



February 7, 2014

pSivida Corp. Reports Second Quarter 2014 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 announced financial results for its second quarter ended December 31, 2013.

"We continued to advance our own pipeline of products. Enrollment continues on schedule for our lead development product, Medidur™ for posterior uveitis, in the first of two planned Phase III trials," said Dr. Paul Ashton, President and CEO of pSivida. "Our lead licensed product, ILUVIEN® for chronic diabetic macular edema (DME), moved closer to potential marketing approval in the U.S. and expanded availability in the EU.

"In posterior uveitis we believe that the trials will show an efficacy profile of Medidur comparable to Retisert®, our FDA-approved implant for posterior uveitis currently being sold by Bausch & Lomb, with a side effect profile superior to Retisert. Preliminary data from a small investigator-sponsored Phase I/II study of Medidur for posterior uveitis patients were consistent with this hypothesis. Medidur, which uses the same micro-insert as ILUVIEN, delivers a lower dosage of the same drug as Retisert," Dr. Ashton continued. Posterior uveitis, an inflammatory disease of one of the layers of the eye, affects approximately 175,000 people in the U.S. Responsible for approximately 30,000 cases of legal blindness, posterior uveitis is the third largest cause of blindness.

"We are very pleased that our licensee Alimera Sciences entered into labeling discussions with the U.S. Food and Drug Administration (FDA) for ILUVIEN for DME and plans to respond to the FDA's October 2013 Complete Response Letter (CRL) in the first quarter of 2014. We understand Alimera will be providing recent safety data from patients in the U.K. and Germany and addressing the concerns raised by the FDA regarding the facility at which ILUVIEN for DME is manufactured. Alimera reported that new clinical trials will not be required by the FDA in connection with its review of ILUVIEN for DME prior to approval. If approved, we will be entitled to a \$25.0 million milestone payment from Alimera and 20% of net profits on sales of ILUVIEN for DME by Alimera in the U.S.

"We are also encouraged by the speed with which ILUVIEN has been made available to U.K. National Health Service (NHS) facilities. Less than seven weeks after the final guidance from the U.K.'s National Institute for Health and Care Excellence (NICE) recommending ILUVIEN as a treatment option for pseudophakic eyes (those that have had cataract surgery) with chronic DME considered insufficiently responsive to available therapies, initial orders were shipped to NHS hospitals and the first NHS patient was treated. Until receipt of this guidance, ILUVIEN had been available in the U.K. only to private pay and privately insured patients, but will now be available through the NHS to this typically large subgroup of chronic DME patients, subject to a patient access scheme.

"We continue to be encouraged by our studies of potential ophthalmic and non-ophthalmic uses of Tethadur™, our second key technology platform designed to provide sustained delivery of peptides, proteins and antibodies. The importance of these biologics in treatment of ophthalmic disease makes Tethadur a very promising technology," continued Dr. Ashton. The use of Tethadur in certain ophthalmic applications is being evaluated under a funded evaluation agreement with a leading global biopharmaceutical company. Other major pharmaceutical companies are evaluating pSivida's technology platforms in other ophthalmic applications under funded agreements.

Revenues for the quarter ended December 31, 2013 totaled \$592,000 compared to \$585,000 for the prior year period. Increased collaborative research and development revenue was offset by lower Retisert royalty income from Bausch & Lomb.

Net loss for the quarter ended December 31, 2013 was \$3.5 million, or \$0.13 per share, compared to a net loss of \$2.6 million, or \$0.11 per share, for the prior year quarter. The higher net loss in the second quarter of fiscal 2014 primarily reflected costs associated with our Phase III clinical trial of Medidur for posterior uveitis, which commenced in the quarter ended June 2013.

Revenues for the six months ended December 31, 2013 totaled \$1.2 million compared to \$1.1 million for the six months ended December 31, 2012. The Company reported a net loss of \$7.2 million, or \$0.27 per share, for the six months ended December 31, 2013, compared to a net loss of \$5.2 million, or \$0.23 per share, for the same period of the prior year.

At December 31, 2013, cash, cash equivalents and marketable securities totaled \$15.7 million compared to \$16.5 million at September 30, 2013, reflecting approximately \$1.2 million received from an existing collaboration agreement and approximately \$1.25 million of net proceeds from sales of common stock under pSivida's at-the-market (ATM) offering program.

Today's Conference Call Reminder

pSivida Corp. will host a live webcast and conference call today, February 7, 2014, 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. A replay of the call will be available approximately two hours following the end of the call through February 14, 2014. 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 52647338.

About the Clinical Trials/Studies

pSivida has initiated the first of two planned pivotal Phase III trials of Medidur for the treatment of posterior uveitis. These trials are expected to enroll a total of approximately 300 patients. The primary end point is the recurrence of uveitis within 12 months. pSivida will be permitted to reference much of the data, including the clinical safety data, from the clinical trials of ILUVIEN for DME conducted by Alimera.

The investigator-sponsored Phase I/II study of Medidur for posterior uveitis is a three-year study that will evaluate the safety and efficacy of Medidur in up to 12 patients with posterior uveitis. Interim results were measured on the twelve month anniversary of the start of enrollment. Through this period, none of the eyes receiving Medidur experienced a recurrence of uveitis and inflammation was reduced in all of these eyes. In contrast, all (untreated) control eyes had either a recurrence of uveitis or a worsening of inflammation. Furthermore, at the last follow-up visit reported in interim results, best corrected visual acuity (on the Early Treatment Diabetic Retinopathy Study eye chart) improved by an average of more than nine letters in treated eyes while untreated eyes declined by an average of one letter. Interim data showed that Medidur was well tolerated, and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of ILUVIEN in DME eyes. Only one eye receiving Medidur measured an increase in intraocular pressure above the normal range.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. The injectable, sustained release micro-insert ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., is marketed in the U.K. and Germany and has also received marketing authorization in Austria, France, Portugal, and Spain and is awaiting authorization in Italy. Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure. Alimera is seeking FDA approval for ILUVIEN for DME in the US. pSivida has instituted the first of two planned pivotal Phase III clinical trials of Medidur™ for the treatment of posterior uveitis, a chronic back-of-the-eye disease. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat posterior uveitis.

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. The following are 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: uncertainties with respect to: Alimera's ability to finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; the ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver proteins, peptides and other large biologic molecules; ability to develop product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors

described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. 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. 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.

Follow pSivida on social media:

Twitter: <https://twitter.com/pSividaCorp>

Facebook: <https://www.facebook.com/pages/PSivida-Corp/544893792199562>

LinkedIn: <http://www.linkedin.com/company/psivida>

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.

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

	Three Months Ended		Six Months Ended	
	December 31,		December 31,	
	2013	2012	2013	2012
Revenues:				
Collaborative research and development	\$ 300	\$ 195	\$ 473	\$ 364
Royalty income	292	390	716	774
Total revenues	<u>592</u>	<u>585</u>	<u>1,189</u>	<u>1,138</u>
Operating expenses:				
Research and development	2,494	1,575	4,998	3,098
General and administrative	1,711	1,658	3,522	3,278
Gain on sale of property and equipment	(72)	-	(72)	-
Total operating expenses	<u>4,133</u>	<u>3,233</u>	<u>8,448</u>	<u>6,376</u>
Loss from operations	<u>(3,541)</u>	<u>(2,648)</u>	<u>(7,259)</u>	<u>(5,238)</u>
Other income (expense), net:				
Interest income	1	4	2	11
Other expense, net	-	(1)	-	(2)
Total other income	<u>1</u>	<u>3</u>	<u>2</u>	<u>9</u>
Loss before income taxes	<u>(3,540)</u>	<u>(2,645)</u>	<u>(7,257)</u>	<u>(5,229)</u>
Income tax benefit	26	37	56	70
Net loss	<u>\$ (3,514)</u>	<u>\$ (2,608)</u>	<u>\$ (7,201)</u>	<u>\$ (5,159)</u>

Net loss per share:

Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.11)</u>	<u>\$ (0.27)</u>	<u>\$ (0.23)</u>
-------------------	------------------	------------------	------------------	------------------

Weighted average common shares outstanding:

Basic and diluted	<u>26,953</u>	<u>23,297</u>	<u>26,435</u>	<u>22,795</u>
-------------------	---------------	---------------	---------------	---------------

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

	<u>December 31,</u> <u>2013</u>	<u>June 30,</u> <u>2013</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 15,721	\$ 10,273
Other current assets	1,511	2,191
<hr/>		
Total current assets	17,232	12,464
Intangible assets, net	3,127	3,430
Other assets	460	355
<hr/>		
Total assets	<u>\$ 20,819</u>	<u>\$ 16,249</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,380	\$ 2,565
Deferred revenue	771	738
<hr/>		
Total current liabilities	2,151	3,303
Deferred revenue	6,069	5,246
<hr/>		
Total liabilities	<u>8,220</u>	<u>8,549</u>
Stockholders' equity:		
Capital	282,443	270,438
Accumulated deficit	(270,859)	(263,658)
Accumulated other comprehensive income	1,015	920
<hr/>		
Total stockholders' equity	<u>12,599</u>	<u>7,700</u>
<hr/>		
Total liabilities and stockholders' equity	<u>\$ 20,819</u>	<u>\$ 16,249</u>

In US:

Martin E. Janis & Company, Inc.

Beverly Jedynak

President

+1 312 943 1123

M: +1 773 350 5793

bjedynak@janispr.com

or

In Australia:

pSivida Corp.

Brian Leedman

Vice President, Investor Relations

+61 (0) 41 228 1780

brianl@psivida.com

Source: pSivida Corp.

News Provided by Acquire Media