



November 7, 2016

## **pSivida Corp. Reports Fiscal 2017 First Quarter Results and Provides Update on Corporate Objectives & Milestone Timeline**

*New Leadership Focused on Increasing Commercial Potential of Proven Durasert™ Sustained Release Platform*

*Company Continues Focus on MAA and NDA Filings for Uveitis Product in 2017*

*Conference Call and Webcast Today, November 7, at 4:30 p.m. ET*

WATERTOWN, Mass., Nov. 07, 2016 (GLOBE NEWSWIRE) -- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug products and technologies, today reported financial results for its fiscal first quarter ended September 30, 2016. In addition, the Company's new leadership team updated corporate objectives and anticipated product development milestone timeline.

"Since joining the Company in mid-September, I have been working with our team to assess the impressive clinical and commercial potential of our pipeline that is largely based on pSivida's proven Durasert™ sustained drug release technology, the only intraocular sustained release technology with approval of three different products," said Nancy Lurker, President & CEO. "We've made significant progress on a number of fronts and I'm even more excited about the potential for pSivida to make a true difference in patients' lives while we build returns to our shareholders. Our assessment reaffirmed the clear strength and quality of clinical data from studies of our Durasert three-year treatment for posterior segment uveitis (formerly known as Medidur) and we remain focused on preparing our submission for approval of this product candidate in both the European Union and United States during 2017. We've also begun a thorough examination of how to most efficiently and effectively launch the Durasert three-year uveitis product in the United States while we actively explore partnership possibilities to address patients with a similar diagnosis in Europe."

"Our review also resulted in our management team deploying more focus on lower risk and nearer term market opportunities as well as a renewed emphasis on potential collaborations for our Durasert technology and implementation of improvements to our product candidate evaluations. Since joining, we have continued to advance our uveitis clinical program and have reprioritized our development programs. These now include a next generation Durasert bio-erodible shorter duration treatment for posterior segment uveitis, increased emphasis on Durasert for severe osteoarthritis (OA) of the knee in conjunction with HSS, and continued work on our Durasert tyrosine kinase inhibitor (TKI) program for Wet AMD. We also continue to pursue our Tethadur™ platform for large molecules," Ms. Lurker added.

### **Fiscal First Quarter 2017 Results**

Revenue for the first fiscal quarter ended September 30, 2016 totaled \$277,000 compared to \$466,000 for the prior year quarter. The year-over-year decrease was primarily attributable to \$157,000 of non-royalty sublicense consideration earned from Alimera in the prior-year period. Operating expenses for the three months ended September 30, 2016 totaled \$7.5 million compared to \$5.4 million a year earlier. The increase was primarily attributable to approximately \$1.1 million of severance costs, professional fees and stock-based compensation expense related to the September CEO transition, \$436,000 of costs for the previously announced U.K. restructuring and approximately \$300,000 of CRO and regulatory contractor costs for our Durasert three-year uveitis product candidate. Net loss for the quarter ended September 30, 2016 was \$7.2 million, or \$0.21 per share, compared to net loss of \$4.9 million, or \$0.17 per share, for the prior year quarter.

At September 30, 2016, cash, cash equivalents and marketable securities totaled \$22.5 million.

### **Product Candidate Program Update & Anticipated Milestones**

**Durasert three-year treatment for posterior segment uveitis:** The Company met its enrollment target in the second uveitis Phase 3 trial of 150 patients in September. Readout of this second trial, which is required by the U.S. Food & Drug Administration for the Company's NDA filing, is currently expected by the end of the first half of 2017. The first Phase 3 study met its primary efficacy endpoint with a p value of < 0.001 and safety data that are consistent with the known effect of

ocular corticosteroid use. With regard to the planned E.U. submission for marketing authorization, management's goal remains to submit during the first quarter of 2017. The Company was recently notified that protocol approval for a pediatric study would be required by the European regulatory authority prior to the acceptance of the application for market authorization. The protocol for the pediatric study has been submitted and the timing of its approval could move the acceptance of the market application into the second quarter of 2017.

**Next Generation Durasert bio-erodible shorter duration treatment for posterior segment uveitis:** The Company has initiated and prioritized a development program for a next generation Durasert bio-erodible for uveitis. The Company is initiating formulation testing now and expects to begin pre-clinical safety and PK studies of this product candidate in the first half of 2017. Management believes this product candidate will provide enhanced benefits to patients and physicians by offering a shorter delivery time period of corticosteroid and providing more flexibility to physicians with multiple Durasert dosing intervals.

**Durasert implant for severe osteoarthritis (OA) of the knee:** On August 1, 2016, the Hospital for Special Surgery in New York, NY and pSivida announced the opening of an IND in support of an investigator-sponsored clinical study of a Durasert implant to treat severe OA of the knee. Management believes severe OA of the knee is a large and growing condition with continued high unmet medical needs. The implant is designed to provide long-term pain relief for this condition, which, if effective, could potentially result in the delay of knee replacement surgery. The study is an open-label, single dose, safety and tolerability study of the screw implant to deliver dexamethasone, a corticosteroid previously proven to provide pain relief in knee OA. Six patients will each receive the implant in one knee. While a safety and tolerability study, change from baseline in weekly mean of pain intensity scored at rest, during activity and at night will be assessed through 24 weeks. To date two patients have received the implant and HSS expects to have all six patients implanted over the next few months.

**Durasert bio-erodible TKI for Wet AMD:** Management believes that pSivida's TKI program could represent a valuable advancement to the treatment of Wet AMD. As part of the new leadership's program assessment, it has been determined that further evaluation of additional TKIs is needed to optimize candidate selection, and management is actively pursuing a lead candidate for the clinic.

**Tethadur for large molecules:** The Tethadur program applies proprietary technology to achieve the sustained release of large molecules such as biologics. Recently, management narrowed its focus to silica-based technology from the earlier silicon-based technology in an effort to advance the program in a cost-effective way. Pre-clinical activities on this program are continuing.

"During the past few weeks I have had the pleasure of getting to know the people that developed pSivida's terrific technology. With the recent additions of Dr. Dario Paggiarino and Deb Jorn, we have a talented and committed team with a singular focus to successfully bring pSivida's products to patients and deliver greater shareholder returns," concluded Ms. Lurker.

## Conference Call

pSivida Corp. will host a live webcast and conference call today, November 7, 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 ID is 9987331. The conference can also be accessed on the pSivida Corp. website at [www.psivida.com](http://www.psivida.com). A replay of the call will be available approximately two hours following the end of the call and can be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID number 9987331.

**About pSivida Corp.** pSivida Corp. ([www.psivida.com](http://www.psivida.com)), headquartered in Watertown, MA, is a leader in the development of sustained release drug technologies for eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN<sup>®</sup>, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold in the US and three EU countries. Retisert<sup>®</sup>, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Durasert 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<sup>™</sup> and Tethadur<sup>™</sup> 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](http://www.psivida.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

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assets; our ability to obtain marketing approvals for and successfully commercialize Durasert three-year uveitis for posterior segment uveitis; performance by CROs, vendors and investigators; timing of filing marketing approval applications for Durasert three-year uveitis; acceptability of data to be filed in support of Durasert three-year uveitis marketing applications; maintenance of European orphan designation for Durasert three-year uveitis; 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)

	<u>Three Months Ended</u> <u>September 30,</u>	
	<u>2016</u>	<u>2015</u>
Revenues:		
Collaborative research and development	\$ 34	\$ 180
Royalty income	243	286
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Total revenues	<u>277</u>	<u>466</u>
Operating expenses:		
Research and development	4,178	3,482
General and administrative	3,285	1,968
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Total operating expenses	<u>7,463</u>	<u>5,450</u>
Loss from operations	(7,186)	(4,984)
Interest and other income	24	10
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Loss before income taxes	(7,162)	(4,974)
Income tax benefit	-	41
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Net loss	<u>\$ (7,162)</u>	<u>\$ (4,933)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.17)</u>

Weighted average common shares outstanding:

Basic and diluted 34,175 29,416

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

	<u>September 30,</u> <u>2016</u>	<u>June 30,</u> <u>2016</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 22,546	\$ 28,992
Other current assets	957	971
	<hr/>	<hr/>
Total current assets	23,503	29,963
Intangible assets, net	910	1,102
Other assets	520	554
	<hr/>	<hr/>
<b>Total assets</b>	<b>\$ 24,933</b>	<b>\$ 31,619</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 4,703	\$ 4,946
Deferred revenue	139	147
	<hr/>	<hr/>
Total current liabilities	4,842	5,093
Deferred revenue	5,585	5,585
Deferred rent	58	60
	<hr/>	<hr/>
<b>Total liabilities</b>	<b>10,485</b>	<b>10,738</b>
<b>Stockholders' equity:</b>		
Capital	312,985	312,242
Accumulated deficit	(299,375)	(292,213)
Accumulated other comprehensive income	838	852
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Total stockholders' equity	14,448	20,881
	<hr/>	<hr/>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 24,933</b>	<b>\$ 31,619</b>

Contact:

Michael Polyviou/Doug Sherk - Investors

[mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com); [dsherker@evcgroup.com](mailto:dsherker@evcgroup.com)

212.850.6020; 646-445-4800

Thomas Gibson - Media

[tom@tomgibsoncommunications.com](mailto:tom@tomgibsoncommunications.com)

201-476-0322

 Primary Logo

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