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

May 10, 2017

ALPHARETTA, Ga., May 10, 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 ended March 31, 2017 and provided an update on its development programs.

“The Clearside team continues our pursuit of transformative, elegant, precise solutions to restore and preserve vision,” said Daniel H. White, Chief Executive Officer and President. “Together, we continued to advance our pipeline in the first quarter of 2017 as our pivotal Phase 3 clinical trial for the treatment of macular edema associated with non-infectious uveitis continues enrollment with preliminary data expected in early 2018. We also enrolled the first patient in a Phase 3 clinical trial for the treatment of macular edema associated with retinal vein occlusion. Additionally, we received notices of allowance of two important U.S. patents, which are representative of a new family of patents that protect the unique drug distribution properties of injecting to the retinal and choroid through the suprachoroidal space.”

Update on Key Development Programs

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

Macular Edema Associated with Non-Infectious Uveitis

In the first quarter of 2017, Clearside continued to enroll patients in PEACHTREE, the Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis. Clearside currently anticipates that it will report initial results from PEACHTREE in early 2018.

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

On February 16, 2017, Clearside announced the enrollment of the first patient in a Phase 3 clinical trial, SAPPHIRE, of suprachoroidal CLS-TA used together with intravitreally administered EYLEA® (aflibercept) (“intravitreal Eylea”) for the treatment of macular edema associated with RVO.

SAPPHIRE is a multicenter, multi-country, randomized, masked, controlled 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 will be to determine the proportion of patients in each 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 enrollment in an exploratory clinical trial, HULK, of suprachoroidal CLS-TA, both with or without intravitreal Eylea, for the treatment of DME.

HULK is an open-label, multi-center Phase 1/2 study designed to assess the safety and efficacy of the administration of a suprachoroidal injection of CLS-TA along with an intravitreal injection of Eylea in patients with DME naïve to treatment, as well as that of a suprachoroidal injection of 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 currently expects to report preliminary results from HULK in the second half of 2017.

Clearside is also planning a multicenter, randomized, masked, controlled Phase 2 trial, TYBEE, to evaluate suprachoroidal CLS-TA along with intravitreal Eylea, compared to intravitreal Eylea only, in patients with DME, over a 6-month evaluation period. The primary endpoint of the trial will be the change in best corrected visual acuity from baseline in the combination treatment arm compared to the intravitreal Eylea only arm. Clearside currently expects to enroll the first patient in TYBEE in mid-2017.

Wet Age-Related Macular Degeneration (“Wet AMD”)

Clearside continues to explore potential opportunities for the use of pharmacological therapies via suprachoroidal injection for the treatment of wet AMD.

Collaborations

As Clearside’s development programs move further into the clinic, opportunities have been created to collaborate with third-party proprietary programs. In this regard, Clearside continues preclinical efforts with multiple collaborations in gene therapy, complement inhibition, and alternative mechanisms in the treatment of complex retinal diseases like AMD.

First Quarter 2017 Financial Results

Clearside’s research and development expenses for the three months ended March 31, 2017 were $7.6 million, compared to $4.6 million for the first quarter of 2016, an increase of $3.0 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 the decrease in costs from completed clinical trials and Clearside’s discontinuation of preclinical trials in its wet AMD program.

General and administrative expenses were $2.7 million for the first quarter of 2017, compared to $1.3 million for the same period last year, an increase of $1.4 million. This year-over-year increase was primarily attributable to an increase of $0.5 million in employee-related costs, a $0.2 million increase in patent and trademark costs, a $0.2 million increase for marketing expenses and a $0.3 million increase in the costs of operating as a public company.

Cash, cash equivalents and short-term investments totaled $77.5 million as of March 31, 2017, compared to $83.6 million as of December 31, 2016. The decrease reflects total operating expenses, partially offset by $5.1 million received in January 2017 upon the underwriters' exercise of their option to purchase additional shares as part of Clearside's follow-on public offering that initially closed in December 2016.

Net loss for the first quarter of 2017 was $10.4 million, or $0.41 per share of common stock, compared to $5.4 million, or $2.05 per share of common stock, for the first 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 17122858, 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 June 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 preclinical 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, and the potential market for, 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 March 31,**	
	2017	**2016**
License revenue	$ 5	$ 505
Operating expenses:		
Research and development	7,590	4,589
General and administrative	2,671	1,273
Total operating expenses	10,261	5,862
Loss from operations	(10,256)	(5,357)
Other expense, net	(117)	(92)
Net loss	$ (10,373)	$ (5,449)
Net loss per share of common stock — basic and diluted	$ (0.41)	$ (2.05)
Weighted average shares outstanding — basic and diluted	25,250,333	2,660,370

Balance Sheet Data	**March 31, 2017**	**December 31, 2016**
Cash, cash equivalents and short-term investments	$ 77,451	$ 83,631
Restricted cash	360	360
Total assets	81,958	84,813
Long-term debt (including current portion)	7,691	7,586
Total liabilities	14,795	13,154
Total stockholders' equity	67,163	71,659

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