

PSIVIDA CORP.

FORM 8-K (Current report filing)

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Address	480 PLEASANT STREET SUITE B300 WATERTOWN, MA, 02472
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): September 11, 2017

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.)

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)

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.

Item 2.02. Results of Operations and Financial Condition.

On September 11, 2017, pSivida Corp. issued a press release announcing its fiscal fourth quarter and fiscal year ended June 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:

<u>No.</u>	<u>Description</u>
99.1	Press release of pSivida Corp. dated September 11, 2017.

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: September 11, 2017

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



pSivida Corp. Achieves Significant Milestones Throughout FY 2017; Reports Fourth Quarter and Fiscal 2017 Results

Executing Plan to File NDA for Durasert Three-year Treatment for Posterior Segment Uveitis

Conference Call and Webcast Today, September 11th, at 4:30 p.m. ET

WATERTOWN, Mass., September 11, 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 fourth quarter and full year ended June 30, 2017. The Company achieved several significant milestones during FY 2017 and has built operational, clinical and business development momentum entering FY 2018.

Recent Operating Highlights

- Reported that data from the second Phase 3 trial of Durasert™ three-year treatment for posterior segment uveitis achieved its primary endpoint. The results demonstrated a significant reduction in the recurrence of posterior segment uveitis through six months: 21.8% of Durasert-treated patients had a recurrence compared to 53.8% of patients in the sham group ($p < 0.001$).
- Successfully completed a pre-NDA meeting with the FDA for Durasert three-year uveitis that included FDA's agreement with pSivida's proposed overall clinical data package. The Company expects to file the NDA in late December or early January.
- Leading retina specialists presented data for the first Phase 3 trial of Durasert at recent medical conferences: the EURETINA Congress and annual meetings of the Association for Research in Vision and Ophthalmology (ARVO) and the American Society of Retinal Specialists (ASRS).
- Amended the existing collaboration agreement for ILUVIEN® to change the payment terms to a net sales royalty paid to pSivida, resulting in improved financial terms for the Company, and to grant regulatory and commercial rights to Durasert three-year uveitis in Europe, the Middle East and Africa (EMEA).
- Hospital for Special Surgery (HSS) completed enrollment in an investigator-sponsored Phase 1 study to evaluate safety and the effect on pain and function of a combination product including Durasert technology providing sustained delivery of dexamethasone for the management of osteoarthritic knees.

“We achieved all of our key objectives during fiscal 2017 and have made great strides towards becoming a fully integrated pharmaceutical company,” commented Nancy Lurker, President and Chief Executive Officer. “Consistent with our first Phase 3 clinical trial, our second Phase 3 study of Durasert three-year treatment in posterior segment uveitis achieved its primary efficacy endpoint, and we are implementing our plan to file an NDA with the FDA by late December or early January 2018. Based on the prior regulatory approvals for Durasert’s three sustained-release treatments for back-of-the-eye diseases utilizing the same core technology, we are optimistic about the regulatory review process for the product and continue to prepare for a direct commercialization effort in the U.S.”

Fiscal Fourth Quarter and Full Year 2017 Results

Revenue for the fourth fiscal quarter ended June 30, 2017 totaled \$701,000 compared to \$304,000 for the prior year quarter. Operating expenses totaled \$6.8 million for each of the three-month periods ended June 30, 2017 and 2016. Net loss for the quarter ended June 30, 2017 was \$6.1 million, or \$0.16 per share compared to a net loss of \$6.4 million, or \$0.19 per share, for the prior year quarter.

Revenue for the full year ended June 30, 2017 was \$7.5 million compared to \$1.6 million for the full year ended June 30, 2016. The year-over-year increase was primarily attributable to the \$5.6 million of revenue recognized (in the fiscal second quarter) upon termination of the Pfizer agreement. Net loss for the year ended June 30, 2017 was \$18.5 million, or \$0.52 per share compared to a net loss of \$21.5 million, or \$0.68 per share, for the corresponding fiscal year ended June 30, 2016.

During the fiscal 2017 fourth quarter, the Company issued approximately 3.7 million shares of common stock for gross proceeds of \$6.4 million through utilization of its existing at-the-market (ATM) equity offering program. At June 30, 2017, the Company’s cash and cash equivalents totaled \$16.9 million.

Anticipated FY2018 milestones:

- File Durasert three-year uveitis NDA in the U.S. in late December 2017/early January 2018.
- Announce 12-month read-out of Durasert three-year uveitis efficacy and safety results for the second Phase 3 clinical trial.
- Present clinical study data at leading medical conferences, including the American Academy of Ophthalmology (AAO) annual meeting.
- Progress Durasert shorter duration uveitis through submission-enabling pre-clinical studies.
- Finalize additional collaboration agreements with biopharmaceutical companies and other third parties.
- Report the initial 24-week data for the Phase 1 trial of knee osteoarthritis (OA).

Conference Call

pSivida Corp. will host a live webcast and conference call today, September 11th, 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 80833777. 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 September 11, 2017 at approximately 7:30 p.m. ET and ending on September 18, 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: 80833777. A replay of the webcast will also be available on the corporate website during that time.

About pSivida Corp .

pSivida Corp. (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-eye diseases. The most recent, ILUVIEN[®], a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold directly in the U.S. and three EU countries. Retisert[®], 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, 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[™] 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 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[®] for diabetic macular edema ("DME"), which depends on Alimera's ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the successful development and, if approved, commercialization of Durasert (under the ILUVIEN trademark) for posterior segment uveitis in Europe, the Middle East and Africa ("EMEA") by Alimera; 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.; 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; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; potential declines in Retisert[®] 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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PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended		Year Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenues:				
Collaborative research and development	\$ 461	\$ 26	\$ 6,569	\$ 398
Royalty income	240	278	970	1,222
Total revenues	<u>701</u>	<u>304</u>	<u>7,539</u>	<u>1,620</u>
Operating expenses:				
Research and development	4,213	4,104	14,880	14,381
General and administrative	2,624	2,656	11,235	9,013
Total operating expenses	<u>6,837</u>	<u>6,760</u>	<u>26,115</u>	<u>23,394</u>
Loss from operations	(6,136)	(6,456)	(18,576)	(21,774)
Interest and other income	20	31	91	72
Loss before income taxes	(6,116)	(6,425)	(18,485)	(21,702)
Income tax benefit	—	38	—	155
Net loss	<u>\$ (6,116)</u>	<u>\$ (6,387)</u>	<u>\$ (18,485)</u>	<u>\$ (21,547)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.19)</u>	<u>\$ (0.52)</u>	<u>\$ (0.68)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>38,673</u>	<u>34,152</u>	<u>35,344</u>	<u>31,623</u>

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

	<u>June 30,</u> <u>2017</u>	<u>June 30,</u> <u>2016</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 16,898	\$ 28,992
Other current assets	842	971
Total current assets	<u>17,740</u>	<u>29,963</u>
Intangible assets, net	364	1,102
Other assets	573	554
Total assets	<u>\$ 18,677</u>	<u>\$ 31,619</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,240	\$ 4,946
Deferred revenue	50	147
Total current liabilities	<u>5,290</u>	<u>5,093</u>
Deferred revenue	—	5,585
Deferred rent	51	60
Total liabilities	<u>5,341</u>	<u>10,738</u>
Stockholders' equity:		
Capital	323,323	312,242
Accumulated deficit	(310,820)	(292,213)
Accumulated other comprehensive income	833	852
Total stockholders' equity	<u>13,336</u>	<u>20,881</u>
Total liabilities and stockholders' equity	<u>\$ 18,677</u>	<u>\$ 31,619</u>