Aerie Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Business Update

November 4, 2021

Third Quarter 2021 Net Revenues of $29.3 Million Increased 46% over Third Quarter 2020

Third Quarter 2021 Net Revenue Per Bottle of $89, up 16% over Third Quarter 2020

Phase 3 Studies for AR-15512 and AR-1105 Expected to Begin in the First Half of 2022

Conference Call and Webcast Today, November 4th, at 5:00 p.m. ET

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 4, 2021-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), an ophthalmic pharmaceutical company, today reported financial results for the third quarter ended September 30, 2021 and provided a general business update.

“Our third quarter 2021 results reflect nearly 46 percent growth in net revenues and 26 percent growth in bottle volumes for our U.S. glaucoma franchise compared to the third quarter of 2020. Our net revenue per bottle remained stable at $89 in the third quarter of 2021, with a year over year increase of $12 per bottle, primarily due to renegotiated wholesaler fees. We ended the third quarter with $168 million in cash and investments and our net cash used in operations for the quarter amounted to $19 million, compared to $22 million in the third quarter of 2020, reflecting stronger revenues and continued well-controlled operating expenses. We continue to remain comfortable with 2021 analyst net revenue consensus estimates,” said Benjamin F. McGraw, III, Pharm.D., Interim Executive Chairman of the Board of Directors.

Dr. McGraw added, “We are pleased to have also made significant progress in the pipeline during the third quarter. In September 2021, we reported successful topline results for our COMET-1 Phase 2b clinical study for AR-15512, our dry eye product candidate. The study results showed the product candidate had a statistically significant effect on both a validated sign and symptom and had a rapid onset of action. Confirmation of these results in our Phase 3 clinical trials would clearly differentiate it from other topical products. We expect to move forward with Phase 3 studies for AR-15512 in the first half of 2022 after the end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2022.”

“Following discussions with both the FDA and European Medicines Agency to finalize our Phase 3 strategy for our sustained-release implant, AR-1105, we now expect to begin Phase 3 activities in the first half of 2022. Supply chain issues for implant injector components have caused this date to be moved from the last quarter of this year.”

“From a globalization perspective, in October 2021, we were pleased to report successful topline Phase 3 results in Japan which showed that netarsudil 0.02% once daily was superior to ripasudil 0.4% twice daily in lowering intraocular pressure after four weeks ($p<0.001$), the primary endpoint of the study. Finally, we continue to have advanced partnership discussions and still expect to announce a collaboration agreement for Europe and other regions of the world for our glaucoma franchise by the end of 2021.”

U.S. Glaucoma Franchise Highlights

- Rhopressa® and Rocklatan® generated third quarter 2021 net revenues of $29.3 million, equivalent to an average of $89 per bottle. Shipments to wholesalers totaled 328,000 bottles during the third quarter of 2021. Commercial coverage for Rhopressa® and Rocklatan® both represent 76 percent of covered lives. Rhopressa® currently has market access for 92 percent of lives covered under Medicare Part D plans and an additional four percent of Medicare Part D lives with affordable access through U.S. government funded Low Income Subsidy (LIS) programs through which co-pays are less than $10 per month. Rocklatan® has market access for 74 percent of Medicare Part D lives and an additional 10 percent of remaining Medicare Part D lives through LIS programs.

Pipeline and Globalization Highlights

- Aerie reported successful topline results for COMET-1, Aerie’s Phase 2b clinical study for AR-15512, its dry eye product candidate, in September 2021. The COMET-1 study showed greatest efficacy in the higher concentration 0.003% BID, which will be advanced to Phase 3 clinical studies. Statistical significance versus vehicle was achieved for multiple pre-specified and validated sign and symptoms endpoints. The study showed statistically significant improvement in both signs and symptoms as early as Day 14 and continuous improvement in symptoms through Day 84. Aerie expects to have an end of Phase 2 meeting with the FDA in the first quarter of 2022 and expects to conduct two additional three-month

Phase 3 efficacy studies and one additional safety study to complete development of AR-15512.

- Aerie also reported positive topline results for its Phase 3 clinical trial of netarsudil ophthalmic solution 0.02% (netarsudil 0.02%) in Japan in October 2021. The results evaluated netarsudil 0.02% versus ripasudil hydrochloride hydrate ophthalmic solution 0.4% (ripasudil 0.4%) and showed that netarsudil 0.02% once daily was superior to ripasudil 0.4% twice daily in lowering intraocular pressure at week four ($p<0.001$), the primary endpoint of the study.
- Discussions with a potential collaborator in Europe and other regions of the world continue to advance and Aerie still expects to announce a new collaboration agreement by year-end 2021.
- Topline results from the AR-1105 (dexamethasone intravitreal implant) Phase 2 clinical trial in patients with macular edema due to retinal vein occlusion were presented at the 39th Annual Scientific Meeting of the American Society of Retina Specialists in October 2021. The presentation entitled “Phase 2 Study of Two Formulations of AR-1105 in Macular Edema (ME) Secondary to Retinal Vein Occlusion (RVO)” was presented by Michael A. Singer, M.D., Clinical Professor of Ophthalmology at the University of Texas Health Science Center. In the study, the AR-1105 product candidate had a sustained efficacy of up to six months, differentiating it from other steroid implants.
- Investigational New Drug Application (IND)-enabling preclinical studies are underway for AR-6121, a ROCK inhibitor-linked steroid. Preclinical data indicates the maintenance of beneficial steroid effect without the usual increase in intraocular pressure. Aerie expects to file the IND application for AR-6121 in the second half of 2022.
- IND-enabling preclinical studies are ongoing for AR-14034 SR, a preclinical sustained-release implant containing the pan-VEGF inhibitor axitinib formulated in a unique bio-erodible polymer blend using Aerie’s exclusive PRINT ® technology. This implant is designed to reduce treatment burden by providing a once per-year injection. Aerie expects to file the IND application for AR-14034 SR in the second half of 2022.
- The first-in-human clinical trial for AR-13503 SR (Rho kinase and protein kinase C inhibitor sustained-release implant), continues to progress. Aerie currently expects to complete the human dose escalation safety evaluation with the current implant design in the first quarter of 2022.

Corporate Updates

- Following the departure of Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie, effective September 17, 2021, Aerie has appointed Benjamin F. McGraw, III, Pharm.D., as Interim Executive Chairman of the Board of Directors and the Company is currently searching for a new Chief Executive Officer. Dr. McGraw’s appointment is effective from September 21, 2021 and upon the appointment of a new Chief Executive Officer, the Company intends to separate the roles of Chairman and Chief Executive Officer.
- Aerie announced the departure of Christopher Staten, Interim Chief Financial Officer and Vice President of Finance at Aerie, effective October 29, 2021. Aerie is conducting a search to fill the role of Chief Financial Officer. Mr. Staten’s departure is not due to a dispute on any matter relating to the Company’s accounting and financial policies or operations.

Net cash used in operating activities for the third quarter ended September 30, 2021 on a GAAP basis totaled approximately $18.9 million, resulting in $167.6 million in cash and cash equivalents and investments as of September 30, 2021.

Third Quarter 2021 Financial Results

For the third quarter ended September 30, 2021, Aerie reported net product revenues of $29.3 million related to the combined sales of Rhopressa® and Rocklatan®. Aerie reported a GAAP net loss of $39.7 million, or $0.86 net loss per share, for the third quarter of 2021, compared to a net loss of $39.6 million and $0.86 net loss per share for the third quarter of 2020. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 46.3 million and 45.9 million for the third quarters of 2021 and 2020, respectively. Total shares outstanding as of September 30, 2021 were 47.2 million. As of September 30, 2021, Aerie had cash and cash equivalents and investments of $167.6 million.

The $39.7 million net loss for the third quarter of 2021 is primarily comprised of $21.4 million of gross profit, including $7.9 million in cost of goods sold, and $53.8 million in total operating expenses, including $34.7 million in selling, general and administrative expenses and $19.1 million in research and development expenses. The cost of goods sold includes $5.4 million in idle capacity costs resulting from the Athlone manufacturing plant having commenced operations earlier in 2020 and not having yet reached full capacity. These idle capacity costs are expected to decline over time as commercial volumes and clinical supply requirements increase. Excluding $6.6 million of stock-based compensation expense, for the third quarter of 2021 adjusted cost of goods sold was $7.6 million and adjusted total operating expenses were $47.5 million, with adjusted selling, general and administrative expenses of $30.3 million and adjusted research and development expenses of $17.2 million. Total adjusted net loss for the third quarter of 2021 was $33.1 million and adjusted net loss per share was $0.72.

In comparison, the $39.6 million net loss for the third quarter of 2020 was 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 commenced operations earlier in 2020 and not having yet reached 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.

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 4696924. 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 4696924. The telephone replay will be available until November 12, 2021.

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 the treatment of dry eye disease, 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 product candidates, implants 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 product candidates, implants 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 product candidates, implants 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 product candidates, implants 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 product candidates, implants or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any product candidates, implants 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 expectations for full year 2021; our ability to protect our proprietary technology and enforce our intellectual property rights or to develop new intellectual property; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies or the consummation or the success of, any proposed collaboration agreements regarding out-licensing our products or product candidates. In particular, FDA and European Medicines Agency (EMA) approval of Rhopressa® and Rocklatan®, and MHRA authorisation of Roclanda® do not constitute regulatory approval of Rhopressa®, Rocklatan® or Roclanda® in other jurisdictions, and there can be no assurance that we will receive regulatory approval for Rhopressa®, Rocklatan® or Roclanda® in such other jurisdictions. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our product candidates or any future product candidates, implants, and there can be no assurance that we will receive FDA approval for our product candidates, implants or any future product candidates. Furthermore, the acceptance of the INDs by the FDA for AR-15512, AR-1105, AR-14034, AR-6121 and AR-13503 do not constitute FDA approval of AR-15512, AR-1105, AR-14034, AR-6121 or AR-13503 and the outcomes of later clinical trials for AR-15512, AR-1105, AR-14034, AR-6121 or AR-13503 may not be sufficient to submit a New Drug Application (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 (generally accepted accounting principles), 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, 2021	**DECEMBER 31, 2020**
Assets		
Current assets		
Cash and cash equivalents	$ 61,847	$ 151,570
Short-term investments	105,760	88,794
Accounts receivable, net	64,566	56,022
Inventory	30,055	27,059
Prepaid expenses and other current assets	13,724	8,310
Total current assets	275,952	331,755
Property, plant and equipment, net	51,681	54,260
Operating lease right-of-use assets	23,171	14,084
Other assets	998	1,946
Total assets	$ 351,802	$ 402,045
Liabilities and Stockholders’ (Deficit) Equity		
Current liabilities		
Accounts payable	$ 8,076	$ 8,826
Accrued expenses and other current liabilities	106,117	90,723

Operating lease liabilities	3,935	4,923
Total current liabilities	118,128	104,472
Convertible notes, net	228,189	210,373
Deferred revenue, non-current	53,700	50,858
Long-term operating lease liabilities	22,496	10,206
Other non-current liabilities	2,165	2,168
Total liabilities	424,678	378,077
Stockholders' (deficit) equity		
Common stock	47	47
Additional paid-in capital	1,126,580	1,103,074
Accumulated other comprehensive loss	(59)	(52)
Accumulated deficit	(1,199,444)	(1,079,101)
Total stockholders' (deficit) equity	(72,876)	23,968
Total liabilities and stockholders' (deficit) equity	$ 351,802	$ 402,045

AERIE PHARMACEUTICALS, INC.

Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,	
	2021	**2020**
Product revenues, net	$ 29,313	$ 20,081
Total revenues, net	29,313	20,081
Costs and expenses:		
Cost of goods sold	7,899	5,381
Selling, general and administrative	34,656	32,029
Pre-approval commercial manufacturing	—	110
Research and development	19,132	16,165

Total costs and expenses	61,687	53,685
Loss from operations	(32,374)	(33,604)
Other (expense) income, net	(7,259)	(6,044)
Loss before income taxes	(39,633)	(39,648)
Income tax expense (benefit)	58	—
Net loss	$ (39,691)	$ (39,648)
Net loss per common share—basic and diluted	$ (0.86)	$ (0.86)
Weighted average number of common shares outstanding—basic and diluted	46,342,905	45,945,745

AERIE PHARMACEUTICALS, INC.

Reconciliation of GAAP to Non-GAAP Financial Measures

(Unaudited)

(in thousands)

	THREE MONTHS ENDED SEPTEMBER 30,	
	2021	**2020**
Net loss (GAAP)	$ (39,691)	$ (39,648)
Add-back: stock-based compensation expense	6,613	9,800
Adjusted Net loss	$ (33,078)	$ (29,848)
Cost of goods sold (GAAP)	$ 7,899	$ 5,381
Less: stock-based compensation expense	(287)	(511)
Adjusted cost of goods sold	$ 7,612	$ 4,870
Selling, general and administrative expenses (GAAP)	$ 34,656	$ 32,029
Less: stock-based compensation expense	(4,385)	(6,716)
Adjusted selling, general and administrative expenses	$ 30,271	$ 25,313
Pre-approval commercial manufacturing expenses (GAAP)	$ —	$ 110

Less: stock-based compensation expense	—	(28)
Adjusted pre-approval commercial manufacturing expenses	$ —	$ 82
Research and development expenses (GAAP)	$ 19,132	$ 16,165
Less: stock-based compensation expense	(1,941)	(2,545)
Adjusted research and development expenses	$ 17,191	$ 13,620
Total operating expenses (GAAP)	$ 53,788	$ 48,304
Less: stock-based compensation expense	(6,326)	(9,289)
Adjusted total operating expenses	$ 47,462	$ 39,015

AERIE PHARMACEUTICALS, INC.

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

(Unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,	
	2021	**2020**
Net loss per common share—basic and diluted (GAAP)	$ (0.86)	$ (0.86)
Add-back: stock-based compensation expense	0.14	0.21
Adjusted Net loss per share—basic and diluted	$ (0.72)	$ (0.65)
Weighted average number of common shares outstanding—basic and diluted	46,342,905	45,945,745

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Media:
Carolyn McAuliffe
cmcauliffe@aeriepharma.com
(949) 526-8733

Investors:
LifeSci Advisors on behalf of Aerie Pharmaceuticals, Inc.
Hans Vitzthum
hans@lifesciadvisors.com
(617) 430-7578

Source: Aerie Pharmaceuticals, Inc.