Clearside Biomedical Announces First Quarter 2021 Financial Results and Provides Corporate Update

May 17, 2021

- Recent New Drug Application Resubmission for XIPERE™

(triamcinolone acetonide suprachoroidal injectable suspension) -

- Cohort 1 Data in OASIS Wet AMD Phase 1/2a Trial Expected in June 2021 -

- Multiple ARVO Presentations Highlight Suprachoroidal Delivery with SCS Microinjector® -

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

ALPHARETTA, Ga., May 17, 2021 (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 first quarter ended March 31, 2021.

"We have made meaningful, value-creating progress over the past several months," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "In late April, we resubmitted our New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for XIPERE ™ for the treatment of macular edema associated with uveitis. This milestone is important as XIPERE would be Clearside's first commercial product if approved by the FDA, and it would also be the first approved drug to be delivered into the suprachoroidal space (SCS®). Our innovative platform represents a potential breakthrough for delivering drugs to the back of the eye using a reliable, non-surgical, office-based method."

"We have also efficiently advanced our lead development asset, CLS-AX, our proprietary small molecule suspension of axitinib delivered via our SCS Microinjector® for the treatment of patients with neovascular age-related macular degeneration, commonly known as wet AMD. We completed enrollment and dosing in Cohort 1 of our OASIS Phase 1/2a clinical trial and expect to announce data from this cohort in June 2021. We believe CLS-AX is attractively differentiated, combining the potential benefits of pan-VEGF inhibition with the compartmentalized safety of suprachoroidal administration," concluded Dr. Lasezkay.

Key Highlights and Anticipated Milestones

- NDA resubmission to the FDA for XIPERE (triamcinolone acetonide suprachoroidal injectable suspension) for the treatment of macular edema associated with uveitis.
- Completion of patient dosing in Cohort 1 of OASIS, Clearside's U.S. based, open-label, dose-escalation Phase 1/2a trial in wet AMD patients, to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector ®, with Cohort 1 data expected in June 2021.
- Completion of registered direct offering of 4.2 million shares in January 2021, resulting in total gross proceeds of approximately $12.0 million.
- Multiple 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 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, the 44th Annual Meeting of The Macula Society and the Angiogenesis, Exudation, and Degeneration 2021 Meeting.
- Two manuscripts were published in the *British Journal of Ophthalmology* including "Suprachoroidal CLS-TA for Non-infectious Uveitis: an Open-label, Safety Trial (AZALEA)" in February 2021 and "Extension Study of the Safety and Efficacy of CLS-TA for Treatment of Macular Oedema Associated with Non-infectious Uveitis (MAGNOLIA)" in March 2021.
- Data was published in *Expert Opinion on Drug Delivery* titled "Biomechanics of Suprachoroidal Drug Delivery: From Benchtop to Clinical Investigation in Ocular Therapies" in January 2021.

First Quarter 2021 Financial Results

Clearside's license and other revenue for the first quarter of 2021 was $34,000, compared to $4.1 million for the first quarter of 2020. This decrease was primarily attributable to lower revenue from partner licensing agreements in the first quarter of 2021.

Research and development expenses for the first quarter of 2021 were $5.5 million, compared to $3.8 million for the first quarter of 2020. This increase was primarily attributable to increased costs for the CLS-AX program, including costs for OASIS, a Phase 1/2a clinical trial of CLS-AX, and costs related to drug manufacturing for XIPERE.

General and administrative expenses for the first quarter of 2021 were $2.9 million, compared to $3.1 million for the first quarter of 2020. This decrease was primarily attributable to a reduction in professional fees.

Other income for the first quarter of 2021 was comprised of the gain on the extinguishment of debt from the forgiveness of the Paycheck Protection Program loan and accrued interest.

Net loss for the first quarter of 2021 was $7.4 million, or $0.13 per share of common stock, compared to a net loss of $2.9 million, or $0.07 per share of common stock, for the first quarter of 2020. This increase in net loss was primarily attributable to higher research and development expenses and lower license revenues in the first quarter of 2021.

As of March 31, 2021, Clearside's cash and cash equivalents totaled $26.1 million. The Company believes it will have sufficient resources to fund its planned operations into the first quarter of 2022, not including receipt of potential partner milestone payments.

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: 1488886. 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 ® 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. 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 clinical development, including the timing of safety data from the OASIS clinical trial, and the potential benefits, of CLS-AX and therapies using Clearside's SCS Microinjector ®, the resubmitted NDA for XIPERE and Clearside's ability to fund its operations into the first quarter of 2022. 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, 2020, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2021, 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.

-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 March 31,**	
	2021	**2020**
License and other revenue	$ 34	$ 4,097
Operating expenses:		
Research and development	5,490	3,811
General and administrative	2,893	3,122
Total operating expenses	8,383	6,933
Loss from operations	(8,349)	(2,836)
Other income	998	—
Other expense	—	(75)
Net loss	$ (7,351)	$ (2,911)
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.07)
Weighted average shares outstanding — basic and diluted	57,038,664	44,753,510

Balance Sheet Data	**March 31, 2021**	**December 31, 2020**
Cash and cash equivalents	$ 26,147	$ 17,287
Total assets	27,821	19,322

Deferred revenue	5,000	5,000
Long-term debt (including current portion)	—	991
Total liabilities	10,836	10,559
Total stockholders' equity	16,985	8,763

Source: Clearside Biomedical, Inc.

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