Clearside Biomedical Announces Second Quarter 2018 Financial Results and Provides Corporate Update

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ALPHARETTA, Ga., Aug. 08, 2018 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, today reported financial results for the quarter ended June 30, 2018 and provided an update on its development programs.

“We remain on track to submit our first NDA before the end of this year and are continuing to make significant progress in advancing our late-stage pipeline,” said Daniel H. White, Chief Executive Officer and President of Clearside. “At the same time, to help us capture the large and growing market opportunities for our proprietary suprachoroidal treatment approach, both at home and abroad, we are also ramping up our commercial capabilities for the United States and laying the groundwork for our key assets in Europe and other jurisdictions. We are excited about Clearside’s planned transition from a clinical-stage to a commercial-stage company.”

Update on Key Development Programs

Suprachoroidal CLS-TA, Clearside’s first investigational treatment program, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via the suprachoroidal space, or SCS®, which is the space located between the choroid and the outer protective layer of the eye known as the sclera. Clearside’s proprietary suprachoroidal treatment approach is designed to enable rapid dispersion of a high amount of medicine to the back of the eye so that adequate medicine reaches and stays at the site of disease and has potential to act longer. This approach has potential to provide efficacy advantages and require fewer treatments and office visits while minimizing harm to the surrounding healthy parts of the eye.

Macular Edema Associated with Non-Infectious Uveitis

Clearside expects to submit a New Drug Application (“NDA”) for suprachoroidal CLS-TA to treat macular edema associated with non-infectious uveitis to the U.S. Food and Drug Administration (“FDA”) by the end of 2018. In addition, following discussions with regulatory agencies in Europe and other jurisdictions, Clearside intends to pursue marketing authorizations outside of the United States.

In July 2018, during a **late-breaking oral presentation** at the 2018 annual meeting of the American Society of Retina Specialists (“ASRS”), Steven Yeh, M.D., Louise M. Simpson Professor of Ophthalmology and Uveitis and Vitreoretinal Surgery Director, Uveitis and Vasculitis Service at the Emory Eye Center, Emory University, shared data from PEACHTREE, Clearside’s pivotal Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis.

In this first public presentation of data from the PEACHTREE trial at a medical conference, Dr. Yeh highlighted that, as previously reported, this 24-week study met its primary endpoint, with 47% of patients in the treatment arm who received suprachoroidal CLS-TA every 12 weeks gaining at least 15 letters in best corrected visual acuity (“BCVA”), as measured using the Early Treatment of Diabetic Retinopathy Study (“ETDRS”) scale, from baseline at week 24, compared to 16% of patients in the control arm who underwent a sham procedure ($p<0.001$). The mean change in BCVA from baseline was better in the treatment arm than in the sham control arm at each monthly evaluation. The mean improvement from baseline seen at the first evaluation at week 4 was maintained throughout the trial, with 9.6 letters gained at week 4 and 13.8 letters at week 24 in the treatment arm, compared to 1.3 letters at week 4 and 3.0 letters at week 24 in the sham control arm. In addition, administration of suprachoroidal CLS-TA resulted in a mean reduction from baseline of 153 microns in central subfield thickness (“CST”) of the retina at week 24 in the treatment arm, compared to an 18 micron mean reduction in the sham control arm, a result that was also statistically significant ($p<0.001$). Suprachoroidal CLS-TA was generally well tolerated, with no treatment-related serious adverse events reported in the trial.

Dr. Yeh also presented additional highlights from the PEACHTREE trial, which are summarized below:

- 52% of patients in the treatment arm could read 70 or more ETDRS letters, the minimum legal limit to qualify for a driver’s license in most states, at week 24, compared to 22% of patients in the control arm;
- Over 85% of the patients in the treatment arm did not require rescue therapy, compared to 28% of patients in the control arm; and
- With respect to safety, based on an analysis which included patients who received rescue therapy, elevated intraocular pressure ("IOP") adverse events pertaining to corticosteroid use were reported for 11.5% (11/96) of patients in the treatment arm, compared to 26.3% (10/38) of patients rescued with local corticosteroids, such as intravitreal OZURDEX® (dexamethasone intravitreal implant) and subtenon and intravitreal triamcinolone acetonide in the sham control arm, resulting in an overall rate of 15.6% (10/64) of patients in the sham control arm through 24 weeks.

“We were honored to share the PEACHTREE data with researchers and clinicians at such an important forum as ASRS,” said Mr. White. “Our confidence in the potential of suprachoroidal CLS-TA, if approved, to become a new treatment option for non-infectious uveitis continues to grow, and we are beginning to build our commercial infrastructure to support that.”

Macular Edema Associated with Retinal Vein Occlusion (“RVO”)

While suprachoroidal CLS-TA is being studied as a monotherapy in macular edema associated with non-infectious uveitis, Clearside is studying

suprachoroidal CLS-TA together with an intravitreal anti-vascular endothelial growth factor ("anti-VEGF") agent in other retinal vascular diseases, such as RVO and diabetic macular edema, which have a high vascular endothelial growth factor response to disease.

RVO is a particularly aggressive eye disease resulting from an occlusion in a vein carrying blood out of the retina. This blockage can lead to the rapid onset of complications, including sudden declines in vision.

In June 2018, Clearside announced the completion of patient enrollment in SAPPHIRE, its first Phase 3 clinical trial of suprachoroidal CLS-TA used in combination with the intravitreal anti-VEGF agent EYLEA® (aflibercept) ("intravitreal Eylea") in treatment naïve patients with RVO.

The objective of the SAPPHIRE trial is to show that suprachoroidal CLS-TA used together with an intravitreal anti-VEGF agent may result in earlier, superior visual acuity outcome as compared to monthly injections of an intravitreal anti-VEGF alone in newly diagnosed branch retinal vein occlusion ("BRVO") and central retinal vein occlusion ("CRVO") patients.

"Ideally, we would like to see better visual outcomes in the early phase of the disease like we saw in our Phase 2 Tanzanite study, where 52% of patients receiving combination treatment recovered 3 lines of vision by month 1, compared to 39% of patients receiving Eylea alone," said Mr. White. "If we achieve similar results in SAPPHIRE, we believe that this Phase 3 study has the potential to demonstrate a better opportunity to recover vision earlier and potentially preserve those vision gains over the long term. We look forward to reporting topline 8-week primary endpoint data from the Phase 3 SAPPHIRE trial in the fourth quarter of 2018."

Clearside also continues to enroll patients in SAPPHIRE's companion Phase 3 trial, TOPAZ, of suprachoroidal CLS-TA with one of two intravitreal anti-VEGF agents, LUCENTIS® (ranibizumab) or AVASTIN® (bevacizumab), in treatment naïve patients with RVO.

If the primary endpoints are met in both the SAPPHIRE and TOPAZ trials, Clearside intends to seek a class label in the United States, which would allow suprachoroidal CLS-TA to be used together with any anti-VEGF agent for the treatment of RVO. In addition, based on recent feedback from the European Medicines Agency ("EMA"), Clearside believes that data from the RVO phase 3 development program are sufficient to support a potential Marketing Authorization Application ("MAA").

Diabetic Macular Edema ("DME")

In May 2018, Clearside announced that TYBEE, its Phase 2 trial to evaluate the safety and efficacy of suprachoroidal CLS-TA used with intravitreal Eylea in 71 patients with DME over a 6-month evaluation period, met its primary endpoint.

Patients in both the combination arm receiving suprachoroidal CLS-TA together with intravitreal Eylea and the control arm receiving Eylea alone achieved a statistically significant improvement in mean BCVA at week 24 from baseline ($p<0.001$). The combination arm achieved a statistically similar outcome to Eylea alone at every visit, including at week 24, with fewer treatments.

Additionally, patients showed [statistically] significantly better resolution of CST in the combination arm at week 4 compared to the resolution in the Eylea alone arm ($p<0.01$); the greater resolution seen in the combination arm was sustained through the end of the study.

Suprachoroidal CLS-TA used together with intravitreal Eylea was generally well tolerated, with no treatment-related serious adverse events reported through the 24-week evaluation period. Elevated IOP adverse events were reported for 8.3% (3/36) of patients in the combination arm, compared to 2.9% (1/35) of patients in the control arm. Cataract adverse events were reported for 5.6% (2/36) of patients in the combination arm and 2.9% (1/35) of patients in the control arm.

"We are pleased with the topline results of the Phase 2 TYBEE trial, which signals the potential utility of suprachoroidal CLS-TA to improve on the existing standard of care in DME," stated Mr. White. "Like in our RVO program, we observed positive outcomes in vision, meaningful improvements in CST and fewer incidences of elevated IOP events than typically associated with local administration of corticosteroids. As we receive the complete data set, we will work closely with our scientific and medical advisors to evaluate the outcomes of the TYBEE trial and develop a plan forward for this program."

Pipeline and Collaborations

Clearside continues nonclinical efforts, both internally and with multiple collaborators, in other ocular diseases and technologies that may benefit from a suprachoroidal treatment approach.

Second Quarter 2018 Financial Results

Clearside's research and development expenses for the three months ended June 30, 2018 were $17.3 million, compared to $11.5 million for the second quarter of 2017, an increase of $5.9 million. This was primarily attributable to an increase in costs related to Clearside's clinical programs. Costs for Clearside's RVO program increased $5.7 million, which included purchases of Eylea for SAPPHIRE and start-up costs and purchases of Lucentis and Avastin for TOPAZ, and costs for its DME program increased $0.3 million. In addition, Clearside incurred a $0.2 million increase in regulatory costs in preparation for an NDA submission for CLS-TA for the treatment of non-infectious uveitis and a $0.3 million increase in employee-related costs due to an increase in headcount to support increased clinical trial activities. These increases were partially offset by a $0.2 million decrease in clinical costs for Clearside's uveitis program, as the PEACHTREE trial was completed during the first quarter of 2018, and a $0.4 million decrease in costs related to device and drug manufacturing.

General and administrative expenses were $3.6 million for the second quarter of 2018, compared to $2.3 million for the same period last year, an increase of $1.3 million. This increase was primarily attributable to an increase of $0.6 million in employee-related costs, an increase of $0.4 million in marketing-related expenses as Clearside prepares for potential commercialization of CLS-TA and an increase of $0.1 million in patent-related expenses.

At June 30, 2018, Clearside had cash, cash equivalents and short-term investments totaling $84.4 million, which it believes, when combined with its anticipated available borrowing capacity under its debt facility, is sufficient to fund the company's planned operations into the fourth quarter of 2019.

Net loss for the second quarter of 2018 was $20.7 million, or $0.65 per share of common stock, compared to $13.8 million, or $0.54 per share of common stock, for the second quarter of 2017. The increase in net loss and net loss per share was primarily attributable to higher research and

development expenses in the second quarter of 2018 compared to the second quarter of 2017.

Conference Call & Webcast Details

Clearside is pleased to invite all interested parties to participate in a conference call today at 8:30 a.m. Eastern Time, during which management will discuss the financial results and provide an update on Clearside's corporate developments. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID 6390517, approximately 10 minutes prior to the start time. A live, listen-only audio webcast of the conference call can accessed by visiting the "Investor Relations" section at www.clearsidebio.com. An archive of the webcast will be available until September 9, 2018.

About Clearside

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform for eye disease treatments is inherently flexible and intended to work with established medicines, new formulations of medicines, as well as future innovations. Clearside's pipeline includes advanced and preclinical product candidates in diseases where macular edema is a common complication, including uveitis, RVO and DME. Clearside's most advanced program is in non-infectious uveitis and it expects to submit an NDA to the FDA for use of suprachoroidal CLS-TA for the treatment of macular edema associated with non-infectious uveitis by the end of 2018. The company is also conducting two ongoing Phase 3 trials of suprachoroidal CLS-TA with an intravitreal anti-VEGF agent in patients with RVO. In addition, Clearside recently announced positive topline results from a Phase 2 clinical trial of suprachoroidal CLS-TA used with Eylea in patients with DME and is continuing to analyze additional data from the trial as it becomes available. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://www.clearsidebio.com. Follow @clearsidebio on Twitter and Linkedin.

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 expectations regarding the potential clinical development of Clearside's product candidates, the availability of data from Clearside's clinical trials, the timing of a potential submission of an NDA with the FDA and an MAA to the EMA, and the potential commercialization of CLS-TA, both in the United States and internationally. 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, 2017, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2018, 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.

CLEARSIDE BIOMEDICAL, INC.
Selected Financial Data
(in thousands, except share and per share data)
(unaudited)

Statements of Operations Data	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
License and collaboration revenue	$ —	$ 130	$ —	$ 135
Operating expenses:				
Research and development	17,343	11,478	30,722	19,068
General and administrative	3,561	2,290	6,635	4,961
Total operating expenses	20,904	13,768	37,357	24,029
Loss from operations	(20,904)	(13,638)	(37,357)	(23,894)
Other income (expense), net	203	(135)	49	(252)
Net loss	$ (20,701)	$ (13,773)	$ (37,308)	$ (24,146)
Net loss per share of common stock — basic and diluted	$ (0.65)	$ (0.54)	$ (1.27)	$ (0.96)
Weighted average shares outstanding — basic and diluted	31,979,158	25,309,966	29,412,904	25,280,314

Balance Sheet Data	June 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 84,430	$ 37,640
Restricted cash	360	360

Total assets	88,016	40,493
Long-term debt (including current portion)	9,848	8,009
Total liabilities	21,344	19,078
Total stockholders' equity	66,672	21,415

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