapeutic agent and suprachoroidal administration of triamcinolone.
- Multiple posters and oral presentations on Clearside's pipeline targeting the suprachoroidal space and its proprietary SCS Microinjector were delivered at the virtual 53rd Annual Scientific Meeting of The Retina Society.
- Data from the Clearside's Phase 2 clinical trial in diabetic macular edema (DME) was published in *Ophthalmology Retina*. The trial, entitled TYBEE, evaluated the investigational suprachoroidally injected drug XIPERE when used with intravitreally administered aflibercept in patients with DME over a 6-month evaluation period. This early data suggest a potential role for XIPERE in reducing treatment burden for DME patients.
- Data was published on the clinical characterization of the suprachoroidal injection procedure across three retinal disorders in *Translational Vision Science and Technology*, a journal of the Association for Research in Vision and Ophthalmology. The data suggest that suprachoroidal injection could be readily adopted in clinical practice for targeted, compartmentalized delivery of ocular therapeutics.

Upcoming Events and Projected Milestones

- Initiation of a Phase 1/2a clinical trial by the end of 2020 to assess safety and tolerability of CLS-AX administered via suprachoroidal injection in wet AMD with initial safety data from the first cohort expected in mid-2021.
- AAV gene therapy partner, REGENXBIO, expects to report initial safety data from the first suprachoroidal cohort of its AAVIATE trial in wet AMD in early 2021 and interim data from its ALTITUDE trial in DR in 2021.
- Data presentations on Clearside's programs will be made at the American Academy of Ophthalmology 2020 Annual Meeting which will be held virtually from Friday, November 13, 2020 through Sunday, November 15, 2020.
- Clearside's management team will present at two virtual investor events: Stifel 2020 Virtual Healthcare Conference on Tuesday, November 17, 2020, and the JMP Securities Wet AMD Call on Friday, November 20, 2020.
- XIPERE New Drug Application (NDA) resubmission is targeted for no later than the first half of 2021.

Third Quarter 2020 Financial Results

Clearside's license revenue for the third quarter of 2020 was $3.4 million, compared to $141,000 for the third quarter of 2019. The $3.3 million increase was primarily attributable to the receipt of a partner milestone payment upon the initiation of a Phase 2 clinical trial using Clearside's SCS Microinjector.

Research and development expenses for the third quarter of 2020 were $3.5 million, compared to $2.7 million for the third quarter of 2019. The $0.8 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 for XIPERE.

General and administrative expenses for the third quarter of 2020 were $2.4 million, compared to $3.8 million for the third quarter of 2019. The $1.4 million decrease was primarily attributable to reduced marketing-related expenses resulting from the out-licensing of XIPERE commercialization.

Net loss for the third quarter of 2020 was $2.4 million, or $0.05 per share of common stock, compared to a net loss of $6.5 million, or $0.17 per share of common stock, for the third quarter of 2019.

As of September 30, 2020, Clearside's cash and cash equivalents totaled $14.8 million. Based on Clearside's current research and development plans and expected near-term partnership milestone payments, Clearside believes it will have sufficient resources to fund its planned operations into the third 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: 3169417.

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, 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 timelines for resubmitting the NDA for and the potential approval of XIPERE, the timing of initiation of future clinical trials, the timing of receipt of data from clinical trials, future management and data presentations and Clearside's ability to fund its operations into the third quarter of 2021, including the receipt of potential milestone payments. 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
License and other revenue	$ 3,432	$ 141	$ 7,883	$ 231
Operating expenses:				
Research and development	3,490	2,728	10,601	14,353
General and administrative	2,374	3,781	8,107	13,169
Total operating expenses	5,864	6,509	18,708	27,522

Loss from operations	(2,432)	(6,368)	(10,825)	(27,291)
Other expense	(1)	(168)	(273)	(383)
Net loss	$ (2,433)	$ (6,536)	$ (11,098)	$ (27,674)
Net loss per share of common stock — basic and diluted	$ (0.05)	$ (0.17)	$ (0.24)	$ (0.75)
Weighted average shares outstanding — basic and diluted	46,976,649	38,414,751	45,653,068	36,747,314

Balance Sheet Data	**September 30, 2020**	**December 31, 2019**
Cash and cash equivalents	$ 14,839	$ 22,595
Restricted cash	360	360
Total assets	17,405	26,776
Deferred revenue	5,000	5,000
Long-term debt (including current portion)	991	5,152
Total liabilities	9,281	15,619
Total stockholders' equity	8,124	11,157

Source: Clearside Biomedical, Inc.