

AERIE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 08/01/17 for the Period Ending 08/01/17

Address	7020 KIT CREEK ROAD SUITE 270 RESEARCH TRIANGLE PARK, NC 27709
Telephone	919-313-9650
CIK	0001337553
Symbol	AERI
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): August 1, 2017

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)

**2030 Main Street, Suite 1500
Irvine, California 92614**
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (949) 526-8700

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 August 1, 2017, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2017. 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 August 1, 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.

AERIE PHARMACEUTICALS, INC.

Date: August 1, 2017

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

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated August 1, 2017.

Aerie Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Business Update

Conference Call and Webcast Today, August 1st, at 5:00 p.m. ET

IRVINE, California -- ([BUSINESS WIRE](#)) -- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), a clinical-stage pharmaceutical company focused on the discovery, development, and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye, today reported financial results for the second quarter ended June 30, 2017, along with a general business update.

Aerie Highlights

- Phase 3 clinical trials required for approval in the U.S. for both Rhopressa™ (netarsudil ophthalmic solution) 0.02%, and Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, are now successfully completed.
- All programs remain on track, with the goal date of February 28, 2018 set for the Rhopressa™ FDA (U.S. Food and Drug Administration) PDUFA (Prescription Drug User Fee Act), and the Company's submission of the Roclatan™ New Drug Application (NDA) anticipated in the first half of 2018.
- Initial scientific introductory meetings on Rhopressa™ have been held with many major U.S. payors.
- Mercury 3, the Roclatan™ Phase 3 clinical trial to be conducted in Europe for European markets, is set to commence in the third quarter of 2017.
- Recently announced collaboration with DSM is focused on the potential of sustained delivery of Aerie compounds to treat retinal diseases, unlocking a new pipeline opportunity.
- As of June 30, 2017, Aerie had \$307.9 million in cash, cash equivalents and investments. Cash burn for the first half of 2017 totaled \$48.4 million. Cash burn for the year ending December 31, 2017 is expected to be in the range of \$100 million to \$110 million.

“This has been a highly productive period for Aerie, and we are actively engaged in all facets of commercialization preparation as we look to make our Rhopressa™ launch as successful as possible, upon approval. For our Roclatan™ program, we also recently completed the Mercury 1 12-month study, and we look forward to the upcoming commencement of the Mercury 3 trial in Europe. Our recent agreement with DSM also continues our journey into treating retinal disease, and we are very excited about the potential of this early program as well,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido continued, “We ended the second quarter with the highest cash, cash equivalents and investments balance in Aerie history, and are well-financed as we continue to build a major ophthalmic pharmaceutical company.”

Second Quarter 2017 Financial Results

As of June 30, 2017, Aerie had cash, cash equivalents and investments of \$307.9 million. For the second quarter ended June 30, 2017, Aerie reported a net loss, as measured in accordance with accounting principles generally accepted in the United States (GAAP), of \$28.4 million, or \$0.82 per share, compared to \$23.2 million and \$0.87 per share for the second quarter of 2016. The weighted average number of shares of common stock outstanding utilized in the calculation of net loss per common share was 34,783,195 and 26,773,337 for the second quarters of 2017 and 2016, respectively. Total shares outstanding as of June 30, 2017, were 36,337,542.

The \$28.4 million net loss for the second quarter of 2017 includes \$27.8 million in total operating expenses, including \$10.6 million in research and development expenses and \$17.2 million in selling, general and administrative expenses. Excluding \$6.7 million of non-cash stock-based compensation expense, adjusted total operating expenses for the second quarter of 2017 were \$21.1 million, with adjusted research and development expenses of \$9.2 million and adjusted selling, general and administrative expenses of \$11.9 million. Total adjusted net loss for the second quarter of 2017 was \$21.8 million, and adjusted net loss per share was \$0.63.

The \$23.2 million net loss for the second quarter of 2016 includes \$22.7 million in total operating expenses, including \$13.3 million in research and development expenses and \$9.4 million in selling, general and administrative expenses. Excluding \$3.9 million of non-cash stock-based compensation expense, adjusted total operating expenses for the second quarter of 2016 were approximately \$18.8 million, with adjusted research and development expenses of \$12.5 million and adjusted selling, general and administrative expenses of \$6.3 million. Total adjusted net loss for the second quarter of 2016 was \$19.3 million, and adjusted net loss per share was \$0.72.

The higher operating expenses in the second quarter of 2017 as compared to the second quarter 2016 primarily reflect increased activities associated with the expansion of our employee base to support the growth of our operations, and preparatory activities associated with our commercialization efforts, including commercial manufacturing for Rhopressa™.

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 51660946. 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 51660946. The telephone replay will be available until August 8, 2017.

About Aerie Pharmaceuticals, Inc.

Aerie is a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye. Aerie's two current product candidates are once-daily intraocular pressure lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA (new drug application) for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was submitted to the U.S. Food and Drug Administration (FDA) in February 2017, and, in May 2017, the FDA set the PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the Rhopressa™ NDA for February 28, 2018. Aerie's second product candidate, Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, which is a fixed dose combination of Rhopressa™ and widely prescribed PGA latanoprost, achieved its primary efficacy endpoint in two Phase 3 registration trials, named Mercury 1 and Mercury 2, and also achieved successful 12-month safety and efficacy results in Mercury 1. The Roclatan™ NDA submission is expected to take place in the first half of 2018. Aerie is also focused on the development of additional product candidates and technologies in ophthalmology.

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: the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our current and potential future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the clinical effectiveness of our 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, our product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for our product candidates; our expectations regarding the commercialization and manufacturing of our product candidates; our expectations related to the use of proceeds from our equity and debt financings; our estimates regarding expected cash burn, anticipated capital requirements and our needs for additional financing; the potential advantages of additional product candidates; our plans to pursue development of our product candidates and technologies in ophthalmology, including development of our product candidates for additional indications and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma; 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 or 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, the receipt of the PDUFA goal date notification does not constitute FDA approval of the Rhopressa™ NDA, and there can be no assurance that the FDA will complete its review by the PDUFA goal date, that the FDA will not require changes or additional data, whether as a result of recommendations, if any, made by any FDA advisory committee or otherwise, that must be made or received before it will approve the NDA, if ever, or that the FDA will approve the

NDA. 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 expense, adjusted selling, general and administrative expense, and adjusted net loss per common share. For a description of the adjusted calculations and reconciliations to the nearest 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 non-cash 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)

	JUNE 30, 2017	DECEMBER 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$ 242,650	\$ 197,945
Short-term investments	65,269	35,717
Prepaid expenses and other current assets	2,057	4,028
Total current assets	309,976	237,690
Property, plant and equipment, net	14,391	7,857
Other assets	2,617	2,707
Total assets	\$ 326,984	\$ 248,254
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities	\$ 13,265	\$ 18,820
Interest payable	545	551
Total current liabilities	13,810	19,371
Convertible notes, net	123,692	123,539
Other non-current liabilities	4,440	—
Total liabilities	141,942	142,910
Stockholders' equity		
Common stock	36	33
Additional paid-in capital	555,930	422,002
Accumulated other comprehensive loss	(81)	(68)
Accumulated deficit	(370,843)	(316,623)
Total stockholders' equity	185,042	105,344
Total liabilities and stockholders' equity	\$ 326,984	\$ 248,254

AERIE PHARMACEUTICALS, INC.**Consolidated Statements of Operations****(Unaudited)**

(in thousands, except share and per share data)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30,		JUNE 30,	
	2017	2016	2017	2016
Operating expenses:				
Selling, general and administrative	\$ 17,153	\$ 9,386	\$ 31,628	\$ 19,187
Research and development	10,615	13,304	21,569	25,613
Total operating expenses	27,768	22,690	53,197	44,800
Loss from operations	(27,768)	(22,690)	(53,197)	(44,800)
Other income (expense), net	(618)	(482)	(930)	(1,030)
Net loss before income taxes	(28,386)	(23,172)	(54,127)	(45,830)
Income tax expense	47	47	93	93
Net loss	\$ (28,433)	\$ (23,219)	\$ (54,220)	\$ (45,923)
Net loss per common share—basic and diluted	\$ (0.82)	\$ (0.87)	\$ (1.58)	\$ (1.72)
Weighted average number of common shares outstanding—basic and diluted	34,783,195	26,773,337	34,283,073	26,748,301

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2017	2016	2017	2016
GAAP Net loss	\$ (28,433)	\$ (23,219)	\$ (54,220)	\$ (45,923)
Non-cash stock-based compensation	6,665	3,881	11,515	7,415
Adjusted Net loss	<u>\$ (21,768)</u>	<u>\$ (19,338)</u>	<u>\$ (42,705)</u>	<u>\$ (38,508)</u>
Selling, general and administrative expense (GAAP)	\$ 17,153	\$ 9,386	\$ 31,628	\$ 19,187
Non-cash stock-based compensation	5,251	3,067	9,037	5,889
Adjusted selling, general and administrative expense	<u>\$ 11,902</u>	<u>\$ 6,319</u>	<u>\$ 22,591</u>	<u>\$ 13,298</u>
Research and development expense (GAAP)	\$ 10,615	\$ 13,304	\$ 21,569	\$ 25,613
Non-cash stock-based compensation	1,414	814	2,478	1,526
Adjusted research and development expense	<u>\$ 9,201</u>	<u>\$ 12,490</u>	<u>\$ 19,091</u>	<u>\$ 24,087</u>
Total operating expenses (GAAP)	\$ 27,768	\$ 22,690	\$ 53,197	\$ 44,800
Non-cash stock-based compensation	6,665	3,881	11,515	7,415
Adjusted total operating expenses	<u>\$ 21,103</u>	<u>\$ 18,809</u>	<u>\$ 41,682</u>	<u>\$ 37,385</u>

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2017	2016	2017	2016
Net loss per common share – basic and diluted (GAAP)	\$ (0.82)	\$ (0.87)	\$ (1.58)	\$ (1.72)
Non-cash stock-based compensation	0.19	0.15	0.34	0.28
Adjusted Net loss per share – basic and diluted	<u>\$ (0.63)</u>	<u>\$ (0.72)</u>	<u>\$ (1.24)</u>	<u>\$ (1.44)</u>
Weighted average number of common shares outstanding – basic and diluted	<u>34,783,195</u>	<u>26,773,337</u>	<u>34,283,073</u>	<u>26,748,301</u>

Contacts

Aerie Pharmaceuticals
Richard Rubino, 908-947-3540
rrubino@aeriepharma.com

or

Burns McClellan, Inc., on behalf of Aerie Pharmaceuticals
Ami Bavishi, 212-213-0006
abavishi@burnsmc.com