
**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): February 25, 2019

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 (*see* General Instruction A.2. below):

- 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 February 25, 2019, Aerie Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2018, along with its 2019 cash burn guidance and a general business update. 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 February 25, 2019.](#)

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated February 25, 2019.

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: 2/25/2019

By: /s/ Richard J. Rubino

Richard J. Rubino

Chief Financial Officer

Aerie Pharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results, Provides 2019 Cash Burn Guidance and Business Update

Conference Call and Webcast Today, February 25th, 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, retinal diseases and other diseases of the eye, today reported financial results for the fourth quarter and full year ended December 31, 2018, along with 2019 cash burn guidance and a general business update.

Aerie Highlights

- Rhopressa[®] (netarsudil ophthalmic solution) 0.02% generated fourth quarter net revenues on a U.S. GAAP (generally accepted accounting principles) basis of \$14.5 million, representing \$129.53 per bottle. For full-year 2018, net revenues totaled \$24.2 million, in line with previous guidance, representing \$127.77 per bottle. Year-end 2018 wholesaler inventory levels remained consistent with the end of the third-quarter 2018, at approximately two weeks of demand.
 - At the time of this press release, Rhopressa[®] market access increased to approximately 90% of commercial lives, including 55% in preferred brand Tier 2 and 35% in Tier 3, and Medicare Part D Tier 2 coverage currently represents approximately 40% of Medicare Part D lives. We expect Medicare Part D Tier 2 equivalent coverage to increase to well over 70% within the next few weeks. As we gain more utilization from covered lives, particularly in Medicare Part D, we expect our net revenue per bottle to ultimately decline to approximately \$100 during 2019.
 - The Rocklatan[™] (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% PDUFA (Prescription Drug User Fee Act) date remains set for March 14, 2019 and the related training of our sales force is well underway.
 - International expansion activities are progressing with the ongoing Rocklatan[™] Mercury 3 Phase 3 clinical trial in Europe, and expansion into Japan with the Rhopressa[®] Phase 2 clinical trial commencing in March 2019 in preparation for potential regulatory submission in Japan.
 - Aerie's retina program continues to advance, with preclinical candidate AR-1105 (dexamethasone steroid implant) clinical trials expected to begin in March 2019 for RVO (retinal vein occlusion). The IND (Investigational New Drug application) for AR-13503 (Rho kinase and Protein kinase C inhibitor implant) is expected to be filed with the FDA (the U.S. Food and Drug Administration) in March 2019, and, if accepted, we expect to begin clinical trials in the second quarter of 2019 for wet age-related macular degeneration and DME (diabetic macular edema).
 - Cash burn for the year ended December 31, 2018 totaled approximately \$215.5 million, consistent with previous guidance, resulting in \$202.8 million in cash and cash equivalents as of December 31, 2018. In addition, we have the \$100 million undrawn credit facility available, bringing total liquidity to over \$300 million. Shares outstanding at December 31, 2018 totaled 45.5 million.
 - Guidance for 2019 full-year cash burn is consistent with full-year 2018 actual results, in the range of \$210 million to \$220 million.
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We plan to communicate full-year 2019 net revenue guidance following the completion of the FDA's review of the NDA (New Drug Application) for Rocklatan™.

“We are delighted to have achieved the revenue guidance that we announced a full year ago, well before Rhopressa® launched in the United States. With Rhopressa® net sales having doubled from third-quarter to fourth-quarter 2018, and our significant progress in gaining market access, we are confident in the continued meaningful growth prospects for this very well-received product. Since we are just two weeks away from the Rocklatan™ PDUFA date, we will communicate full-year 2019 net revenue guidance after the FDA completes its review of Rocklatan™. As we continue to successfully build our glaucoma franchise in the United States, we are making excellent progress in expanding this franchise to Europe and Japan, which have the potential to be very large markets for us. Further, our retina program is proceeding very quickly, and we believe our unique sustained-release implant product candidates and technologies create a highly innovative and leverageable platform to potentially drive the next generation of treatments in the very large retinal disease market,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

“We are entering 2019 very well financed, with over \$300 million in available liquidity, and have no current intention of raising additional equity capital to fund our ongoing operations. Also, our receivable collections have been quite strong, and as we progress through 2019 this will become an increasingly important source of cash for us, further bolstering our liquidity.”

Fourth Quarter 2018 Financial Results

As of December 31, 2018, Aerie had cash and cash equivalents of \$202.8 million and available borrowing capacity of \$100 million through its undrawn credit facility. For the fourth quarter ended December 31, 2018, Aerie reported a GAAP net loss of \$51.5 million, or \$1.14 loss per share, compared to a net loss of \$58.5 million and \$1.60 loss per share for the fourth quarter of 2017. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 45,101,458 and 36,487,669 for the fourth quarters of 2018 and 2017, respectively. Total shares outstanding as of December 31, 2018 were 45,478,883.

The \$51.5 million net loss for the fourth quarter of 2018 is comprised of \$14.1 million of gross profit, and \$66.0 million in total operating expenses, including \$31.9 million in selling, general and administrative expenses, \$7.6 million in pre-approval commercial manufacturing expenses and \$26.5 million in research and development expenses. Excluding \$9.7 million of stock-based compensation expense, adjusted total operating expenses for the fourth quarter of 2018 were \$56.3 million, with adjusted selling, general and administrative expenses of \$25.5 million, adjusted pre-approval commercial manufacturing expenses of \$6.8 million and adjusted research and development expenses of \$24.0 million. Total adjusted net loss for the fourth quarter of 2018 was \$41.7 million, and adjusted net loss per share was \$0.92.

The \$58.5 million net loss for the fourth quarter of 2017, a period in which no gross profit was reported, is comprised of \$60.3 million in total operating expenses, including \$38.1 million in research and development expenses, which reflects \$24.8 million of expense resulting from the acquisition of assets from Envisia Therapeutics Inc. in the fourth quarter of 2017, \$18.5 million in selling, general and administrative expenses and \$3.7 million in pre-approval commercial manufacturing expenses. Excluding \$8.0 million of stock-based compensation expense, adjusted total operating expenses for the fourth quarter of 2017 were \$52.3 million, with adjusted research and development expenses of \$36.0 million, adjusted selling, general and administrative expenses of \$13.0 million and adjusted pre-approval commercial manufacturing expenses of \$3.3 million. Total adjusted net loss for the fourth quarter of 2017 was \$50.5 million, and adjusted net loss per share was \$1.38.

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 7633869. 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 7633869. The telephone replay will be available until March 5, 2019.

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, retinal 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, corneal 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, such as statements in this press release regarding any expected clinical trials for AR-1105 or AR-13503 and results of such clinical trials; our cash burn guidance for full-year 2019; 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[®], 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[®], 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; 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 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). 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[™], AR-1105, AR-13503 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 acceptance of the IND discussed in this press release does not constitute FDA approval of AR-1105 and the outcome of later clinical trials for AR-1105 may not be sufficient to submit an NDA with the FDA or to receive FDA approval. The expected filing of the IND for AR-13503 discussed in this press release does not constitute FDA acceptance of the IND or FDA approval of AR-13503 and the outcome of later clinical trials may not be sufficient to submit an NDA with the FDA or receive FDA approval. 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, adjusted pre-approval commercial manufacturing 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)

	DECEMBER 31,	
	2018	2017
Assets		
Current assets		
Cash and cash equivalents	\$ 202,818	\$ 197,569
Short-term investments	—	52,086
Accounts receivable, net	2,715	—
Inventory	10,112	—
Prepaid expenses and other current assets	4,530	4,487
Total current assets	220,175	254,142
Property, plant and equipment, net	60,525	31,932
Other assets	4,344	4,202
Total assets	\$ 285,044	\$ 290,276
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 12,403	\$ 6,245
Accrued expenses and other current liabilities	38,381	18,939
Total current liabilities	50,784	25,184
Convertible notes, net	—	123,845
Other non-current liabilities	6,454	5,648
Total liabilities	57,238	154,677
Stockholders' equity		
Common stock	45	37
Additional paid-in capital	924,180	597,318
Accumulated other comprehensive loss	—	(28)
Accumulated deficit	(696,419)	(461,728)
Total stockholders' equity	227,806	135,599
Total liabilities and stockholders' equity	\$ 285,044	\$ 290,276

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2018	2017	2018	2017
Product revenues, net	\$ 14,456	\$ —	\$ 24,181	\$ —
Total revenues, net	14,456	—	24,181	—
Costs and expenses:				
Cost of goods sold	377	—	641	—
Selling, general and administrative	31,887	18,471	120,614	56,905
Pre-approval commercial manufacturing	7,625	3,742	26,545	16,710
Research and development	26,492	38,101	86,123	72,078
Total costs and expenses	66,381	60,314	233,923	145,693
Loss from operations	(51,925)	(60,314)	(209,742)	(145,693)
Other income (expense), net	467	(99)	(22,824)	(1,170)
Loss before income taxes	(51,458)	(60,413)	(232,566)	(146,863)
Income tax expense (benefit)	—	(1,900)	3	(1,758)
Net loss	\$ (51,458)	\$ (58,513)	\$ (232,569)	\$ (145,105)
Net loss per common share—basic and diluted	\$ (1.14)	\$ (1.60)	\$ (5.58)	\$ (4.11)
Weighted average number of common shares outstanding—basic and diluted	45,101,458	36,487,669	41,663,958	35,324,472

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2018	2017	2018	2017
Net loss (GAAP)	\$ (51,458)	\$ (58,513)	\$ (232,569)	\$ (145,105)
Add-back: stock-based compensation expense	9,713	8,006	38,728	26,078
Adjusted Net loss	<u>\$ (41,745)</u>	<u>\$ (50,507)</u>	<u>\$ (193,841)</u>	<u>\$ (119,027)</u>
Selling, general and administrative expenses (GAAP)	\$ 31,887	\$ 18,471	\$ 120,614	\$ 56,905
Less: stock-based compensation expense	(6,410)	(5,458)	(26,432)	(18,613)
Adjusted selling, general and administrative expenses	<u>\$ 25,477</u>	<u>\$ 13,013</u>	<u>\$ 94,182</u>	<u>\$ 38,292</u>
Pre-approval commercial manufacturing expenses (GAAP)	\$ 7,625	\$ 3,742	\$ 26,545	\$ 16,710
Less: stock-based compensation expense	(818)	(482)	(2,622)	(1,359)
Adjusted pre-approval commercial manufacturing expenses	<u>\$ 6,807</u>	<u>\$ 3,260</u>	<u>\$ 23,923</u>	<u>\$ 15,351</u>
Research and development expenses (GAAP)	\$ 26,492	\$ 38,101	\$ 86,123	\$ 72,078
Less: stock-based compensation expense	(2,485)	(2,066)	(9,674)	(6,106)
Adjusted research and development expenses	<u>\$ 24,007</u>	<u>\$ 36,035</u>	<u>\$ 76,449</u>	<u>\$ 65,972</u>
Total operating expenses (GAAP)	\$ 66,004	\$ 60,314	\$ 233,282	\$ 145,693
Less: stock-based compensation expense	(9,713)	(8,006)	(38,728)	(26,078)
Adjusted total operating expenses	<u>\$ 56,291</u>	<u>\$ 52,308</u>	<u>\$ 194,554</u>	<u>\$ 119,615</u>

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2018	2017	2018	2017
Net loss per common share—basic and diluted (GAAP)	\$ (1.14)	\$ (1.60)	\$ (5.58)	\$ (4.11)
Add-back: stock-based compensation expense	0.22	0.22	0.93	0.74
Adjusted Net loss per share—basic and diluted	<u>\$ (0.92)</u>	<u>\$ (1.38)</u>	<u>\$ (4.65)</u>	<u>\$ (3.37)</u>
Weighted average number of common shares outstanding—basic and diluted	<u>45,101,458</u>	<u>36,487,669</u>	<u>41,663,958</u>	<u>35,324,472</u>

Contacts

Aerie Pharmaceuticals

Media: Tad Heitmann 949-526-8747; theitmann@aeriepharma.com

Investors: Ami Bavishi 908-947-3949; abavishi@aeriepharma.com