# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

## **CURRENT REPORT**

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 6, 2013

# **PSIVIDA CORP.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 000-51122 (Commission File Number) 26-2774444 (IRS Employer Identification No.)

400 Pleasant Street Watertown, MA 02472

(Address of Principal Executive Offices) (Zip Code)

(617) 926-5000

(Registrant's Telephone Number, Including Area Code)

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

On February 6, 2013, pSivida Corp. issued a press release announcing its second quarter fiscal year 2013 results and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this report, including Items 2.02 and 9.01 and Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

#### Item 9.01 Financial Statements and Exhibits

#### (d) Exhibits.

The following Exhibit is furnished with this report on Form 8-K:

No. Description

99.1 Press release of pSivida Corp. dated February 6, 2013

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### PSIVIDA CORP.

Date: February 6, 2013

By: <u>/s/ Lori Freedman</u>

Lori Freedman, Vice President, Corporate Affairs, General Counsel and Secretary



#### PSIVIDA CORP. REPORTS SECOND QUARTER

#### FISCAL YEAR 2013 RESULTS

WATERTOWN, MA – February 6, 2013 – 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 second quarter ended December 31, 2012.

"We are pleased with the progress of our lead development product, an injectable micro-insert for posterior uveitis. We expect to begin Phase III trials early next quarter on schedule," said Dr. Paul Ashton, President and CEO. "We intend these trials to form the basis for a future NDA submission and are excited about the role this product could play in treating this serious, underserved disease. The investigator-sponsored Phase II clinical study of this micro-insert in this disease has completed enrollment ahead of schedule and has been expanded to allow the treatment of more patients."

"Because our posterior uveitis product uses the same micro-insert as ILUVIEN®, which has received marketing authorizations in various EU countries for chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies, and delivers the same drug as our surgically implanted Retisert® product already approved for posterior uveitis, we expect our Phase III trials will show efficacy similar to Retisert but with a side-effect profile in uveitis patients comparable to that seen in DME patients. We are optimistic therefore that our micro-insert will be efficacious for posterior uveitis, but with fewer side effects and a favorable risk/benefit profile compared to Retisert," continued Dr. Ashton. "The U.S. Food and Drug Admnistration's (FDA) decision to allow us to reference much of the ILUVIEN data for DME, including the clinical safety data, from Alimera Sciences' already-completed pivotal Phase III clinical trials, has the potential to both simplify any future NDA submission and to shorten development time. 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."

"Our pre-clinical studies of applications of Tethadur™, our protein/anti-body delivery technology platform, continue to progress well. We believe Tethadur has the potential to provide sustained release of peptides and proteins in many therapeutic areas, and its 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 injection into the eye every one or two months."

Alimera Sciences, pSivida's licensee for ILUVIEN for DME, has announced plans for a direct commercial launch in three EU countries in 2013, with Germany expected in the first quarter, and the United Kingdom and France later in the year. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France, Germany and Spain, and has been recommended for marketing authorization in Italy, for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Alimera has estimated that there are approximately one million people suffering from DME in the 7 EU countries where marketing authorization has either been received or recommended. pSivida is entitled to receive 20% of net profits, as defined, on a country-by-country basis from sales of ILUVIEN by Alimera.

Alimera has also reported that, based on a June 2012 meeting with the FDA, it intends to respond in the first quarter of 2013 to issues raised by the FDA in its Complete Response Letter using data from Alimera's two previously completed pivotal Phase III clinical trials, focusing on the population of patients with chronic DME, the same indication for which marketing approval for ILUVIEN has been granted in various EU countries. 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.

Revenues for the fiscal 2013 second quarter were \$585,000 compared to \$630,000 for the second quarter last year. The Company reported a net loss of \$2.6 million, or \$0.11 per share, for the second quarter ended December 31, 2012, compared to a net loss of \$17.5 million, or \$0.84 per share, for the second quarter 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.

Revenues for the six months ended December 31, 2012 totaled \$1.1 million compared to \$2.3 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 \$5.2 million, or \$0.23 per share, for the six months ended December 31, 2012, compared to a net loss of \$19.9 million, or \$0.96 per share, for the same period of the prior year.

At December 31, 2012, cash, cash equivalents and marketable securities totaled \$15.7 million compared to \$17.6 million at September 30, 2012.

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

pSivida Corp. will host a live webcast and conference call today, February 6, 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 www.psivida.com. A replay of the call will be available approximately two hours following the end of the call through February 13, 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 95328173.

#### 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<sup>®</sup> 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 microinsert 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 two FDA-approved products, Retisert<sup>®</sup> and Vitrasert<sup>®</sup>, are implants that provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

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 commercialize and achieve market acceptance of, and generate revenues to pSivida from. ILUVIEN for DME in the EU: Alimera's resubmission of its NDA for ILUVIEN for DME and its 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 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; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; 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 forwardlooking 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.

#### Released by:

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

		Three Months Ended December 31,		Six Months Ended December 31,	
	2012	2011	2012	2011	
Revenues:					
Collaborative research and development	\$ 195	\$ 204	\$ 364	\$ 1,665	
Royalty income	390	426	774	624	
Total revenues	585	630	1,138	2,289	
Operating expenses:					
Research and development	1,575	1,992	3,098	4,121	
General and administrative	1,658	1,451	3,278	3,512	
Impairment of intangible assets		14,830		14,830	
Total operating expenses	3,233	18,273	6,376	22,463	
Loss from operations	(2,648)	(17,643)	(5,238)	(20,174)	
Other income (expense):					
Change in fair value of derivatives		128	—	170	
Interest income	4	11	11	20	
Other expense, net	(1)		(2)	(2)	
Total other income	3	139	9	188	
Loss before income taxes	(2,645)	(17,504)	(5,229)	(19,986)	
Income tax benefit	37	44	70	99	
Net loss	\$ (2,608)	\$(17,460)	\$ (5,159)	\$(19,887)	
Net loss per share:					
Basic and diluted	<u>\$ (0.11)</u>	\$ (0.84)	\$ (0.23)	\$ (0.96)	
Weighted average common shares outstanding:					
Basic and diluted	23,297	20,803	22,795	20,780	

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

	December 31, 2012	June 30, 2012
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 15,720	\$ 14,571
Other current assets	1,090	1,388
Total current assets	16,810	15,959
Intangible assets, net	3,883	4,226
Other assets	349	412
Total assets	\$ 21,042	\$ 20,597
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,299	\$ 1,002
Deferred revenue	784	2,176
Total current liabilities	2,083	3,178
Deferred revenue	5,149	3,783
Total liabilities	7,232	6,961
Stockholders' equity:		
Capital	269,726	264,452
Accumulated deficit	(256,917)	(251,758)
Accumulated other comprehensive income	1,001	942
Total stockholders' equity	13,810	13,636
Total liabilities and stockholders' equity	\$ 21,042	\$ 20,597