

pSivida Corp. Reports Third Quarter Fiscal Year 2013 Results

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV)(ASX: PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, today announced financial results for its third quarter ended March 31, 2013.

"We are very pleased that the FDA has accepted Alimera Sciences' recently resubmitted New Drug Application for ILUVIEN® for chronic Diabetic Macular Edema (DME) and has set a PDUFA target date of October 17, 2013. Approval in the U.S. would entitle pSivida to a \$25 million milestone payment from Alimera and 20% of net profits, as defined, from U.S. sales of ILUVIEN by Alimera," said Dr. Paul Ashton, President and CEO of pSivida. "Further good news was Alimera's recent announcements of the commercial launch of ILUVIEN in Germany and for private pay and privately insured patients in the U.K. Alimera also reported that a simple patient access scheme for ILUVIEN is being evaluated by the UK's National Institute for Clinical Excellence (NICE), and, if accepted, ILUVIEN would be funded throughout England and Wales by the National Health System."

"Concurrent with these exciting developments for ILUVIEN, we continue to move forward with our own lead development product, an injectable micro-insert for posterior uveitis, for which we expect to begin the first Phase III trial shortly," said Dr. Ashton. "Because this product uses the same micro-insert as ILUVIEN for DME, the FDA has agreed that we can use much of the data, including clinical safety data, from the completed ILUVIEN Phase III trials to support the application for uveitis. This should shorten and simplify the regulatory process. We are planning to target enrollment of a total of 300 patients in our two trials, with a primary end point of recurrence of uveitis at 12 months."

"We believe that our pre-clinical studies of applications of Tethadur<sup>™</sup>, our protein/anbiody delivery technology platform, continue to progress very well. Tethadur's use in certain ophthalmic applications is currently being evaluated under an agreement with a leading global biopharmaceutical company. A sustained delivery system for proteins and antibodies used in ophthalmic treatments could offer a significant clinical advantage because current therapies require an injection into the eye every one or two months."

"Our recent technology evaluation agreement with another major pharmaceutical company to evaluate our drug delivery platforms in the ophthalmic space offers another potential path forward to the development of new products."

Revenues for the fiscal 2013 third quarter were \$513,000 compared to \$538,000 for the third quarter last year. The Company reported a net loss of \$2.8 million, or \$0.12 per share, for the third quarter ended March 31, 2013, compared to a net loss of \$2.7 million, or \$0.13 per share, for the third quarter of the prior year.

Revenues for the nine months ended March 31, 2013 totaled \$1.7 million compared to \$2.8 million for the prior year period. Prior year revenues included \$1.1 million of revenue recognition from the termination of a 2008 field-of-use license. The Company reported a net loss of \$8.0 million, or \$0.35 per share, for the nine months ended March 31, 2013, compared to a net loss of \$22.6 million, or \$1.09 per share, for the same period of the prior year. The prior year net loss included a \$14.8 million impairment write-down of the Company's finite-lived intangible assets.

At March 31, 2013, cash, cash equivalents and marketable securities totaled \$13.7 million compared to \$15.7 million at December 31, 2012.

## Today's Conference Call Reminder

pSivida Corp. will host a live webcast and conference call today, May 13, 2013, at 4:30 pm ET. The conference call may be accessed by dialing (877) 303-9236 from the U.S. and Canada, or (760) 666-3569 from international locations. The conference can also be accessed on the pSivida Corp. website at <u>www.psivida.com</u>. A replay of the call will be available approximately two hours following the end of the call through May 20, 2013. 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 68825398.

## 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<sup>™</sup> and BioSilicon<sup>™</sup>. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic Diabetic Macula Edema (DME), licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal, the U.K. and Spain and is awaiting authorization in Italy. ILUVIEN for DME has not been approved in the US. pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis with the same micro-insert as ILUVIEN for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension. pSivida's FDA-approved product, Retisert® for the treatment of posterior uveitis, is licensed to Bausch & Lomb.

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, successfully complete pricing and reimbursement discussions for, 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.; financing and success of planned Phase III posterior uveitis trials, including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon and potential collaborations for those products; 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 revenues; 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; possible influence by Pfizer; 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, 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 March 31,			Nine Months Ended March 31,				
	2013		2012		2013		2012	
Revenues: Collaborative research and development Royalty income	\$	239 274	\$	158 380	\$	603 1,048	\$	1,823 1,004
Total revenues		513		538		1,651		2,827
Operating expenses: Research and development General and administrative Impairment of intangible assets		1,587 1,738 -		1,508 1,757 -		4,685 5,016 -		5,629 5,269 14,830

Total operating expenses	3,325	3,265	9,701	25,728
Loss from operations	(2,812)	(2,727)	(8,050)	(22,901)
Other income:				
Change in fair value of derivatives	-	-	-	170
Interest income	3	10	14	30
Other income (expense), net	-	1	(2)	(1)
-				
Total other income	3	11	12	199
Loss before income taxes	(2,809)	(2,716)	(8,038)	(22,702)
Income tax benefit	15	30	85	129
-				
Net loss	\$ (2,794)	\$ (2,686)	\$ (7,953)	\$ (22,573)
Net loss per share:				
	\$ (0.12)	\$ (0.13)	\$ (0.35)	\$ (1.09)
Weighted average common shares outstanding:				
Basic and diluted	23,297	20,803	22,960	20,787

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

	March 31, 2013		June 30, 2012		
Assets Current assets: Cash, cash equivalents and marketable securities Other current assets	\$	13,697 1,508	\$	14,571 1,388	
Total current assets Intangible assets, net Other assets		15,205 3,619 296		15,959 4,226 412	
Total assets	\$	19,120	\$	20,597	
Liabilities and stockholders' equity Current liabilities: Accounts payable and accrued expenses Deferred revenue	\$	1,792 893	\$	1,002 2,176	
Total current liabilities Deferred revenue		2,685 5,194		3,178 3,783	

Total liabilities	 7,879		6,961
Stockholders' equity: Capital	270,038		264,452
Accumulated deficit	(259,711)		(251,758)
Accumulated other comprehensive income	 914		942
Total stockholders' equity	 11,241		13,636
Total liabilities and stockholders' equity	\$ 19,120	\$	20,597

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Source: pSivida Corp.

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