PSIVIDA CORP.

FORM 8-K
(Current report filing)

Filed 06/22/17 for the Period Ending 06/22/17

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): June 22, 2017

PSIVIDA CORP.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**000-51122**	**26-2774444**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 8.01. Other Events.

On June 22, 2017, pSivida Corp. issued a press release announcing that the Company has submitted a Marketing Authorization Application to the European Medicines Agency, seeking approval to market the Company's Durasert three-year treatment for posterior segment uveitis in the European Union. A copy of the press release making such announcement is filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 22, 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: June 22, 2017

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

pSivida Submits Marketing Authorization Application (MAA) for Approval of Durasert ™ Three-year Treatment for Posterior Segment Uveitis in the European Union

WATERTOWN, Mass., June 22, 2017 — pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug products and technologies, has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), seeking approval to market the Company's Durasert three-year treatment for posterior segment uveitis in the European Union (EU).

"Our MAA submission is another significant milestone delivered on time by the pSivida team," commented Nancy Lurker, President and Chief Executive Officer. "Durasert three-year uveitis treatment, our lead product candidate, has now proven to be highly effective in reducing the recurrence of uveitis in two Phase 3 studies. Both studies illustrate the benefits Durasert brings to those patients suffering from this disease, which is a leading cause of blindness. As we await the review from the EU regulators, we continue to have advanced discussions with potential partners and are focused on entering into an out-licensing agreement for Durasert in the EU sometime this summer."

In each of pSivida's two Phase 3 trials for its Durasert three-year uveitis treatment, the primary efficacy endpoint was successfully achieved at six months with a p value <0.001. In addition, the safety profile of patients treated with Durasert three-year uveitis treatment was comparable to the safety profile of existing steroid uveitis treatments, which are considered standard of care for this disease.

Posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is believed to be a leading cause of blindness in the developed and developing countries. It affects people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S. and EU, posterior uveitis affects ~200,000 people, annually. Today, patients with posterior uveitis are typically treated with systemic steroids, but over time frequently develop serious side effects that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer.

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 being independently developed, is currently in pivotal Phase 3 clinical trials. 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; further impairment of our intangible assets; successful commercialization of, and receipt of revenues from, ILUVIEN ® 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; 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 ® 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.

Contact:

EVC Group

Michael Polyviou/Doug Sherk – Investors
mpolyviou@evcgroup.com ; dsherk@evcgroup.com
212.850.6020; 646-445-4800

Thomas Gibson – Media
tom@tomgibsoncommunications.com
201-476-0322