
**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): November 6, 2018

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))

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 2.02. Results of Operations and Financial Condition.

On November 6, 2018, Aerie Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 2018. A copy of the press release is furnished as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 2.02.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

[99.1](#) [Press Release dated November 6, 2018.](#)

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated November 6, 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.

AERIE PHARMACEUTICALS, INC.

Date: November 6, 2018

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

Aerie Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Business Update

Conference Call and Webcast Today, November 6th, at 5:00 p.m. ET

Durham, N.C. -- ([BUSINESS WIRE](#)) -- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), 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, retina diseases and other diseases of the eye, today reported financial results for the third quarter ended September 30, 2018, along with a general business update.

Aerie Highlights

- Rhopressa[®] (netarsudil ophthalmic solution) 0.02% generated third quarter net revenues on a U.S. GAAP (generally accepted accounting principles) basis of \$7.3 million, representing \$122 per bottle.
 - As of October 1, 2018, Rhopressa[®] market access increased to approximately 85% of commercial lives, including 45% in Tier 3 and 40% in preferred brand Tier 2, and Medicare Part D Tier 2 coverage increased to approximately 40% of Medicare Part D lives.
 - Roclatan[™] (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% has been renamed Rocklatan[™] in the U.S., with the PDUFA (Prescription Drug User Fee Act) date set for March 14, 2019.
 - Topline results reported in August 2018 provide clinical confirmation of the effect of Rhopressa[®] on trabecular meshwork outflow facility in patients with open-angle glaucoma or ocular hypertension, indicating a statistically significant increase in trabecular outflow facility of approximately 35% over baseline.
 - In early October 2018, the European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application (MAA) for Rhokiinsa[®] (netarsudil ophthalmic solution) 0.02%, marketed as Rhopressa[®] in the United States. Aerie expects an opinion regarding approval in the second half of 2019.
 - Additional international expansion activities are progressing with the ongoing Rocklatan[™] Mercury 3 Phase 3 clinical trial in Europe, and the expected expansion into Japan with an additional Rhopressa[®] Phase 2 clinical trial in preparation for potential regulatory submission in Japan, along with the establishment of an Aerie office in Tokyo.
 - Aerie's retina program continues to advance, with preclinical candidates AR-13503 (Rho kinase and Protein kinase C inhibitor implant) and AR-1105 (dexamethasone steroid implant) expected to enter the clinic in 2019, and the expansion of our agreement with DSM opens new opportunities for further advancement of Aerie's sustained release ophthalmic pipeline.
 - Cash burn for the nine months ended September 30, 2018 totaled approximately \$163 million, with \$236.0 million in cash, cash equivalents and investments as of September 30, 2018. Results for third-quarter 2018 include \$24.1 million in non-cash expense associated with the conversion of the entire outstanding principal amount of the \$125 million in convertible notes, recorded in other income (expense), and \$6.0 million in cash expense recorded in research and development expense from the DSM collaboration agreement, both of which took place in July 2018. Shares outstanding at quarter-end totaled 45,451,227.
 - Aerie reiterated that it expects full year 2018 Rhopressa[®] net revenues in the range of \$20 million to \$30 million, on a U.S. GAAP basis, and adjusted the total projected 2018 cash burn from the previous range of \$200 million to \$210 million to a revised \$210 million to \$215 million, which includes the \$6.0 million payment to DSM in July 2018.
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“Having just returned from the American Academy of Ophthalmology Annual Meeting in Chicago, we remain delighted with the level of physician interest in Rhopressa[®] and how they are characterizing product performance in their practices. The launch has been proceeding very well and based on our increased market access coverage and ongoing volume growth, we are reiterating our 2018 net sales guidance in the range of \$20 million to \$30 million. We also continue to observe a very high level of interest in the potential for Rocklatan[™], if approved, and we continue to refine our Rocklatan[™] launch plans,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. “Along with our international expansion activities, we are also very excited about our plans to bring our two sustained-release retina product candidates into the clinic in 2019.”

Third Quarter 2018 Financial Results

As of September 30, 2018, Aerie had cash, cash equivalents and investments of \$236.0 million. For the third quarter ended September 30, 2018, Aerie reported net product revenues of \$7.3 million related to sales of Rhopressa[®], which was launched in the United States on April 30, 2018. The Company reported a GAAP net loss of \$85.4 million, or \$1.96 loss per share, for the third quarter of 2018, compared to a net loss of \$32.4 million and \$0.89 loss per share for the third quarter of 2017. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 43,657,423 and 36,210,329 for the third quarters of 2018 and 2017, respectively. Total shares outstanding as of September 30, 2018 were 45,451,227.

The \$85.4 million net loss for the third quarter of 2018 is primarily comprised of \$68.4 million in total operating expenses, reflecting \$28.5 million in research and development expenses including a \$6.0 million payment to DSM, and \$39.9 million in selling, general and administrative expenses. Excluding \$10.0 million of stock-based compensation expense, adjusted total operating expenses for the third quarter of 2018 were \$58.5 million, with adjusted research and development expenses of \$25.9 million and adjusted selling, general and administrative expenses of \$32.6 million. Total adjusted net loss for the third quarter of 2018 was \$75.4 million, and adjusted net loss per share was \$1.73, and includes \$24.1 million of other expense related to the conversion of our 2014 Convertible Notes in July 2018.

The \$32.4 million net loss for the third quarter of 2017 is primarily comprised of \$32.2 million in total operating expenses, including \$12.4 million in research and development expenses and \$19.8 million in selling, general and administrative expenses. Excluding \$6.6 million of stock-based compensation expense, adjusted total operating expenses for the third quarter of 2017 were \$25.6 million, with adjusted research and development expenses of \$10.8 million and adjusted selling, general and administrative expenses of \$14.8 million. Total adjusted net loss for the third quarter of 2017 was \$25.8 million, and adjusted net loss per share was \$0.71.

The higher operating expenses in the third quarter of 2018 as compared to the third quarter of 2017 primarily reflect increased activities associated with the expansion of our employee base to support the growth of our operations, and activities associated with our Rhopressa[®] commercialization efforts.

Conference Call / Webcast Information

Aerie management will host a live conference call and webcast at 5:00 p.m. Eastern Time today to discuss Aerie’s financial results and provide a general business update.

The live webcast and a replay may be accessed by visiting the Company's website at <http://investors.aeriepharma.com>. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (888) 734-0328 (U.S.) or (678) 894-3054 (international) to listen to the live conference call. The conference ID number for the live call is 9894007. Please dial in approximately 10 minutes prior to the call. Telephone replay will be available approximately two hours after the call. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-

3406 (international). The conference ID number for the replay is 9894007. The telephone replay will be available until November 14, 2018.

About Aerie Pharmaceuticals, Inc.

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, retina diseases and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eyedrop 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, cornea verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie's advanced-stage product candidate, Rocklatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, a fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, achieved its 3-month primary efficacy endpoint in two Phase 3 registration trials, Mercury 1 and Mercury 2, and also showed safety and efficacy throughout 12 months in Mercury 1. Aerie submitted the Rocklatan™ New Drug Application (NDA) in May 2018 and, in July 2018, the FDA set the PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the Rocklatan™ NDA for March 14, 2019. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

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 include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding the commercialization and manufacturing of Rhopressa® and Rocklatan™ or any future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan™ or any future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa®, with respect to regulatory approval outside of the United States or additional indications, and Rocklatan™ or any future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our guidance for full year 2018; our estimates regarding expected net revenues, expected cash burn, anticipated capital requirements and our needs for additional financing; our expectations related to the use of proceeds from our equity and debt financings and credit facility; our expectations regarding the effectiveness of Rhopressa®, Rocklatan™ or any future product candidates and results of our clinical trials; 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® and Rocklatan™ or any future product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, Rhopressa® and Rocklatan™ or any future product candidates; the potential advantages of Rhopressa® and Rocklatan™ or any future product candidates; our plans to pursue development of additional product candidates and technologies within and beyond ophthalmology, including development of Rhopressa® and Rocklatan™ for additional indications and other therapeutic opportunities; 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. 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 circum

stances 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). In particular, FDA approval of Rhopressa® does not constitute FDA approval of Rocklatan™, and there can be no assurance that we will receive FDA approval for Rocklatan™ or any future product candidates. FDA approval of Rhopressa® also does not constitute regulatory approval of Rhopressa® in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® in jurisdictions outside the United States. Our receipt of a Prescription Drug User Fee Act (PDUFA) goal date notification for Rocklatan™ does not constitute FDA approval of the Rocklatan™ New Drug Application (NDA), and there can be no assurance that the FDA will complete its review by the PDUFA goal date of March 14, 2019, that the FDA will not require changes or additional data that must be made or received before it will approve the NDA, if ever, or that the FDA will approve the NDA. In addition, the preclinical research discussed in this press release is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later clinical trials. Any future clinical trials may not demonstrate safety and efficacy sufficient to obtain regulatory approval related to the preclinical research findings discussed in this press release, and we may suspend or discontinue research programs at any time for any reason. 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.

Non-GAAP Financial Measures

To supplement our financial statements, which are prepared and presented in accordance with GAAP, we use the following non-GAAP financial measures, some of which are discussed above: adjusted net loss, adjusted total operating expenses, adjusted research and development expenses, adjusted selling, general and administrative expenses, and adjusted net loss per share. For reconciliations of non-GAAP measures to the most directly comparable GAAP measures, please see the “Reconciliation of GAAP to Non-GAAP Financial Measures” and “Reconciliation of GAAP Net Loss Per Share to Adjusted Net Loss Per Share” tables in this press release.

We believe these non-GAAP financial measures provide investors with useful supplemental information about the financial performance of our business, enable comparison of financial results between periods where certain items may vary independent of business performance, and allow for greater transparency with respect to key metrics used by management in operating our business.

The presentation of these financial measures is not intended to be considered in isolation from, or as a substitute for, financial information prepared and presented in accordance with GAAP. Investors are cautioned that there are material limitations associated with the use of non-GAAP financial measures as an analytical tool. In particular, the adjustments to our GAAP financial measures reflect the exclusion of stock-based compensation expense, which is recurring and will be reflected in our financial results for the foreseeable future. In addition, these measures may be different from non-GAAP financial measures used by other companies, limiting their usefulness for comparison purposes. We compensate for these limitations by providing specific information regarding the GAAP amounts excluded from these non-GAAP financial measures.

AERIE PHARMACEUTICALS, INC.
Consolidated Balance Sheets
(Unaudited)
(in thousands)

	SEPTEMBER 30, 2018	DECEMBER 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$ 234,954	\$ 197,569
Short-term investments	1,000	52,086
Accounts receivable, net	1,961	—
Inventory	5,612	—
Prepaid expenses and other current assets	3,290	4,487
Total current assets	246,817	254,142
Property, plant and equipment, net	58,360	31,932
Other assets	4,017	4,202
Total assets	\$ 309,194	\$ 290,276
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 7,066	\$ 6,245
Accrued expenses and other current liabilities	27,948	18,939
Total current liabilities	35,014	25,184
Convertible notes, net	—	123,845
Other non-current liabilities	5,598	5,648
Total liabilities	40,612	154,677
Stockholders' equity		
Common stock	45	37
Additional paid-in capital	913,499	597,318
Accumulated other comprehensive loss	(1)	(28)
Accumulated deficit	(644,961)	(461,728)
Total stockholders' equity	268,582	135,599
Total liabilities and stockholders' equity	\$ 309,194	\$ 290,276

AERIE PHARMACEUTICALS, INC.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017	2018	2017
Product revenues, net	\$ 7,302	\$ —	\$ 9,725	\$ —
Total revenues, net	7,302	—	9,725	—
Costs and expenses:				
Cost of goods sold	205	—	264	—
Selling, general and administrative	39,933	19,774	107,647	51,402
Research and development	28,502	12,408	59,631	33,977
Total costs and expenses	68,640	32,182	167,542	85,379
Loss from operations	(61,338)	(32,182)	(157,817)	(85,379)
Other income (expense), net	(24,050)	(141)	(23,291)	(1,071)
Loss before income taxes	(85,388)	(32,323)	(181,108)	(86,450)
Income tax expense	—	49	3	142
Net loss	\$ (85,388)	\$ (32,372)	\$ (181,111)	\$ (86,592)
Net loss per common share—basic and diluted	\$ (1.96)	\$ (0.89)	\$ (4.47)	\$ (2.48)
Weighted average number of common shares outstanding—basic and diluted	43,657,423	36,210,329	40,505,534	34,932,551

AERIE PHARMACEUTICALS, INC.
Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited)
(in thousands)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017	2018	2017
Net loss (GAAP)	\$ (85,388)	\$ (32,372)	\$ (181,111)	\$ (86,592)
Add-back: stock-based compensation expense	9,978	6,557	29,015	18,072
Adjusted Net loss	<u>\$ (75,410)</u>	<u>\$ (25,815)</u>	<u>\$ (152,096)</u>	<u>\$ (68,520)</u>
Selling, general and administrative expenses (GAAP)	\$ 39,933	\$ 19,774	\$ 107,647	\$ 51,402
Less: stock-based compensation expense	(7,382)	(4,995)	(21,826)	(14,032)
Adjusted selling, general and administrative expenses	<u>\$ 32,551</u>	<u>\$ 14,779</u>	<u>\$ 85,821</u>	<u>\$ 37,370</u>
Research and development expenses (GAAP)	\$ 28,502	\$ 12,408	\$ 59,631	\$ 33,977
Less: stock-based compensation expense	(2,596)	(1,562)	(7,189)	(4,040)
Adjusted research and development expenses	<u>\$ 25,906</u>	<u>\$ 10,846</u>	<u>\$ 52,442</u>	<u>\$ 29,937</u>
Total operating expenses (GAAP)	\$ 68,435	\$ 32,182	\$ 167,278	\$ 85,379
Less: stock-based compensation expense	(9,978)	(6,557)	(29,015)	(18,072)
Adjusted total operating expenses	<u>\$ 58,457</u>	<u>\$ 25,625</u>	<u>\$ 138,263</u>	<u>\$ 67,307</u>

AERIE PHARMACEUTICALS, INC.
Reconciliation of GAAP Net Loss Per Share to Adjusted Net Loss Per Share
(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2017	2018	2017
Net loss per common share—basic and diluted (GAAP)	\$ (1.96)	\$ (0.89)	\$ (4.47)	\$ (2.48)
Add-back: stock-based compensation expense	0.23	0.18	0.72	0.52
Adjusted Net loss per share—basic and diluted	<u>\$ (1.73)</u>	<u>\$ (0.71)</u>	<u>\$ (3.75)</u>	<u>\$ (1.96)</u>
Weighted average number of common shares outstanding—basic and diluted	<u>43,657,423</u>	<u>36,210,329</u>	<u>40,505,534</u>	<u>34,932,551</u>

Contacts

Aerie Pharmaceuticals

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