
**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): October 28, 2020

Aerie Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36152
(Commission
File Number)

20-3109565
(I.R.S. Employer
Identification Number)

**4301 Emperor Boulevard, Suite 400
Durham, North Carolina 27703**
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (919) 237-5300

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Shares of common stock, par value \$0.001 per share	AERI	Nasdaq Global Market

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 Material Definitive Agreement.

On October 28, 2020, Aerie Pharmaceuticals Ireland, Ltd. (“Aerie”), a subsidiary of Aerie Pharmaceuticals, Inc. (the “Company”), entered into a Collaboration and License Agreement (the “Agreement”) with Santen Pharmaceutical Co., Ltd (“Santen”). Pursuant to the Agreement, Aerie granted to Santen the exclusive right to develop, manufacture, market and commercialize Rhopressa® and Rocklatan® (the “Licensed Products”) in Japan, South Korea, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam and Taiwan (such jurisdictions collectively, the “Territories”). Aerie is the sole manufacturer of the Licensed Products for Santen. Under the Agreement, Aerie granted Santen a first right of negotiation for the rights to the Licensed Products in any Asian countries other than the Territories.

Under the Agreement, Santen must pay Aerie an upfront payment of \$50.0 million (“Upfront Payment”) and various development milestones of up to \$39.0 million and sales milestones of up to \$60.0 million. In addition, Santen will pay Aerie a royalty in excess of 25% of the Licensed Products’ net sales, such consideration consisting of the cost of products supplied to Santen from Aerie and a royalty for Aerie’s intellectual property. Santen will be responsible for sales, marketing and pricing decisions relating to the Licensed Products. Santen is also responsible for all development and commercialization costs and activities related to the Licensed Products in the Territories, except that Aerie shares 50% of the costs related to conducting the first Rhopressa® Phase 3 clinical trial in Japan.

The term of the Agreement continues on a country-by-country basis in the Territory until the later of (i) the expiration of the last to expire valid patent claim covering the Licensed Products and (ii) 12 years from the date of the first commercial sale of each Licensed Product under an NDA approval, marketing authorization or the equivalent. The Agreement may be terminated by either Aerie or Santen upon the other party’s material breach or bankruptcy or insolvency. Aerie may also terminate the Agreement upon a patent challenge by Santen, and Santen may terminate the Agreement in its discretion if, following marketing authorization for Rhopressa® in Japan, Santen reasonably determines that the Licensed Products are not commercially viable in the Territory (effective upon 180 days’ prior written notice). In addition, in the event that patents are issued that may prevent the commercialization of the Licensed Products, Santen would have the right to terminate the Agreement and require Aerie’s repayment of up to approximately 85% of the Upfront Payment, all development milestone payments, and 50% of the development expenses incurred by Santen. In the event of termination, the Licensed Products in the applicable Territories will revert to Aerie.

The above description of the Agreement is a summary only and is subject to, and qualified entirely by, the Agreement, which the Company intends to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2020.

Item 7.01. Regulation FD Disclosure.

On October 28, 2020, the Company issued a press release announcing the signing of a collaboration and license agreement with Santen. A copy of this press release is furnished as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 7.01.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Item 7.01 is not intended to, and does not, constitute a determination or admission by the Company that this information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1 [Press release, dated October 28, 2020.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

AERIE PHARMACEUTICALS, INC.

Date: October 28, 2020

By: /s/ Richard J. Rubino
Richard J. Rubino
Chief Financial Officer



**Santen and Aerie Conclude Exclusive License Agreement
for Rhopressa® and Rocklatan® in Japan and Several Other Asian Countries**

Osaka, Japan and Durham, NC, October 28th, 2020 – Santen Pharmaceutical Co., Ltd. (“Santen”) and Aerie Pharmaceuticals, Inc. (NASDAQ: AERI, “Aerie”) announced that Santen and Aerie have entered into an exclusive development and commercialization agreement for Rhopressa® and Rocklatan® in Japan, along with rights for several other Asian countries.

Aerie is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, ocular surface diseases and retinal diseases. Rhopressa® (netarsudil ophthalmic solution) 0.02% and Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% are approved and being sold in the United States by Aerie. Preparations for the first Phase 3 study in Japan for Rhopressa® are ongoing and the study is expected to commence before the end of 2020.

“In the treatment of glaucoma, where the number of glaucoma patients continues to increase and unmet medical needs remain, we are excited to see an increase in our product lineup and the opportunity to offer patients new treatment options,” said Shigeo Taniuchi, President and CEO of Santen. “Santen and Aerie both aim to further contribute to the treatment of glaucoma patients through these products, by taking advantage of Santen’s sales platform and relationships with local ophthalmologists in Japan and other Asian countries.”

“We are delighted to partner with Santen, which is a leading global ophthalmology company and the largest in Japan. We believe that Santen has unparalleled capabilities to develop and commercialize our glaucoma products and to enhance the treatment options for patients with glaucoma or ocular hypertension, an about \$1 billion market in Japan and East Asia. We look forward to a successful collaboration with Santen,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Under the terms of the agreement, Aerie will receive an upfront payment of \$50 million, and various development and sales milestones of up to \$99 million. Aerie is also eligible to receive additional consideration in excess of 25% of the products’ net sales, such consideration consisting of the cost of products supplied to Santen from Aerie and a royalty for Aerie’s intellectual property. Santen will be responsible for sales, marketing and pricing decisions relating to the products. Santen will also be responsible for all development and commercialization costs and activities related to the products in the territories covered by the agreement, however, Aerie and Santen will collaborate for the first Phase 3 study for Rhopressa® in Japan. In addition to customary termination rights for both parties, in the event that patents are issued that may prevent the commercialization of the products, Santen would have the right to terminate the agreement and require Aerie’s repayment of a portion of the upfront payment, all development milestone payments, and a portion of the development expenses incurred by Santen.

About Glaucoma

Glaucoma is a disorder which causes optic nerve damage leading to visual field loss and is a major cause of visual impairment including decreased vision and blindness in many countries, especially in Japan and several other Asian countries. Since glaucomatous optic nerve damage and visual field defects are generally progressive and irreversible, early detection and treatment for controlling progression of damage is crucial in the treatment of glaucoma.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website (www.santen.com).

Santen Forward-Looking Statements

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

About Aerie

Aerie is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, ocular surface diseases and retinal diseases. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eye drop approved by the U.S. Food and Drug Administration (FDA) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, was launched in the United States in April 2018. In clinical trials of Rhopressa®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie's second product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, Rocklatan® (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, the first and only fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, was approved by the FDA and was launched in the United States in the second quarter of 2019. In clinical trials of Rocklatan®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan®, including the product label, is available at www.rocklatan.com. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for dry eye, wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

Aerie Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “exploring,” “pursuing” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this release include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the duration and severity of the coronavirus disease (COVID-19) outbreak, including the impact on our clinical and commercial operations, demand for our products, our financial results and condition and our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any current or future product candidates, including the timing, cost or other aspects of their commercial launch; our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa® and Rocklatan®, with respect to regulatory approval outside of the United States, and any current or future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current or future product candidates; the timing of and our ability to request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, as applicable, Rhopressa®, Rocklatan® or any current or future product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, Rhopressa®, Rocklatan® or any current or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any current or future product candidates; our plans to pursue development of additional product candidates and technologies; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma, including development of our retina program; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, statements in this press release regarding our license agreement with Santen, and payments related thereto, are forward-looking statements. In addition, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including EMA approval of Roclanda®. Additionally, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our current or any future product candidates, and there can be no assurance that we will receive FDA approval for our current or any future product candidates. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, industry change and other factors beyond our control, and depend on regulatory approvals and economic and other environmental circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We discuss many of these risks in greater detail under the heading “Risk Factors” in the quarterly and annual reports that we file with the Securities and Exchange Commission (SEC). Forward-looking statements are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contacts

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