



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

May 6, 2020

Conference Call and Webcast Today, May 6th, at 5:00 p.m. ET

DURHAM, N.C.--(BUSINESS WIRE)--May 6, 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 potentially other diseases of the eye, today reported financial results for the first quarter ended March 31, 2020 and provided a general business update, including the impact of the COVID-19 pandemic on company operations.

Aerie First Quarter Highlights

- The Aerie glaucoma franchise, including Rhopressa[®] (netarsudil ophthalmic solution) 0.02% and Rocklatan[®] (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, generated first quarter 2020 net revenues of \$20.3 million, equivalent to an average of \$88 per bottle. Wholesaler shipments totaled 232,000 bottles during the first quarter of 2020 compared to 206,000 bottles shipped during the fourth quarter of 2019. The net revenue per bottle is lower than prior quarters reflecting higher penetration of Medicare Part D and other government-funded programs.
- Market access for Medicare Part D plans increased considerably effective May 1, 2020. Rhopressa[®] now has market access for 88 percent of lives covered under Medicare Part D plans, up from 75 percent previously. Rocklatan[®] currently has market access for 55 percent of Medicare Part D lives, up from 38 percent previously, and currently has an additional 15 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. Commercial coverage for Rhopressa[®] and Rocklatan[®] remain at 90 percent and 88 percent of covered lives, respectively.
- Aerie remains focused on its dry eye product candidate now named AR-15512 obtained through the December 2019 acquisition of Avizorex Pharma S.L. (Avizorex). Toxicology studies are underway as part of the evaluation of different concentrations of the product candidate, and Aerie plans to initiate a large Phase 2b study in late 2020.
- Aerie's retina program continues to advance. The AR-1105 (dexamethasone steroid implant) Phase 2 clinical trial, which commenced in March 2019 for macular edema due to RVO (retinal vein occlusion), was fully enrolled ahead of schedule in October 2019 with a readout expected in the second half of 2020. The first-in-human clinical trial for AR-13503 (Rho kinase and Protein kinase C inhibitor implant) commenced in the third quarter of 2019 for neovascular age-related macular degeneration and DME (diabetic macular edema). Aerie currently expects to commence enrollment of the Phase 2 clinical trial in the second half of 2020, with a readout expected in 2021.
- Aerie held a meeting with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in April 2020 to discuss Phase 3 trial designs for Rhopressa[®], while continuing to prepare for the trials. Aerie expects to initiate a Rhopressa[®] Phase 3 clinical trial in Japan, potentially commencing in the second half of 2020, along with exploring a collaboration with a potential partner in Japan to advance Aerie's clinical development and ultimately commercialize Rhopressa[®] and Rocklatan[®] in Japan.
- Aerie received approval from the U.S. Food and Drug Administration (FDA) in January 2020 to produce Rocklatan[®] in Aerie's Athlone, Ireland, manufacturing facility for commercial distribution in the U.S. market. The manufacturing plant began production of commercial supplies of Rocklatan[®] during the first quarter of 2020. Aerie also plans to file a Prior Approval Supplement with the FDA in second-quarter 2020 to obtain FDA approval to manufacture Rhopressa[®] in Athlone for commercial distribution in the U.S. market.
- The European Commission granted a centralised marketing authorisation for Rhokiinsa[®] (netarsudil ophthalmic solution) 0.02% in November 2019. The European Medicines Agency (EMA) accepted for review the marketing authorisation application (MAA) for Roclanda[®] (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (marketed as Rocklatan[®] in the U.S.) in December 2019. An opinion from the EMA's Committee for Medicinal Products for Human Use on the MAA

for Roclanda® is expected in the fourth quarter of 2020. Topline data from the Rocklatan® Mercury 3 Phase 3 clinical trial in Europe is expected potentially in late 2020, the results of which will help determine commercial prospects in the region.

- Net cash used in operating activities for the quarter ended March 31, 2020 on a U.S. GAAP basis totaled approximately \$41.8 million, resulting in \$264.7 million in cash and cash equivalents and investments as of March 31, 2020.

Impact of the COVID-19 Pandemic

- In December 2019, there was an outbreak of a new strain of coronavirus (COVID-19) and on March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and workforce participation due to “shelter-in-place” restrictions by various governments worldwide and created significant volatility and disruption of financial markets.
- While Aerie sales volumes increased in the first quarter of 2020 compared to the fourth quarter of 2019 for both Rhopressa® and Rocklatan®, total prescription volumes, as seen within the entire pharmaceutical market according to IQVIA data, has declined as the COVID-19 impact grew commencing in late March 2020. There has been a partial volume offset for Aerie due to an increasing proportion of prescriptions for 90-days’ supply, however, with many eye care professionals’ offices closed or operating with limited capacity, new prescription growth has slowed. Our sales force remains engaged with eye care professionals primarily through virtual means, and we are diligently managing our expenses including reducing travel and meeting expenses.
- Aerie does not yet know whether or how the progress of the COVID-19 pandemic will affect clinical operations or the timing of the approval by the EMA of the MAA for Roclanda®.
- Aerie has observed no disruptions to date in its supply chain for production of Rhopressa® and Rocklatan®. Aerie believes it has approximately three years of starting materials and active pharmaceutical ingredient in inventory, and adequate supply of finished product on hand to support its commercial efforts for at least the next six months. Production of Rhopressa® and Rocklatan® is continuing.

2020 Guidance

- Considering the rapidly evolving status of the unprecedented COVID-19 situation and the uncertainty around its ultimate impact, Aerie announced on April 9, 2020 the withdrawal of its 2020 guidance for net revenues and net cash used in operations. Guidance will be updated when there is clarity going forward.

“First and foremost, we are focused on the health and safety of our employees and their families, along with our patients and eye care professionals as we endure the COVID-19 pandemic. I am personally very grateful to our employees for their diligence in executing their responsibilities in a largely virtual environment. 2020 was off to a strong start for Aerie, but the momentum was unfortunately cut short by the COVID-19 impact late in the first quarter and continuing to the second quarter of this year. While we have seen a reduction in total prescriptions and particularly in new prescriptions, our average weekly sales-out to pharmacies was approximately 17,000 bottles in April, consistent with volumes experienced during the fourth quarter of 2019. It is difficult to project if this trend will continue but we appear to be experiencing a lower level of weekly decreases in the last few weeks than in early April. Further, we are delighted to have gained significant additional Medicare Part D coverage effective May 1 and, certainly once in a ‘normal’ environment, this should bode very well for our future volume growth,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

“Our clinical programs and plans, both in the United States and abroad remain largely on track, and we remain well-funded with approximately \$265 million of cash and investments as of March 31, 2020.”

First Quarter 2020 Financial Results

As of March 31, 2020, Aerie had cash and cash equivalents and investments of \$264.7 million. For the first quarter ended March 31, 2020, Aerie reported net product revenues of \$20.3 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 \$49.1 million, or \$1.07 loss per share, for the first quarter of 2020, compared to a net loss of \$48.0 million and \$1.06 loss per share for the first quarter of 2019. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 45.8 million and 45.3 million for the first quarters of 2020 and 2019, respectively. Total shares outstanding as of March 31, 2020 were 46.5 million.

The \$49.1 million net loss for the first quarter of 2020 is primarily comprised of \$14.2 million of gross profit, including \$6.1 million in cost of goods sold, and \$58.2 million in total operating expenses, including \$36.9 million in selling, general and administrative expenses, \$2.1 million in pre-approval commercial manufacturing expenses and \$19.2 million in research and development expenses. Excluding \$10.5 million of stock-based compensation expense, for the first quarter of 2020 adjusted cost of goods sold was \$5.6 million and adjusted total operating expenses were \$48.2 million, with adjusted selling, general and administrative expenses of \$30.0 million, adjusted pre-approval commercial manufacturing expenses of \$1.8 million and adjusted research and development expenses of \$16.3 million. Total adjusted net loss for the first quarter of 2020 was \$38.6 million, and adjusted net loss per share was \$0.84.

The \$48.0 million net loss for the first quarter of 2019 was primarily comprised of \$58.6 million in total operating expenses, including \$36.3 million in selling, general and administrative expenses, \$4.5 million in pre-approval commercial manufacturing expenses and \$17.9 million in research and development expenses. Excluding \$12.6 million of stock-based compensation expense, adjusted total operating expenses for the first quarter of 2019 were \$46.0 million, with adjusted selling, general and administrative expenses of \$27.2 million, adjusted pre-approval commercial manufacturing expenses of \$3.6 million and adjusted research and development expenses of \$15.2 million. Total adjusted net loss for the first quarter of 2019 was \$35.3 million, and adjusted net loss per share was \$0.78.

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 1480679. 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 1480679. The telephone replay will be available until May 14, 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 potentially 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 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 recent 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, such as statements in this press release regarding any expected clinical trials for AR-15512 (formerly AVX-012), AR-1105 or AR-13503 and the results of such clinical 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)

MARCH 31, 2020 DECEMBER 31, 2019

Assets

Current assets

Cash and cash equivalents	\$ 134,179	\$ 143,940
Short-term investments	130,552	165,250
Accounts receivable, net	42,941	38,354
Inventory	20,225	21,054
Prepaid expenses and other current assets	10,540	7,744
Total current assets	338,437	376,342
Property, plant and equipment, net	57,223	58,147
Operating lease right-of-use assets	15,465	16,523
Other assets	1,152	1,596
Total assets	\$ 412,277	\$ 452,608

Liabilities and Stockholders' Equity

Current liabilities

Accounts payable	\$ 9,208	\$ 12,770
Accrued expenses and other current liabilities	64,323	65,376
Operating lease liabilities	5,614	5,502

Total current liabilities	79,145	83,648
Convertible notes, net	193,833	188,651
Long-term operating lease liabilities	10,829	12,102
Other non-current liabilities	1,261	1,257
Total liabilities	285,068	285,658
Stockholders' equity		
Common stock	46	46
Additional paid-in capital	1,072,412	1,062,996
Accumulated other comprehensive loss	(120)	(92)
Accumulated deficit	(945,129)	(896,000)
Total stockholders' equity	127,209	166,950
Total liabilities and stockholders' equity	\$ 412,277	\$ 452,608

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

	THREE MONTHS ENDED MARCH 31,	
	2020	2019
Product revenues, net	\$ 20,341	\$ 10,852
Total revenues, net	20,341	10,852
Costs and expenses:		
Cost of goods sold	6,092	381
Selling, general and administrative	36,902	36,282
Pre-approval commercial manufacturing	2,114	4,457
Research and development	19,173	17,884
Total costs and expenses	64,281	59,004
Loss from operations	(43,940)	(48,152)
Other (expense) income, net	(5,222)	111

Loss before income taxes	(49,162)	(48,041)
Income tax (benefit) expense	(33)	(90)
Net loss	\$ (49,129)	\$ (47,951)
Net loss per common share—basic and diluted	\$ (1.07)	\$ (1.06)
Weighted average number of common shares outstanding—basic and diluted	45,792,504	45,270,660

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

	THREE MONTHS ENDED MARCH 31,	
	2020	2019
Net loss (GAAP)	\$ (49,129)	\$ (47,951)
Add-back: stock-based compensation expense	10,529	12,620
Adjusted Net loss	\$ (38,600)	\$ (35,331)
Cost of goods sold (GAAP)	\$ 6,092	\$ 381
Less: stock-based compensation expense	(497)	—
Adjusted cost of goods sold	\$ 5,595	\$ 381
Selling, general and administrative expenses (GAAP)	\$ 36,902	\$ 36,282
Less: stock-based compensation expense	(6,908)	(9,121)
Adjusted selling, general and administrative expenses	\$ 29,994	\$ 27,161
Pre-approval commercial manufacturing expenses (GAAP)	\$ 2,114	\$ 4,457
Less: stock-based compensation expense	(294)	(849)
Adjusted pre-approval commercial manufacturing expenses	\$ 1,820	\$ 3,608
Research and development expenses (GAAP)	\$ 19,173	\$ 17,884

Less: stock-based compensation expense	(2,830)	(2,650)
Adjusted research and development expenses	\$ 16,343	\$ 15,234
Total operating expenses (GAAP)	\$ 58,189	\$ 58,623
Less: stock-based compensation expense	(10,032)	(12,620)
Adjusted total operating expenses	\$ 48,157	\$ 46,003

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

	THREE MONTHS ENDED MARCH 31,	
	2020	2019
Net loss per common share—basic and diluted (GAAP)	\$ (1.07)	\$ (1.06)
Add-back: stock-based compensation expense	0.23	0.28
Adjusted Net loss per share—basic and diluted	\$ (0.84)	\$ (0.78)
Weighted average number of common shares outstanding—basic and diluted	45,792,504	45,270,660

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Source: Aerie Pharmaceuticals, Inc.