



September 12, 2016

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

WATERTOWN, Mass., Sept. 12, 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 fourth quarter and fiscal year ended June 30, 2016.

"Fiscal 2016 was a year of substantial progress for pSivida. We significantly advanced Medidur™ for posterior segment uveitis toward planned EU and U.S. marketing applications, progressing toward a treatment with the potential to inhibit the disease for three years from a single injection without significant side effects and without systemic therapy," said Dr. Paul Ashton, president and chief executive officer of pSivida. "Additionally, fiscal 2016 marked the first use of our Durasert™ technology outside of ophthalmology with the commencement of an investigator-sponsored pilot study of a sustained-release implant being developed in collaboration with Hospital for Special Surgery designed to provide long-term pain relief for severe knee osteoarthritis. Also, based on pre-clinical studies completed in fiscal 2016, we commenced the first of two IND-enabling studies for an injectable, bioerodible Durasert insert for sustained delivery of a tyrosine kinase inhibitor (TKI) for treatment of wet age-related macular degeneration."

Business Highlights

- | The first of the two Phase 3 trials for Medidur for posterior segment uveitis 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) with encouraging safety results.
- | pSivida's utilization study of its proprietary, smaller diameter 27-gauge inserter met its primary endpoint, ease of intravitreal administration, showing it facilitated the administration of Medidur compared to the larger diameter inserter.
- | The European Commission designated Medidur as an orphan medicinal product and the Company plans to submit a European marketing authorization application (MAA) for Medidur under the centralized procedure in the first quarter of 2017 based on data from the single, first Phase 3 trial, the inserter utilization study and the ILUVIEN® for diabetic macular edema (DME) trials.
- | The second Medidur Phase 3 trial is expected to complete enrollment next month. Pending positive results, a U.S. new drug application (NDA) based on both Phase 3 trials is planned for the third quarter of 2017.
- | An investigator-sponsored pilot study commenced for a Durasert sustained-release implant being developed together with Hospital for Special Surgery that is designed to provide long-term pain relief for severe knee osteoarthritis.
- | Following the successful results of earlier reported animal studies comparing a TKI insert to an injection of a commercially available biologic indicated for wet AMD, pSivida commenced the first of two investigational new drug (IND)-enabling studies of the TKI insert for wet AMD.
- | Results of pSivida's pre-clinical studies of Tethadur™ reported in July demonstrated that Tethadur could provide prolonged, sustained delivery of Avastin® with high drug efficacy. pSivida plans to conduct additional pre-clinical studies seeking to develop Tethadur for ophthalmic and systemic delivery of biologics.
- | In the first quarter of fiscal 2017, pSivida enhanced its research and product development with the addition of Dario Paggiarino, M.D. as chief medical officer. The Company also closed its U.K. research facility and consolidated all of its research into its state-of-the-art, cGMP U.S. facility coordinated by Dr. Paggiarino in an effort to improve the flow of research to product candidates while reducing overhead.
- | pSivida replenished its capital resources with a \$17.8 million underwritten public offering of common stock earlier in the year.

Results for the Fourth Quarter and Year Ended June 30, 2016. At June 30, 2016, cash, cash equivalents and marketable securities totaled \$29.0 million compared to \$28.5 million at the end of the prior year. In January 2016, pSivida enhanced its cash position with net proceeds of \$16.5 million from an underwritten public offering of its common stock. Net operating cash usage in the fiscal 2016 fourth quarter totaled \$4.3 million, the same as the prior quarter. Net operating cash usage is expected to increase during fiscal 2017 compared to fiscal 2016 and to vary from quarter to quarter during the fiscal year, primarily as a result of the amount and timing of payments for Medidur clinical development and regulatory submissions and, in the first quarter, the previously announced U.K. consolidation costs and incentive compensation payments.

Revenues for the quarter ended June 30, 2016 totaled \$304,000 compared to \$409,000 for the prior year quarter.

Research and development expense increased by \$906,000, or 28%, to \$4.1 million for the fiscal 2016 fourth quarter compared to \$3.2 million for the prior year quarter. This was primarily attributable to increased Medidur CRO and regulatory preparation costs and increased personnel costs, including incentive compensation and contractual severance obligations.

General and administrative expense increased by \$245,000, or 10%, to \$2.7 million for the quarter ended June 30, 2016 compared to \$2.4 million for the prior year quarter. The increase was primarily attributable to higher incentive compensation.

Net loss for the quarter ended June 30, 2016 was \$6.4 million, or \$0.19 per share, compared to a net loss of \$5.1 million, or \$0.17 per share, for the prior year quarter.

Revenues for the year ended June 30, 2016 totaled \$1.6 million compared to \$26.6 million for the year ended June 30, 2015. The decrease in fiscal 2016 reflected the \$25.0 million milestone for FDA approval of ILUVIEN earned in the fiscal 2015 first quarter.

Research and development expense increased by \$2.3 million, or 19%, to \$14.4 million for fiscal 2016 compared to \$12.1 million for fiscal 2015. The increase was primarily attributable to a \$1.7 million increase in Medidur CRO and regulatory preparation costs and pre-clinical and other third-party research costs and \$475,000 of personnel costs, including incentive compensation and contractual severance obligations.

General and administrative expense increased by \$957,000, or 12%, to \$9.0 million for fiscal year 2016 compared to \$8.1 million for the prior year. The increase was primarily attributable to a \$564,000 increase in personnel costs, including higher incentive compensation accruals and stock-based compensation, and a \$303,000 increase in professional fees.

Income tax benefit was \$155,000 for the year ended June 30, 2016 compared to income tax expense of \$96,000 in fiscal 2015. Federal alternative minimum tax totaled \$4,000 and \$263,000 for fiscal 2016 and fiscal 2015, respectively, based upon U.S. taxable income for calendar year 2014, which was primarily due to the \$25.0 million ILUVIEN FDA-approval milestone. Refundable foreign research and development tax credits totaled \$159,000 in fiscal 2016 compared to \$167,000 in fiscal 2015.

Today's Conference Call Reminder.

pSivida Corp. will host a live webcast and conference call today, September 12, 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 September 19, 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 71781786.

About Posterior Segment Uveitis. Posterior segment 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 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 segment 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 segment uveitis. These are randomized, sham-controlled, double-masked trials. The primary

endpoint of both trials is recurrence of posterior segment uveitis at six months, with patients in both trials followed for three years. The first Phase 3 Medidur trial enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. The second trial will enroll up to 150 patients in approximately 15 centers in India.

About pSivida Corp. pSivida Corp. (www.psvida.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 segment uveitis being independently developed, is currently in pivotal Phase 3 clinical trials. 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.psvida.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 obtain needed capital; our ability to achieve profitable operations; potential declines in Retisert royalties; fluctuations in our operating results; further impairment of our intangible assets; our ability to obtain marketing approvals for and successfully commercialize Medidur for posterior segment uveitis; performance by CROs, vendors and investigators; timing of filing marketing approval applications for Medidur; acceptability of data to be filed in support of Medidur marketing applications; maintenance of orphan designation for Medidur, potential off-label sales of ILUVIEN for posterior segment uveitis; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; Alimera's ability to continue as a going concern; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; outcome of dispute with Alimera on commercialization expenses; 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; efficacy and future development of severe OA implant by us; 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; effects of potential U.K. exit from the EU; 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		Year Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenues:				
Collaborative research and development	\$ 26	\$ 56	\$ 398	\$25,411
Royalty income	278	353	1,222	1,154
	<hr/>	<hr/>	<hr/>	<hr/>
Total revenues	304	409	1,620	26,565
	<hr/>	<hr/>	<hr/>	<hr/>
Operating expenses:				
Research and development	4,104	3,198	14,381	12,088

General and administrative	2,656	2,411	9,013	8,056
	<hr/>	<hr/>	<hr/>	<hr/>
Total operating expenses	6,760	5,609	23,394	20,144
(Loss) income from operations	(6,456)	(5,200)	(21,774)	6,421
Interest and other income, net	31	6	72	22
	<hr/>	<hr/>	<hr/>	<hr/>
(Loss) income before income taxes	(6,425)	(5,194)	(21,702)	6,443
Income tax benefit (expense)	38	48	155	(96)
	<hr/>	<hr/>	<hr/>	<hr/>
Net (loss) income	<u>\$ (6,387)</u>	<u>\$ (5,146)</u>	<u>\$(21,547)</u>	<u>\$ 6,347</u>
Net (loss) income per share:				
Basic	<u>\$ (0.19)</u>	<u>\$ (0.17)</u>	<u>\$ (0.68)</u>	<u>\$ 0.22</u>
Diluted	<u>\$ (0.19)</u>	<u>\$ (0.17)</u>	<u>\$ (0.68)</u>	<u>\$ 0.21</u>
Weighted average common shares outstanding:				
Basic	<u>34,152</u>	<u>29,412</u>	<u>31,623</u>	<u>29,378</u>
Diluted	<u>34,152</u>	<u>29,412</u>	<u>31,623</u>	<u>30,584</u>

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

	<u>June 30,</u> <u>2016</u>	<u>June 30,</u> <u>2015</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 28,992	\$ 28,535
Other current assets	971	1,303
	<hr/>	<hr/>
Total current assets	29,963	29,838
Intangible assets, net	1,102	1,925
Other assets	554	604
	<hr/>	<hr/>
Total assets	<u>\$ 31,619</u>	<u>\$ 32,367</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,946	\$ 3,315
Deferred revenue	147	33
	<hr/>	<hr/>
Total current liabilities	5,093	3,348
Deferred revenue, less current portion	5,585	5,596
Deferred rent	60	55
	<hr/>	<hr/>
Total liabilities	10,738	8,999

Stockholders' equity:		
Capital	312,242	293,089
Accumulated deficit	(292,213)	(270,666)
Accumulated other comprehensive income	852	945
Total stockholders' equity	20,881	23,368
Total liabilities and stockholders' equity	\$ 31,619	\$ 32,367

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Source: pSivida Corp

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