

# PSIVIDA CORP.

## **FORM 8-K** (Current report filing)

Filed 11/07/17 for the Period Ending 11/07/17

Address	480 PLEASANT STREET SUITE B300 WATERTOWN, MA, 02472
Telephone	617-926-5000
CIK	0001314102
Symbol	PSDV
SIC Code	3826 - Laboratory Analytical Instruments
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	06/30

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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, 2017**

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**pSivida Corp.**  
(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-51122**  
(Commission  
File Number)

**26-2774444**  
(I.R.S. Employer  
Identification No.)

**480 Pleasant Street, Watertown, MA 02472**  
(Address of Principal Executive Offices) (Zip Code)

**Registrant's telephone number, including area code: (617) 926-5000**

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

On November 7, 2017, pSivida Corp. issued a press release announcing its fiscal first quarter ended September 30, 2017 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:

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of pSivida Corp. dated November 7, 2017.</a>

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**SIGNATURES**

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.**

By: /s/ Nancy Lurker

Nancy Lurker

President and Chief Executive Officer

Date: November 7, 2017



**pSivida Corp. Builds Momentum During First Quarter FY18; Continues Operating Milestone Execution**

*NDA Filing for Durasert Three-year Treatment for Posterior Segment Uveitis Remains on Track  
for Late December 2017/Early January 2018*

*Conference Call and Webcast Today, November 7th, at 8:30 a.m. ET*

WATERTOWN, Mass., November 7, 2017 — pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug products and technologies, today reported financial results for its fiscal 2018 first quarter.

**Recent Operating Highlights**

- Following a pre-NDA meeting with the FDA for Durasert three-year uveitis, which resulted in no changes to our proposed clinical data package, we continue to execute plans to file an NDA in late December 2017/early January 2018.
- Entered into two collaboration agreements with global pharmaceutical companies to develop sustained release formulations of glaucoma drugs.
- Improved upon the existing collaboration agreement for ILUVIEN<sup>®</sup> to change the terms of the arrangement to a net sales-based royalty to pSivida, effective as of July 1, 2017.
- Commenced a GLP safety and pharmacokinetic (PK) study of a shorter-duration Durasert for posterior segment uveitis.

“We continued to build our operating momentum during the fiscal first quarter,” commented Nancy Lurker, President & CEO. “We signed two collaboration agreements with leading pharmaceutical companies that illustrate our ability to leverage our proven drug release technology to generate non-dilutive financing. We have a number of milestones over the next few months, primarily the NDA filing for posterior segment uveitis, which we continue to expect to file in late December 2017 or early January 2018. We await the data from the Phase 1 knee osteoarthritis (OA) trial and continue pre-clinical work on our shorter-duration Durasert.”

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## **Fiscal First Quarter Results**

Revenue for the first fiscal quarter ended September 30, 2017 totaled \$385,000 compared to \$277,000 for the prior year quarter. Operating expenses for the three months ended September 30, 2017 totaled \$6.4 million compared to \$7.5 million a year earlier. Net loss for the quarter ended September 30, 2017 was \$6.0 million, or \$0.15 per share, compared to a net loss of \$7.2 million, or \$0.21 per share, for the prior year quarter.

During the fiscal 2018 first quarter, the Company issued 843,784 shares of common stock for gross proceeds of approximately \$1.0 million through utilization of its existing at-the-market (ATM) equity offering program. At September 30, 2017, the Company's cash and cash equivalents totaled \$11.8 million. Subsequent to the first quarter, the Company has continued to strengthen its balance sheet by further utilizing the ATM program, issuing approximately 5.0 million additional shares of common stock for gross proceeds of approximately \$6.2 million.

### **Anticipated Near-Term Milestones:**

- File the Durasert three-year posterior segment uveitis NDA in the U.S. in late December 2017/early January 2018.
- Present clinical study data at leading medical conferences, including the American Academy of Ophthalmology (AAO) annual meeting.
- Report the initial 24-week data for the Phase 1 trial of knee osteoarthritis (OA).
- Finalize additional collaboration agreements with biopharmaceutical companies and other third parties.
- Successful completion of GLP safety and PK studies of a shorter-duration Durasert for posterior segment uveitis in the fourth quarter of calendar 2018.

### **Conference Call**

pSivida Corp. will host a live webcast and conference call today, November 7, 2017 at 8:30am 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 ID is 99811898. A live webcast will be available on the Investor Relations section of the corporate website at <http://www.psivida.com>.

A replay of the call will be available beginning November 7, 2017, at approximately 11:30 a.m. ET and ending on November 14, 2017, at 11:59 p.m. ET. 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: 99811898. A replay of the webcast will also be available on the corporate website during that time.

### **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 products for treating eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-

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eye diseases. The most recent, ILUVIEN<sup>®</sup>, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold directly in the U.S. and three EU countries. Retisert<sup>®</sup>, an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. pSivida's lead product candidate, Durasert<sup>™</sup> micro-insert for posterior segment uveitis, is being independently developed. Two pivotal Phase 3 studies with Durasert achieved their primary efficacy endpoint of prevention of recurrence of uveitis at six months of follow-up with statistical significance, and the Company plans to file an NDA by late December 2017/early January 2018. pSivida's pre-clinical development program is focused on using its core platform technology Durasert<sup>™</sup> to deliver drugs to treat wet age-related macular degeneration, glaucoma, osteoarthritis and other diseases. To learn more about pSivida, please visit [www.psivida.com](http://www.psivida.com) and connect on Twitter, LinkedIn, Facebook and Google+.

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 needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN<sup>®</sup> for diabetic macular edema ("DME"), which depends on Alimera's ability to continue as a going concern; Alimera's ability to obtain marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the number of clinical trials and data required for the Durasert three-year uveitis marketing approval application in the U.S.; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis NDA in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; our ability to successfully commercialize Durasert three-year uveitis, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; the development of our next-generation Durasert shorter-duration treatment for posterior segment uveitis; potential declines in Retisert<sup>®</sup> royalties; efficacy and our future development of an implant to treat severe osteoarthritis; 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, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; 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; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. 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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**Contact:**

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

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Revenues:</b>		
Collaborative research and development	\$ 140	\$ 34
Royalty income	245	243
Total revenues	<u>385</u>	<u>277</u>
<b>Operating expenses:</b>		
Research and development	3,819	4,178
General and administrative	2,572	3,285
Total operating expenses	<u>6,391</u>	<u>7,463</u>
Loss from operations	(6,006)	(7,186)
Interest and other income	23	24
Net loss	<u>\$ (5,983)</u>	<u>\$ (7,162)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.21)</u>
Weighted average common shares outstanding:		
Basic and diluted	<u>39,430</u>	<u>34,175</u>

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

	<u>September 30,</u> <u>2017</u>	<u>June 30,</u> <u>2016</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 11,833	\$ 16,898
Other current assets	714	842
Total current assets	<u>12,547</u>	<u>17,740</u>
Intangible assets, net	184	364
Other assets	596	573
<b>Total assets</b>	<u>\$ 13,327</u>	<u>\$ 18,677</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 4,269	\$ 5,240
Deferred revenue	10	50
Total current liabilities	<u>4,279</u>	<u>5,290</u>
Deferred rent	47	51
<b>Total liabilities</b>	<u>4,326</u>	<u>5,341</u>
<b>Stockholders' equity:</b>		
Capital	324,967	323,323
Accumulated deficit	(316,803)	(310,820)
Accumulated other comprehensive income	837	833
Total stockholders' equity	<u>9,001</u>	<u>13,336</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 13,327</u>	<u>\$ 18,677</u>