



September 9, 2015

## **pSivida Corp. Provides Company Update and Reports Fourth Quarter and FY 2015 Results**

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 provided a Company update and announced financial results for its fourth quarter and fiscal year ended June 30, 2015.

Fiscal 2015 was a year marked by excellent progress toward pSivida's goal of becoming the leader in sustained release drug delivery products in ophthalmology and beyond.

Phase III clinical trials for Medidur™ for posterior uveitis, pSivida's lead development product, continued on pace for an expected NDA filing in the first half of 2017. Enrollment of the first trial was completed in March 2015, and enrollment in the second trial is ongoing. Medidur is designed to deliver three years of treatment of posterior uveitis, a blinding eye disease, from a single injection.

"We remain optimistic that Medidur will be safe and effective in treating posterior uveitis. Recent top-line results from an investigator-sponsored study and safety data from our first Phase III trial have been very encouraging in this regard," said Paul Ashton, Ph.D., President and CEO of pSivida.

Top-line results from the investigator-sponsored study of low and high doses of Medidur (pSivida is studying only the low dose) showed a statistically significant reduction in recurrence of uveitis ( $p=0.014$ ) and a statistically significant improvement in visual acuity ( $p=0.014$ ) in eyes treated with Medidur compared to those that were not treated with Medidur.

For all 129 enrolled patients in pSivida's first Phase III trial at three months of follow-up, 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). This was consistent with the IOP safety data earlier reported by pSivida for the first 105 patients at three months follow-up.

pSivida expects that an investigational new drug application (IND) will shortly be filed in the U.S. to commence an investigator-sponsored study of an implant utilizing pSivida's patented Durasert™ technology to treat pain associated with severe osteoarthritis of the knee. pSivida and Hospital for Special Surgery, the leading specialty hospital for orthopedics and rheumatology, have been collaborating on this product. It will be surgically implanted in the knee to provide approximately six months of sustained delivery of a corticosteroid directly to the joint, designed to offer long-term pain relief and delay or eliminate the need for knee replacement surgery. "With over 10 million cases of knee osteoarthritis and 700,000 knee replacement surgeries last year in the U.S. alone and a population that is aging and increasingly overweight, a product that would offer a new treatment alternative for the pain of severe osteoarthritis of the knee would be a very welcome clinical development," said Dr. Ashton.

pSivida also continued work on its pre-clinical programs focused on creating products for chronic ophthalmic diseases and delivering biologics using its core Durasert and Tethadur™ technologies. "We have seen excellent progress recently with both of these technologies. We are particularly pleased at the advances we have made in our development of Tethadur to deliver antibodies. With our latest iteration of the technology, we have achieved higher molecule loading capacity and enhanced antibody stability. These are key elements for sustained delivery of biologics to a small space such as the eye," said Dr. Ashton. "We commenced a new pre-clinical program to use Durasert to deliver drug to treat age-related macular degeneration and continued to progress our research with respect to other ophthalmic applications."

ILUVIEN® for diabetic macular edema (DME), pSivida's lead licensed product, which is the same micro-insert as Medidur, completed its first quarter of commercialization in the U.S. with solid sales. ILUVIEN is also sold in the U.K., and was recently launched in Portugal and relaunched in Germany. 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. "We believe the three years of effective treatment from a single injection of ILUVIEN should make it a very attractive treatment alternative in the significant DME market, and we look forward to benefitting through our profit participation," said Dr. Ashton.

"Our \$28.5 million in cash at the end of fiscal year 2015 marks our highest year-end liquidity. It 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 Fourth Quarter and FY 2015.** Revenues for the quarter ended June 30, 2015 totaled \$409,000 compared to \$292,000 for the prior year's fourth quarter. The increase was primarily due to higher Retisert royalties.

Operating expenses for the three months ended June 30, 2015 totaled \$5.6 million compared to \$4.3 million a year earlier. The increase was primarily attributable to higher CRO costs for the Medidur clinical development program and higher professional fees.

Net loss for the quarter ended June 30, 2015 was \$5.1 million, or \$0.17 per share, compared to a net loss of \$4.0 million, or \$0.14 per share, for the prior year quarter.

Revenues for the year ended June 30, 2015 totaled \$26.6 million compared to \$3.5 million for the year ended June 30, 2014. The increase reflected the \$25.0 million milestone for FDA approval of ILUVIEN recorded in the fiscal 2015 first quarter, partially offset by an approximate \$1.8 million reduction in revenues from funded technology evaluation agreements.

Operating expenses for the year ended June 30, 2015 totaled \$20.1 million compared to \$17.0 million for the same period of the prior year, with the \$3.1 million net increase primarily due to increased CRO costs for the Medidur clinical development program as well as increased professional fees and stock-based compensation.

Income tax expense totaled \$96,000 for the year ended June 30, 2015 compared to an income tax benefit of \$130,000 for the year ended June 30, 2014. Fiscal 2015 included \$263,000 of federal alternative minimum tax expense based on 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 totaled \$167,000 in fiscal 2015 compared to \$130,000 in fiscal 2014.

Net income for the year ended June 30, 2015 totaled \$6.3 million, or \$0.21 per diluted share, compared to a net loss of \$13.4 million, or \$0.49 per share, for the year ended June 30, 2014.

At June 30, 2015, cash, cash equivalents and marketable securities totaled \$28.5 million.

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

pSivida Corp. will host a live webcast and conference call today, September 9, 2015, at 4:30 pm 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](http://www.psivida.com). A replay of the call will be available approximately two hours following the end of the call through September 16, 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 27613566.

**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 the 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 end point of both trials is recurrence of posterior uveitis, 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. The last 12-month follow-up visit for patients in this trial is scheduled for March 2016, and top-line data is expected in the second quarter of 2016. The second trial will enroll up to 150 patients in approximately 15 centers in India. We plan to seek approval of Medidur based on 12-month data from the first Phase III trial, six-month data from the second Phase III trial and data from a short-duration utilization study of our redesigned proprietary inserter, together with data referenced from the Phase III trials of ILUVIEN for DME. Pending favorable results in our ongoing clinical trials and concurrence from regulatory authorities regarding our proposed data package, we expect to file an NDA in the first half of 2017.

**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 delivery products for treating eye diseases. pSivida has developed three of only four FDA-approved

treatments for back-of-the-eye diseases. The most recent, ILUVIEN®, a micro-insert for diabetic macular edema, is licensed to Alimera Sciences and 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, 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/or Tethadur™, to deliver drugs and biologics to treat wet and dry-age related macular degeneration (AMD), 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. 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; fluctuations in our operating results; ability to use of 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.

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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)**

	<b>Three Months Ended</b>		<b>Year Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenues:				
Collaborative research and development	\$ 56	\$ 6	\$25,411	\$ 2,155
Royalty income	353	286	1,154	1,318
<b>Total revenues</b>	<b>409</b>	<b>292</b>	<b>26,565</b>	<b>3,473</b>

Operating expenses:				
Research and development	3,198	2,306	12,088	9,573
General and administrative	2,411	2,000	8,056	7,468
Gain on sale of property and equipment	-	(2)	-	(78)
Total operating expenses	<u>5,609</u>	<u>4,304</u>	<u>20,144</u>	<u>16,963</u>
(Loss) income from operations	<u>(5,200)</u>	<u>(4,012)</u>	<u>6,421</u>	<u>(13,490)</u>
Other income, net:				
Interest income	7	3	19	6
Other (expense) income, net	(1)	(1)	3	(1)
Total other income	<u>6</u>	<u>2</u>	<u>22</u>	<u>5</u>
(Loss) income before income taxes	(5,194)	(4,010)	6,443	(13,485)
Income tax benefit (expense)	48	43	(96)	130
Net (loss) income	<u>\$ (5,146)</u>	<u>\$ (3,967)</u>	<u>\$ 6,347</u>	<u>\$ (13,355)</u>
Net (loss) income per share:				
Basic	<u>\$ (0.17)</u>	<u>\$ (0.14)</u>	<u>\$ 0.22</u>	<u>\$ (0.49)</u>
Diluted	<u>\$ (0.17)</u>	<u>\$ (0.14)</u>	<u>\$ 0.21</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding:				
Basic	<u>29,412</u>	<u>29,256</u>	<u>29,378</u>	<u>27,444</u>
Diluted	<u>29,412</u>	<u>29,256</u>	<u>30,584</u>	<u>27,444</u>

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

	<u>June 30,</u> <u>2015</u>	<u>June 30,</u> <u>2014</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 28,535	\$ 18,278
Other current assets	1,303	1,064
Total current assets	<u>29,838</u>	<u>19,342</u>
Intangible assets, net	1,925	2,765
Other assets	604	564
<b>Total assets</b>	<u>\$ 32,367</u>	<u>\$ 22,671</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 3,315	\$ 1,988
Deferred revenue	33	138
Total current liabilities	<u>3,348</u>	<u>2,126</u>
Deferred revenue, less current portion	5,596	5,584
Deferred rent	55	37

<b>Total liabilities</b>	8,999	7,747
<b>Stockholders' equity:</b>		
Capital	293,089	290,893
Accumulated deficit	(270,666)	(277,013)
Accumulated other comprehensive income	945	1,044
Total stockholders' equity	23,368	14,924
<b>Total liabilities and stockholders' equity</b>	<b>\$ 32,367</b>	<b>\$ 22,671</b>

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Source: pSivida Corp.

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