

pSivida Corp.

8-K

Current report filing

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**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): November 7, 2011

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)
 - ☐ Pre-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))
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Item 2.02. Results of Operations and Financial Condition.

On November 7, 2011, pSivida Corp. issued a press release announcing its first quarter fiscal year 2012 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 November 7, 2011

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: November 7, 2011

By:

/s/ Lori Freedman

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



**PSIVIDA CORP. REPORTS RESULTS FOR THE FIRST QUARTER
ENDED SEPTEMBER 30, 2011**

WATERTOWN, MA – November 7, 2011 — 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 first quarter ended September 30, 2011.

At September 30, 2011, cash, cash equivalents and marketable securities totaled \$21.3 million compared to \$24.1 million at June 30, 2011.

"We have a very full plate with three clinical-stage product candidates for the treatment of back-of-the-eye diseases. Most advanced is ILUVIEN® for diabetic macular edema (DME) being developed by our licensee Alimera Sciences, for which Alimera has resubmitted a New Drug Application and is awaiting a response from the FDA. We are also independently developing a product to treat uveitis affecting the posterior segment of the eye (posterior uveitis) and a product to treat glaucoma and ocular hypertension in collaboration with Pfizer," said Dr. Paul Ashton, President and CEO.

The Prescription Drug User Fee Act (PDUFA) date for ILUVIEN for DME is November 12, 2011. Last week Alimera announced that in September 2011, it commenced a physician utilization study of its intended commercial inserter for ILUVIEN for DME in response to a request from the FDA. Alimera further announced that it has enrolled 54 of a targeted 100 patients eyes in this study evaluating the safety and utility of the commercial version of the inserter. Data from this study may be required by the FDA for its consideration of the approval of ILUVIEN for DME.

The product the Company is developing for the treatment of posterior uveitis uses the same micro insert (with a different inserter) as ILUVIEN for DME. The Company's collaboration agreement with Alimera allows it to reference the ILUVIEN for DME regulatory filings, which provides the potential for an abbreviated clinical development and regulatory approval process for the posterior uveitis product. Posterior uveitis is an inflammatory condition which can be extremely serious. In the United States, this disease has been estimated to affect approximately 175,000 people and is responsible for approximately 30,000 cases of blindness. An investigator-sponsored trial in posterior uveitis opened in September 2011.

The Company's proposed product to treat glaucoma is an injectable, bioerodible sustained release insert delivering latanoprost and is the subject of a dose ranging study. The Company granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of this insert for human ophthalmic disease other than uveitis.

The Company is continuing to advance its Tethadur[®] system (based on BioSilicon technology) designed to deliver large biologic molecules, including peptides and proteins, on a sustained basis.

Revenues for the first quarter were \$1.7 million compared to \$476,000 a year earlier, primarily reflecting recognition of deferred collaborative research and development revenues from the amended and restated Pfizer agreement in June 2011 and the termination of a 2008 field of use license by Intrinsiq in July 2011. The Company reported a net loss of \$2.4 million, or \$0.12 per share, for the first quarter ended September 30, 2011, compared to a net loss of \$3.1 million, or \$0.17 per share, for the first quarter of the prior year.

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[®]. ILUVIEN[®] for the treatment of Diabetic Macular Edema (DME), which is licensed to Alimera Sciences Inc., is pSivida's most advanced product candidate and is currently under review by the U.S. Food and Drug Administration. An investigator-sponsored Investigational New Drug application opened for an injectable insert to treat posterior uveitis of the same design as ILUVIEN for DME, and an investigator-sponsored trial is ongoing for an injectable, bioerodible insert to treat glaucoma and ocular hypertension. pSivida's two FDA-approved products, Retisert[®] and Vitrasert[®], 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: ability to obtain additional capital if needed; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera's ability to obtain regulatory approval of ILUVIEN for DME; Alimera's ability to successfully commercialize ILUVIEN for DME if approved; risk/benefit profile of ILUVIEN for DME; timeliness of approval, if any, of ILUVIEN for DME and any limitations on uses thereof; ability to complete clinical trials, reference data and obtain regulatory approval of other product candidates; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others' intellectual property; 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 through exercise of outstanding warrants and stock options or future stock issuances; possible influence by Pfizer; ability to pay any registration penalties; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. 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.

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 September 30,	
	2011	2010
Revenues:		
Collaborative research and development	\$ 1,461	\$ 74
Royalty income	198	402
Total revenues	1,659	476
Operating expenses:		
Research and development	2,129	1,742
General and administrative	2,061	2,169
Total operating expenses	4,190	3,911
Loss from operations	(2,531)	(3,435)
Other income (expense):		
Change in fair value of derivatives	42	338
Interest income	9	6
Other expense, net	(2)	(8)
Total other income	49	336
Loss before income taxes	(2,482)	(3,099)
Income tax benefit (expense)	55	(9)
Net loss	\$ (2,427)	\$ (3,108)
Net loss per share:		
Basic and diluted	\$ (0.12)	\$ (0.17)
Weighted average common shares outstanding:		
Basic and diluted	20,757	18,531

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

	September 30, 2011	June 30, 2011
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 21,271	\$ 24,128
Other current assets	1,009	1,238
	<hr/>	<hr/>
Total current assets	22,280	25,366
Intangible assets, net	20,387	21,564
Other assets	473	183
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Total assets	\$ 43,140	\$ 47,113
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Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,356	\$ 1,650
Deferred revenue	2,509	3,212
Derivative liabilities	128	170
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Total current liabilities	3,993	5,032
Deferred revenue	3,915	4,635
Deferred tax liabilities	—	13
	<hr/>	<hr/>
Total liabilities	7,908	9,680
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Stockholders' equity:		
Capital	263,518	262,927
Accumulated deficit	(229,350)	(226,923)
Accumulated other comprehensive income	1,064	1,429
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Total stockholders' equity	35,232	37,433
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Total liabilities and stockholders' equity	\$ 43,140	\$ 47,113
	<hr/> <hr/>	<hr/> <hr/>