



## **Aerie Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Business Update**

August 4, 2021

**Second Quarter 2021 Net Revenues of \$27.2 Million Increased 50.8% over Second Quarter 2020**

**Second Quarter 2021 Net Revenue Per Bottle of \$89, up 14.7% over Second Quarter 2020**

**Phase 2b Topline Results for AR-15512 (COMET-1) Expected in the Third Quarter of 2021**

**Conference Call and Webcast Today, August 4<sup>th</sup>, at 5:00 p.m. ET**

DURHAM, N.C.--(BUSINESS WIRE)--Aug. 4, 2021-- 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 second quarter ended June 30, 2021 and provided a general business update.

"Our second quarter 2021 results reflect nearly 51 percent growth in net revenues and 31 percent growth in bottle volumes for our U.S. glaucoma franchise compared to the second quarter of 2020. Our net revenue per bottle remained stable at \$89 in the second quarter of 2021, with a year over year increase of \$11 per bottle, primarily due to renegotiated wholesaler fees. We ended the second quarter with \$188 million in cash and investments and our net cash used in operations for the quarter amounted to \$20 million, compared to \$23 million in the second 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 ongoing uncertainties surrounding the impact of the pandemic on ophthalmic practices, we continue to remain comfortable with current analyst consensus estimates," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido added, "We continue to make significant progress with our pipeline. Later in the third-quarter of 2021 we expect to read out the topline data from the COMET-1 Phase 2b clinical trial of AR-15512, our dry eye product candidate. We continue discussions with both the FDA and EMA to finalize a Phase 3 strategy for our sustained-release retinal implant, AR-1105, and expect to begin Phase 3 activities by year-end of 2021. Our IND-enabling preclinical studies are underway for our newest pipeline addition, the preclinical ROCK inhibitor-linked steroid, AR-6121, for post-op inflammation. Our plans for a second-half 2022 IND filing for the axitinib sustained-release retinal implant candidate, AR-14034 SR, remain on track. From a globalization perspective, the first Phase 3 trial for Rhopressa<sup>®</sup> in Japan is fully enrolled and we expect the Phase 3 trial to be completed by the end of 2021 with topline results to be reported shortly thereafter. We continue discussions with potential collaborators to commercialize our glaucoma products in Europe and still expect to announce a new collaboration by year-end 2021."

### **U.S. Glaucoma Franchise Highlights**

- Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> generated second quarter 2021 net revenues of \$27.2 million, equivalent to an average of \$89 per bottle. Shipments to wholesalers totaled 306,000 bottles during the second quarter of 2021. Rhopressa<sup>®</sup> currently has market access for 92 percent of lives covered under Medicare Part D plans and commercial coverage for 77 percent of covered lives. Rocklatan<sup>®</sup> has market access for 74 percent of Medicare Part D lives and an additional 10 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. Commercial coverage for Rocklatan<sup>®</sup> represents 75 percent of covered lives. Commercial coverage shows a decline due to unemployment remaining higher than pre-pandemic levels as well as commercial payors seeking money-saving opportunities such as moving to generic-only formulary configurations. Aerie's commercial business accounted for 24 percent of the Company's total revenue during the second quarter of 2021, having consistently decreased since launch.

### **Pipeline and Globalization Highlights**

- Aerie expects to report topline results for COMET-1, Aerie's Phase 2b clinical trial for its dry eye product candidate, AR-15512, in the third quarter of 2021. The study, which was initiated in October 2020 and fully enrolled in April 2021, is powered as a Phase 3 clinical trial.

- The first Phase 3 clinical trial for Rhopressa® in Japan began in the fourth quarter of 2020 and is now fully enrolled. Aerie expects the Phase 3 trial to be completed by the end of 2021 with topline results to be reported shortly thereafter.
- Discussions with potential collaborators in Europe and potentially beyond are ongoing and we expect to announce a new collaboration agreement by year-end 2021.
- Investigational New Drug Application (IND)-enabling preclinical studies are underway for AR-6121, a ROCK inhibitor-linked steroid. Aerie expects to file the IND application for AR-6121 in the second half of 2022.
- IND-enabling preclinical studies are ongoing for AR-14034 SR, a sustained-release implant containing the pan-VEGF inhibitor axitinib formulated in a unique bio-erodible polymer blend using Aerie's exclusive PRINT® technology. Aerie expects to file the IND application for AR-14034 SR in the second half of 2022.
- The first-in-human clinical trial for AR-13503 SR (Rho kinase and protein kinase C inhibitor sustained-release implant), continues to progress. Aerie currently expects to complete the dose escalation safety evaluation with the current implant design in the first quarter of 2022.

#### Corporate Update

- Following the resignation of Richard J. Rubino, Chief Financial Officer at Aerie, effective July 30, 2021, Aerie has appointed Christopher Staten, Aerie's Vice President of Finance, as interim Chief Financial Officer. Mr. Staten's appointment is effective from July 30, 2021 and he will serve as interim Chief Financial Officer until a permanent replacement is announced.

Net cash used in operating activities for the second quarter ended June 30, 2021 on a GAAP basis totaled approximately \$20.1 million, resulting in \$188.3 million in cash and cash equivalents and investments as of June 30, 2021.

#### Second Quarter 2021 Financial Results

For the second quarter ended June 30, 2021, Aerie reported net product revenues of \$27.2 million related to the combined sales of Rhopressa® and Rocklatan®. Aerie reported a GAAP net loss of \$38.7 million, or \$0.84 net loss per share, for the second quarter of 2021, compared to a net loss of \$48.2 million and \$1.05 net loss per share for the second quarter of 2020. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 46.2 million and 45.9 million for the second quarters of 2021 and 2020, respectively. Total shares outstanding as of June 30, 2021 were 47.0 million. As of June 30, 2021, Aerie had cash and cash equivalents and investments of \$188.3 million.

The \$38.7 million net loss for the second quarter of 2021 is primarily comprised of \$21.0 million of gross profit, including \$6.2 million in cost of goods sold, and \$52.5 million in total operating expenses, including \$34.5 million in selling, general and administrative expenses and \$18.0 million in research and development expenses. The cost of goods sold includes \$3.9 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 \$8.0 million of stock-based compensation expense, for the second quarter of 2021 adjusted cost of goods sold was \$5.7 million and adjusted total operating expenses were \$44.9 million, with adjusted selling, general and administrative expenses of \$28.9 million and adjusted research and development expenses of \$16.0 million. Total adjusted net loss for the second quarter of 2021 was \$30.7 million and adjusted net loss per share was \$0.67.

The \$48.2 million net loss for the second quarter of 2020 was primarily comprised of \$10.7 million of gross profit, including \$7.3 million in cost of goods sold, and \$53.3 million in total operating expenses, including \$33.2 million in selling, general and administrative expenses, \$0.1 million in pre-approval commercial manufacturing expenses and \$19.9 million in research and development expenses. The cost of goods sold includes \$5.0 million in idle capacity costs resulting from the Athlone manufacturing plant having commenced operations earlier in 2020 and not having yet reached full capacity. Excluding \$10.2 million of stock-based compensation expense, for the second quarter of 2020 adjusted cost of goods sold was \$6.7 million and adjusted total operating expenses were \$43.8 million, with adjusted selling, general and administrative expenses of \$26.3 million, adjusted pre-approval commercial manufacturing expenses of \$0.1 million and adjusted research and development expenses of \$17.4 million. Total adjusted net loss for the second quarter of 2020 was \$38.0 million and adjusted net loss per share was \$0.83.

#### 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 9845827. 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 9845827. The telephone replay will be available until August 12, 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<sup>®</sup>, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa<sup>®</sup>, including the product label, is available at [www.rhopressa.com](http://www.rhopressa.com). Aerie's second product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, Rocklatan<sup>®</sup> (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, the first and only fixed-dose combination of Rhopressa<sup>®</sup> and the widely-prescribed PGA (prostaglandin analog) latanoprost, was launched in the United States in May 2019. In clinical trials of Rocklatan<sup>®</sup>, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan<sup>®</sup>, including the product label, is available at [www.rocklatan.com](http://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](http://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<sup>®</sup>, Rocklatan<sup>®</sup>, Rhokiinsa<sup>®</sup> and Roclanda<sup>®</sup> 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<sup>®</sup> and Rocklatan<sup>®</sup>, 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<sup>®</sup>, Rocklatan<sup>®</sup>, Rhokiinsa<sup>®</sup>, Roclanda<sup>®</sup> 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<sup>®</sup>, Rocklatan<sup>®</sup> 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<sup>®</sup>, Rocklatan<sup>®</sup> or any product candidates, preclinical implants or future product candidates; the potential advantages of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> 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<sup>®</sup> and Rocklatan<sup>®</sup>, and MHRA authorisation of Roclanda<sup>®</sup> do not constitute regulatory approval of Rhopressa<sup>®</sup>, Rocklatan<sup>®</sup> or Roclanda<sup>®</sup> in other jurisdictions, and there can be no assurance that we will receive regulatory approval for Rhopressa<sup>®</sup>, Rocklatan<sup>®</sup> or Roclanda<sup>®</sup> in such other jurisdictions. In addition, FDA approval of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> 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, AR-6121 and AR-13503 do not constitute FDA approval of AR-15512, AR-1105, AR-14034, AR-6121 or AR-13503 and the outcomes of later clinical trials for AR-15512, AR-1105, AR-14034, AR-6121 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)

**JUNE 30, 2021    DECEMBER 31, 2020****Assets**

## Current assets

Cash and cash equivalents	\$ 79,956	\$ 151,570
Short-term investments	108,331	88,794
Accounts receivable, net	59,151	56,022
Inventory	30,704	27,059
Prepaid expenses and other current assets	10,876	8,310
Total current assets	289,018	331,755
Property, plant and equipment, net	52,715	54,260
Operating lease right-of-use assets	12,830	14,084
Other assets	965	1,946
<b>Total assets</b>	<b>\$ 355,528</b>	<b>\$ 402,045</b>

**Liabilities and Stockholders' (Deficit) Equity**

## Current liabilities

Accounts payable	\$ 7,437	\$ 8,826
Accrued expenses and other current liabilities	96,761	90,723
Operating lease liabilities	3,888	4,923
Total current liabilities	108,086	104,472
Convertible notes, net	222,023	210,373
Deferred revenue, non-current	52,829	50,858
Long-term operating lease liabilities	10,031	10,206

Other non-current liabilities	2,173	2,168
Total liabilities	395,142	378,077
Stockholders' (deficit) equity		
Common stock	47	47
Additional paid-in capital	1,120,153	1,103,074
Accumulated other comprehensive loss	(61 )	(52 )
Accumulated deficit	(1,159,753 )	(1,079,101 )
Total stockholders' (deficit) equity	(39,614 )	23,968
<b>Total liabilities and stockholders' (deficit) equity</b>	<b>\$ 355,528</b>	<b>\$ 402,045</b>

**AERIE PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations**

**(Unaudited)**

(in thousands, except share and per share data)

	<b>THREE MONTHS ENDED JUNE 30,</b>	
	<b>2021</b>	<b>2020</b>
Product revenues, net	\$ 27,185	\$ 18,033
Total revenues, net	27,185	18,033
Costs and expenses:		
Cost of goods sold	6,177	7,326
Selling, general and administrative	34,542	33,237
Pre-approval commercial manufacturing	—	80
Research and development	17,967	19,943
Total costs and expenses	58,686	60,586
Loss from operations	(31,501 )	(42,553 )
Other (expense) income, net	(7,169 )	(5,634 )
Loss before income taxes	(38,670 )	(48,187 )

Income tax expense (benefit)	18	—
Net loss	\$ (38,688 )	\$ (48,187 )
Net loss per common share—basic and diluted	\$ (0.84 )	\$ (1.05 )
Weighted average number of common shares outstanding—basic and diluted	46,197,656	45,876,106

**AERIE PHARMACEUTICALS, INC.**

**Reconciliation of GAAP to Non-GAAP Financial Measures**

**(Unaudited)**

(in thousands)

	<b>THREE MONTHS ENDED JUNE 30,</b>	
	<b>2021</b>	<b>2020</b>
Net loss (GAAP)	\$ (38,688 )	\$ (48,187 )
Add-back: stock-based compensation expense	7,996	10,176
Adjusted Net loss	\$ (30,692 )	\$ (38,011 )
Cost of goods sold (GAAP)	\$ 6,177	\$ 7,326
Less: stock-based compensation expense	(431 )	(670 )
Adjusted cost of goods sold	\$ 5,746	\$ 6,656
Selling, general and administrative expenses (GAAP)	\$ 34,542	\$ 33,237
Less: stock-based compensation expense	(5,598 )	(6,900 )
Adjusted selling, general and administrative expenses	\$ 28,944	\$ 26,337
Pre-approval commercial manufacturing expenses (GAAP)	\$ —	\$ 80
Less: stock-based compensation expense	—	(22 )
Adjusted pre-approval commercial manufacturing expenses	\$ —	\$ 58

Research and development expenses (GAAP)	\$ 17,967	\$ 19,943
Less: stock-based compensation expense	(1,967 )	(2,584 )
Adjusted research and development expenses	\$ 16,000	\$ 17,359
Total operating expenses (GAAP)	\$ 52,509	\$ 53,260
Less: stock-based compensation expense	(7,565 )	(9,506 )
Adjusted total operating expenses	\$ 44,944	\$ 43,754

**AERIE PHARMACEUTICALS, INC.**

**Reconciliation of GAAP Net Loss Per Share to Adjusted Net Loss Per Share**

(Unaudited)

	<b>THREE MONTHS ENDED JUNE 30,</b>	
	<b>2021</b>	<b>2020</b>
Net loss per common share—basic and diluted (GAAP)	\$ (0.84 )	\$ (1.05 )
Add-back: stock-based compensation expense	0.17	0.22
Adjusted Net loss per share—basic and diluted	\$ (0.67 )	\$ (0.83 )
Weighted average number of common shares outstanding—basic and diluted	46,197,656	45,876,106

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210804005757/en/): <https://www.businesswire.com/news/home/20210804005757/en/>

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Source: Aerie Pharmaceuticals, Inc.