

# PSIVIDA CORP.

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

Filed 05/04/17 for the Period Ending 05/04/17

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

---

---

**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): May 4, 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 May 4, 2017, pSivida Corp. issued a press release announcing its third 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 8.01 Other Events.**

Set forth below is the relevant portion of the press release attached hereto as Exhibit 99.1 whereby pSivida Corp. addresses its planned Special Meeting of Stockholders (the “Special Meeting”), which pSivida Corp. expects to hold on Tuesday, June 27, 2017, at 10:00 am. (Eastern Daylight Time) at its Corporate Headquarters located at 480 Pleasant Street, Watertown, Massachusetts 02472.

“Because the Company’s shares are listed on the Australian Stock Exchange (the “ASX”), the Company’s ability to sell shares under the ATM Program is subject to an ASX rule limiting the number of shares the Company may issue to 15% in any 12-month period without shareholder approval, as well as other applicable rules and regulations of ASX. The effective and efficient use of the ATM has resulted in the Company having nearly reached its current ASX limit. Therefore, in order to have a variety of strategies available to meet the future capital resource needs required to achieve the Company’s growth objectives, a preliminary proxy statement has been filed for a special meeting of stockholders to seek approval to refresh the Company’s capacity to issue an additional 15% shares of common stock.”

**Important Additional Information**

In connection with the Special Meeting referenced above, pSivida Corp. will be filing a definitive proxy statement concerning the Special Meeting with the U.S. Securities and Exchange Commission. BEFORE MAKING ANY DECISION ON HOW TO VOTE AT THE SPECIAL MEETING, PSIVIDA CORP.’S STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. pSivida Corp.’s stockholders can obtain free copies of the definitive proxy statement and other documents when they become available by contacting pSivida Corp.’s Secretary, c/o pSivida Corp., 480 Pleasant Street, Watertown, MA 02472 United States. In addition, documents filed with the SEC will be available at no charge on the SEC’s website at [www.sec.gov](http://www.sec.gov). pSivida Corp. and its executive officers and directors may, under SEC rules, be deemed to be participants in the solicitation of proxies from its stockholders in connection with the Special Meeting. Certain information about such individuals, such as their ownership of shares of pSivida Corp. common stock and their interests in the solicitation with respect to the Special Meeting, will be more specifically set forth in the definitive proxy statement concerning the Special Meeting that will be filed with the SEC, which will be available free of charge from the SEC and pSivida Corp. as noted above.

**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 May 4, 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: May 4, 2017

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



**pSivida Corp. Reports Fiscal 2017 Third Quarter Results; Key Milestones on Track**

*EU and US Calendar 2017 Registration Filing Milestones for Durasert™ for Posterior Segment Uveitis Remain on Schedule*

*Conference Call and Webcast Today, May 4th, at 4:30 p.m. ET*

WATERTOWN, Mass., May 4, 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 third quarter and nine months ended March 31, 2017. The Company's progress during the third quarter has set the stage for the achievement of several near-term goals during the remainder of calendar 2017 including:

**Durasert™ Three-Year for Posterior Segment Uveitis:**

- Report top line results from the second pivotal Phase 3 clinical trial in June 2017.
- Submit the European Market Authorization Application (MAA) in June 2017.
- File an NDA in the U.S. during the fourth quarter of calendar 2017.
- Pre-clinical safety and PK studies of its next generation shorter acting Durasert for posterior segment uveitis remain on track to commence in the second quarter of calendar 2017.
- Present clinical study data at leading medical conferences, including the Association for Research in Vision and Ophthalmology (ARVO) annual meeting on May 8, 2017 and American Society of Retina Specialists (ASRS) annual meeting in August 2017.

**Other Durasert Related Developments:**

- Full enrollment for the Phase 1 knee osteoarthritis (OA) investigator-sponsored clinical trial was achieved with Hospital for Special Surgery (HSS). The Company expects HSS to report the initial 24-week data by the fourth quarter of calendar 2017.
- The Company entered into a funded feasibility study agreement with a leading biopharmaceutical company in March 2017. The Company expects to consummate one or more additional collaboration agreements in calendar 2017.

---

“We continue to make substantial regulatory, clinical and collaborative progress with our Durasert technology,” commented Nancy Lurker, President and Chief Executive Officer. “Our near-term goals remain: 1) unmask our second pivotal Phase 3 clinical trial for Durasert three-year uveitis and file regulatory approval applications in both the EU and US in calendar 2017, 2) establish additional collaboration partnerships for our proven Durasert technology, and 3) finalize an EU out-license partner for our three-year uveitis product candidate. Our efforts to date are yielding promising results and the successful achievement of these upcoming milestones will demonstrate the potential of our moderate risk/nearer term product development programs.”

### **Fiscal Third Quarter and Nine Months 2017 Results**

Revenue for the third fiscal quarter ended March 31, 2017 totaled \$590,000 compared to \$324,000 for the prior year quarter. Operating expenses for the three months ended March 31, 2017 totaled \$5.8 million compared to \$5.4 million a year earlier. Net loss for the quarter ended March 31, 2017 was \$5.1 million, or \$0.15 per share compared to a net loss of \$5.0 million, or \$0.15 per share, for the prior year quarter.

Revenue for the nine months ended March 31, 2017 was \$6.8 million compared to \$1.3 million for the nine months ended March 31, 2016. The year-over-year increase was primarily attributable to the \$5.6 million of revenue recognized upon termination of the Pfizer collaboration agreement. Operating expenses for the first nine months of fiscal 2017 were \$19.3 million compared to \$16.6 million a year earlier. The increase was attributable primarily to (i) severance costs and professional fees related to the CEO transition and other previously disclosed executive team changes and (ii) clinical and 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 nine months ended March 31, 2017 was \$12.4 million, or \$0.36 per share, compared to a net loss of \$15.2 million, or \$0.49 per share, for the corresponding fiscal 2016 year-to-date period.

During the fiscal 2017 third quarter, the Company issued 1,411,686 shares of common stock for gross proceeds of approximately \$2.5 million through utilization of its existing at-the-market equity offering program (the “ATM Program”). At March 31, 2017, the Company’s cash, cash equivalents and marketable securities totaled \$15.4 million. Subsequent to the end of the fiscal third quarter, the Company has continued to strengthen its balance sheet by further utilizing the ATM Program, issuing approximately 3.6 million additional shares of common stock for gross proceeds of approximately \$6.3 million.

Because the Company’s shares are listed on the Australian Stock Exchange (the “ASX”), the Company’s ability to sell shares under the ATM Program is subject to an ASX rule limiting the number of shares the Company may issue to 15% in any 12-month period without shareholder approval, as well as other applicable rules and regulations of ASX. The effective and efficient use of the ATM Program has resulted in the Company having nearly reached its current ASX limit. Therefore, in order to have a variety of strategies available to meet the future capital resource needs required to achieve the Company’s growth objectives, a preliminary proxy statement has been filed for a special meeting of stockholders to seek approval to refresh the Company’s capacity to issue an additional 15% shares of common stock.

---

## Conference Call

pSivida Corp. will host a live webcast and conference call today, May 4, 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 7711761. 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 May 4, 2017, at approximately 7:30 p.m. ET and ending on May 11, 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 7711761. 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-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 being independently developed by pSivida, is currently in pivotal Phase 3 clinical trials. 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+.

## Important Additional Information

In connection with the special meeting of stockholders referenced above, the Company will be filing a definitive proxy statement concerning the special meeting with the U.S. Securities and Exchange Commission. BEFORE MAKING ANY DECISION ON HOW TO VOTE AT THE SPECIAL MEETING, THE COMPANY'S STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. The Company's stockholders can obtain free copies of the definitive proxy statement and other documents when they become available by contacting the Company Secretary, c/o pSivida Corp., 480 Pleasant Street, Watertown, MA 02472 United States. In addition, documents filed with the SEC will be available at no charge on the SEC's website at [www.sec.gov](http://www.sec.gov). The Company and its executive officers and directors may, under SEC rules, be deemed to be participants in the solicitation of proxies from stockholders of the Company in connection with the special meeting. Certain information about such individuals, such as their ownership of shares of Company common stock and their interests in the solicitation with respect to the special meeting, will be more specifically set forth in the definitive proxy statement concerning the special meeting that will be filed with the SEC, which will be available free of charge from the SEC and the Company as noted above.

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<sup>™</sup> 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; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; potential declines in Retisert<sup>®</sup> royalties; our ability to develop Tethadur<sup>™</sup> 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.

**Contact:**

**EVC Group**

Michael Polyviou/Doug Sherk – Investors  
[mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com); [dsherk@evcgroup.com](mailto:dsherk@evcgroup.com)  
212.850.6020; 646-445-4800

Thomas Gibson – Media  
[tom@tomgibsoncommunications.com](mailto:tom@tomgibsoncommunications.com)  
201-476-0322

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

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2017	2016	2017	2016
<b>Revenues:</b>				
Collaborative research and development	\$ 372	\$ 50	\$ 6,108	\$ 372
Royalty income	218	274	730	944
Total revenues	<u>590</u>	<u>324</u>	<u>6,838</u>	<u>1,316</u>
<b>Operating expenses:</b>				
Research and development	3,324	3,074	10,667	10,277
General and administrative	2,426	2,346	8,611	6,357
Total operating expenses	<u>5,750</u>	<u>5,420</u>	<u>19,278</u>	<u>16,634</u>
Loss from operations	<u>(5,160)</u>	<u>(5,096)</u>	<u>(12,440)</u>	<u>(15,318)</u>
Interest and other income	20	21	71	41
Loss before income taxes	<u>(5,140)</u>	<u>(5,075)</u>	<u>(12,369)</u>	<u>(15,277)</u>
Income tax benefit	—	34	—	117
Net loss	<u>\$ (5,140)</u>	<u>\$ (5,041)</u>	<u>\$ (12,369)</u>	<u>\$ (15,160)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.15)</u>	<u>\$ (0.36)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>34,366</u>	<u>33,538</u>	<u>34,238</u>	<u>30,787</u>

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

	<u>March 31,</u> <u>2017</u>	<u>June 30,</u> <u>2016</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 15,370	\$ 28,992
Other current assets	1,100	971
Total current assets	<u>16,470</u>	<u>29,963</u>
Intangible assets, net	540	1,102
Other assets	495	554
<b>Total assets</b>	<u>\$ 17,505</u>	<u>\$ 31,619</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 4,684	\$ 4,946
Deferred revenue	256	147
Total current liabilities	<u>4,940</u>	<u>5,093</u>
Deferred revenue	—	5,585
Deferred rent	55	60
<b>Total liabilities</b>	<u>4,995</u>	<u>10,738</u>
<b>Stockholders' equity:</b>		
Capital	316,268	312,242
Accumulated deficit	(304,582)	(292,213)
Accumulated other comprehensive income	824	852
Total stockholders' equity	<u>12,510</u>	<u>20,881</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 17,505</u>	<u>\$ 31,619</u>