February 8, 2016

pSivida Corp. Provides Company Update and Reports Second Quarter FY 2016 Results

WATERTOWN, Mass., Feb. 08, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV), (ASX:PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, today provided a Company update and announced financial results for its second fiscal quarter ended December 31, 2015.

Highlighting the quarter were the positive topline results reported from the first of two Phase 3 trials of the Company's lead product candidate Medidur™ for posterior uveitis. The 129 patient, multi-center, randomized and double-masked trial met its primary efficacy endpoint of prevention of recurrence of disease at six months with high statistical significance (p less than 0.00000001; intent to treat analysis). Safety results were also positive. Only 10.9% more Medidur-treated eyes than control eyes experienced an increase in intraocular pressure (IOP) above 21 mmHg through six months, which was reduced to 6.1% through the most recent follow-up visits (some as long as 24 months). Exploratory analyses of Medidur-treated eyes relative to control through six months also showed statistical significance for improvement in visual acuity (gain of 15 or more letters on the ETDRS Eye Chart), prevention of vision loss (loss of 15 or more letters) and reduction in systemic therapy.

As a result of the high statistical significance achieved in the trial results, pSivida intends to file for European Union (EU) marketing approval based on data from the single Phase 3 trial. The U.K. Medicines and Healthcare Products Regulatory Agency earlier advised pSivida that, consistent with published EU regulatory guidance, an application for a product treating a condition like posterior uveitis could be based on statistically compelling and clinically relevant results from just one pivotal trial.

"We believe that the level of statistical significance achieved in our first Phase 3 trial results should permit us to file our EU marketing approval application based on those results, accelerating the timing of planned submission toward the end of this year, rather than in 2017 as was originally planned," said Paul Ashton, Ph.D., president and CEO of pSivida.

"We have also requested a meeting with the U.S. Food and Drug Administration (FDA) to confirm, in light of our first Phase 3 trial results, that data from two trials will continue to be required for our U.S. New Drug Application (NDA), currently planned for the first half of calendar 2017," continued Dr. Ashton.

Following announcement of the trial results, pSivida completed a $17.8 million underwritten public offering of common stock. "With the addition of approximately $16.4 million of net proceeds from the offering, we believe we are in a position to continue our planned operations past the planned Medidur NDA filing and into the fourth quarter of calendar 2017," said Dr. Ashton.

pSivida and Hospital for Special Surgery, the leading specialty hospital for orthopedics and rheumatology, have collaborated to develop a Durasert™ implant to provide sustained treatment of pain associated with severe knee osteoarthritis (OA) with a goal of delaying or eliminating the need for knee replacement surgery. An investigational new drug application (IND) for an investigator-sponsored, six-month open label study of the implant was submitted to the FDA in the fourth quarter of calendar 2015. The FDA advised the principal investigator that stability data for the implants to be used in the study will be required prior to initiating the study. "The data requested by the FDA should not be difficult to develop, but will take time. We understand that HSS expects the study to commence this summer. Severe knee OA, the first use of our Durasert technology outside ophthalmology, could be a significant opportunity, with over 700,000 knee replacement surgeries from the disease in the US alone each year," said Dr. Ashton.

pSivida continued to advance its pre-clinical programs evaluating the use of Durasert to deliver off-patent or soon-to-be off-patent anti-cancer drugs that inhibit VEGF and PDGF to treat wet and dry age-related macular degeneration and Tethadur™ to deliver antibodies.

Results for the Second Quarter and Six Months Ended December 31, 2015. At December 31, 2015, cash, cash equivalents and marketable securities totaled $21.1 million compared to $24.0 million at the end of the prior quarter. Net cash usage in the fiscal 2016 second quarter was less than the prior quarter due to the timing of CRO payments for Medidur clinical development and, to a lesser extent, proceeds from stock option exercises, refundable foreign tax credits and the absence of incentive compensation awards paid in the prior quarter. pSivida expects net cash usage to vary from

quarter to quarter, primarily as a result of the amount and timing of payments for the Medidur clinical development program, which are expected to increase in the last two quarters of fiscal 2016.

In January 2016, pSivida enhanced its cash position with approximately $16.4 million of net proceeds from the consummation of a $17.8 million underwritten public offering of 4,440,000 shares of common stock.

Revenues for the quarter ended December 31, 2015 totaled $526,000 compared to $521,000 for the prior year quarter.

Operating expenses for the three months ended December 31, 2015 totaled $5.8 million compared to $4.6 million a year earlier. The increase was primarily attributable to higher costs for the Medidur clinical development program.

Net loss for the quarter ended December 31, 2015 was $5.2 million, or $0.18 per share, compared to a net loss of $4.1 million, or $0.14 per share, for the prior year quarter.

Revenues for the six months ended December 31, 2015 totaled $992,000 compared to $25.8 million for the six months ended December 31, 2014. The decrease reflected the $25.0 million milestone for FDA approval of ILUVIEN earned in the fiscal 2015 first quarter.

Operating expenses for the six months ended December 31, 2015 totaled $11.2 million compared to $9.2 million for the same period of the prior year, with the increase primarily due to costs of the Medidur clinical development program and, to a lesser degree, pre-clinical and other third party research costs, professional fees and stock-based compensation.

Income tax benefit of $83,000 for the six months ended December 31, 2015 compared to income tax expense of $188,000 for the six months ended December 31, 2014. In addition to refundable foreign research and development tax credits in both periods, pSivida recorded federal alternative minimum tax expense of $260,000 for the six months ended December 31, 2014.

Today's Conference Call Reminder.
pSivida Corp. will host a live webcast and conference call today, February 8, 2016, at 4:30pm ET. The conference call may be accessed by dialing (877) 312-7507 from the U.S. and Canada, or (631) 813-4828 from international locations. The conference can also be accessed on the pSivida Corp. website at www.psivida.com. A replay of the call will be available approximately two hours following the end of the call through February 15, 2016. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID number 42054739.

About Posterior Uveitis. Posterior uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is a leading cause of blindness in the developed and developing countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior uveitis affects approximately 175,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S.

Patients with posterior uveitis are typically treated with systemic steroids, but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects, including an increased risk of cancer. Medidur is designed to provide improved outcomes compared to standard of care, but with a significant reduction in side effects.

About Medidur Phase III Trials. pSivida is conducting two Phase 3 trials to assess the safety and efficacy of Medidur for the treatment of posterior uveitis. These are randomized, sham-controlled, double-masked trials. The primary endpoint of both trials is recurrence of posterior uveitis at six months, with patients in both trials followed for three years. The first Phase 3 Medidur trial, which is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S., met its primary efficacy endpoint with high statistical significance. The second trial, which will include up to 150 patients in approximately 15 centers in India, is currently being enrolled.

About pSivida Corp. pSivida Corp. (www.psivida.com), headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold in the U.S. and three EU countries. Retisert®, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Medidur™, a micro-insert for posterior uveitis being independently developed, is currently in pivotal Phase 3 clinical trials, with an NDA anticipated in the first half of 2017. pSivida's pre-clinical development program is focused on using its core platform technologies Durasert™ and Tethadur™ to deliver drugs and biologics to treat wet and dry age-related macular degeneration, glaucoma, osteoarthritis and other diseases. *To learn more about pSivida please visit* www.psivida.com *and connect on* Twitter, LinkedIn, Facebook *and* Google+.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements include uncertainties with respect to: our ability to achieve profitable operations and access to capital; fluctuations in our operating results; further impairment of our intangible assets; declines in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; safety and efficacy results of the second Medidur Phase 3 trial, number of trials and data required for, and timing of filing and acceptance of, the Medidur NDA and EU marketing approval applications, if at all; ability to use data in a U.S. NDA from trials outside the U.S.; any exercise by Pfizer of its option with respect to the latanoprost product; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. You should read and interpret any forward-looking statements in light of these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements, even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Collaborative research and development	$ 142	$ 164	$ 322	$ 25,245
Royalty income	384	357	670	583
Total revenues	526	521	992	25,828
Operating expenses:				
Research and development	3,721	2,767	7,203	5,551
General and administrative	2,043	1,870	4,011	3,604
Total operating expenses	5,764	4,637	11,214	9,155
(Loss) income from operations	(5,238)	(4,116)	(10,222)	16,673
Interest and other income	10	3	20	6
(Loss) income before income taxes	(5,228)	(4,113)	(10,202)	16,679
Income tax benefit (expense)	42	38	83	(188)

Net (loss) income	$ (5,186)	$ (4,075)	$ (10,119)	$ 16,491
Net (loss) income per common share:				
Basic	$ (0.18)	$ (0.14)	$ (0.34)	$ 0.56
Diluted	$ (0.18)	$ (0.14)	$ (0.34)	$ 0.54
Weighted average common shares outstanding:				
Basic	29,437	29,367	29,426	29,345
Diluted	29,437	29,367	29,426	30,618

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	December 31, 2015	June 30, 2015
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 21,091	$ 28,535
Other current assets	771	1,303
Total current assets	21,862	29,838
Intangible assets, net	1,512	1,925
Other assets	576	604
Total assets	$ 23,950	$ 32,367
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,855	$ 3,315
Deferred revenue	28	33
Total current liabilities	3,883	3,348
Deferred revenue	5,584	5,596
Deferred rent	59	55
Total liabilities	9,526	8,999
Stockholders' equity:		
Capital	294,315	293,089
Accumulated deficit	(280,785)	(270,666)
Accumulated other comprehensive income	894	945
Total stockholders' equity	14,424	23,368

Total liabilities and stockholders' equity	$ 23,950	$ 32,367

Beverly Jedynak

+1 312 943 1123

M: +1 773 350 5793

bjedynak@janispr.com

Primary Logo

Source: pSivida Corp

News Provided by Acquire Media