



## **Aerie Pharmaceuticals Reports Third Quarter 2019 Financial Results, Updates Full-Year 2019 Guidance and Provides Business Update**

November 6, 2019

**Conference Call and Webcast Today, November 6<sup>th</sup>, at 5:00 p.m. ET**

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 6, 2019-- 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 third quarter ended September 30, 2019 and provided a general business update.

### **Aerie Third Quarter Highlights**

- The Aerie glaucoma franchise, including Rhopressa<sup>®</sup> (netarsudil ophthalmic solution) 0.02% and Rocklatan<sup>®</sup> (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, generated third quarter 2019 net revenues on a U.S. GAAP (generally accepted accounting principles) basis of \$18.5 million, equivalent to an average of \$94 per bottle. September year-to-date net revenues totaled \$45.2 million, equivalent to an average of \$95 per bottle. Third quarter 2019 net revenues increased over second quarter 2019 by 17.1%.
- Aerie currently expects full-year 2019 net revenues in the range of \$61 to \$66 million on a U.S. GAAP basis for the combined net revenues for Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> based on recent volume trends, compared to the previous guidance range of \$70 to \$80 million. Additionally, Aerie reiterated its net cash burn guidance for full-year 2019 in the range of \$160 to \$170 million.
- Net cash burn for the nine months ended September 30, 2019 was approximately \$131 million, with \$345.8 million in cash and cash equivalents and investments at September 30, 2019. In September 2019, the Company issued 1.5% Convertible Senior Notes due 2024 for gross proceeds of \$316 million and net proceeds of approximately \$275 million.
- Rhopressa<sup>®</sup> has market access for the majority of lives covered under commercial and Medicare Part D plans. Rocklatan<sup>®</sup> now has market access for 80 percent of commercial lives and 36 percent of Medicare Part D lives. In addition, Rocklatan<sup>®</sup> has an additional 18 percent of remaining Medicare Part D lives, which, while not yet covered on formulary, have affordable access through U.S. government funded Low Income Subsidy programs through which co-pays are less than \$10 per month.
- New data reflecting the topline results of the Rhopressa<sup>®</sup> Multi-center Open-label Study ("MOST") Phase 4 study demonstrate positive efficacy and favorable adverse event profiles in both adjunctive and monotherapy real-world clinical settings. In the study, Rhopressa<sup>®</sup> was equally effective when added to prior prostaglandin analogue (PGA) therapy or when added to prior multi-drug therapy, with additional intraocular pressure (IOP) reductions of 4.3 millimeters of mercury (mmHg) and 4.5 mmHg, respectively. When used as monotherapy following a switch from a PGA, Rhopressa<sup>®</sup> maintained equal IOP-lowering to the prior PGA. The topline results, which covered 260 subjects on an intent to treat basis, will be presented on Aerie's third-quarter conference call, details for which are included below, and the corresponding presentation is available at <http://investors.aeriepharma.com>.
- Clinical development and expansion activities related to Japan are progressing rapidly. The recently released positive topline results from the Rhopressa<sup>®</sup> Phase 2 clinical trial in Japan set the stage for advancing a number of different activities, including potential partnering discussions, to gain approval and ultimately commercialize our products in Japan. The topline Phase 2 data will be presented on Aerie's third-quarter conference call, and the corresponding presentation is available at <http://investors.aeriepharma.com>.
- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in September recommending approval of the marketing authorisation application (MAA) for Rhokiinsa<sup>®</sup> (netarsudil ophthalmic solution) 0.02%. The CHMP positive opinion has been referred to the European Commission for a final decision

on the MAA, which is expected in the fourth quarter of 2019. The Rocklatan® Mercury 3 Phase 3 clinical trial in Europe, designed to support commercialization in that region, continues to progress.

- Aerie submitted a Prior Approval Supplement (PAS) to the U.S. Food and Drug Administration (FDA) in September to allow commercial production of Rocklatan® in Aerie's Athlone, Ireland, manufacturing facility. Aerie also plans to file a PAS in the first half of 2020 to obtain FDA approval to manufacture Rhopressa® in Athlone.
- Aerie's retina program continues to advance. The clinical trial for AR-13503 (Rho kinase and Protein kinase C inhibitor implant) commenced in August 2019 for wet age-related macular degeneration and DME (diabetic macular edema). The AR-1105 (dexamethasone steroid implant) Phase 2 clinical trial, which commenced in March 2019 for macular edema due to RVO (retina vein occlusion) has fully enrolled ahead of schedule.

"We are lowering our full-year 2019 net revenue guidance to a range of \$61 to \$66 million, reflecting recent volume trends and our expectations through the upcoming holiday season. As we look at recent patterns, there have been strong growth weeks interspersed with weeks of somewhat slower growth. Our previous guidance assumed more consistent weekly growth. We believe this is a short-term launch phenomenon. Recent Rocklatan® volume gains are certainly promising, and we look forward to a meaningful growth trajectory over the next several years, and the long-term potential of our glaucoma franchise remains intact. New and impressive data from our MOST Phase 4 study point to the long-term potential of Rhopressa® driven by its real-world efficacy in many settings and positive tolerability profile. The Japan Phase 2 clinical results once again demonstrate the value proposition for Rhopressa® in Japan while also being informative as it relates to product performance on the large population of glaucoma patients on a global basis with normal-tension glaucoma," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido continued, "The key to our long-term growth will be continued gains in physician experience with both Rhopressa® and Rocklatan®, and along with that continued penetration of the available patient base. We currently have nearly 12,000 prescribers of our products out of a target population of 14,000, and nearly 4,000 of the prescribers are writing prescriptions consistently on a weekly basis. When analyzing prescription volumes from the top five prescribers of our glaucoma products, essentially those with the greatest experience with our products, the Aerie share of total prescriptions in their practices ranges from nearly 8 percent to over 26 percent, which we believe is an important indicator of how continued physician experience can drive our market share significantly higher over time. Regarding market access, when including affordable access for Low Income Subsidy patients, Rocklatan® already has affordable copays for the majority of Medicare Part D patients. Further, we continue to make excellent progress with our expansion efforts in Europe and Japan, great strides as we prepare our plant in Ireland for production in early 2020, and we are delighted by the progress we are making in the clinic with our sustained-release retinal implant product candidates."

### Third Quarter 2019 Financial Results

As of September 30, 2019, Aerie had cash and cash equivalents and investments of \$345.8 million, reflecting the net proceeds from the convertible debt offering in September 2019. For the third quarter ended September 30, 2019, Aerie reported net product revenues of \$18.5 million related to the combined sales of Rhopressa®, which was launched in the United States in April 2018, and Rocklatan®, which was launched in the United States on May 1, 2019. Aerie reported a U.S. GAAP net loss of \$49.4 million, or \$1.09 loss per share, for the third quarter of 2019, compared to a net loss of \$85.4 million and \$1.96 loss per share for the third quarter of 2018. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 45,448,190 and 43,657,423 for the third quarters of 2019 and 2018, respectively. Total shares outstanding as of September 30, 2019 were 45,998,956.

The \$49.4 million net loss for the third quarter of 2019 is primarily comprised of \$16.5 million of gross profit and \$59.8 million in total operating expenses, including \$32.2 million in selling, general and administrative expenses, \$5.8 million in pre-approval commercial manufacturing expenses and \$21.8 million in research and development expenses. Excluding \$10.6 million of stock-based compensation expense, adjusted total operating expenses for the third quarter of 2019 were \$49.2 million, with adjusted selling, general and administrative expenses of \$25.1 million, adjusted pre-approval commercial manufacturing expenses of \$5.0 million and adjusted research and development expenses of \$19.0 million. Total adjusted net loss for the third quarter of 2019 was \$38.8 million, and adjusted net loss per share was \$0.86.

The \$85.4 million net loss for the third quarter of 2018 was primarily comprised of \$68.4 million in total operating expenses, including \$32.7 million in selling, general and administrative expenses, \$7.2 million in pre-approval commercial manufacturing expenses and \$28.5 million in research and development expenses. Excluding \$10.0 million of stock-based compensation expense, adjusted total operating expenses for the third quarter of 2018 were \$58.5 million, with adjusted selling, general and administrative expenses of \$26.0 million, adjusted pre-approval commercial manufacturing expenses of \$6.5 million and adjusted research and development expenses of \$25.9 million. Total adjusted net loss for the third quarter of 2018 was \$75.4 million, and adjusted net loss per share was \$1.73.

### 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 3884357. 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 3884357. The telephone replay will be available until November 14, 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 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 the second quarter of 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: our expectations regarding the commercialization and manufacturing of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup>, including the timing, cost or other aspects of the commercial launch of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup>; 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 current or 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 the results of such clinical trials; our guidance for full-year 2019 including expectations through the holiday season; our estimates regarding expected net revenues, expected cash burn, anticipated capital requirements and our needs for additional financing; our expectations regarding the effectiveness of Rhopressa<sup>®</sup>, Rocklatan<sup>®</sup> or any current 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 current 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 current or future product candidates; the potential advantages of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> or any current 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 ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding strategic operations. 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<sup>®</sup> and Rocklatan<sup>®</sup> do not constitute FDA approval of AR-1105, AR-13503 or any future product candidates, and there can be no assurance that we will receive FDA approval for AR-1105, AR-13503 or any future product candidates. FDA approval of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> also do not constitute regulatory approval of Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa<sup>®</sup> and Rocklatan<sup>®</sup> in jurisdictions outside of the United States. In addition, the acceptance of the INDs by the FDA for AR-1105 and AR-13503 does not constitute FDA approval of AR-1105 or AR-13503 and the outcome of later clinical trials for AR-1105 or AR-13503 may not be sufficient to submit an NDA with the FDA or to 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 pre-approval commercial manufacturing expenses, adjusted selling, general and administrative expenses and adjusted net loss per share. For reconciliations of non-GAAP measures to the most directly comparable GAAP measures, please see the “Reconciliation of GAAP to Non-GAAP Financial Measures” and “Reconciliation of GAAP Net Loss Per Share to Adjusted Net Loss Per Share” tables in this press release.

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

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

## AERIE PHARMACEUTICALS, INC.

### Consolidated Balance Sheets

(Unaudited)

(in thousands)

**SEPTEMBER 30, 2019 DECEMBER 31, 2018****Assets**

## Current assets

Cash and cash equivalents	\$ 248,702	\$ 202,818
Short-term investments	92,075	—
Accounts receivable, net	33,278	2,715
Inventory	14,673	10,112
Prepaid expenses and other current assets	7,940	4,530
Total current assets	396,668	220,175
Long-term investments	5,020	—
Property, plant and equipment, net	58,277	60,525
Operating lease right-of-use assets	17,216	—
Other assets	2,027	4,344
<b>Total assets</b>	<b>\$ 479,208</b>	<b>\$ 285,044</b>

**Liabilities and Stockholders' Equity**

## Current liabilities

Accounts payable	\$ 11,480	\$ 12,403
Accrued expenses and other current liabilities	55,728	38,381
Operating lease liabilities	5,802	—
Total current liabilities	73,010	50,784
Convertible notes, net	183,553	—
Long-term operating lease liabilities	12,235	—
Other non-current liabilities	1,206	6,454
Total liabilities	270,004	57,238

## Stockholders' equity

Common stock	46	45	
Additional paid-in capital	1,050,252	924,180	
Accumulated other comprehensive loss	(158	) —	
Accumulated deficit	(840,936	) (696,419	)
Total stockholders' equity	209,204	227,806	
<b>Total liabilities and stockholders' equity</b>	<b>\$ 479,208</b>	<b>\$ 285,044</b>	

**AERIE PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations**

**(Unaudited)**

(in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,		
	2019	2018	2019	2018	
Product revenues, net	\$ 18,544	\$ 7,302	\$ 45,231	\$ 9,725	
Total revenues, net	18,544	7,302	45,231	9,725	
Costs and expenses:					
Cost of goods sold	2,063	205	3,149	264	
Selling, general and administrative	32,171	32,685	102,935	88,727	
Pre-approval commercial manufacturing	5,841	7,248	16,117	18,920	
Research and development	21,796	28,502	60,584	59,631	
Total costs and expenses	61,871	68,640	182,785	167,542	
Loss from operations	(43,327	) (61,338	) (137,554	) (157,817	)
Other (expense) income, net	(6,075	) (24,050	) (7,053	) (23,291	)
Loss before income taxes	(49,402	) (85,388	) (144,607	) (181,108	)
Income tax (benefit) expense	—	—	(90	) 3	
Net loss	\$ (49,402	) \$ (85,388	) \$ (144,517	) \$ (181,111	)
Net loss per common share—basic and diluted	\$ (1.09	) \$ (1.96	) \$ (3.19	) \$ (4.47	)
Weighted average number of common shares outstanding—basic and diluted	45,448,190	43,657,423	45,372,608	40,505,534	

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

(in thousands)

	<b>THREE MONTHS ENDED SEPTEMBER 30,</b>		<b>NINE MONTHS ENDED SEPTEMBER 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Net loss (GAAP)	\$ (49,402 )	\$ (85,388 )	\$ (144,517 )	\$ (181,111 )
Add-back: stock-based compensation expense	10,606	9,978	33,921	29,015
Adjusted Net loss	\$ (38,796 )	\$ (75,410 )	\$ (110,596 )	\$ (152,096 )
Selling, general and administrative expenses (GAAP)	\$ 32,171	\$ 32,685	\$ 102,935	\$ 88,727
Less: stock-based compensation expense	(7,041 )	(6,682 )	(23,253 )	(20,022 )
Adjusted selling, general and administrative expenses	\$ 25,130	\$ 26,003	\$ 79,682	\$ 68,705
Pre-approval commercial manufacturing expenses (GAAP)	\$ 5,841	\$ 7,248	\$ 16,117	\$ 18,920
Less: stock-based compensation expense	(807 )	(700 )	(2,490 )	(1,804 )
Adjusted pre-approval commercial manufacturing expenses	\$ 5,034	\$ 6,548	\$ 13,627	\$ 17,116
Research and development expenses (GAAP)	\$ 21,796	\$ 28,502	\$ 60,584	\$ 59,631
Less: stock-based compensation expense	(2,758 )	(2,596 )	(8,178 )	(7,189 )
Adjusted research and development expenses	\$ 19,038	\$ 25,906	\$ 52,406	\$ 52,442
Total operating expenses (GAAP)	\$ 59,808	\$ 68,435	\$ 179,636	\$ 167,278
Less: stock-based compensation expense	(10,606 )	(9,978 )	(33,921 )	(29,015 )
Adjusted total operating expenses	\$ 49,202	\$ 58,457	\$ 145,715	\$ 138,263

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2019	2018	2019	2018
Net loss per common share—basic and diluted (GAAP)	\$ (1.09 )	\$ (1.96 )	\$ (3.19 )	\$ (4.47 )
Add-back: stock-based compensation expense	0.23	0.23	0.75	0.72
Adjusted Net loss per share—basic and diluted	\$ (0.86 )	\$ (1.73 )	\$ (2.44 )	\$ (3.75 )
Weighted average number of common shares outstanding—basic and diluted	45,448,190	43,657,423	45,372,608	40,505,534

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Source: Aerie Pharmaceuticals, Inc.

Aerie Pharmaceuticals

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