



May 5, 2016

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

WATERTOWN, Mass., May 05, 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 third fiscal quarter ended March 31, 2016.

pSivida continued to advance its lead product candidate, Medidur™. The European Commission granted Medidur orphan medicinal product designation for the treatment of posterior uveitis. Orphan designation provides up to 10 years of market exclusivity in Europe upon marketing approval as well as other regulatory and financial incentives. In accordance with published EU regulatory guidance, pSivida plans to file for EU marketing approval based upon the strength of the results from Medidur's first Phase 3 trial. The trial met its primary efficacy endpoint with high statistical significance with positive safety results.

"We are very pleased with the regulatory position of Medidur in the EU and are planning to file for regulatory approval under the centralized marketing authorization procedure around the end of 2016," said Dr. Paul Ashton, Ph.D., president and Chief Executive Officer of pSivida.

pSivida recently met with the U.S. Food and Drug Administration (FDA) to confirm the data required to support the U.S. New Drug Application (NDA) for Medidur. As a result of the meeting, pSivida continues to plan for an NDA submission based on the results of two Phase 3 trials together with data incorporated from the ILUVIEN® Phase 3 trials and data from a short inserter utilization study. The second Phase 3 trial is approximately 60% enrolled. With favorable results, pSivida plans to file an NDA for Medidur around mid-2017.

With the addition of the net proceeds from a \$17.8 million underwritten public offering of common stock during the quarter, the Company's cash position at the end of the quarter was \$33.3 million. "With this solid cash position, we should have adequate funding through our planned Medidur NDA filing and into the fourth quarter of calendar 2017," said Dr. Ashton.

Development of our Durasert™ product candidate for severe knee osteoarthritis (OA) being developed in partnership with Hospital for Special Surgery is proceeding on schedule. "The stability work requested by the FDA for the Investigational New Drug Application for the severe knee OA product candidate has been completed as planned, and we understand the principal investigator will submit it to the FDA shortly," added Dr. Ashton.

pSivida also continued its work on potential new product candidates. Research continued in its evaluation of 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 of Tethadur™ to deliver antibodies.

Results for the Third Quarter and Nine Months Ended March 31, 2016. At March 31, 2016, cash, cash equivalents and marketable securities totaled \$33.3 million compared to \$21.1 million at the end of the prior quarter. In January 2016, pSivida enhanced its cash position with approximately \$16.5 million of net proceeds from the consummation of a \$17.8 million underwritten public offering of 4,440,000 shares of common stock. Net operating cash usage in the fiscal 2016 third quarter totaled \$4.3 million, a \$1.1 million increase over the prior quarter. The increase primarily reflected expected increases in CRO payments for Medidur clinical development. pSivida expects net cash usage to increase in its fiscal fourth quarter and to continue to vary from quarter to quarter, primarily as a result of the amount and timing of payments for Medidur clinical development.

Revenues for the quarter ended March 31, 2016 totaled \$324,000 compared to \$328,000 for the prior year quarter.

Research and development expense decreased by \$265,000, or 8%, to \$3.1 million for the three months ended March 31, 2016 compared to \$3.3 million for the three months ended March 31, 2015. This was primarily attributable to lower CRO costs, partially offset by higher personnel costs, for the Medidur clinical development program.

General and administrative expense increased by \$305,000, or 15%, to \$2.3 million for the quarter ended March 31, 2016 compared to \$2.0 million for the prior year quarter. The increase was primarily attributable to higher professional fees and personnel costs, including stock-based compensation.

Net loss for the quarter ended March 31, 2016 was \$5.0 million, or \$0.15 per share, compared to a net loss of \$5.0 million, or \$0.17 per share, for the prior year quarter.

Revenues for the nine months ended March 31, 2016 totaled \$1.3 million compared to \$26.2 million for the nine months ended March 31, 2015. The decrease reflected the \$25.0 million milestone for FDA approval of ILUVIEN earned in the fiscal 2015 first quarter.

Research and development expense increased by \$1.4 million, or 16%, to \$10.3 million for the nine months ended March 31, 2016 compared to \$8.9 million for the nine months ended March 31, 2015. The increase was primarily attributable to higher costs related to Medidur clinical development.

General and administrative expense increased by \$712,000, or 13%, to \$6.4 million for the first nine months of fiscal year 2016 compared to \$5.6 million for the prior year period. The increase was primarily the result of higher professional fees, stock-based compensation and personnel-related costs.

Income tax benefit was \$117,000 for the nine months ended March 31, 2016 compared to income tax expense of \$144,000 for the nine months ended March 31, 2015. Both periods included refundable foreign research and development tax credits, which amounts for the nine months ended March 31, 2015 were more than offset by federal alternative minimum tax expense of \$263,000 attributable to receipt of the \$25.0 million ILUVIEN FDA approval milestone.

Today's Conference Call Reminder.

pSivida Corp. will host a live webcast and conference call today, May 5, 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 May 12, 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 1692802.

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 3 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 around mid-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: Designation of Medidur as an orphan medicinal product; 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)

	<u>Three Months Ended</u> <u>March 31,</u>		<u>Nine Months Ended</u> <u>March 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
Collaborative research and development	\$ 50	\$ 110	\$ 372	\$ 25,355
Royalty income	274	218	944	801
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Total revenues	324	328	1,316	26,156
Operating expenses:				
Research and development	3,074	3,339	10,277	8,890
General and administrative	2,346	2,041	6,357	5,645
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Total operating expenses	5,420	5,380	16,634	14,535
(Loss) income from operations	(5,096)	(5,052)	(15,318)	11,621
Interest and other income	21	10	41	16
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(Loss) income before income taxes	(5,075)	(5,042)	(15,277)	11,637
Income tax benefit (expense)	34	44	117	(144)
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Net (loss) income	<u>\$ (5,041)</u>	<u>\$ (4,998)</u>	<u>\$ (15,160)</u>	<u>\$ 11,493</u>
Net (loss) income per common share:				
Basic	<u>\$ (0.15)</u>	<u>\$ (0.17)</u>	<u>\$ (0.49)</u>	<u>\$ 0.39</u>
Diluted	<u>\$ (0.15)</u>	<u>\$ (0.17)</u>	<u>\$ (0.49)</u>	<u>\$ 0.38</u>

Weighted average common shares outstanding:

Basic	<u>33,538</u>	<u>29,412</u>	<u>30,787</u>	<u>29,367</u>
Diluted	<u>33,538</u>	<u>29,412</u>	<u>30,787</u>	<u>30,612</u>

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

	<u>March 31,</u> <u>2016</u>	<u>June 30,</u> <u>2015</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 33,274	\$ 28,535
Other current assets	1,004	1,303
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Total current assets	34,278	29,838
Intangible assets, net	1,311	1,925
Other assets	576	604
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Total assets	<u>\$ 36,165</u>	<u>\$ 32,367</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,949	\$ 3,315
Deferred revenue	19	33
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Total current liabilities	3,968	3,348
Deferred revenue	5,584	5,596
Deferred rent	60	55
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Total liabilities	<u>9,612</u>	<u>8,999</u>
Stockholders' equity:		
Capital	311,497	293,089
Accumulated deficit	(285,826)	(270,666)
Accumulated other comprehensive income	882	945
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Total stockholders' equity	<u>26,553</u>	<u>23,368</u>
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Total liabilities and stockholders' equity	<u>\$ 36,165</u>	<u>\$ 32,367</u>

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Source: pSivida Corp

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