Clearside Biomedical Announces Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 12, 2024

- Phase 2b ODYSSEY Wet AMD Trial Remains on Track with Topline Data Expected in Q3 2024 -

- Partner Programs Continue to Report Positive Clinical Data Utilizing SCS Microinjector® -

- Strengthened Capital Position from Registered Direct Equity Offering and Recent SCS Microinjector License Agreement -

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

ALPHARETTA, Ga., March 12, 2024 (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, 2023, and provided a corporate update.

“This is an exciting time for Clearside with substantial progress in our tyrosine kinase inhibitor (TKI) program and expanded use of our injection device technology for drug delivery into the suprachoroidal space,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “We are laser focused on completing our ODYSSEY Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) in wet AMD and expect to report topline data in the third quarter of this year.”

Dr. Lasezkay continued, “Our proprietary SCS Microinjector® enables reliable, simple, in-office, non-surgical drug delivery into the suprachoroidal space targeted directly to the site of disease in the back of the eye. This trusted delivery method, combined with axitinib’s differentiated mechanism of action and high potency, offers the potential for CLS-AX to be a best-in-class product for long-term maintenance therapy for wet AMD patients. In ODYSSEY, we are looking to replicate the excellent safety profile, stable vision, and reduced frequency of injections over 6 months that we observed in our OASIS Phase 1/2a and Extension Study.”

“In addition, our development and commercialization partners continue to report positive safety and efficacy results utilizing our SCS Microinjector. We are very excited to begin working closely with our newest licensing partner, BioCryst Pharmaceuticals, on their program targeting diabetic macular edema (DME) exclusively using suprachoroidal delivery of their proprietary plasma kallikrein inhibitor, avoralstat. With the upfront licensing fee from BioCryst combined with our recently completed equity financing, we expect our existing cash and cash equivalents will enable us to fund our operating expenses into the third quarter of 2025,” concluded Dr. Lasezkay.

Key Highlights

- Completion of a registered direct offering in February 2024, which generated $15.0 million in gross proceeds to Clearside.
- On January 1, 2024, a new permanent Category 1 Current Procedural Terminology (CPT) code for XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use became available for physician use.
- Completion of participant randomization in December 2023 in ODYSSEY, Clearside’s Phase 2b clinical trial of CLS-AX using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD), with topline data expected in the third quarter of 2024.
- Entered into an exclusive, worldwide license with BioCryst Pharmaceuticals in November 2023 to use Clearside’s SCS Microinjector for the delivery of BioCryst’s proprietary plasma kallikrein inhibitor, avoralstat, for the treatment of DME. The terms of the agreement include an upfront license fee from BioCryst of $5.0 million and an additional $77.5 million in potential clinical, regulatory and post-approval sales-based milestone payments plus tiered mid-single digit royalties on annual global net product sales.
- Multiple data presentations on the use of Clearside’s suprachoroidal delivery platform were featured at prominent medical meetings, including American Academy of Ophthalmology (AAO), American Society of Retina Specialists, The Retina Society, Macula Society and Hawaiian Eye and Retina.
    - Presentations of data on CLS-AX in wet AMD highlighted the excellent safety profile, stable vision and reduced frequency of injections observed for up to 6-months in the OASIS® Phase 1/2a clinical trial and Extension Study.
    - Positive data was presented on the extended treatment duration of XIPERE utilizing suprachoroidal delivery. Real-world data showed excellent durability in which more than 75% of eyes did not require retreatment for 6 months after a single dose of XIPERE, supporting Clearside’s approach to extended drug release and reduced treatment burden for patients by delivering drug directly to the back of the eye via suprachoroidal administration with the SCS Microinjector.
    - REGENXBIO’s ABBV-RGX-314 gene therapy using suprachoroidal delivery continues to be well tolerated in the

Phase 2 ALTITUDE® trial for treatment of diabetic retinopathy and the Phase 2 AAVIATE® trial for treatment of wet AMD.

- Aura Biosciences presented positive clinical safety and efficacy updates of bel-sar for early-stage choroidal melanoma from its ongoing Phase 2 clinical trial with suprachoroidal administration. Additionally, in November 2023, Aura received FDA Agreement under a Special Protocol Assessment (SPA) for its CoMpass Phase 3 clinical trial of belzupacap sarotalocan (bel-sar) in early-stage choroidal melanoma. Aura dosed the first patient in the CoMpass trial in December 2023.

Fourth Quarter 2023 Financial Results

- License Revenue: License and other revenue for the fourth quarter of 2023 was $6.3 million, compared to $0.3 million for the fourth quarter of 2022. The $6.0 million increase was primarily attributable to the receipt of $5.0 million in an upfront license fee from BioCryst and $1.0 million in a milestone payment from Aura Biosciences.
- Research and Development (R&D) Expenses**:** R&D expenses for the fourth quarter of 2023 were $6.3 million, compared to $5.0 million for the fourth quarter of 2022. The increase was primarily due to ODYSSEY clinical trial costs.
- General and Administrative (G&A) Expenses**:** G&A expenses for the fourth quarter of 2023 were $2.9 million, compared to $3.2 million for the fourth quarter of 2022. The decrease was primarily due to lower insurance premiums and timing of patent-related costs.
- Other Expense**:** Non-cash interest expense for the fourth quarter of 2023 was $2.3 million, compared to $2.0 million for the fourth quarter of 2022. Non-cash interest expense was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.
- Net Loss: Net loss for the fourth quarter of 2023 was $4.8 million, or $0.08 per share of common stock, compared to net loss of $9.7 million, or $0.16 per share of common stock, for the fourth quarter of 2022. The decrease in net loss was primarily attributable to the receipt of $5.0 million in an upfront license fee from BioCryst in the fourth quarter of 2023.
- Cash Position: As of December 31, 2023, Clearside's cash and cash equivalents totaled $28.9 million. Subsequent to the quarter end, in February 2024, Clearside completed a registered direct offering of stock and warrants which generated $15.0 million in gross proceeds. The Company believes that with the inclusion of the net proceeds from this offering, it will have sufficient resources to fund its planned operations into the third quarter of 2025.

Full Year 2023 Financial Results

- License Revenue: License and other revenue for the year ended December 31, 2023 was $8.2 million, compared to $1.3 million for the year ended December 31, 2022. The $6.9 million increase was primarily attributable to the receipt of $5.0 million in an upfront license fee from BioCryst and $1.4 million in milestone payments from Aura Biosciences.
- R&D Expenses**:** R&D expenses for the year ended December 31, 2023 were $20.8 million, compared to $19.6 million for the year ended December 31, 2022. The increase was primarily due to ODYSSEY clinical trial costs, offset by decreases in other miscellaneous expenses.
- G&A Expenses**:** G&A expenses for the year ended December 31, 2023 were $11.9 million, compared to $11.8 million for the year ended December 31, 2022.
- Other Income: Other income for the year ended December 31, 2023 was $1.7 million, compared to $0.7 million for the year ended December 31, 2022. The increase was due to higher interest rates earned on cash and cash equivalents.
- Other Expense**:** Non-cash interest expense for the year ended December 31, 2023 was $9.4 million, compared to $3.3 million for the year ended December 31, 2022. Non-cash interest expense was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.
- Net Loss: Net loss for the year ended December 31, 2023 was $32.5 million, or $0.53 per share of common stock, compared to net loss of $32.9 million, or $0.55 per share of common stock, for the year ended December 31, 2022.

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 888-506-0062 (U.S.) or 973-528-0011 (international) and entering conference code: 694916. The Company suggests participants join 15 minutes in advance of the event.

About Clearside Biomedical, Inc.

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 patented 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. The Company's lead program, CLS-AX (axitinib injectable suspension), for the treatment of neovascular age-related macular degeneration (wet AMD), is in Phase 2b clinical testing. Clearside developed and gained approval for its first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, which is available in the U.S. through a commercial partner. Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. For more information, please visit

clearsidebio.com and follow us on LinkedIn and X.

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, the expected timing of topline results from the ODYSSEY clinical trial, the potential benefits of CLS-AX, Clearside's suprachoroidal delivery technology and Clearside's SCS Microinjector ® and Clearside's ability to fund its operations into the third quarter of 2025. 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, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on March 12, 2024 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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CLEARSIDE BIOMEDICAL, INC.
Selected Financial Data
(in thousands, except share and per share data)
(unaudited)

Statements of Operations Data	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
License and other revenue	$ 6,345	$ 330	$ 8,226	$ 1,327
Operating expenses:				
Cost of goods sold	—	204	355	204
Research and development	6,313	5,027	20,846	19,630
General and administrative	2,947	3,169	11,869	11,770
Total operating expenses	9,260	8,400	33,070	31,604
Loss from operations	(2,915)	(8,070)	(24,844)	(30,277)
Other income	360	449	1,719	669
Non-cash interest expense on liability related to the sales of future royalties	(2,277)	(2,042)	(9,360)	(3,339)
Net loss	$ (4,832)	$ (9,663)	$ (32,485)	$ (32,947)
Net loss per share of common stock — basic and diluted	$ (0.08)	$ (0.16)	$ (0.53)	$ (0.55)
Weighted average shares outstanding — basic and diluted	62,404,329	60,412,700	61,806,959	60,204,862

Balance Sheet Data	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 28,920	$ 48,258
Total assets	34,018	51,303
Liabilities related to the sales of future royalties, net	41,988	33,977
Total liabilities	49,930	40,696
Total stockholders' (deficit) equity	(15,912)	10,607

Source: Clearside Biomedical, Inc.