Clearside Biomedical Announces Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

March 10, 2022

- XIPERE® -Related Milestones Generated $20 Million in Non-Dilutive Funding in Q4 2021 -

- Continued Progress in CLS-AX OASIS Wet AMD Phase 1/2a Trial with Cohort 3 Results Expected Mid-2022 -

- New Cohort 4 Planned in Q2 2022 to Expand CLS-AX Dose Escalation in OASIS Trial-

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

ALPHARETTA, Ga., March 10, 2022 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), today reported financial results for the fourth quarter and year ended December 31, 2021 and provided a corporate update.

“Our suprachoroidal injection platform is a proven approach for ocular drug delivery that offers potential advantages over other types of administration,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “Following the approval and launch of XIPERE™, the first product approved for suprachoroidal delivery, there is a growing base of retinal specialists trained to use our proprietary SCS Microinjector®. With more than 1,200 clinical injections to date and six clinical trials underway using our technology, we have established our leadership in this space.”

Dr. Lasezkay continued, “Our lead development asset, CLS-AX, combines the targeting, compartmentalization and potential durability of suprachoroidal delivery with the pan-VEGF inhibition of a potent tyrosine kinase inhibitor. We are making progress in OASIS, our ongoing Phase 1/2a trial of CLS-AX in patients with wet AMD. In the first two cohorts of OASIS, CLS-AX was well tolerated with no serious adverse events."

“Based on this positive safety profile to date and input from our scientific and clinical advisors, we are planning to add a fourth cohort in this trial to explore a broad range of doses to take into a Phase 2b clinical trial. Prior to moving forward with a higher dose in Cohort 4, we will review preliminary one-month safety data from Cohort 3. Unless we see dose limiting toxicities, we plan to initiate Cohort 4 promptly after this safety data review. We expect this review to occur in the second quarter of this year and that Cohorts 3 and 4 will overlap. We remain on track to report results from Cohort 3 mid-year and we expect to report results from Cohort 4 later this year. We have begun planning for our Phase 2b clinical trial, and we are targeting to open recruitment for this trial by the end of this year,” concluded Dr. Lasezkay.

Key Highlights

- XIPERE™ (triamcinolone acetonide injectable suspension) for suprachoroidal use for the treatment of macular edema associated with uveitis launched by Bausch + Lomb in Q1 2022 for commercial sale in the U.S., following approval by the U.S. Food and Drug Administration in October 2021.
- Total of $20 million generated in Q4 2021 in non-dilutive funding related to development, approval and pre-launch milestones from XIPERE commercialization partners, Bausch + Lomb and Arctic Vision.
- Cohort 3 enrollment ongoing with results expected mid-2022 in OASIS, Clearside’s U.S. based, open-label, dose-escalation Phase 1/2a trial in patients with wet AMD, to assess the safety and tolerability of a 0.5 mg dose of CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside’s SCS Microinjector.
- New Cohort 4 planned in OASIS to enable exploration of a broad range of doses in preparation for Phase 2b clinical trial.
- Arctic Vision began dosing patients in China in its Phase 3 study of ARVN001 for the treatment of macular edema associated with uveitis. Arctic Vision also announced in March 2022 that they began dosing patients with diabetic macular edema in a Phase 1 trial in China.
- REGENXBIO presented positive interim data from two Phase 2 clinical trials testing RGX-314 using suprachoroidal delivery for the treatment of wet AMD and diabetic retinopathy.
- Aura Biosciences presented interim Phase 2 safety data evaluating suprachoroidal administration of AU-011 in patients with choroidal melanoma, reporting that there have been no related serious adverse events, dose limiting toxicities, or grade 3 adverse events observed during the trial and that suprachoroidal administration may improve the therapeutic index and optimize treatment parameters.
- Multiple presentations featuring the use of Clearside’s proprietary suprachoroidal space injection platform were highlighted at global conferences, including the Angiogenesis, Exudation, and Degeneration Virtual Conference, American Academy of Ophthalmology, American Uveitis Society Meeting, American Society of Retina Specialists Annual Meeting, Retina Society Annual Scientific Meeting, OIS Retina Summit and Ophthalmology Futures European 2021 Virtual Retina Forum.

Fourth Quarter 2021 Financial Results

Clearside's license and other revenue for the fourth quarter of 2021 was $25.7 million, compared to $11,000 for the fourth quarter of 2020. The $25.7 million increase was primarily attributable to milestone payments received from XIPERE licensing partners in the fourth quarter of 2021, including the recognition of $5 million in previously deferred revenue from Bausch + Lomb's original upfront payment.

Research and development expenses for the fourth quarter of 2021 were $3.8 million, compared to $4.5 million for the fourth quarter of 2020. The $0.6 million decrease was primarily attributable to reduced XIPERE-related expenses which offset CLS-AX Phase 1/2a clinical trial costs.

General and administrative expenses for the fourth quarter of 2021 were $3.1 million, compared to $2.6 million for the fourth quarter of 2020. The $0.5 million increase was primarily attributable to share-based compensation and higher salary costs.

Net income for the fourth quarter of 2021 was $18.7 million, or $0.31 per share of common stock, compared to a net loss of $7.1 million, or $0.14 per share of common stock, for the fourth quarter of 2020. The increase in net income was primarily attributable to higher license revenue in the fourth quarter of 2021.

Full Year 2021 Financial Results

Clearside's license and other revenue for the year ended December 31, 2021 was $29.6 million, compared to $7.9 million for the year ended December 31, 2020. The $21.7 million increase was primarily attributable to milestone payments received from XIPERE licensing partners in 2021.

Research and development expenses for the year ended December 31, 2021 were $18.5 million, compared to $15.1 million for the year ended December 31, 2020. The $3.5 million increase was primarily attributable to CLS-AX Phase 1/2a clinical trial costs.

General and administrative expenses for the year ended December 31, 2021 were $11.7 million, compared to $10.8 million for the year ended December 31, 2020. The $0.9 million increase was primarily attributable to share-based compensation and higher salary costs.

Net income for the year ended December 31, 2021 was $376,000, or $0.01 per share of common stock, compared to a net loss of $18.2 million, or $0.39 per share of common stock, for the year ended December 31, 2020. The increase in net income was primarily attributable to higher license revenue in 2021.

As of December 31, 2021, Clearside's cash and cash equivalents totaled $30.4 million. This year-end total does not include $10 million in cash collected in the first quarter of 2022 related to the XIPERE pre-launch milestones. The Company believes it will have sufficient resources to fund its planned operations into the second quarter of 2023.

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: 6354534. An archive of the webcast will be available for three months.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector ®, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector and strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. Clearside's first product, XIPERE ™ (triamcinolone acetonide injectable suspension) for suprachoroidal use, was approved by the U.S. Food and Drug Administration in October 2021. 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 of CLS-AX, including the expected timing of data from the OASIS clinical trial and our plans for the Phase 2b trial, the potential benefits of CLS-AX and product candidates using Clearside's SCS Microinjector ® and Clearside's ability to fund its operations into the second quarter of 2023. 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.

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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,	
	2021	2020	2021	2020
License and other revenue	$ 25,687	$ 11	$ 29,575	$ 7,894
Operating expenses:				
Research and development	3,840	4,472	18,537	15,073
General and administrative	3,140	2,649	11,665	10,756
Total operating expenses	6,980	7,121	30,202	25,829
Income (loss) from operations	18,707	(7,110)	(627)	(17,935)
Other income	2	—	1,003	—
Other expense	—	(2)	—	(275)
Net income (loss)	$ 18,709	$ (7,112)	$ 376	$ (18,210)
Net income (loss) per share of common stock — basic and diluted	$ 0.31	$ (0.14)	$ 0.01	$ (0.39)
Weighted average shares outstanding — basic	59,669,759	49,048,402	58,491,986	46,506,540
Weighted average shares outstanding — diluted	61,182,414	49,048,402	59,906,602	46,506,540

Balance Sheet Data	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 30,436	$ 17,287
Accounts receivable	10,000	—
Total assets	42,903	19,322
Deferred revenue	—	5,000
Long-term debt (including current portion)	—	991
Total liabilities	4,928	10,559
Total stockholders' equity	37,975	8,763

Source: Clearside Biomedical, Inc.