Clearside Biomedical, Inc. Announces Second Quarter 2017 Financial Results and Provides Corporate Update

August 9, 2017

ALPHARETTA, Ga., Aug. 09, 2017 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today reported financial results for the quarter and six months ended June 30, 2017 and provided an update on its development programs.

“Clearside’s pursuit of transformative, elegant, precise solutions to restore and preserve vision resulted in the achievement of a number of recent key milestones,” said Daniel H. White, Chief Executive Officer and President. “Noteworthy among those was completion of patient enrollment in our pivotal Phase 3 trial for the treatment of macular edema associated with non-infectious uveitis, Clearside’s most advanced clinical development program, and the enrollment of the first patient in our Phase 3 trial for the treatment of patients with macular edema associated with retinal vein occlusion.”

Update on Key Development Programs

CLS-TA for suprachoroidal administration (“suprachoroidal CLS-TA”), Clearside’s proprietary suspension formulation of the corticosteroid triamcinolone acetonide, is part of Clearside’s pipeline of potential treatments for unmet or underserved blinding eye diseases where the pathologies manifest in the choroid and retina. Suprachoroidal CLS-TA is being studied for potential administration both alone and together with an intravitreal anti-VEGF agent.

Macular Edema Associated with Non-Infectious Uveitis

In early August 2017, Clearside completed patient enrollment in PEACHTREE, the pivotal Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis. Patient follow-up in PEACHTREE will continue for 6 months after initial treatment. Accordingly, Clearside expects to report top-line results from the trial in the first quarter of 2018.

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

On June 8, 2017, Clearside announced that, at the 40th Annual Macula Society Meeting, Charles C. Wykoff, M.D., Ph.D. presented preliminary results from a non-interventional trial (the “Extension Study”) of patients who had participated in the completed Phase 2 clinical trial (“TANZANITE”) of suprachoroidal CLS-TA used together with intravitreally administered EYLEA® (aflibercept) (“intravitreal Eylea”) for the treatment of RVO. Based on the small number of patients in the TANZANITE trial’s combination arm that received additional retreatment, the substantial unmet need associated with frequent office visits and injections required in this patient population, and after feedback from investigators, Clearside performed a retrospective analysis of patient charts that included 3 months from the TANZANITE trial and at least a 6-month follow-on period to more thoroughly assess the duration of effect of the combination treatment and the potential to reduce the burden of therapy. In the analysis presented by Dr. Wykoff, 17 of the 23 patients in the combination arm of the TANZANITE trial, or 74%, did not receive any additional treatment over the 9-month time frame, compared to only 4 of 23 patients, or 17%, in the Eylea-only arm during that same period of time who did not need further treatment.

Clearside continues to enroll patients in SAPPHIRE, a multicenter, multi-country, randomized, masked, controlled Phase 3 clinical trial designed to assess the safety and efficacy of suprachoroidal CLS-TA used with intravitreal Eylea in subjects with RVO. The primary objective of this trial is to determine the proportion of patients in a combination treatment arm, compared to a control arm, with best corrected visual acuity improvement of at least 15 letters from baseline at eight weeks after initial treatment. Several secondary efficacy and safety outcomes will also be evaluated.

Diabetic Macular Edema (“DME”)

On April 20, 2017, Clearside announced the completion of patient enrollment in HULK, an exploratory, open-label, multicenter Phase 1/2 clinical trial designed to assess the safety and efficacy of suprachoroidal CLS-TA along with an intravitreal injection of Eylea in patients with DME naïve to treatment. The trial is also assessing the safety and efficacy of suprachoroidal CLS-TA alone in patients with DME who have previously been treated with intravitreal anti-VEGF or intravitreal corticosteroid treatment and still require further treatment. Clearside expects to report preliminary results from the HULK trial by the end of 2017.

On July 11, 2017, Clearside announced the enrollment of the first patient in TYBEE, a multicenter, randomized, masked, controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of suprachoroidal CLS-TA in patients with DME who are naïve to pharmacologic treatment. In this trial, patients will be randomized into either a combination arm to receive suprachoroidal CLS-TA together with intravitreal Eylea or a control arm to receive only intravitreal Eylea. The primary outcome measure is a comparison between the two study arms of change from baseline in best corrected visual acuity at 3 months after initial treatment. Clearside currently expects to report three-month preliminary data from the TYBEE trial in the first half of 2018.

Collaborations

Clearside continues nonclinical efforts with multiple collaborations in gene therapy, complement inhibition, and alternative mechanisms in the treatment of complex retinal diseases.

Second Quarter 2017 Financial Results

Clearside’s research and development expenses for the three months ended June 30, 2017 were $11.5 million, compared to $4.2 million for the second quarter of 2016, an increase of $7.3 million. This increase was primarily attributable to increased costs related to Clearside’s ongoing clinical development programs for CLS-TA and an increase in device manufacturing costs, partially offset by a decrease in costs from completed clinical trials and Clearside’s discontinuation of preclinical studies in its wet AMD program.

General and administrative expenses were $2.3 million for the second quarter of 2017, compared to $1.0 million for the same period last year, an increase of $1.3 million. This year-over-year increase was primarily attributable to an increase of $0.6 million in employee-related costs, a $0.2 million increase for marketing expenses and a $0.5 million increase related to the costs of operating as a public company.

Cash, cash equivalents and short-term investments totaled $66.0 million as of June 30, 2017, compared to $83.6 million as of December 31, 2016.

Net loss for the second quarter of 2017 was $13.8 million, or $0.54 per share of common stock, compared to $5.1 million, or $0.62 per share of common stock, for the second quarter of 2016. The increase in net loss is primarily attributable to higher research and development expenses, while the decrease in net loss per share of common stock is primarily due to an increase in the number of shares of common stock outstanding resulting from Clearside's financing activities in 2016.

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 the results will be discussed. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID 65348144, 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 10, 2017.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage clinical ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and nonclinical product candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the suprachoroidal space (SCS™). This offers potentially meaningful treatment benefit to patients suffering from sight threatening diseases like uveitis, RVO, DME, and wet AMD. To learn more about how Clearside is changing ophthalmology, please visit us at 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 expectations regarding the clinical development of Clearside's product candidates and the availability of data from Clearside's clinical trials. 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, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2017 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,**	
	2017	**2016**	**2017**	**2016**
License and collaboration revenue	$ 130	$ 5	$ 135	$ 510
Operating expenses:				
Research and development	11,478	4,213	19,068	8,802
General and administrative	2,290	970	4,961	2,243
Total operating expenses	13,768	5,183	24,029	11,045
Loss from operations	(13,638)	(5,178)	(23,894)	(10,535)
Other (expense) income, net	(135)	76	(252)	(16)
Net loss	$ (13,773)	$ (5,102)	$ (24,146)	$ (10,551)
Net loss per share of common stock — basic and diluted	$ (0.54)	$ (0.62)	$ (0.96)	$ (1.94)
Weighted average shares outstanding — basic and diluted	25,309,966	8,243,864	25,280,314	5,452,105

Balance Sheet Data	**June 30, 2017**	**December 31, 2016**
Cash, cash equivalents and short-term investments	$ 66,035	$ 83,631
Restricted cash	360	360
Total assets	68,415	84,813
Long-term debt (including current portion)	7,796	7,586
Total liabilities	14,089	13,154
Total stockholders' equity	54,326	71,659

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