



May 8, 2015

## **pSivida Corp. Reports Third Quarter FY 2015 Results**

### **Clear FDA Regulatory Path for Medidur™ for Posterior Uveitis**

#### **NDA Filing Planned in First Half of 2017**

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release, drug delivery products for treating eye diseases, today announced financial results for its third quarter ended March 31, 2015.

Our licensee Alimera Sciences launched ILUVIEN® in the U.S. for diabetic macular edema (DME) in the quarter. ILUVIEN is now widely available to the estimated 575,000 patients with clinically significant DME in the country. In the U.S. ILUVIEN is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure.

ILUVIEN was also launched in Portugal in the quarter, making it the third EU market. ILUVIEN has been sold in the U.K. and Germany since 2013. Three more EU countries granted approvals in the quarter, completing the last applications and bringing the number of EU country approvals to 17. ILUVIEN is indicated in the EU for treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN has been sublicensed in Australia and New Zealand by Alimera.

"We are very pleased ILUVIEN has been launched in the U.S. The efficacy and three-year treatment duration of ILUVIEN should make it a very attractive treatment alternative for patients with clinically significant DME in comparison to anti-VEGF therapy, which requires frequent injections and may not optimally manage the disease," said Paul Ashton, Ph.D., President and CEO of pSivida. "Our licensee, Alimera Sciences, is making a significant investment in the U.S. launch, which we are optimistic will ultimately benefit us through our net profit participation from U.S. sales." pSivida is entitled to 20% of the net profits from sales of ILUVIEN by its licensee on a country-by-country, quarter-by-quarter basis and 20% of royalties and 33% of other amounts from sublicenses of ILUVIEN.

**Clear FDA Regulatory Path for Medidur™ for Posterior Uveitis.** Medidur™ for posterior uveitis, pSivida's lead development product, which uses the same injectable, sustained-release micro-insert as ILUVIEN (same design, same drug, same polymer, same release rate), also provides three years of treatment from a single injection. Posterior uveitis is the third leading cause of blindness in developed countries.

In recent meetings, pSivida reached agreement with the U.S. Food and Drug Administration (FDA) on a clear regulatory path for Medidur that allows for a new drug application (NDA) to be filed in the first half of 2017. The FDA agreed, pending clinical trial results, that it would accept an NDA based on data from the ongoing Medidur Phase III trial (which has a primary endpoint at 12 months), data from a second Phase III trial with a shorter, 6-month primary endpoint and data referenced from the already completed Phase III ILUVIEN trials. pSivida will also submit data from a small utilization study of its newly designed inserter that uses a standard 27 gauge needle.

"We are very pleased that we have a clear regulatory path that should permit us to file the NDA for Medidur with only a short delay from the timing we anticipated based on a single Phase III trial. We had budgeted for the second trial pending FDA guidance, so the second trial does not change our liquidity projections," said Dr. Ashton. This quarter we completed enrollment in the first Phase III trial with the longer 12-month primary endpoint, and we expect top-line data in the second quarter of 2016. We have already initiated the second Phase III trial, which will enroll up to 150 patients in India.

"Our \$31.7 million in cash at the end of the quarter should give us the capital resources to continue our planned product development programs, including both Medidur trials, into 2017, even without any potential future net profits contribution from ILUVIEN," said Dr. Ashton.

The Company continued its pre-clinical development program focused on developing pharmaceutical products to treat chronic diseases of the retina using pSivida's platform technologies.

"We are working to develop micro-inserts delivering already approved drugs for the treatment of wet and dry age-related macular degeneration (AMD) and glaucoma. We are particularly excited about the potential opportunity for dry AMD treatment as there is currently no approved treatment for this devastating disease. Dry AMD accounts for 85 to 90% of all cases of AMD, which currently affects several million Americans alone. Dry AMD has an estimated prevalence of 3 - 4% in the U.S., and that is projected to increase as the population ages. In osteoarthritis we are making good progress in our collaboration with Hospital for Special Surgery to take a sustained release implant into clinical trials. Our work with Tethadur, our sustained release system for peptides, proteins and anti-bodies, is continuing to progress toward clinical trials."

**Results for the FY2015 Third Quarter.** Revenues for the quarter ended March 31, 2015 totaled \$328,000 compared to \$2.0 million for the prior year's third quarter. The decrease was primarily due to recognition of \$1.5 million in the prior year quarter under a completed feasibility study agreement and lower Retisert royalties.

Operating expenses for the three months ended March 31, 2015 totaled \$5.4 million compared to \$4.2 million a year earlier. The increase was primarily attributable to CRO costs for the Medidur clinical development program and higher stock-based compensation.

Net loss for the quarter ended March 31, 2015 was \$5.0 million, or \$0.17 per share, compared to a net loss of \$2.2 million, or \$0.08 per share, for the prior year quarter.

Revenues for the nine months ended March 31, 2015 totaled \$26.2 million compared to \$3.2 million for the nine months ended March 31, 2014. The increase reflected the \$25.0 million milestone for FDA approval of ILUVIEN recorded in the fiscal 2015 first quarter, partially offset by a \$1.8 million reduction in revenues from funded technology evaluation agreements.

Operating expenses for the nine months ended March 31, 2015 totaled \$14.5 million compared to \$12.7 million for the same period of the prior year, with the increase primarily due to costs of the Medidur clinical development program and higher stock-based compensation.

Net income for the nine months ended March 31, 2015 totaled \$11.5 million, or \$0.38 per diluted share, compared to a net loss of \$9.4 million, or \$0.35 per share, for the nine months ended March 31, 2014.

At March 31, 2015, cash, cash equivalents and marketable securities totaled \$31.7 million. The Company's quarterly cash burn is expected to vary from quarter to quarter based on the timing and amounts of cash payments, including CRO payments, and cash receipts under collaboration agreements.

### **Today's Conference Call Reminder**

pSivida Corp. will host a live webcast and conference call today, May 8, 2015, at 8:30am 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.pshivida.com](http://www.pshivida.com). A replay of the call will be available approximately two hours following the end of the call through May 15, 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 39251264.

### **About pSivida Corp.**

pSivida Corp., headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. pSivida's lead product candidate, Medidur™ for treatment of posterior uveitis, is being studied in pivotal clinical trials. Medidur uses the same injectable, sustained release micro-insert as pSivida's lead licensed product, ILUVIEN® for the treatment of DME. ILUVIEN is marketed in the U.S., U.K., Germany and Portugal and has marketing authorization in 14 other EU countries. pSivida's other licensed product, Retisert®, an implant that treats posterior uveitis, is sold in the U.S. pSivida's pre-clinical research is focused on ocular and systemic delivery of biologics and drugs to treat wet and dry age-related macular degeneration, glaucoma, osteoarthritis and other diseases.

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. These forward looking statements include, but are not limited to, statements regarding the regulatory path to obtain regulatory approval of Medidur in the United States, the benefit we may receive from our share of net profits on sales of ILUVIEN, the timing of the filing of an NDA for Medidur, FDA's willingness to accept the NDA, the timing of results of our phase III trial of Medidur, and the length of time our capital resources will last and be sufficient to fund our planned development programs. 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: ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME;

effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; number and cost of clinical trials and data necessary to support an NDA for, approval by Indian regulators of the trial design for, timing of filing the NDA for, and regulatory approval and successful commercialization of, Medidur; delays in completion of clinical trials; increases in cost of clinical trials; changes in, or misunderstandings with respect to, FDA guidance on required clinical trials; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and to develop products using it; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of 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 together with 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.

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Google+: <https://plus.google.com/u/0/b/113754643626984244726/113754643626984244726/posts>

The President's Blog: <http://www.thechairmansblog.com/paul-ashton>

For more information on pSivida, visit [www.psivida.com](http://www.psivida.com).

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2015	2014	2015	2014
Revenues:				
Collaborative research and development	\$ 110	\$ 1,676	\$ 25,355	\$ 2,149
Royalty income	218	316	801	1,032
	328	1,992	26,156	3,181
Total revenues				
Operating expenses:				
Research and development	3,339	2,269	8,890	7,267
General and administrative	2,041	1,946	5,645	5,468
Gain on sale of property and equipment	-	(4)	-	(76)
	5,380	4,211	14,535	12,659
Total operating expenses				

(Loss) income from operations	<u>(5,052)</u>	<u>(2,219)</u>	<u>11,621</u>	<u>(9,478)</u>
Other income:				
Interest income	6	1	12	3
Other income, net	<u>4</u>	<u>-</u>	<u>4</u>	<u>-</u>
Total other income	<u>10</u>	<u>1</u>	<u>16</u>	<u>3</u>
(Loss) income before income taxes	<u>(5,042)</u>	<u>(2,218)</u>	<u>11,637</u>	<u>(9,475)</u>
Income tax benefit (expense)	<u>44</u>	<u>31</u>	<u>(144)</u>	<u>87</u>
Net (loss) income	<u>\$ (4,998)</u>	<u>\$ (2,187)</u>	<u>\$ 11,493</u>	<u>\$ (9,388)</u>
Net (loss) income per share:				
Basic	<u>\$ (0.17)</u>	<u>\$ (0.08)</u>	<u>\$ 0.39</u>	<u>\$ (0.35)</u>
Diluted	<u>\$ (0.17)</u>	<u>\$ (0.08)</u>	<u>\$ 0.38</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding:				
Basic	<u>29,412</u>	<u>27,672</u>	<u>29,367</u>	<u>26,842</u>
Diluted	<u>29,412</u>	<u>27,672</u>	<u>30,612</u>	<u>26,842</u>

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

	<u>March 31,</u> <u>2015</u>	<u>June 30,</u> <u>2014</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 31,658	\$ 18,278
Other current assets	<u>1,419</u>	<u>1,064</u>
Total current assets	33,077	19,342
Intangible assets, net	2,080	2,765
Other assets	<u>545</u>	<u>564</u>
<b>Total assets</b>	<u>\$ 35,702</u>	<u>\$ 22,671</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 2,183	\$ 1,988
Deferred revenue	<u>35</u>	<u>138</u>
Total current liabilities	2,218	2,126
Deferred revenue	5,584	5,584
Deferred rent	<u>53</u>	<u>37</u>
<b>Total liabilities</b>	<u>7,855</u>	<u>7,747</u>

**Stockholders' equity:**

Capital	292,468	290,893
Accumulated deficit	(265,520)	(277,013)
Accumulated other comprehensive income	899	1,044
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Total stockholders' equity	27,847	14,924
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<b>Total liabilities and stockholders' equity</b>	<b>\$ 35,702</b>	<b>\$ 22,671</b>
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