Aerie Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results, Provides 2020 Guidance and Business Update

February 20, 2020

Conference Call and Webcast Today, February 20th, at 5:00 p.m. ET

DURHAM, N.C.--(BUSINESS WIRE)--Feb. 20, 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, dry eye, retinal diseases and other diseases of the eye, today reported financial results for the fourth quarter and full year ended December 31, 2019, along with 2020 guidance and a general business update.

Aerie Highlights

- The Aerie glaucoma franchise, including Rhopressa® (netarsudil ophthalmic solution) 0.02% and Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, generated fourth quarter 2019 net revenues on a U.S. GAAP (generally accepted accounting principles) basis of $24.7 million, representing an average of $120 per bottle. For full-year 2019, net revenues totaling $69.9 million exceeded the upper end of previous guidance of $61 to $66 million, representing an average of $103 per bottle. Net revenue benefited from a lower than expected fourth-quarter 2019 Medicare Part D coverage gap invoice.
- Rhopressa® has market access for the majority of lives covered under commercial and Medicare Part D plans. Rocklatan® now has market access for 82 percent of commercial lives and 36 percent of Medicare Part D lives. In addition, Rocklatan® has an additional 18 percent of market access for patients covered under Medicare Part D that are not covered on formulary but have affordable access through U.S. government funded Low Income Subsidy programs through which co-pays are less than $10 per month.
- Net cash used in operating activities for the year ended December 31, 2019 on a U.S. GAAP basis totaled approximately $150.4 million, resulting in $309.2 million in cash and cash equivalents and investments as of December 31, 2019.
- Aerie recently acquired Avizorex Pharma S.L. (Avizorex), a Spanish ophthalmic pharmaceutical company, developing therapeutics for the treatment of dry eye disease. Avizorex completed a Phase 2a study in dry eye subjects in 2019 with its lead product candidate AVX-012. Aerie plans to initiate a larger Phase 2b study in late 2020.
- Aerie's retina program continues to advance. The clinical trial for AR-13503 (Rho kinase and Protein kinase C inhibitor implant) commenced in the third quarter of 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 in October 2019 with topline data expected later in 2020.
- Aerie expects to move forward with plans for Rhopressa® Phase 3 clinical trial initiation in Japan, along with exploring a collaboration with a potential partner in Japan to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan.
- Aerie received approval from the U.S. Food and Drug Administration (FDA) in January to produce Rocklatan® for commercial distribution in the U.S. market in Aerie's Athlone, Ireland, manufacturing facility. Aerie also plans to file a Prior Approval Supplement with the FDA in the first half of 2020 to obtain FDA approval to manufacture Rhopressa® in Athlone for commercial distribution in the U.S. market.
- The European Commission granted a marketing authorisation for Rhokiinsa® (netarsudil ophthalmic solution) 0.02%. The European Medicines Agency (EMA) has accepted for review the marketing authorisation application (MAA) for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%. An opinion from the EMA's Committee for Medicinal Products for Human Use on the MAA for Roclanda® is expected in late 2020. Topline data from the Rocklatan® Mercury 3 Phase 3 clinical trial in Europe is expected in the second half of 2020, the results of which will help determine commercial

prospects in the region.

2020 Guidance

- Aerie currently expects full-year 2020 net revenues to be in the range of $100 to $110 million on a U.S. GAAP basis for Rhopressa® and Rocklatan® combined. Aerie also currently expects full-year 2020 net cash used in operating activities to be in the range of $110 million to $120 million, on a U.S. GAAP basis, with operating expenses in full-year 2020 remaining consistent with full-year 2019.

“We are delighted to have exceeded the revenue guidance that we announced in our third quarter 2019 release. The net revenue and net revenue per bottle exceeded our expectations largely as the result of having received a lower than expected fourth quarter 2019 coverage gap invoice for our Medicare Part D prescriptions. This was our first year of experiencing a full four quarters of coverage gap invoices and this history will be helpful as we estimate future net revenues. In addition, our volumes were ahead of expectations in our guidance and co-pay coupon card utilization for patients covered under commercial insurance was below our expectations, a testament to our high levels of commercial coverage across the franchise and correspondingly low patient co-pays. As we look to 2020, our net revenue guidance of $100 to $110 million reflects projected volume growth as we proceed with the ongoing refinement of our commercialization approach. Net revenue per bottle in 2020 is expected to remain at or above $90,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

“We are entering 2020 with approximately $309 million of cash and investments. For 2020, we expect continued revenue growth while expenses remain consistent with 2019 levels. With that, we are guiding to considerably lower net cash used in operations than in 2019 and we expect to have adequate resources to continue executing on our clinical programs focused on dry eye and retina, along with our Japanese and European initiatives.”

Fourth Quarter 2019 Financial Results

As of December 31, 2019, Aerie had cash and cash equivalents and investments of $309.2 million, reflecting the net proceeds from the convertible notes debt offering in September 2019. For the fourth quarter ended December 31, 2019, Aerie reported net product revenues of $24.7 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 GAAP net loss of $55.1 million, or $1.21 net loss per share, compared to a net loss of $51.5 million and $1.14 net loss per share for the fourth quarter of 2018. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 45,589,014 and 45,101,458 for the fourth quarters of 2019 and 2018, respectively. Total shares outstanding as of December 31, 2019 were 46,464,669.

The $55.1 million net loss for the fourth quarter of 2019 is comprised of $23.0 million of gross profit, and $72.9 million in total operating expenses, including $35.5 million in selling, general and administrative expenses, $6.7 million in pre-approval commercial manufacturing expenses and $30.8 million in research and development expenses. Excluding $11.2 million of stock-based compensation expense, adjusted total operating expenses for the fourth quarter of 2019 were $61.7 million, with adjusted selling, general and administrative expenses of $28.3 million, adjusted pre-approval commercial manufacturing expenses of $5.5 million and adjusted research and development expenses of $28.0 million. Total adjusted net loss for the fourth quarter of 2019 was $43.9 million, and adjusted net loss per share was $0.96.

The $51.5 million net loss for the fourth quarter of 2018, comprised of $14.1 million of gross profit, $66.0 million in total operating expenses, including $31.9 million in selling, general and administrative expenses, $7.6 million in pre-approval commercial manufacturing expenses and $26.5 million in research and development expenses. Excluding $9.7 million of stock-based compensation expense, adjusted total operating expenses for the fourth quarter of 2018 were $56.3 million, with adjusted selling, general and administrative expenses of $25.5 million, adjusted pre-approval commercial manufacturing expenses of $6.8 million and adjusted research and development expenses of $24.0 million. Total adjusted net loss for the fourth quarter of 2018 was $41.7 million, and adjusted net loss per share was $0.92.

Conference Call / Webcast Information

Aerie management will host a live conference call and webcast at 5:00 p.m. Eastern Time today to discuss Aerie’s financial results and provide a general business update.

The live webcast and a replay may be accessed by visiting the Company's website at http://investors.aeriepharma.com. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (888) 734-0328 (U.S.) or (678) 894-3054 (international) to listen to the live conference call. The conference ID number for the live call is 6595386. 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 6595386. The telephone replay will be available until February 28, 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, dry eye, 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®, 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/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 approved by the FDA and was launched in the United States in the second quarter of 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 dry eye, 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: 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, such as statements in this press release regarding any expected clinical trials for AVX-012, AR-1105 or AR-13503 and the results of such clinical trials; our guidance for full-year 2020; 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 AVX-012, AR-1105 and AR-13503 do not constitute FDA approval of AVX-012, AR-1105 or AR-13503 and the outcomes of later clinical trials for AVX-012, 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 total operating expenses, adjusted selling, general and administrative expenses, adjusted pre-approval commercial manufacturing expenses, adjusted research and development expenses and adjusted net loss and 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)

	DECEMBER 31,	
	2019	**2018**
Assets		
Current assets		
Cash and cash equivalents	$ 143,940	$ 202,818
Short-term investments	165,250	—
Accounts receivable, net	38,354	2,715
Inventory	21,054	10,112
Prepaid expenses and other current assets	7,744	4,530
Total current assets	376,342	220,175
Property, plant and equipment, net	58,147	60,525
Operating lease right-of-use-assets	16,523	—
Other assets	1,596	4,344
Total assets	$ 452,608	$ 285,044
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 12,770	$ 12,403
Accrued expenses and other current liabilities	65,376	38,381
Operating lease liabilities	5,502	—
Total current liabilities	83,648	50,784
Convertible notes, net	188,651	—
Long-term operating lease liabilities	12,102	—
Other non-current liabilities	1,257	6,454
Total liabilities	285,658	57,238
Stockholders' equity		
Common stock	46	45
Additional paid-in capital	1,062,996	924,180

Accumulated other comprehensive loss	(92)	—
Accumulated deficit	(896,000)	(696,419)
Total stockholders' equity	166,950	227,806
Total liabilities and stockholders' equity	$ 452,608	$ 285,044

AERIE PHARMACEUTICALS, INC.

Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share data)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2019	**2018**	**2019**	**2018**
Product revenues, net	$ 24,657	$ 14,456	$ 69,888	$ 24,181
Total revenues, net	24,657	14,456	69,888	24,181
Costs and expenses:				
Cost of goods sold	1,684	377	4,833	641
Selling, general and administrative	35,467	31,887	138,402	120,614
Pre-approval commercial manufacturing	6,650	7,625	22,767	26,545
Research and development	30,794	26,492	91,378	86,123
Total costs and expenses	74,595	66,381	257,380	233,923
Loss from operations	(49,938)	(51,925)	(187,492)	(209,742)
Other (expense) income, net	(5,126)	467	(12,179)	(22,824)
Loss before income taxes	(55,064)	(51,458)	(199,671)	(232,566)
Income tax (benefit) expense	—	—	(90)	3
Net loss	$ (55,064)	$ (51,458)	$ (199,581)	$ (232,569)
Net loss per common share—basic and diluted	$ (1.21)	$ (1.14)	$ (4.39)	$ (5.58)
Weighted average number of common shares outstanding—basic and diluted	45,589,014	45,101,458	45,427,154	41,663,958

AERIE PHARMACEUTICALS, INC.

Reconciliation of GAAP to Non-GAAP Financial Measures

(Unaudited)

(in thousands)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2019	**2018**	**2019**	**2018**
Net loss (GAAP)	$ (55,064)	$ (51,458)	$ (199,581)	$ (232,569)
Add-back: stock-based compensation expense	11,172	9,713	45,093	38,728
Adjusted Net loss	$ (43,892)	$ (41,745)	$ (154,488)	$ (193,841)
Selling, general and administrative expenses (GAAP)	$ 35,467	$ 31,887	$ 138,402	$ 120,614
Less: stock-based compensation expense	(7,210)	(6,410)	(30,463)	(26,432)
Adjusted selling, general and administrative expenses	$ 28,257	$ 25,477	$ 107,939	$ 94,182
Pre-approval commercial manufacturing expenses (GAAP)	$ 6,650	$ 7,625	$ 22,767	$ 26,545
Less: stock-based compensation expense	(1,144)	(818)	(3,634)	(2,622)
Adjusted pre-approval commercial manufacturing expenses	$ 5,506	$ 6,807	$ 19,133	$ 23,923
Research and development expenses (GAAP)	$ 30,794	$ 26,492	$ 91,378	$ 86,123
Less: stock-based compensation expense	(2,818)	(2,485)	(10,996)	(9,674)
Adjusted research and development expenses	$ 27,976	$ 24,007	$ 80,382	$ 76,449
Total operating expenses (GAAP)	$ 72,911	$ 66,004	$ 252,547	$ 233,282
Less: stock-based compensation expense	(11,172)	(9,713)	(45,093)	(38,728)
Adjusted total operating expenses	$ 61,739	$ 56,291	$ 207,454	$ 194,554

AERIE PHARMACEUTICALS, INC.

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

(Unaudited)

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2019	**2018**	**2019**	**2018**
Net loss per common share—basic and diluted (GAAP)	$ (1.21)	$ (1.14)	$ (4.39)	$ (5.58)
Add-back: stock-based compensation expense	0.25	0.22	0.99	0.93
Adjusted Net loss per share—basic and diluted	$ (0.96)	$ (0.92)	$ (3.40)	$ (4.65)
Weighted average number of common shares outstanding—basic and diluted	45,589,014	45,101,458	45,427,154	41,663,958

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Source: Aerie Pharmaceuticals, Inc.

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