Aerie Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Business Update

November 5, 2020

Year-to-Date Net Revenues of $58.5 Million Increased 29% over 2019

Third Quarter Net Revenues of $20.1 Million or $77 Per Bottle

U.S. Dry Eye Trial Initiated and Japanese Glaucoma Trial Set to Commence

Conference Call and Webcast Today, November 5th, at 5:00 p.m. ET

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 5, 2020-- 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 third quarter ended September 30, 2020 and provided a general business update.

"Our third quarter results demonstrated over 12 percent sequential growth in our U.S. glaucoma franchise volumes compared to second quarter, reflecting increased demand for both Rhopressa® (netarsudil ophthalmic solution) 0.02% and Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%. We believe our glaucoma franchise is benefitting from heightened prescription levels reflecting broader physician awareness of the two product profiles and broad formulary access. In addition, we estimate that approximately 85 percent of ophthalmologist offices were open in the third quarter, up from approximately 75 percent in the second quarter. The value of our glaucoma franchise was further demonstrated by the recently announced collaboration with Santen Pharmaceuticals Co., Ltd. (Santen) in Japan and several other countries in Asia, and we expect to commence the first Phase 3 clinical trial in Japan for Rhopressa® by the end of this year. Additionally, our recent positive Mercury 3 results and associated interest from potential collaborators point to the excellent potential of our glaucoma franchise in Europe," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido added, "Turning to the most advanced product candidates in our pipeline, we recently commenced the Phase 2b clinical trial of AR-15512, our dry eye product candidate. We also remain excited about the recently 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, a significantly differentiated profile for a retinal steroid implant. The potential of AR-1105 in the United States and especially European retina markets could be quite meaningful and we are evaluating the clinical and regulatory path in both markets. Finally, we remain well-funded with approximately $218 million of cash and investments as of September 30, 2020, and our third quarter net cash used in operating activities was $22.4 million, slightly better than the $22.9 million reported in the second quarter and significantly better than prior quarters. Our cash and investments position of $218 million will be further bolstered with the $50 million upfront cash payment from the Santen collaboration expected later this month."

U.S. Glaucoma Franchise Highlights

- Rhopressa® and Rocklatan® generated third quarter 2020 net revenues of $20.1 million, compared to $18.5 million in the third quarter of 2019, equivalent to an average of $77 per bottle, relatively consistent with the $78 per bottle in the second quarter of 2020. Shipments to wholesalers totaled 261,000 bottles during the third quarter of 2020, over 12 percent higher than the 232,500 bottles in the second quarter of 2020. Net revenues for the nine months ended September 30, 2020 totaled $58.5 million, compared to $45.2 million for the nine months ended September 30, 2019, reflecting a 29 percent increase.
- Rhopressa® currently has market access for 89 percent of lives covered under Medicare Part D plans and commercial coverage for 90 percent of lives. Rocklatan® has market access for 56 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. Commercial coverage for Rocklatan® is at 89 percent of covered lives.
- Aerie received approval from the U.S. Food and Drug Administration (FDA) in September 2020 to manufacture Rhopressa® in Aerie's manufacturing plant in Athlone, Ireland for commercial distribution in the U.S. market. The FDA approved the production of Rocklatan® in the Athlone manufacturing plant earlier this year and Aerie began production of commercial supplies of Rocklatan® in the first quarter of 2020. As volumes produced in the Athlone manufacturing plant

increase over time, idle capacity costs are expected to decline. Idle capacity costs decreased from $5.0 million in the second quarter of 2020 to $3.8 million in the third quarter of 2020.

Pipeline and International Highlights

- Aerie and Santen recently announced that they executed an exclusive license agreement for the development and commercialization of Rhopressa® and Rocklatan® in Japan and several other Asian countries. The agreement includes an upfront payment to Aerie of $50 million. Aerie expects to initiate the first Phase 3 trial in Japan for Rhopressa® by the end of this year.
- Aerie recently initiated COMET-1, its Phase 2b clinical trial for dry eye product candidate AR-15512. COMET-1 is powered as a Phase 3 clinical trial, and topline results are expected in the third quarter of 2021.
- Aerie reported positive topline data from the Rocklatan® Mercury 3 Phase 3 clinical trial in Europe in September 2020. Rocklatan® (known as Roclanda® in Europe) achieved non-inferiority to a fixed-dose combination in Europe (Ganfort®) and has received early interest from potential collaborators.
- Aerie expects an opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use on the marketing authorisation application (MAA) for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (marketed as Rocklatan® in the United States) in the fourth quarter of 2020. The European Commission granted a centralised marketing authorisation for Rhokiinsa® (netarsudil ophthalmic solution) 0.02% in November 2019.
- Aerie completed a Phase 2 clinical trial for AR-1105 (dexamethasone steroid implant) for macular edema due to retinal vein occlusion in July 2020, which indicates up to six months sustained release, and is evaluating the clinical and regulatory pathway for both the U.S. and European markets.

Net cash used in operating activities for the quarter ended September 30, 2020 on a U.S. GAAP basis totaled approximately $22.4 million, resulting in $218.4 million in cash and cash equivalents and investments as of September 30, 2020.

Third Quarter 2020 Financial Results

As of September 30, 2020, Aerie had cash and cash equivalents and investments of $218.4 million. For the third quarter ended September 30, 2020, Aerie reported net product revenues of $20.1 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 in May 2019. Aerie reported a U.S. GAAP net loss of $39.6 million, or $0.86 loss per share, for the third quarter of 2020, compared to a net loss of $49.4 million and $1.09 loss per share for the third quarter of 2019. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 45.9 million and 45.4 million for the third quarters of 2020 and 2019, respectively. Total shares outstanding as of September 30, 2020 were 46.8 million.

The $39.6 million net loss for the third quarter of 2020 is primarily comprised of $14.7 million of gross profit, including $5.4 million in cost of goods sold, and $48.3 million in total operating expenses, including $32.0 million in selling, general and administrative expenses, $0.1 million in pre-approval commercial manufacturing expenses and $16.2 million in research and development expenses. The cost of goods sold includes $3.8 million in idle capacity costs resulting from the Athlone manufacturing plant having just recently become operational and not yet reaching full capacity. Excluding $9.8 million of stock-based compensation expense, for the third quarter of 2020 adjusted cost of goods sold was $4.9 million and adjusted total operating expenses were $39.0 million, with adjusted selling, general and administrative expenses of $25.3 million, adjusted pre-approval commercial manufacturing expenses of $0.1 million and adjusted research and development expenses of $13.6 million. Total adjusted net loss for the third quarter of 2020 was $29.8 million, and adjusted net loss per share was $0.65.

The $49.4 million net loss for the third quarter of 2019 was primarily comprised of $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.

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 6776445. 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 6776445. The telephone replay will be available until November 13, 2020.

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 current 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 current 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 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®, Rocklatan® 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®, Rocklatan® or any current or future product candidates; the potential advantages of Rhopressa® and Rocklatan® 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, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including EMA approval of Roclanda®. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our current or any future product candidates, and there can be no assurance that we will receive FDA approval for our current or any future product candidates. Furthermore, EMA acceptance of the MAA for Roclanda® does not constitute EMA approval of Roclanda®, and there can be no assurance that we will receive EMA approval of Roclanda®. In addition, the acceptance of the INDs by the FDA for AR-15512, AR-1105 and AR-13503 do not constitute FDA approval of AR-15512, AR-1105 or AR-13503 and the outcomes of later clinical trials for AR-15512, AR-1105 or AR-13503 may not be sufficient to submit an 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, 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)

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 129,787	$ 143,940
Short-term investments	88,645	165,250
Accounts receivable, net	46,848	38,354
Inventory	20,842	21,054
Prepaid expenses and other current assets	9,091	7,744
Total current assets	295,213	376,342
Property, plant and equipment, net	55,293	58,147
Operating lease right-of-use assets	15,041	16,523
Other assets	1,139	1,596
Total assets	$ 366,686	$ 452,608
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,536	$ 12,770
Accrued expenses and other current liabilities	78,806	65,376
Operating lease liabilities	5,303	5,502
Total current liabilities	88,645	83,648
Convertible notes, net	204,688	188,651
Long-term operating lease liabilities	10,759	12,102
Other non-current liabilities	2,497	1,257
Total liabilities	306,589	285,658
Stockholders' equity		
Common stock	47	46
Additional paid-in capital	1,093,026	1,062,996

Accumulated other comprehensive income (loss)	(12)	(92)
Accumulated deficit	(1,032,964)	(896,000)
Total stockholders' equity	60,097	166,950
Total liabilities and stockholders' equity	$ 366,686	$ 452,608

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,	
	2020	**2019**	**2020**	**2019**
Product revenues, net	$ 20,081	$ 18,544	$ 58,455	$ 45,231
Total revenues, net	20,081	18,544	58,455	45,231
Costs and expenses:				
Cost of goods sold	5,381	2,063	18,799	3,149
Selling, general and administrative	32,029	32,171	102,168	102,935
Pre-approval commercial manufacturing	110	5,841	2,304	16,117
Research and development	16,165	21,796	55,281	60,584
Total costs and expenses	53,685	61,871	178,552	182,785
Loss from operations	(33,604)	(43,327)	(120,097)	(137,554)
Other (expense) income, net	(6,044)	(6,075)	(16,900)	(7,053)
Loss before income taxes	(39,648)	(49,402)	(136,997)	(144,607)
Income tax benefit	—	—	(33)	(90)
Net loss	$ (39,648)	$ (49,402)	$ (136,964)	$ (144,517)
Net loss per common share—basic and diluted	$ (0.86)	$ (1.09)	$ (2.99)	$ (3.19)
Weighted average number of common shares outstanding—basic and diluted	45,945,745	45,448,190	45,871,723	45,372,608

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

	THREE MONTHS ENDED SEPTEMBER 30,	NINE MONTHS ENDED SEPTEMBER 30,

	2020	2019	2020	2019
Net loss (GAAP)	$ (39,648)	$ (49,402)	$ (136,964)	$ (144,517)
Add-back: stock-based compensation expense	9,800	10,606	30,505	33,921
Adjusted Net loss	$ (29,848)	$ (38,796)	$ (106,459)	$ (110,596)
Cost of goods sold (GAAP)	$ 5,381	$ 2,063	$ 18,799	$ 3,149
Less: stock-based compensation expense	(511)	—	(1,678)	—
Adjusted cost of goods sold	$ 4,870	$ 2,063	$ 17,121	$ 3,149
Selling, general and administrative expenses (GAAP)	$ 32,029	$ 32,171	$ 102,168	$ 102,935
Less: stock-based compensation expense	(6,716)	(7,041)	(20,524)	(23,253)
Adjusted selling, general and administrative expenses	$ 25,313	$ 25,130	$ 81,644	$ 79,682
Pre-approval commercial manufacturing expenses (GAAP)	$ 110	$ 5,841	$ 2,304	$ 16,117
Less: stock-based compensation expense	(28)	(807)	(344)	(2,490)
Adjusted pre-approval commercial manufacturing expenses	$ 82	$ 5,034	$ 1,960	$ 13,627
Research and development expenses (GAAP)	$ 16,165	$ 21,796	$ 55,281	$ 60,584
Less: stock-based compensation expense	(2,545)	(2,758)	(7,959)	(8,178)
Adjusted research and development expenses	$ 13,620	$ 19,038	$ 47,322	$ 52,406
Total operating expenses (GAAP)	$ 48,304	$ 59,808	$ 159,753	$ 179,636
Less: stock-based compensation expense	(9,289)	(10,606)	(28,827)	(33,921)
Adjusted total operating expenses	$ 39,015	$ 49,202	$ 130,926	$ 145,715

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,

	2020	2019	2020	2019
Net loss per common share—basic and diluted (GAAP)	$ (0.86)	$ (1.09)	$ (2.99)	$ (3.19)
Add-back: stock-based compensation expense	0.21	0.23	0.67	0.75
Adjusted Net loss per share—basic and diluted	$ (0.65)	$ (0.86)	$ (2.32)	$ (2.44)
Weighted average number of common shares outstanding—basic and diluted	45,945,745	45,448,190	45,871,723	45,372,608

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Aerie Pharmaceuticals

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