

PSIVIDA CORP.

FORM 8-K (Current report filing)

Filed 12/20/16 for the Period Ending 12/19/16

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

**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): December 19, 2016

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
(Address of principal executive offices)

02472
(Zip Code)

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

(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))
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Item 8.01. Other Events.

On December 19, 2016, pSivida Corp. (the “Company”) distributed a letter to the Company’s investors email distribution list discussing its recent changes to the Company’s leadership team and its future plans for research, development and commercialization. A copy of the letter is attached as Exhibit 99.1 hereto.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995:

Various statements made in the letter are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that the Company intends, expects or believes 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 the Company’s forward-looking statements include uncertainties with respect to: the Company’s ability to obtain needed capital; the Company’s ability to achieve profitable operations; potential declines in Retisert royalties; fluctuations in the Company’s operating results; further impairment of the Company’s intangible assets; the Company’s ability to obtain marketing approvals for and successfully commercialize Durasert three-year uveitis for posterior segment uveitis; performance by CROs, vendors and investigators; timing of filing marketing approval applications for Durasert three-year uveitis; acceptability of data to be filed in support of Durasert three-year uveitis marketing applications; maintenance of European orphan designation for Durasert three-year uveitis; potential off-label sales of ILUVIEN for posterior segment uveitis; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; Alimera’s ability to continue as a going concern; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; outcome of dispute with Alimera on commercialization expenses; any exercise by Pfizer of its option with respect to the latanoprost product; the Company’s ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; efficacy and future development of severe OA implant by the Company; the Company’s ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; the Company’s ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; 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 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 the Company’s filings with the SEC. 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. The Company’s forward-looking statements speak only as of the dates on which they are made. The Company does not undertake any obligation to publicly update or revise its 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Letter to Stockholders dated December 19, 2016

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Document</u>
99.1	Letter to Stockholders dated December 19, 2016



December 19, 2016

To Our Shareholders:

As 2016 draws to a close, I want to provide you with an update on our progress at pSivida. Since I joined the Company in September of this year, I have undertaken a thorough review of the company's assets and how we are deploying our people, our technology and our capital. I am very pleased with the significant strength of our proven Durasert[®] sustained release drug technology and the scientific, regulatory and manufacturing team here at pSivida, along with the corporate and administrative staff. We have a talented group of people who are very committed to seeing our products brought to market for the benefit of patients as well as our shareholders. We recently have strengthened the team by the addition of Dr. Dario Paggiarino, our Chief Medical Officer, who joined in August, and Deb Jorn, a proven commercial and licensing executive who joined in November. Both Dario and Deb bring a wealth of experience from multiple biopharmaceutical companies to enhance the already talented group of people here at pSivida. Together, we are keenly focused on *executing* our operating plan and *delivering results*.

While we continue to develop our novel sustained release drug technologies, we are shifting the deployment of our efforts and capital more towards our proven Durasert technology for small molecules and with established drugs that are already approved by the regulatory authorities. This will allow us to take on less technology and regulatory risk, while potentially bringing products to market faster.

We currently have three programs that are well positioned to achieve multiple significant catalysts during 2017. In addition, a key objective for our team is to increase the number of partnered collaboration programs based on our unique technologies as the year progresses. A brief review of progress since our third quarter report and conference call with investors follows:

Our Durasert three-year treatment for posterior segment uveitis met its enrollment target in the second uveitis Phase 3 trial of 150 patients in September. We continue to expect to complete the readout from this second trial by mid-year 2017. The first Phase 3 study data was positive and highly statistically significant and will be used in our E.U. marketing authorization application, for which we continue to target a first half 2017 submission. Our team is actively pursuing a partnership to market the Durasert three-year treatment for posterior segment uveitis in Europe, and as developments merit we will update you on this key strategic

480 Pleasant Street
Suite B300
Watertown, MA 02472

Main: 617-926-5000
Fax: 617-926-5050
Web: www.psivida.com

commercial effort. At the same time, should our second Phase 3 trial also prove to have positive results, as we expect, we remain confident in our ability to file a New Drug Application (NDA) for this product to the U.S. Food & Drug Administration (FDA) during the second half of 2017.

In addition to the three-year Durasert treatment, we have begun a development program for a next generation Durasert bio-erodible shorter duration treatment for posterior segment uveitis. We continue to plan to begin pre-clinical safety and PK studies of this product candidate in the first half of 2017.

The Hospital for Special Surgery (HSS) and pSivida investigator-sponsored clinical study of a Durasert implant to treat severe Osteoarthritis (OA) of the knee continues. The implant is designed to provide long-term pain relief for this condition, which, if effective, could potentially result in the delay of knee replacement surgery. The study is an open-label, single dose, safety and tolerability study of the screw implant to deliver dexamethasone, a corticosteroid previously proven to provide pain relief in knee OA. To date, three patients have received the implant and full enrollment will be reported when achieved.

In addition, we are encouraged by the progress the team has made in identifying and pursuing additional collaborations with drug developers for our Durasert and potential Tethadur technologies and in out-licensing our EU rights for our Durasert Uveitis product. As developments get finalized, we will announce additional collaborations.

While we move to advance both the clinical and commercialization efforts of the company, we also have taken a hard look at our infrastructure and costs and have implemented actions designed to reduce administrative costs over the long term. At the same time, we are expanding our efforts to educate investors about our company, its progress and its potential. I've just finished a series of meetings last week in the Midwest and we are planning for a very full schedule during the JP Morgan Healthcare Conference in San Francisco January 9-11, 2017.

In summary, we are very excited about our potential to build value over the next year. Specifically, our goal is to achieve the following catalysts by this time next year:

- Submit E.U. marketing approval application for Durasert three-year treatment for posterior segment uveitis
- Enter into a strategic partnership to market the Durasert treatment for uveitis in Europe
- Announce results of our second Phase 3 clinical trial in posterior segment uveitis by mid year 2017
- Submit NDA to the U.S. FDA for Durasert three-year treatment for posterior segment uveitis in the second half of 2017
- Announce 24-week post-treatment results of HSS investigator-sponsored study of Durasert implant to treat severe OA
- Enter into additional collaborations with drug developers for our Durasert and potential Tethadur technologies





We look forward to reporting on our progress as details are finalized. If we can answer any questions, please contact our investor relations team at 212-850-6020 and thank you for your continued support of pSivida.

Best wishes for a healthy, happy holiday season,

Nancy Lurker
President & CEO

480 Pleasant Street
Suite B300
Watertown, MA 02472

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