PSIVIDA CORP.

FORM 8-K
(Current report filing)

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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): July 10, 2017

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

Delaware	000-51122	26-2774444
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 1.01. Entry into a Definitive Material Agreement.

On July 10, 2017, pSivida US, Inc. (the "Company"), a wholly owned subsidiary of pSivida Corp., entered into a Second Amended and Restated Collaboration Agreement (the "New Collaboration Agreement") with Alimera Sciences, Inc., ("Alimera"), which amended and restated the Amended and Restated Collaboration Agreement entered into between the parties on March 14, 2008 (as amended to date, the "Prior Collaboration Agreement").

Under the Prior Collaboration Agreement, the Company granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN ® for the treatment and prevention of human eye diseases other than uveitis. ILUVIEN is marketed in the United States and in certain countries in Europe for the treatment of diabetic macular edema ("DME"). Under the New Collaboration Agreement, in addition to the rights to ILUVIEN for the treatment of DME, we also granted Alimera rights to the Company's Durasert™ three-year treatment for posterior segment uveitis in Europe, the Middle East and Africa (the "EMEA"). The New Collaboration Agreement allows Alimera to pursue an indication for posterior segment uveitis for ILUVIEN ® in the EMEA. The Company retained commercialization rights for posterior segment uveitis in all other countries, including the United States. The New Collaboration Agreement also modified the parties' global licensing arrangement with respect to sales of ILUVIEN for the treatment of DME.

The New Collaboration Agreement converted the Prior Collaboration Agreement's profit sharing arrangement based on net profits from sales of ILUVIEN for the treatment of DME on a country-by-country basis to a tiered sales-based royalty arrangement based on global net revenues, effective July 1, 2017. Sales-based royalty payments to the Company start at 2% and increase to 6% upon the earliest of (i) January 1, 2019; (ii) Alimera's receipt of the first European Union country marketing approval for ILUVIEN for the treatment of posterior segment uveitis; and (iii) one year from Alimera's filing of a marketing authorization application in the European Union for posterior segment uveitis. The sales-based royalty payments will rise to 8% based on total ILUVIEN revenues in excess of $75 million in any calendar year.

In connection with the New Collaboration Agreement, Alimera forgave $10 million of the Company's share of previous losses associated with the commercialization of ILUVIEN (capped at $25 million under the New Collaboration Agreement), which were to be utilized to partially offset future profit sharing payments under the Prior Collaboration Agreement, and has the right to recover $15 million of such previous losses as a partial offset to future royalty payments. Alimera will forgive an additional $5 million of the remaining $15 million of the previous losses upon approval of ILUVIEN for posterior uveitis in any European Union country or January 1, 2020, whichever occurs first, unless certain conditions under the New Collaboration Agreement are not met. If the amounts recoverable by Alimera are less than $5 million at that time, Alimera will pay the Company the difference in cash.

In connection with entering into the New Collaboration Agreement, the Company will withdraw its marketing approval application and orphan drug designation for posterior segment uveitis in the European Union. Going forward, Alimera will be responsible for a number of due diligence and development obligations, including filing a Type II variation for ILUVIEN for the treatment of posterior segment uveitis in the 17 countries in the European Union where ILUVIEN is currently approved for the treatment of DME.

A copy of the New Collaboration Agreement will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2017. The foregoing description of the terms of the New Collaboration Agreement is qualified in its entirety by reference to the full text of such exhibit.

The press release announcing the entry into the New Collaboration Agreement is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 10, 2017.

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: July 10, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 10, 2017.

Exhibit 99.1

pSivida Out-licenses EMEA Rights for Durasert™ Three-year Treatment for Posterior Segment Uveitis While Retaining U.S. Commercial Rights; Amended Global Collaboration Agreement with Alimera for ILUVIEN ® Improves pSivida's Revenue Generation

WATERTOWN, MA., July 10, 2017 — pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug products and technologies, today announced an amendment of its exclusive license and collaboration agreement with Alimera Sciences, Inc. (NASDAQ: ALIM) that grants Alimera rights to pSivida's Durasert™ three-year treatment for posterior segment uveitis (Durasert) in Europe, the Middle East and Africa (EMEA). With this license, Alimera plans to pursue a secondary indication for ILUVIEN for posterior segment uveitis in EMEA, which could accelerate the uveitis indication approval as well as commercialization. pSivida retains commercialization rights for posterior segment uveitis in all other countries, including the United States. The amended agreement also modifies the companies' existing global licensing agreement for ILUVIEN for the treatment of diabetic macular edema (DME).

Key terms of the restructured global licensing agreement for ILUVIEN include:

- pSivida grants Alimera the rights to Durasert in EMEA under the ILUVIEN trademark in exchange for tiered sales-based royalty payments.
- Converts the existing profit share arrangement for the global ILUVIEN DME indication to the same tiered sales-based royalty payments as the uveitis indication effective July 1, 2017, and improves pSivida's revenue generation from DME indication sales.
- Sales-based royalty payments to pSivida start at 2% and increases to 6% upon the earliest of (i) Alimera's receipt of the first EU country marketing approval for ILUVIEN for the treatment of posterior segment uveitis; (ii) January 1, 2019 and (iii) one year from Alimera's filing of a marketing authorization application in the EU for posterior segment uveitis. The sales-based royalty payment will rise to 8% based on total ILUVIEN revenues in excess of $75 million in any calendar year.
- Under the previous agreement, pSivida's net profits were to be partially offset by accumulated net ILUVIEN commercialization losses. The balance of accumulated losses has now been capped at $25 million, of which $10 million is cancelled in exchange for granting Alimera license rights for posterior uveitis in EMEA. An additional $5 million will be cancelled based on certain milestones achieved by Alimera. The remaining $10 million of accumulated ILUVIEN commercialization losses is subject to a partial offset against sales-based royalty payments over time.

- pSivida will withdraw its EU marketing approval application (MAA) and orphan drug designation for posterior segment uveitis and Alimera will be responsible for filing a Type II variation for ILUVIEN for the treatment of posterior segment uveitis in the 17 countries in the EU where ILUVIEN is currently approved for the treatment of DME.

Benefits of the EMEA out-license and revised ILUVIEN agreement for pSivida include:

- Standardizes and improves revenue generation from the ILUVIEN global collaboration agreement and is expected to provide a more predictable and steady flow of revenue for pSivida.
- Management of EMEA regulatory filings and manufacturing is transferred to Alimera, thereby potentially accelerating the uveitis indication approval and commercialization timing.
- Leverages Alimera's established EMEA ILUVIEN field force with retinal specialists.
- Reduces pSivida's financial outlays for European regulatory and manufacturing matters, allowing pSivida to focus resources on the New Drug Application (NDA) with the US Food and Drug Administration (FDA) and commercialization readiness efforts for Durasert for posterior segment uveitis in the US.

"Today's announcement fulfills a core pSivida objective to out-license Durasert EMEA rights as a means to optimize product value," said Nancy Lurker, President and CEO of pSivida. "We believe the EMEA out-license to Alimera, a company that is familiar with the complexity of the EU reimbursement environment and is currently marketing to target specialty physicians, could accelerate commercialization uptake and revenue realization for pSivida. The EMEA revenue opportunity for Durasert is estimated to be $30 to $50 million, and in the US it is estimated to be $80 to $120 million. We remain on track to file an NDA with the FDA by the end of this year. In parallel, the restructured global collaboration agreement benefits our shareholders as we immediately begin to recognize royalty income from sales of ILUVIEN as well as increase its long-term revenue opportunity."

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 approximately 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, Inc. 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 Inc. pSivida's lead product candidate, Durasert™ micro-insert for posterior segment uveitis is being independently developed. Two pivotal Phase 3 clinical trials achieved their primary efficacy endpoint 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; 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.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; ours and Alimera's ability to successfully commercialize Durasert three-year uveitis, if approved; consequences of fluocinolone acetonide side effects; 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 agreements with Alimera; termination or breach of current license agreements, including our agreements 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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