Aerie Pharmaceuticals Provides 2020 Company and Guidance Update Associated with COVID-19

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DURHAM, N.C.--(BUSINESS WIRE)--Apr. 9, 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 provided a business update associated with the impact of the global Coronavirus disease (COVID-19) pandemic on Company operations.

While Aerie volumes increased in the first-quarter of 2020 compared to the fourth-quarter of 2019 for both Rhopressa® (netarsudil ophthalmic solution) 0.02% and Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, the pace of volumes, as seen with the entire pharmaceutical market according to IQVIA data, has declined as the COVID-19 impact became elevated in late March and into April 2020 to date. There has been a positive partial offset from increasing 90-days' supply activity, but with many eye care professionals' offices closed or in the process of closing, new prescription growth has slowed. The Company is using various virtual tools to remain in contact with eye care professionals, and Aerie's territory managers are experiencing successful engagement largely working from their homes.

Considering the rapidly evolving status of the COVID-19 situation and the uncertainty around its ultimate impact, Aerie is withdrawing its 2020 guidance for net revenues and net cash used in operations, which includes the net revenue guidance as a component. As would be expected, the Company is currently experiencing travel and meeting expenses below original internal expectations. Guidance will be updated when there is clarity going forward.

Aerie has observed no disruptions to date in its supply chain for production of Rhopressa® and Rocklatan®. The Company 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, and production continues.

Regarding Aerie's globalization strategy, the regulatory review in Europe of Roclanda® (Rocklatan® in the United States) remains on track, while the results for the Mercury 3 trial for Roclanda®, which is designed to gauge commercialization prospects in Europe, are now expected in late 2020 or early 2021. Aerie expects to hold a meeting with the regulatory authorities in Japan during the second quarter of 2020 to discuss Phase 3 trial designs for Rhopressa® while continuing to prepare for the trials and exploring partnership opportunities. From a pipeline perspective, Aerie's early stage retina implant trials remain on track, and Aerie hopes to commence its Phase 2b clinical study for dry eye candidate AR-15512 (formerly AVX-012) by the end of 2020.

"The health and safety of our employees, patients, prescribers and community are of utmost importance during this time," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. "We are complying with all requirements and mandates from various agencies and governments, and we are operating quite effectively with most of our employees working diligently from home. While we believe we had been on track to execute our plan for 2020, including the growth we experienced in first-quarter 2020 volumes, given the uncertainties around COVID-19 and the unprecedented nature of this pandemic, we feel it is necessary to withdraw our current 2020 guidance. Despite these short-term disruptions, we remain confident in the long-term growth of our glaucoma franchise and Aerie's future."

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 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, has been 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: 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, our financial results and condition and 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 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 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.

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