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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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 13, 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 13, 2017, pSivida Corp. issued a press release announcing that the Company's second Phase 3 clinical trial of Durasert three-year treatment for posterior segment uveitis achieved the trial's primary efficacy endpoint. A copy of the press release making such announcement is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 13, 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 13, 2017

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

Exhibit 99.1

pSivida's Durasert ™ Three-year Treatment for Posterior Segment Uveitis Successfully Achieves Primary Efficacy Endpoint in Second Phase 3 Study

Highly Significant Difference Observed Between Durasert and Control Group in Primary Efficacy Analysis of Prevention of Uveitis Recurrence

Conference Call Today at 4:30 p.m. ET

WATERTOWN, Mass., June 13, 2017 — pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug products and technologies, today announced the Company's second Phase 3 trial of Durasert three-year treatment for posterior segment uveitis achieved the trial's primary endpoint. The study involved 153 patients and the primary endpoint was prevention of recurrence of posterior uveitis at six months with patients continuing to be followed for 36 months. Durasert three-year insert 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 ($p<0.001$).

"The data from this trial confirms previous clinical research demonstrating our three-year Durasert insert for posterior segment uveitis may significantly help patients suffering from this devastating disease — the third leading cause of blindness', said Nancy Lurker, President and CEO of pSivida Corp. "Our market research indicates strong interest in using the product driven by the results of our first Phase 3 clinical trial. We continue to expect the submission of the European Market Authorization Application (MAA) by the end of June, and we remain on track to also file a New Drug Application (NDA) with the FDA in the calendar fourth quarter of 2017."

Additional safety results from the trial included:

- Intraocular pressure (IOP) elevation, which can lead to glaucoma, was 2.4 and 1.3 mm Hg (mean) at six months (vs baseline) for Durasert and sham, respectively.
- Patients requiring IOP-lowering therapy at any time during the first six months follow-up were 41.6% for Durasert and 34.6% for sham. No subject required IOP surgery during the first six months of follow-up.
- In patients with a natural (phakic) lens at baseline, 4.9% in the Durasert group required a cataract surgery through six months compared to 8.6% in the sham group.

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., posterior uveitis affects between 80,000 – 100,000 people. 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.

“The results of the second Phase 3 study confirm the efficacy and safety profile of the Durasert three-year insert demonstrated in the first Phase 3 study. Consistent, durable control of chronic posterior segment uveitis is a critical goal of treatment. The three-year Durasert insert has the potential to be the first product approved to help prevent the recurrence of this devastating condition for up to three years with a single intravitreal injection,” commented Dr. Jyotirmay Biswas, Professor of Ophthalmology and Director of Uveitis & Ocular Pathology Department, Sankara Nethralaya Ophthalmic Center, Tamil Nadu, India and primary investigator of the study.

“Chronic posterior uveitis is challenging to treat as the disease tends to wax and wane over time. Durasert three-year insert is a single-injection office-based treatment that can last 2-3 years. Therefore, it addresses the need to help prevent recurrences over an extended time period, rather than to treat them episodically, and may represent an exciting new approach to manage these patients,” added Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC and one of the world’s leading uveitis experts.

Conference Call Information

pSivida Corp. will host a live webcast and conference call today, June 13th, at 4:30pm ET. Company management will be joined by Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC. 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 36482967. A live webcast, with accompanying slides, will be available on the ‘Investors’ section of the corporate website at http://www.psivida.com, under ‘Resources’ and ‘Events and Presentations.’

A replay of the call will be available beginning June 13, 2017, at approximately 7:30pm ET and ending on June 20, 2017, at 11:59pm 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 36482967. 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 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; safety and efficacy results of the second Durasert 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® 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.

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