

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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SIC Code	3826 - Laboratory Analytical Instruments
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): February 7, 2018

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

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

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 February 7, 2018, pSivida Corp. issued a press release announcing its fiscal second quarter ended December 31, 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:

Exhibit No.	Description
99.1	Press release of pSivida Corp. dated February 7, 2018.

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: February 7, 2018



pSivida Corp. Reports Second Quarter FY2018 Results; Continues to Achieve Milestones and Timelines

Newly Released Second Phase 3 Study Data for Durasert Three-Year Treatment for Posterior Segment Uveitis Shows Positive Efficacy and Safety Profile Maintained at 12 Months

Awaiting FDA Decision to Accept NDA Submission for Review

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

WATERTOWN, Mass., February 7, 2018 — 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 second quarter and six months ended December 31, 2017 and provided an update on its continued operating progress.

Recent Operating Highlights

- Submitted the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Durasert™ three-year treatment for posterior segment uveitis
- Obtained from the FDA a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee of approximately \$2.4 million in connection with the NDA filing
- Newly released second Phase 3 study data for Durasert three-year treatment for posterior segment uveitis continued to demonstrate positive efficacy and safety profile at 12 months
- Presented Phase 3 data at several medical conferences, including the American Academy of Ophthalmology (AAO) annual meeting and the American Uveitis Society (AUS) winter meeting
- Reported positive Phase 1 knee osteoarthritis pain study data indicating that the implant was well tolerated and showed potential for pain reduction through the six-month study period

“We achieved several milestones in the fiscal second quarter and the past few weeks and continue to make material progress in the transformation of pSivida into a fully integrated commercial stage pharmaceutical enterprise,” commented Nancy Lurker, President & CEO. “Our highest priority was the NDA submission for Durasert three-year treatment for posterior segment uveitis, which we accomplished in early January. We are also pleased with the continued positive read out of our clinical uveitis data and look forward to presenting these data at upcoming congresses. Meanwhile, we will continue to refine our go-to-market plan in the U.S. and I am confident we have the experienced team and strategy to execute our launch plan with precision.”

Fiscal Second Quarter and Six-Month Results

Revenue for the second fiscal quarter ended December 31, 2017 totaled \$933,000 compared to \$6.0 million for the prior year quarter. The year-ago second quarter included the recognition of deferred collaborative research and development revenue totaling \$5.6 million resulting from termination of the Pfizer collaboration agreement. Excluding the Pfizer termination, revenue from feasibility study agreements and royalty income increased to \$933,000 for the three months ended December 31, 2017 compared to \$387,000 in the prior year quarter. Current period revenues included \$196,000 of royalty income received from Alimera Sciences, representing the first quarterly reporting under our July 2017 restructured collaboration agreement. Operating expenses for the three months ended December 31, 2017 increased to \$6.7 million from \$6.1 million a year earlier, due primarily to professional services costs associated with the NDA filing for Durasert three-year uveitis. Net loss for the quarter ended December 31, 2017 was \$5.8 million, or \$0.13 per share, compared to net loss of \$67,000, or break-even per share, for the prior year quarter.

Revenue for the six months ended December 31, 2017 was \$1.3 million compared to \$6.2 million for the six months ended December 31, 2016. Excluding the \$5.6 million revenue recognized in the prior year period upon termination of the Pfizer agreement, revenues from feasibility study agreements and royalty income increased to \$1.3 million for the six months ended December 31, 2017 compared to \$664,000 in the prior year six-month period. Operating expenses for the first six months of fiscal 2018 were \$13.1 million compared to \$13.5 million a year earlier. Higher professional services costs related to the Company's NDA filing were substantially offset by the absence in the current year-to-date period of severance costs and professional fees related to the Company's CEO transition and elimination of the position of Vice President, Corporate Affairs and General Counsel in the prior year-to-date period. Net loss for the six months ended December 31, 2017 was \$11.8 million, or \$0.28 per share, compared to a net loss of \$7.2 million, or \$0.21 per share for the corresponding fiscal 2017 year-to-date period.

At December 31, 2017, the Company's cash and cash equivalents totaled \$12.9 million.

Anticipated Calendar 2018 Milestones:

- FDA acceptance for review of the NDA for Durasert three-year treatment for posterior segment uveitis in calendar Q1
- Present 12-month efficacy and safety data from the second Phase 3 clinical study at leading medical conferences
- Continue business development efforts and enter into one or more new collaboration agreements with biopharmaceutical companies and other third parties
- Expect to complete the GLP safety and pharmacokinetic study for a shorter duration product for posterior segment uveitis

Conference Call

pSivida Corp. will host a live webcast and conference call today, February 7, 2018 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 8399835. 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 February 7, 2018, at approximately 7:30 p.m. ET and ending on February 14, 2018, 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: 8399835. 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 several EU countries. Retisert[®], an implant for posterior uveitis, is licensed to and sold by Bausch & Lomb. In January 2018, pSivida filed an NDA with the FDA for its lead product candidate, Durasert[™] micro-insert for posterior segment uveitis, which 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. 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; 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.; 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[®] royalties; efficacy and the 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		Six Months Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Revenues:				
Collaborative research and development	\$ 461	\$ 5,702	\$ 601	\$ 5,736
Royalty income	472	269	717	512
Total revenues	<u>933</u>	<u>5,971</u>	<u>1,318</u>	<u>6,248</u>
Operating expenses:				
Research and development	4,269	3,165	8,088	7,343
General and administrative	2,472	2,900	5,044	6,185
Total operating expenses	<u>6,741</u>	<u>6,065</u>	<u>13,132</u>	<u>13,528</u>
Loss from operations	(5,808)	(94)	(11,814)	(7,280)
Interest and other income	26	27	49	51
Net loss	<u>\$ (5,782)</u>	<u>\$ (67)</u>	<u>\$ (11,765)</u>	<u>\$ (7,229)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.13)</u>	<u>\$ —</u>	<u>\$ (0.28)</u>	<u>\$ (0.21)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>44,530</u>	<u>34,177</u>	<u>41,980</u>	<u>34,176</u>

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

	December 31, 2017	June 30, 2017
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 12,876	\$ 16,898
Other current assets	769	842
Total current assets	13,645	17,740
Intangible assets, net	—	364
Other assets	552	573
Total assets	\$ 14,197	\$ 18,677
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,745	\$ 5,240
Deferred revenue	505	50
Total current liabilities	4,250	5,290
Deferred rent	42	51
Total liabilities	4,292	5,341
Stockholders' equity:		
Capital	331,654	323,323
Accumulated deficit	(322,585)	(310,820)
Accumulated other comprehensive income	836	833
Total stockholders' equity	9,905	13,336
Total liabilities and stockholders' equity	\$ 14,197	\$ 18,677