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PSIVIDA CORP.

FORM 8-K
(Current report filing)

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Telephone	617-926-5000
CIK	0001314102
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SIC Code	3826 - Laboratory Analytical Instruments
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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): March 19, 2018

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)*

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))

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 March 19, 2018, pSivida Corp. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted for review the Company's New Drug Application for Durasert three-year treatment for posterior segment uveitis. 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 March 19, 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.

Date: March 19, 2018

By: /s/ Nancy Lurker
Name: Nancy Lurker
Title: President and Chief Executive Officer

Exhibit 99.1

pSivida Announces FDA Acceptance For Filing of New Drug Application (NDA) for Durasert™ Three-Year Treatment for Posterior Segment Uveitis

WATERTOWN, Mass., March 19, 2018 (GLOBE NEWSWIRE) — pSivida Corp. (NASDAQ:PSDV) (ASX:PVA), a leader in the development of sustained release drug products and technologies, today announced that its New Drug Application (NDA) for Durasert three-year treatment for posterior segment uveitis has been accepted by the U.S. Food and Drug Administration (FDA) for filing. The acceptance of the NDA reflects the FDA's determination that the application is sufficiently complete to permit a substantive review. The application will be subject to a standard review and will have a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018. The PDUFA date is the goal date for the FDA to complete its review of the NDA.

The NDA includes data from two Phase 3 studies that each successfully achieved the primary efficacy endpoint at six months with a p value < 0.001. In addition, the safety profile in patients treated with Durasert three-year for posterior segment uveitis was consistent with the safety profile of steroid treatments that are currently considered standard of care for this disease.

"The FDA's acceptance for review of our Durasert NDA submission is a major milestone for pSivida and we look forward to continuing to work with the FDA as they review our application," commented Nancy Lurker, President and CEO. "Given the high unmet medical need, we believe that Durasert, if approved, has the potential to become an important new treatment option for the thousands of patients suffering from posterior segment uveitis, the third leading cause of blindness."

About Posterior Segment Uveitis

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 segment 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.

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 submitted a New Drug Application (NDA) to the U.S. FDA for its lead product candidate, Durasert™ micro-insert for posterior segment uveitis. The NDA has been accepted for filing and is currently under standard review with a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018. 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.; 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 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, 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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