



November 5, 2015

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

WATERTOWN, Mass., Nov. 05, 2015 (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 first fiscal quarter ended September 30, 2015.

Development of Medidur™ for posterior uveitis, pSivida's lead product candidate, advanced significantly in the first quarter of fiscal 2016. pSivida now plans to file a New Drug Application (NDA) for Medidur based on six-month efficacy data from its two Phase III trials, rather than 12-month data from one trial and six-month data from the second, after the U.S. Food & Drug Administration (FDA) advised pSivida that this data will be acceptable for review by the agency. Because all patients in the first Phase III trial completed six months of follow-up in September 2015, pSivida now expects to report top-line results from the first Phase III trial in December 2015. Enrollment in the second trial continues on schedule, with a planned NDA for Medidur in the first half of 2017. pSivida has begun discussions with the MHRA (Medicines and Healthcare Products Regulatory Agency) to determine the requirements for approval in the EU.

Top-line results from a three-year, ongoing investigator-sponsored study of low and high doses of Medidur showed a statistically significant reduction in recurrence of uveitis ($p=0.014$), which is also the primary endpoint in pSivida's Phase III trials, and a statistically significant improvement in visual acuity ($p=0.014$) at the last follow-up visit in eyes treated with Medidur compared to those that were not treated with Medidur (pSivida is studying only the low dose). pSivida also reported that, in its first Phase III trial, only 5% more study eyes (2/3's of which received Medidur) experienced elevated intraocular pressure (IOP) (over 21 mm Hg) than the fellow non-study eyes (none of which received Medidur) at three months of follow-up. Because initial IOP elevation is an indication of the likelihood of subsequent clinically significant IOP increases, a key safety measure, the minimal difference at three months suggests favorable results for the safety of Medidur in the Phase III trials.

"We look forward to reporting the top-line results from our first Phase III trial, which we now expect to be available at the end of this year," said Paul Ashton, Ph.D., President and CEO of pSivida.

pSivida is working on expanding the use of its patented Durasert™ technology platform beyond ophthalmology. pSivida and Hospital for Special Surgery, the leading specialty hospital for orthopedics and rheumatology, have been collaborating to develop an implant for the treatment of pain associated with severe knee osteoarthritis (OA). This implant is comprised of a screw with an embedded Durasert device that is surgically implanted in the knee. The implant is designed to deliver a corticosteroid directly to the joint on a sustained basis to provide long-term pain relief and thereby delay or eliminate the need for knee replacement surgery. Following promising pre-clinical data showing maintenance of sustained drug levels in the knee, the principal investigator filed an investigational new drug (IND) application and is awaiting information from the FDA as to any additional requirements it may have for initiating the clinical trial. "Knee OA is the primary reason for knee replacement surgery, with over 700,000 performed last year in the U.S. alone. These numbers are expected to increase with projected increases in aging and overweight populations. The potential to provide sustained treatment of the pain associated with severe knee OA and avoid knee replacement with a simple implant procedure is very exciting," said Dr. Ashton.

pSivida continued to make good progress in its programs to use its Durasert technology to create treatments for additional chronic eye diseases age-related macular degeneration (AMD) and glaucoma, both of which have known drug treatments and represent very significant market potentials. pSivida initiated a pre-clinical program 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 AMD, the leading cause of vision loss in people age 60 and older. pSivida also was successful in optimizing the ability of Tethadur to deliver antibodies in *in vitro* studies. "Higher molecule loading capacity and enhanced antibody stability are critical attributes for sustained antibody delivery to a small cavity like the eye for an extended period so we are very pleased with our success in achieving these attributes in the lab. We are moving on to confirmatory testing of Tethadur. We are targeting INDs for both AMD and Tethadur products in the next year," said Dr. Ashton.

"We had \$24.0 million in cash at September 30, 2015. That should give us the capital resources to continue our planned product development programs, including our two Medidur trials, into early 2017, even without any potential future payments arising from ILUVIEN," said Dr. Ashton.

Results for the FY 2016 First Quarter. Revenues for the quarter ended September 30, 2015 totaled \$466,000 compared to

\$25.3 million for the prior year quarter. The decrease was primarily due to the ILUVIEN FDA approval milestone earned in September 2014.

Operating expenses for the three months ended September 30, 2015 totaled \$5.4 million compared to \$4.5 million a year earlier. The increase was primarily attributable to higher CRO costs for the Medidur clinical development program.

Income tax benefit of \$41,000 for the three months ended September 30, 2015 compared to income tax expense of \$226,000 for the three months ended September 30, 2014. The prior year quarter included \$260,000 of federal alternative minimum tax expense based on projected U.S. taxable income for calendar year 2014, which was primarily attributable to the \$25.0 million ILUVIEN FDA approval milestone. Refundable foreign research and development tax credits were earned in both periods.

Net loss for the quarter ended September 30, 2015 was \$4.9 million, or \$0.17 per share, compared to net income of \$20.6 million, or \$0.67 per diluted share, for the prior year quarter.

At September 30, 2015, cash, cash equivalents and marketable securities totaled \$24.0 million.

Today's Conference Call Reminder.

pSivida Corp. will host a live webcast and conference call today, November 5, 2015, 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 November 12, 2015. 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 67983411.

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 III 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 III Medidur trial is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. As the last 6-month follow-up visit for patients in this trial occurred in September 2015, top-line data is expected in December 2015. The second trial will enroll up to 150 patients in approximately 15 centers in India. We plan to seek FDA approval of Medidur based on 6-month data from the two Phase III trials and a short-duration utilization study of our redesigned proprietary inserter, together with data referenced from the Phase III trials of ILUVIEN for DME.

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 microinsert for posterior uveitis being independently developed, is currently in pivotal Phase III 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; further impairment of our intangible assets; fluctuations in our operating results; 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 Medidur Phase III trials, timing of filing and

acceptance of the Medidur NDA, 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	
	September 30,	
	2015	2014
Revenues:		
Collaborative research and development	\$ 180	\$ 25,081
Royalty income	286	226
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Total revenues	466	25,307
Operating expenses:		
Research and development	3,482	2,784
General and administrative	1,968	1,734
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Total operating expenses	5,450	4,518
(Loss) income from operations	(4,984)	20,789
Interest and other income	10	3
	<hr/>	<hr/>
(Loss) income before income taxes	(4,974)	20,792
Income tax benefit (expense)	41	(226)
	<hr/>	<hr/>
Net (loss) income	<u>\$ (4,933)</u>	<u>\$ 20,566</u>
Net (loss) income per common share:		
Basic	<u>\$ (0.17)</u>	<u>\$ 0.70</u>
Diluted	<u>\$ (0.17)</u>	<u>\$ 0.67</u>
Weighted average common shares outstanding:		
Basic	<u>29,416</u>	<u>29,323</u>
Diluted	<u>29,416</u>	<u>30,765</u>

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

	<u>September 30,</u> <u>2015</u>	<u>June 30,</u> <u>2015</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 24,005	\$ 28,535
Other current assets	1,158	1,303
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Total current assets	25,163	29,838
Intangible assets, net	1,713	1,925
Other assets	584	604
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Total assets	\$ 27,460	\$ 32,367
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Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,960	\$ 3,315
Deferred revenue	33	33
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Total current liabilities	2,993	3,348
Deferred revenue	5,587	5,596
Deferred rent	57	55
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Total liabilities	8,637	8,999
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Stockholders' equity:		
Capital	293,503	293,089
Accumulated deficit	(275,599)	(270,666)
Accumulated other comprehensive income	919	945
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Total stockholders' equity	18,823	23,368
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Total liabilities and stockholders' equity	\$ 27,460	\$ 32,367

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Source: pSivida Corp

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