

# PSIVIDA CORP.

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

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Address	480 PLEASANT STREET SUITE B300 WATERTOWN, MA 02472
Telephone	617-926-5000
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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): February 7, 2017**

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**PSIVIDA CORP.**

(Exact Name of Registrant as Specified in Its Charter)

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

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

**26-2774444**  
(IRS Employer  
Identification No.)

**480 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)

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

On February 7, 2017, pSivida Corp. issued a press release announcing its second quarter fiscal year 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:

<u>No.</u>	<u>Description</u>
99.1	Press release of pSivida Corp. dated February 7, 2017.

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**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 7, 2017

By: /s/ Nancy Lurker  
Name: Nancy Lurker  
Title: President and CEO



## **pSivida Corp. Reports Fiscal 2017 Second Quarter and First Half Results**

*EU and U.S. 2017 Registration Filing Milestones for Durasert™ for Posterior Segment Uveitis Remain on Track*

*Conference Call and Webcast Today, February 7, at 4:30 p.m. ET*

WATERTOWN, Mass., February 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 2017 second quarter and first half ended December 31, 2016. In addition, the Company reported that it continues to expect to file a European Market Authorization Application (MAA) in the second quarter of calendar 2017 and a New Drug Application (NDA) in the U.S. in the second half of calendar 2017 for its Durasert three-year treatment for posterior segment uveitis.

“Our efforts begun in late September 2016 to reprioritize pSivida’s development program profile from a higher risk, longer term focus to one that is moderate risk and nearer term, are making progress towards achieving our objectives,” said Nancy Lurker, President and Chief Executive Officer. “In addition to our planned EU and U.S. registration filings this year for our Durasert three-year treatment for posterior segment uveitis, we are actively pursuing a partnership agreement to commercialize the product in the EU post approval.

“In the U.S., our second Phase 3 trial of Durasert three-year uveitis requested by the FDA completed enrollment and we continue to expect top line read out of this trial by the end of the second quarter of calendar 2017,” continued Ms. Lurker. “We remain optimistic that the second trial will provide positive results due to the robustness of the first trial and the similar trial design. Concurrently, the robustness of our Durasert technology has led us to embark on an aggressive strategy to pursue collaboration agreements with other drug manufacturers. A key corporate objective remains to enter into at least one such agreement during calendar 2017.”

### **Fiscal Second Quarter and First Half 2017 Results**

Revenue for the second fiscal quarter ended December 31, 2016 totaled \$6.0 million compared to \$526,000 for the prior year quarter. The year-over-year increase was primarily attributable to the recognition of deferred collaborative research and development revenue totaling \$5.6 million resulting from the termination of the Pfizer collaboration agreement

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reported on December 30, 2016. Operating expenses for the three months ended December 31, 2016 totaled \$6.1 million compared to \$5.8 million a year earlier. Net loss for the quarter ended December 31, 2016 was \$67,000, or break-even per share compared to a net loss of \$5.2 million, or \$0.18 per share, for the prior year quarter.

Revenue for the six months ended December 31, 2016 was \$6.2 million compared to \$1.0 million for the six months ended December 31, 2015. The year-over-year increase was primarily attributable to the \$5.6 million of revenue recognized upon termination of the Pfizer agreement. Operating expenses for the first six months of fiscal 2017 were \$13.5 million compared to \$11.2 million a year earlier. The increase was primarily attributable to (i) severance costs and professional fees related to the CEO transition and other previously disclosed executive team changes and (ii) regulatory consulting services related to preparation of MAA and NDA registration filings for Durasert three-year uveitis, partially offset by lower CRO costs for the Phase 3 clinical development of Durasert three-year uveitis. Net loss for the six months ended December 31, 2016 was \$7.2 million, or \$0.21 per share, compared to a net loss of \$10.1 million, or \$0.34 per share, for the corresponding fiscal 2016 year-to-date period.

At December 31, 2016, cash, cash equivalents and marketable securities totaled \$17.5 million.

### **Product Candidate Program Update & Anticipated Milestones**

***Durasert three-year treatment for posterior segment uveitis*** : The Company met its enrollment target in the second uveitis Phase 3 trial of 150 patients in September 2016. Readout of this second trial, which is required by the U.S. Food & Drug Administration for the Company's NDA filing, is currently expected by the end of the second calendar quarter of 2017. The first Phase 3 trial met its primary efficacy endpoint with a p value of  $< 0.001$  and safety data that are consistent with the known effect of ocular corticosteroid use. As previously disclosed on November 7, 2016, the Company was notified that protocol approval for a pediatric study would be required by the European regulatory authority prior to the acceptance of the application for market authorization. The Company is in discussions with the European regulatory authority on the final design of the pediatric study and expects to file the application in the second quarter of calendar 2017. The Company expects to file its NDA in the U.S. during the second half of calendar 2017.

***Next Generation Durasert bio-erodible shorter duration treatment for posterior segment uveitis and collaborations*** : Based on recently conducted market research, the Company believes the 6 month bio-erodible product candidate for uveitis with FA and for use with other small molecules through collaborations has the potential to provide enhanced benefits to patients and physicians by offering a shorter delivery time period and providing more flexibility to physicians with multiple Durasert dosing intervals. The Company has initiated and prioritized a development program for a next generation shorter acting bio-erodible Durasert for posterior segment uveitis. The Company is conducting formulation testing and expects to begin pre-clinical safety and PK studies of this product candidate in the second quarter of calendar 2017. The Company also will make this version of Durasert available for collaborations with other pharmaceutical companies to use with their small molecules.

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**Durasert implant for severe osteoarthritis (OA) of the knee:** In August 2016, the Hospital for Special Surgery (HSS) in New York, NY and pSivida announced the opening of an IND in support of an investigator-sponsored clinical trial of a Durasert implant to treat severe OA of the knee. To date five patients have received the implant and HSS expects to have the final patient implanted within the next month. The Company is in next-step discussions for this program.

**Durasert bio-erodible TKI for Wet AMD:** pSivida's TKI program is focused on developing a treatment for Wet AMD. The evaluations of additional TKIs are underway and the Company has identified multiple suitable TKI candidates for further formulation work. Pending the evaluation of TKI candidates, the Company intends to advance this program only through the development of a corporate partnership.

**Tethadur for large molecules:** The Tethadur program applies proprietary technology to achieve the sustained release of large molecules such as biologics through a silica-based technology. Pre-clinical activities on this program are continuing and the Company is implementing a strategy to pursue partnerships to advance the program's development.

### **Conference Call**

pSivida Corp. will host a live webcast and conference call today, February 7, 2017, at 4:30pm 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 56729898. The conference can also be accessed on the pSivida Corp. website at [www.psivida.com](http://www.psivida.com). A replay of the call will be available approximately two hours following the end of the call and can be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID number 56729898.

### **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 technologies for eye diseases. pSivida has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. The most recent, ILUVIEN<sup>®</sup>, a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold in the US 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 micro-insert for posterior segment uveitis being independently developed, is currently in pivotal Phase 3 clinical trials. pSivida's pre-clinical development program is focused on using its core platform technologies Durasert<sup>™</sup> and Tethadur<sup>™</sup> to deliver drugs and biologics to treat uveitis, wet and dry age-related macular degeneration, 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+](#).

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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; further impairment of our intangible assets; successful commercialization of, and receipt of revenues from, ILUVIEN<sup>®</sup> for diabetic macular edema (“ILUVIEN”), which depends on Alimera’s ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; safety and efficacy results of the second Durasert three-year uveitis Phase 3 clinical trial and the number of clinical trials and data required for the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; maintenance of European orphan designation for Durasert three-year uveitis; our ability to successfully commercialize Durasert three-year uveitis, if approved; the outcome of a dispute with Alimera regarding commercialization expenses; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetate side effects; potential declines in Retisert<sup>®</sup> royalties; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; 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; termination or breach of current license agreements; 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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**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,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Collaborative research and development	\$ 5,702	\$ 142	\$ 5,736	\$ 322
Royalty income	269	384	512	670
Total revenues	<u>5,971</u>	<u>526</u>	<u>6,248</u>	<u>992</u>
<b>Operating expenses:</b>				
Research and development	3,165	3,721	7,343	7,203
General and administrative	2,900	2,043	6,185	4,011
Total operating expenses	<u>6,065</u>	<u>5,764</u>	<u>13,528</u>	<u>11,214</u>
Loss from operations	(94)	(5,238)	(7,280)	(10,222)
Interest and other income	27	10	51	20
Loss before income taxes	(67)	(5,228)	(7,229)	(10,202)
Income tax benefit	—	42	—	83
Net loss	<u>\$ (67)</u>	<u>\$ (5,186)</u>	<u>\$ (7,229)</u>	<u>\$ (10,119)</u>
Net loss per common share:				
Basic and diluted	<u>\$ —</u>	<u>\$ (0.18)</u>	<u>\$ (0.21)</u>	<u>\$ (0.34)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>34,177</u>	<u>29,437</u>	<u>34,176</u>	<u>29,426</u>

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

	<u>December 31,</u> <u>2016</u>	<u>June 30,</u> <u>2016</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 17,532	\$ 28,992
Other current assets	1,003	971
Total current assets	<u>18,535</u>	<u>29,963</u>
Intangible assets, net	718	1,102
Other assets	493	554
<b>Total assets</b>	<u>\$ 19,746</u>	<u>\$ 31,619</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 4,791	\$ 4,946
Deferred revenue	136	147
Total current liabilities	<u>4,927</u>	<u>5,093</u>
Deferred revenue	—	5,585
Deferred rent	57	60
<b>Total liabilities</b>	<u>4,984</u>	<u>10,738</u>
<b>Stockholders' equity:</b>		
Capital	313,381	312,242
Accumulated deficit	(299,442)	(292,213)
Accumulated other comprehensive income	823	852
Total stockholders' equity	<u>14,762</u>	<u>20,881</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 19,746</u>	<u>\$ 31,619</u>