
**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): May 5, 2021

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
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 2.02. Results of Operations and Financial Condition.

On May 5, 2021, Aerie Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2021, along with 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.

Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 [Press Release dated May 5, 2021](#)
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.

May 5, 2021

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

Aerie Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Business Update

First Quarter 2021 Net Revenue Per Bottle of \$89, up 11.3% over Fourth Quarter 2020

First Quarter 2021 Net Revenues of \$23.0 Million Increased 12.9% over First Quarter 2020

Significant Progress Made Across the Pipeline

Conference Call and Webcast Today, May 5th, 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, ocular surface diseases and retinal diseases, today reported financial results for the first quarter ended March 31, 2021 and provided a general business update.

“Our first quarter 2021 results reflect nearly 13 percent growth in net revenues and 11 percent growth in bottle volumes for our U.S. glaucoma franchise compared to the first quarter of 2020. Our franchise has grown from the pre-COVID levels experienced in the first quarter of 2020 whereas the overall U.S. glaucoma market prescription volumes have declined six percent for the same period. Our net revenue per bottle increased to \$89 in the first quarter of 2021, the highest level since 2019, with a sequential quarter increase of \$9 per bottle, primarily due to renegotiated wholesaler fees. We ended the first quarter with \$208 million in cash and investments and our net cash used in operations amounted to \$30 million, compared to \$42 million in the first quarter of 2020, reflecting stronger revenues and continued well-controlled operating expenses. While we are not currently providing full year 2021 financial guidance due to continuing uncertainties surrounding the impact of the ongoing pandemic on ophthalmic practices, based on our volume and net revenue per bottle trajectory, we remain comfortable with current consensus analyst estimates,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido added, “Turning to our pipeline, the COMET-1 Phase 2b clinical trial of AR-15512, our dry eye product candidate, is now fully enrolled and we continue to expect to read out topline data from this clinical trial in the third-quarter of this year. Regarding our sustained-release retinal implant, AR-1105, we remain excited about the previously announced topline Phase 2 results for AR-1105, which indicated up to six months of sustained efficacy for patients with macular edema associated with retinal vein occlusion. We continue discussions with both the FDA and EMA to develop a Phase 3 strategy for AR-1105 in the United States and Europe. Our IND-enabling preclinical studies are underway for our new preclinical implant, AR-14034 SR, for the potential treatment of wet age-related macular degeneration and diabetic macular edema. AR-14034 SR is a sustained-release retinal implant containing the pan-VEGF inhibitor axitinib formulated in a unique bio-erodible polymer blend using our exclusive PRINT[®] technology. We believe, based on the predictability of our PRINT[®] platform and the formulation capabilities provided by our access to a large variety of polymers, that AR-14034 SR may have the potential to provide up to one year of treatment from a single injection with potentially better efficacy than currently available products and product candidates. From a globalization perspective, the first Phase 3 trial for Rhopressa[®] is well underway in Japan and our collaboration with Santen remains on track as we prepare for additional Phase 3 studies in Japan. We continue discussions with multiple potential collaborators to commercialize our glaucoma products in Europe and are hoping to announce a new collaboration by year-end 2021.”

U.S. Glaucoma Franchise Highlights

- Rhopressa[®] and Rocklatan[®] generated first quarter 2021 net revenues of \$23.0 million, equivalent to an average of \$89 per bottle. Shipments to wholesalers totaled 257,000 bottles during the first quarter of 2021.
- Rhopressa[®] currently has commercial coverage for 90 percent of lives and market access for 89 percent of lives covered under Medicare Part D plans. Commercial coverage for Rocklatan[®] represents 89 percent of covered lives. Rocklatan[®] has market access for 59 percent of Medicare Part D lives and an additional 15 percent of remaining Medicare Part D lives with affordable access through U.S. government funded Low Income Subsidy programs through which co-pays are less than \$10 per month.
- Aerie recently announced the publication of a peer-reviewed paper in eLife, a science journal, entitled, “Antifibrotic activity of a rho-kinase inhibitor restores outflow function and intraocular pressure homeostasis” in March 2021. The paper evaluates the treatment effect of netarsudil, marketed as Rhopressa[®], on steroid-induced ocular hypertension in a mouse model and steroid-induced glaucoma in humans. In the mouse model, netarsudil reversed the tissue stiffness and fibrosis at the trabecular meshwork. The paper also reviews clinical data for Rhopressa[®] from retrospective chart reviews of two cohorts of patients with steroid induced glaucoma whose IOP was not controlled on other medications. When Rhopressa[®] was added, usually as a third or fourth medication, patients achieved an average decrease in IOP of 7 to 8 mmHg (millimeters of mercury).

Pipeline and Globalization Highlights

- COMET-1, Aerie’s Phase 2b clinical trial for its dry eye product candidate, AR-15512, continues to progress forward. Aerie currently expects topline results in the third quarter of 2021. This now fully enrolled study was initiated in October 2020 and is powered as a Phase 3 clinical trial.
- In April 2021, Roclanda[®] received marketing authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA) in Great Britain. Roclanda[®] was previously granted a marketing authorisation by the European Commission (EC) in January 2021. Discussions with potential collaborators in Europe are ongoing.
- The first Phase 3 clinical trial for Rhopressa[®] in Japan began in the fourth quarter of 2020. Aerie expects topline results in the fourth quarter of 2021.
- Aerie continues to evaluate the clinical and regulatory pathways for Phase 3 clinical trials for AR-1105 (dexamethasone steroid implant) in both the U.S. and European markets.
- Investigational New Drug Application (IND)-enabling preclinical studies are underway for AR-14034 SR, a sustained-release implant containing the pan-VEGF inhibitor axitinib formulated in a unique bio-erodible polymer blend using our exclusive PRINT[®] technology.
- The first-in-human clinical trial for AR-13503 SR (Rho kinase and protein kinase C inhibitor sustained-release implant), continues to advance. Aerie currently expects to complete the dose escalation safety evaluation with the current implant design in the first quarter of 2022.

Net cash used in operating activities for the first quarter ended March 31, 2021 on a GAAP basis totaled approximately \$30.1 million, resulting in \$208.2 million in cash and cash equivalents and investments as of March 31, 2021.

First Quarter 2021 Financial Results

For the first quarter ended March 31, 2021, Aerie reported net product revenues of \$23.0 million related to the combined sales of Rhopressa[®] and Rocklatan[®]. Aerie reported a GAAP net loss of \$42.0 million, or \$0.91 net loss per share, for the first quarter of 2021, compared to a net loss of \$49.1 million and \$1.07 net loss per share for the

first quarter of 2020. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 46.1 million and 45.8 million for the first quarters of 2021 and 2020, respectively. Total shares outstanding as of March 31, 2021 were 46.9 million. As of March 31, 2021, Aerie had cash and cash equivalents and investments of \$208.2 million.

The \$42.0 million net loss for the first quarter of 2021 is primarily comprised of \$16.3 million of gross profit, including \$6.7 million in cost of goods sold, and \$50.5 million in total operating expenses, including \$32.6 million in selling, general and administrative expenses and \$17.9 million in research and development expenses. The cost of goods sold includes \$4.4 million in idle capacity costs resulting from the Athlone manufacturing plant having commenced operations earlier in 2020 and not having yet reached full capacity. These idle capacity costs are expected to decline over time as commercial volumes and clinical supply requirements increase. Excluding \$8.7 million of stock-based compensation expense, for the first quarter of 2021 adjusted cost of goods sold was \$6.2 million and adjusted total operating expenses were \$42.2 million, with adjusted selling, general and administrative expenses of \$26.3 million and adjusted research and development expenses of \$15.9 million. Total adjusted net loss for the first quarter of 2021 was \$33.2 million and adjusted net loss per share was \$0.72.

The \$49.1 million net loss for the first quarter of 2020 was primarily comprised of \$14.2 million of gross profit, including \$6.1 million in cost of goods sold, and \$58.2 million in total operating expenses, including \$36.9 million in selling, general and administrative expenses, \$2.1 million in pre-approval commercial manufacturing expenses and \$19.2 million in research and development expenses. The cost of goods sold includes \$3.5 million in idle capacity costs resulting from the Athlone manufacturing plant having commenced operations earlier in 2020 and not having yet reached full capacity. These idle capacity charges commenced during the first quarter of 2020 and do not represent a full quarter of activity. Excluding \$10.5 million of stock-based compensation expense, for the first quarter of 2020 adjusted cost of goods sold was \$5.6 million and adjusted total operating expenses were \$48.2 million, with adjusted selling, general and administrative expenses of \$30.0 million, adjusted pre-approval commercial manufacturing expenses of \$1.8 million and adjusted research and development expenses of \$16.3 million. Total adjusted net loss for the first quarter of 2020 was \$38.6 million and adjusted net loss per share was \$0.84.

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 Aerie's website at <http://investors.aeriepharma.com>. Please connect to Aerie'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 2748249. 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 2748249. The telephone replay will be available until May 13, 2021.

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, 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 and 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 launched in the United States in May 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 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 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 and financial results and condition of our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any product candidates 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 product candidates 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 product candidates 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 product candidates, preclinical implants 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 product candidates, preclinical implants or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any product candidates 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 expectations for full year 2021; our ability to protect our proprietary technology and enforce our intellectual property rights or to develop new intellectual property; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, FDA and European Medicines Agency (EMA) approval of Rhopressa® and Rocklatan®, and MHRA authorisation of Roclanda® do not constitute regulatory approval of Rhopressa®, Rocklatan® or Roclanda® in other jurisdictions, and there can be no assurance that we will receive regulatory approval for Rhopressa®, Rocklatan® or Roclanda® in such other jurisdictions. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our product candidates or any future product candidates, and there can be no assurance that we will receive FDA approval for our product candidates or any future product candidates. Furthermore, the acceptance of the INDs by the FDA for AR-15512, AR-1105, AR-14034 and AR-13503 do not constitute FDA approval of AR-15512, AR-1105, AR-14034 or AR-13503 and the outcomes of later clinical trials for AR-15512, AR-1105, AR-14034 or AR-13503 may not be sufficient to submit a New Drug Application (NDA) with the FDA or to receive FDA approval. 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.

Non-GAAP Financial Measures

To supplement our financial statements, which are prepared and presented in accordance with GAAP (generally accepted accounting principles), we use the following non-GAAP financial measures, some of which are discussed above: adjusted net loss, adjusted cost of goods sold, adjusted selling, general and administrative expenses, adjusted pre-approval commercial manufacturing expenses, adjusted research and development expenses, adjusted total operating 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)

	MARCH 31, 2021	DECEMBER 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 122,695	\$ 151,570
Short-term investments	85,509	88,794
Accounts receivable, net	46,150	56,022
Inventory	28,324	27,059
Prepaid expenses and other current assets	10,899	8,310
Total current assets	293,577	331,755
Property, plant and equipment, net	53,283	54,260
Operating lease right-of-use assets	13,241	14,084
Other assets	2,627	1,946
Total assets	\$ 362,728	\$ 402,045
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable	\$ 6,520	\$ 8,826
Accrued expenses and other current liabilities	82,792	90,723
Operating lease liabilities	4,052	4,923
Total current liabilities	93,364	104,472
Convertible notes, net	216,088	210,373
Deferred revenue, non-current	51,605	50,858
Long-term operating lease liabilities	9,914	10,206
Other non-current liabilities	2,125	2,168
Total liabilities	373,096	378,077
Stockholders' (deficit) equity		
Common stock	47	47
Additional paid-in capital	1,110,714	1,103,074
Accumulated other comprehensive loss	(64)	(52)
Accumulated deficit	(1,121,065)	(1,079,101)
Total stockholders' (deficit) equity	(10,368)	23,968
Total liabilities and stockholders' (deficit) equity	\$ 362,728	\$ 402,045

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

	THREE MONTHS ENDED MARCH 31,	
	2021	2020
Product revenues, net	\$ 22,970	\$ 20,341
Total revenues, net	22,970	20,341
Costs and expenses:		
Cost of goods sold	6,700	6,092
Selling, general and administrative	32,598	36,902
Pre-approval commercial manufacturing	—	2,114
Research and development	17,891	19,173
Total costs and expenses	57,189	64,281
Loss from operations	(34,219)	(43,940)
Other (expense) income, net	(7,714)	(5,222)
Loss before income taxes	(41,933)	(49,162)
Income tax expense (benefit)	31	(33)
Net loss	\$ (41,964)	\$ (49,129)
Net loss per common share—basic and diluted	\$ (0.91)	\$ (1.07)
Weighted average number of common shares outstanding—basic and diluted	46,109,080	45,792,504

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

	THREE MONTHS ENDED MARCH 31,	
	2021	2020
Net loss (GAAP)	\$ (41,964)	\$ (49,129)
Add-back: stock-based compensation expense	8,749	10,529
Adjusted Net loss	<u>\$ (33,215)</u>	<u>\$ (38,600)</u>
Cost of goods sold (GAAP)	\$ 6,700	\$ 6,092
Less: stock-based compensation expense	(507)	(497)
Adjusted cost of goods sold	<u>\$ 6,193</u>	<u>\$ 5,595</u>
Selling, general and administrative expenses (GAAP)	\$ 32,598	\$ 36,902
Less: stock-based compensation expense	(6,255)	(6,908)
Adjusted selling, general and administrative expenses	<u>\$ 26,343</u>	<u>\$ 29,994</u>
Pre-approval commercial manufacturing expenses (GAAP)	\$ —	\$ 2,114
Less: stock-based compensation expense	—	(294)
Adjusted pre-approval commercial manufacturing expenses	<u>\$ —</u>	<u>\$ 1,820</u>
Research and development expenses (GAAP)	\$ 17,891	\$ 19,173
Less: stock-based compensation expense	(1,987)	(2,830)
Adjusted research and development expenses	<u>\$ 15,904</u>	<u>\$ 16,343</u>
Total operating expenses (GAAP)	\$ 50,489	\$ 58,189
Less: stock-based compensation expense	(8,242)	(10,032)
Adjusted total operating expenses	<u>\$ 42,247</u>	<u>\$ 48,157</u>

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

	THREE MONTHS ENDED MARCH 31,	
	2021	2020
Net loss per common share—basic and diluted (GAAP)	\$ (0.91)	\$ (1.07)
Add-back: stock-based compensation expense	0.19	0.23
Adjusted Net loss per share—basic and diluted	<u>\$ (0.72)</u>	<u>\$ (0.84)</u>
Weighted average number of common shares outstanding—basic and diluted	<u>46,109,080</u>	<u>45,792,504</u>

Contacts

Aerie Pharmaceuticals

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