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

August 10, 2020

- IND Accepted by FDA for Suprachoroidal CLS-AX (axitinib injectable suspension) -
- Expanded Internal Suprachoroidal Pipeline with Two New Preclinical Programs -
- Engaged New Contract Manufacturer for XIPERE ™-
- Management to Host Webcast and Conference Call Today at 4:30 P.M. ET -

ALPHARETTA, Ga., Aug. 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 second quarter ended June 30, 2020 and provided a corporate update on key initiatives.

Key Highlights

- The Investigational New Drug (IND) application for suprachoroidal CLS-AX (axitinib injectable suspension) was submitted as planned and accepted by the U.S. Food and Drug Administration (FDA).
- Expanded the suprachoroidal development pipeline by initiating two new programs:
  - A non-viral vector gene therapy program ("therapeutic biofactory") designed to express and secrete anti-VEGF therapeutic protein after suprachoroidal administration of DNA nanoparticles containing the corresponding gene.
  - A preclinical development program utilizing suprachoroidal administration of an integrin inhibitor small molecule suspension.
- Engaged a new contract manufacturing partner for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) to allow for a more efficient and predictable process for New Drug Application (NDA) resubmission and review.
- Clearside's ophthalmic oncology partner, Aura Biosciences, presented preclinical research at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting regarding the ocular distribution and efficacy in a rabbit model of AU-011 utilizing Clearside's SCS Microinjector ®. According to Aura, the data showed distribution of AU-011 in the suprachoroidal space (SCS®) and complete necrosis of tumors following laser activation of choroidal melanoma. Preclinical studies have been completed, and Aura expects to initiate a Phase 2 clinical trial evaluating suprachoroidal delivery of AU-011 during the third quarter of 2020.
- Clearside's adeno-associated virus (AAV)-based gene therapy partner, REGENXBIO, announced that their Phase 2 clinical trial (AAVIATE) for RGX-314 for the treatment of wet AMD using suprachoroidal delivery is active, with enrollment expected to begin in the third quarter of 2020 and an interim data update from the first cohort expected by the end of 2020. REGENXBIO also expects to initiate a Phase 2 clinical trial for RGX-314 using suprachoroidal delivery in diabetic retinopathy in the second half of 2020.
- In April 2020, Clearside and Bausch Health Companies Inc. and its leading global eye health business, Bausch + Lomb, amended their licensing agreement for the commercialization and development of XIPERE.
- Experienced research and development executive, Nancy J. Hutson, Ph.D., was appointed to Clearside's Board of Directors.
- A Scientific Advisory Board was established with highly respected and experienced retinal physicians who will provide input on new technology, preclinical programs and clinical development.
- Multiple posters and oral presentations on Clearside's pipeline targeting the suprachoroidal space and its proprietary SCS Microinjector were delivered at the 2020 Virtual Annual Meetings of ARVO and the American Society of Retina Specialists (ASRS).

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 in neovascular age-related macular degeneration (wet AMD) with initial safety data from the first cohort expected in mid-2021.
- XIPERE NDA resubmission targeted in the first half of 2021.
- Data presentations on Clearside's programs will be made at the Retina Society 2020 Annual Meeting which will be held virtually.
- Clearside's management team will present at two virtual investor conferences: 2020 Wedbush PacGrow Healthcare Conference and the H.C. Wainwright 22nd Annual Global Investment Conference.

George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer, commented, "Over the past year, we have worked purposefully and diligently

to reorient Clearside from a single product company to one that has multiple relevant and promising opportunities targeting the suprachoroidal space. We have made important progress in our key clinical and preclinical programs and we are positioning ourselves to have a strong year in 2021 with potential approval of XIPERE and initial patient data from our CLS-AX program."

Dr. Lasezkay continued, "Our IND application for CLS-AX was accepted and we are preparing to initiate a Phase 1/2a trial in wet AMD later this year to assess the safety and tolerability of our proprietary suspension of axitinib delivered via our SCS Microinjector. We also continue to expand our internal suprachoroidal pipeline with two new preclinical programs: a 'therapeutic biofactory' program which is our second, non-viral vector, suprachoroidal gene therapy preclinical program; and a small molecule preclinical program utilizing a suprachoroidal integrin inhibitor suspension. We look forward to advancing our expanded internal development pipeline over the next year."

"We have also engaged a new, U.S.-based contract manufacturing organization (CMO) for XIPERE, which we believe will allow for a more efficient and predictable process for NDA resubmission and review. We were recently notified by our previous CMO that it is no longer willing to serve as our commercial supplier for XIPERE. While this news was unexpected, we had proactively begun evaluating alternative manufacturers given previously disclosed delays due to manufacturing and facility issues. Therefore, we were able to quickly engage a new CMO and rapidly initiate manufacturing technology transfer activities," said Dr. Lasezkay.

"This transition is a positive step forward to achieving XIPERE approval as the new CMO provides Clearside and our licensees with an experienced and reliable partner for the manufacture of registration batches and future commercial supplies of XIPERE, if approved. The new CMO has an established track record with respect to FDA inspections, has extensive experience with production of small molecule suspensions, steroids and ophthalmic products, and is prepared to move quickly to produce the necessary batches of XIPERE to support our NDA resubmission. We expect to resubmit the XIPERE NDA as quickly as possible after the transfer of the manufacturing process has been completed and the required three-month stability data is generated. Although we are still in the process of finalizing the timelines with the new CMO, our current expectation is that resubmission will occur no later than the first half of 2021," Dr. Lasezkay concluded.

Second Quarter 2020 Financial Results

Clearside's license revenue for the second quarter of 2020 was $0.4 million, compared to $45,000 for the second quarter of 2019.

Research and development expenses for the second quarter of 2020 were $3.3 million, compared to $0.7 million for the second quarter of 2019. The $2.6 million increase was attributable to vendor credits of $2.6 million received in the second quarter of 2019 upon reconciliation of final costs from the closure of two late-stage clinical trials.

General and administrative expenses for the second quarter of 2020 were $2.6 million, compared to $5.0 million for the second quarter of 2019. The $2.4 million decrease was primarily attributable to reduced employee and marketing expenses resulting from executive management changes and the out-licensing of XIPERE commercialization.

Net loss for the second quarter of 2020 was $5.8 million, or $0.13 per share of common stock, compared to a net loss of $5.7 million, or $0.15 per share of common stock, for the second quarter of 2019.

As of June 30, 2020, Clearside's cash and cash equivalents totaled $15.1 million. During the second quarter of 2020, due to various restrictions and other limiting covenants, the Company elected to make an early payoff of its outstanding $5.0 million principal balance under its bank loan, plus $0.3 million reflecting the final payment fee and accrued interest. 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 second 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: 2290836. 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, 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 XIPERE, initiation of future clinical trials, future management and data presentations, manufacturing expectations with respect to XIPERE and Clearside's ability to fund its operations into the second 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 June 30, 2020 to be filed with the SEC on August 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)

Statement of Operations Data	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
	2020	**2019**	**2020**	**2019**
License and other revenue	$ 354	$ 45	$ 4,451	$ 90
Operating expenses:				
Research and development	3,300	658	7,111	11,625
General and administrative	2,611	5,004	5,733	9,388
Total operating expenses	5,911	5,662	12,844	21,013
Loss from operations	(5,557)	(5,617)	(8,393)	(20,923)
Other expense	(197)	(117)	(272)	(215)
Net loss	$ (5,754)	$ (5,734)	$ (8,665)	$ (21,138)
Net loss per share of common stock — basic and diluted	$ (0.13)	$ (0.15)	$ (0.19)	$ (0.59)
Weighted average shares outstanding — basic and diluted	45,214,500	37,636,053	44,984,005	35,899,777

Balance Sheet Data	**June 30, 2020**	**December 31, 2019**
Cash and cash equivalents	$ 15,071	$ 22,595
Restricted cash	360	360
Total assets	17,738	26,776
Deferred revenue	5,000	5,000
Long-term debt (including current portion)	991	5,152
Total liabilities	10,451	15,619
Total stockholders' equity	7,287	11,157

Source: Clearside Biomedical, Inc.