



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

November 8, 2017

ALPHARETTA, Ga., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today reported financial results for the quarter and nine months ended September 30, 2017 and provided an update on its key development programs.

"More than 300 patients suffering from sight-threatening diseases have received suprachoroidal injections of CLS-TA in Clearside's clinical development programs designed to support our pursuit of transformative, elegant, precise solutions to restore and preserve vision," said Daniel H. White, Chief Executive Officer and President. "By leveraging exclusive access to the suprachoroidal space and proprietary technology for suprachoroidal injection of CLS-TA to access the retina and choroid, we believe that we can provide greater bioavailability to the diseased tissue and that drug may last more than 90 days in the eye. We believe clinicians may more effectively treat sight-threatening diseases like uveitis, retinal vein occlusion and diabetic macular edema, with less incidence of side effects than with traditional routes of administration. We have a number of key milestones, including preliminary data readouts, coming up over the next few months, and look forward to updating our stakeholders as we continue to advance our pipeline."

Update on Key Development Programs

CLS-TA, Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide for suprachoroidal administration ("suprachoroidal CLS-TA"), 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, its 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 preliminary results from this trial in the first quarter of 2018.

Macular Edema Associated with Retinal Vein Occlusion ("RVO")

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 in combination with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") in patients with RVO. The primary objective of this trial is to determine the proportion of patients in the combination treatment arm, compared to the intravitreal Eylea alone 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 endpoints will also be evaluated. Patient enrollment is proceeding as planned, and Clearside currently expects to report preliminary data from this trial in the first quarter of 2019.

Clearside is also making preparations to initiate TOPAZ, a second multicenter, randomized, masked, controlled Phase 3 clinical trial of suprachoroidal CLS-TA in combination with an anti-VEGF agent for the treatment of patients with RVO. While Clearside plans to announce detailed information about TOPAZ at a later date, this trial is expected to have a similar design to the SAPPHIRE trial. Clearside anticipates enrollment of the first patient in the TOPAZ Phase 3 trial in the first quarter of 2018.

Diabetic Macular Edema ("DME")

In April 2017, Clearside completed enrolling 20 patients with DME in HULK, an open-label, multi-center Phase 1/2 clinical trial. The goal of the HULK trial was to obtain safety data and to observe efficacy outcomes from administering a combination of intravitreal Eylea and suprachoroidal CLS-TA, as well as suprachoroidal CLS-TA alone, over a six-month evaluation period in the DME patient population. Initial results suggest encouraging efficacy with a trend toward durability, particularly in the combination treatment arm. Suprachoroidal CLS-TA, both alone and in combination with intravitreal Eylea, has been well tolerated to date.

Clearside expects to report preliminary results from the HULK trial on November 10th at the Retina Subspecialty Day of the American Academy of Ophthalmology 2017 Annual Meeting in New Orleans.

In October 2017, Clearside announced completion of patient enrollment in TYBEE, a multicenter, randomized, masked, controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of suprachoroidal CLS-TA used in combination with intravitreal Eylea in patients with DME who are naïve to treatment. In this trial, 71 patients were 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 of mean change from baseline in best corrected visual acuity between the two study arms. An additional analysis will include a comparison between the number of injections required between the two groups. Patient follow-up in the TYBEE trial is 6 months after initial treatment and Clearside expects to announce preliminary data in the second quarter of 2018.

Pipeline and Collaborations

Clearside continues nonclinical efforts both internally and with multiple collaborations in development areas such as gene therapy for inherited retinal

disorders, wet age-related macular degeneration (“wet AMD”), and other ocular diseases that may benefit from a suprachoroidal administration of treatment approach.

Third Quarter 2017 Financial Results

Clearside’s research and development expenses for the three months ended September 30, 2017 were \$16.1 million, compared to \$3.7 million for the third quarter of 2016, an increase of \$12.4 million. This was primarily attributable to an increase in costs related to Clearside’s clinical programs. Costs for Clearside’s uveitis program increased \$1.8 million, costs for its RVO program increased \$8.4 million, which included purchases of Eylea for SAPPHIRE and start-up costs for TOPAZ, and costs for its DME program increased \$1.9 million. In addition, Clearside incurred a \$0.6 million increase in employee-related costs due to an increase in headcount to support the increased clinical trial activities.

General and administrative expenses were \$2.3 million for the third quarter of 2017, compared to \$1.6 million for the same period last year, an increase of \$0.7 million. This year-over-year increase was primarily attributable to an increase of \$0.6 million in employee-related costs and an increase of \$0.1 million in patent-related expenses.

Cash, cash equivalents and short-term investments totaled \$52.6 million as of September 30, 2017, compared to \$83.6 million as of December 31, 2016. Clearside believes that its current financial resources are sufficient to fund operations into the fourth quarter of 2018.

Net loss for the third quarter of 2017 was \$18.3 million, or \$0.72 per share of common stock, compared to \$5.6 million, or \$0.28 per share of common stock, for the third quarter of 2016. The increase in net loss and net loss per share is primarily attributable to higher research and development expenses in the third quarter of 2017 compared to the third quarter of 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 6892799, approximately 10 minutes prior to the start time. A live, listen-only audio webcast of the conference call can be accessed by visiting the “Investor Relations” section at www.clearsidebio.com. An archive of the webcast will be available until December 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
License and collaboration revenue	\$ 155	\$ 5	\$ 290	\$ 515
Operating expenses:				
Research and development	16,050	3,682	35,118	12,484
General and administrative	2,298	1,629	7,259	3,872
Total operating expenses	18,348	5,311	42,377	16,356
Loss from operations	(18,193)	(5,306)	(42,087)	(15,841)
Other expense, net	(143)	(339)	(395)	(355)
Net loss	\$ (18,336)	\$ (5,645)	\$ (42,482)	\$ (16,196)
Net loss per share of common stock — basic and diluted	\$ (0.72)	\$ (0.28)	\$ (1.68)	\$ (1.54)
Weighted average shares outstanding — basic and diluted	25,338,462	20,493,377	25,299,910	10,502,459

Balance Sheet Data

	September 30, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	\$ 52,627	\$ 83,631
Restricted cash	360	360
Total assets	54,875	84,813
Long-term debt (including current portion)	7,903	7,586
Total liabilities	17,980	13,154
Total stockholders' equity	36,895	71,659

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