

# AERIE PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 03/07/17 for the Period Ending 03/07/17

|             |                                                                      |
|-------------|----------------------------------------------------------------------|
| Address     | 7020 KIT CREEK ROAD<br>SUITE 270<br>RESEARCH TRIANGLE PARK, NC 27709 |
| Telephone   | 919-313-9650                                                         |
| CIK         | 0001337553                                                           |
| Symbol      | AERI                                                                 |
| SIC Code    | 2836 - Biological Products, Except Diagnostic Substances             |
| Industry    | Biotechnology & Medical Research                                     |
| Sector      | Healthcare                                                           |
| Fiscal Year | 12/31                                                                |

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 7, 2017**

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**Aerie Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36152**  
(Commission  
File Number)

**20-3109565**  
(I.R.S. Employer  
Identification Number)

**2030 Main Street, Suite 1500**  
**Irvine, California 92614**  
(Address of principal executive offices) (Zip code)

**Registrant's telephone number, including area code: (949) 526-8700**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions ( *see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On March 7, 2017, Aerie Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter ended December 31, 2016. A copy of the press release is furnished as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 2.02.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated March 7, 2017.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AERIE PHARMACEUTICALS, INC.**

Date: March 7, 2017

By: /s/ Richard J. Rubino  
Richard J. Rubino  
Chief Financial Officer

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**EXHIBIT INDEX**

| <u>Exhibit</u> | <u>Description</u>                 |
|----------------|------------------------------------|
| 99.1           | Press Release dated March 7, 2017. |



**Aerie Pharmaceuticals Reports Fourth Quarter and Full Year 2016  
Financial Results and Provides Business Update**

**Conference Call and Webcast Today, March 7, at 5:00 p.m. ET**

IRVINE, California - (BUSINESS WIRE)—Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), a clinical-stage pharmaceutical company focused on the discovery, development, and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye, today reported financial results for the fourth quarter and full year ended December 31, 2016, along with a general business update.

**Aerie Highlights and Outlook**

- Rhopressa <sup>TM</sup> (netarsudil ophthalmic solution) 0.02% NDA (new drug application) filing was resubmitted on February, 28, 2017, with a standard one-year FDA review expected from the date of resubmission.
- Topline six-month efficacy and safety data from Rocket 4, the Rhopressa <sup>TM</sup> Phase 3 clinical trial designed to provide adequate safety data for European regulatory filings, are expected in the second quarter of 2017.
- Topline 90-day efficacy and safety data from the second Phase 3 clinical trial for Roclatan <sup>TM</sup> (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, named Mercury 2, are also expected in the second quarter of 2017. If both Mercury 1 and Mercury 2 are successful, the Roclatan <sup>TM</sup> NDA is expected to be filed in late 2017 or early 2018.
- As of December 31, 2016, Aerie had \$233.7 million in cash, cash equivalents, and investments. For the full year ended December 31, 2016, cash burn totaled \$84.9 million, in line with our previous guidance of \$85 million.
- Cash burn for 2017 is expected to approximate \$100 million and includes the previously announced \$16 million in Ireland manufacturing plant capital build-out costs. Projected operating expenses for 2017 are similar to 2016, with increased commercialization and scale-up expenses offset by reductions in clinical spend.

“We are off to a great start in 2017, with over \$230 million in cash and investments, our Rhopressa <sup>TM</sup> NDA resubmitted, and our readouts from Rocket 4 and Mercury 2 on track for the second quarter of this year. We also look forward to commencing our first European clinical trial for Roclatan <sup>TM</sup>, known as Mercury 3, in mid-2017,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

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Dr. Anido continued, “Our strategic initiatives, including our ongoing review of drug delivery technologies, our progress in defining our clinical trial path forward in Japan, and the commencement of build-out of our Ireland manufacturing plant, are also all proceeding on plan.”

#### **Fourth Quarter 2016 Financial Results**

As of December 31, 2016, Aerie had cash, cash equivalents, and investments of \$233.7 million. For the fourth quarter ended December 31, 2016, Aerie reported a net loss attributable to common stockholders, as measured in accordance with U.S. generally accepted accounting principles (“GAAP”), of \$29.3 million, or \$0.87 per share, compared to \$20.4 million and \$0.76 per share for the fourth quarter of 2015. The weighted average number of shares of common stock outstanding utilized in the calculation of net loss per common share was 33,613,375 and 26,593,158 for the fourth quarters of 2016 and 2015, respectively. Total shares outstanding as of December 31, 2016 were 33,458,607.

The \$29.3 million net loss attributable to common stockholders for the fourth quarter of 2016 includes \$28.8 million in operating expenses, reflecting \$14.1 million in research and development expenses and \$14.7 million in general and administrative expenses. Excluding \$5.3 million of non-cash stock-based compensation expense, adjusted operating expenses for the fourth quarter of 2016 were \$23.5 million, with adjusted research and development expenses of \$12.5 million and adjusted general and administrative expenses of \$11.0 million. Total adjusted net loss for the fourth quarter of 2016 was \$24.0 million, and adjusted net loss per share was \$0.72.

The \$20.4 million net loss attributable to common stockholders for the fourth quarter of 2015 includes \$20.0 million in operating expenses, reflecting \$12.3 million in research and development expenses and \$7.7 million in general and administrative expenses. Excluding \$3.4 million of non-cash stock-based compensation expense, adjusted operating expenses for the fourth quarter of 2015 were \$16.5 million, with adjusted research and development expenses of \$11.5 million and adjusted general and administrative expenses of \$5.0 million. Total adjusted net loss for the fourth quarter of 2015 was \$17.0 million, and adjusted net loss per share was \$0.64.

The higher operating expenses in the fourth quarter of 2016 as compared to the fourth quarter of 2015 primarily reflect the expansion of our employee base to support the growth of our operations, including clinical activities related to our Phase 3 programs for our product candidates, and activities associated with preparing for commercialization efforts.

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## Conference Call / Web Cast 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 61259874. 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 61259874. The telephone replay will be available until March 14, 2017.

## About Aerie Pharmaceuticals, Inc.

Aerie is a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye. Aerie's two lead product candidates are once-daily intraocular pressure lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA filing for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was resubmitted to the FDA in February 2017. Aerie's second product candidate, Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, is a fixed dose combination of Rhopressa™ and latanoprost, a widely prescribed prostaglandin analogue. Roclatan™ currently has two Phase 3 registration trials underway, named Mercury 1 and Mercury 2. If these trials are successful, an NDA for Roclatan™ is expected to be filed in late 2017 or early 2018. Aerie is also focused on the development of additional product candidates and technologies in ophthalmology.

## 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 include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the clinical effectiveness of our product candidates and results of our clinical trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; our expectations regarding the commercialization and manufacturing of our product candidates; our expectations related to the use of proceeds from our equity and debt financings; our estimates regarding expected cash burn and expenses, anticipated capital requirements and our needs

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for additional financing; the potential advantages of our product candidates; our plans to pursue development of our product candidates for additional indications and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma; 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 or product candidates. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on regulatory approvals and economic 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). In particular, the preclinical research discussed in this press release is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later clinical trials. Any future clinical trial results may not demonstrate safety and efficacy sufficient to obtain regulatory approval related to the preclinical research findings discussed in this press release. 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 operating expenses, adjusted research and development expenses, adjusted general and administrative expenses, adjusted other income (expense) and adjusted net loss per share. For a description of the adjusted calculations and reconciliations to the nearest GAAP measures, please see the “Reconciliation of GAAP Net Loss to Adjusted Net Loss” 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 non-cash 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, except share and per share data)

|                                                                                                                                                                                                                                   | <u>DECEMBER 31,<br/>2016</u> | <u>DECEMBER 31,<br/>2015</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------------------------------|
| <b>Assets</b>                                                                                                                                                                                                                     |                              |                              |
| Current assets                                                                                                                                                                                                                    |                              |                              |
| Cash and cash equivalents                                                                                                                                                                                                         | \$ 197,945                   | \$ 91,060                    |
| Short-term investments                                                                                                                                                                                                            | 35,717                       | 45,502                       |
| Prepaid expenses and other current assets                                                                                                                                                                                         | 4,028                        | 1,865                        |
| Total current assets                                                                                                                                                                                                              | <u>237,690</u>               | <u>138,427</u>               |
| Long-term investments                                                                                                                                                                                                             | —                            | 13,808                       |
| Furniture, fixtures and equipment, net                                                                                                                                                                                            | 7,857                        | 3,816                        |
| Other assets, net                                                                                                                                                                                                                 | 2,707                        | 3,076                        |
| Total assets                                                                                                                                                                                                                      | <u>\$ 248,254</u>            | <u>\$ 159,127</u>            |
| <b>Liabilities and Stockholders' Equity</b>                                                                                                                                                                                       |                              |                              |
| Current liabilities                                                                                                                                                                                                               |                              |                              |
| Accounts payable and other current liabilities                                                                                                                                                                                    | \$ 18,820                    | \$ 16,565                    |
| Interest payable                                                                                                                                                                                                                  | 551                          | 551                          |
| Total current liabilities                                                                                                                                                                                                         | <u>19,371</u>                | <u>17,116</u>                |
| Convertible notes, net of discounts                                                                                                                                                                                               | 123,539                      | 123,236                      |
| Total liabilities                                                                                                                                                                                                                 | <u>142,910</u>               | <u>140,352</u>               |
| Commitments and contingencies                                                                                                                                                                                                     |                              |                              |
| Stockholders' Equity                                                                                                                                                                                                              |                              |                              |
| Preferred stock, \$0.001 par value; 15,000,000 shares authorized as of December 31, 2016 and December 31, 2015; None issued and outstanding                                                                                       | —                            | —                            |
| Common stock, \$0.001 par value; 150,000,000 shares authorized as of December 31, 2016 and December 31, 2015; 33,458,607 and 26,458,495 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively | 33                           | 26                           |
| Additional paid-in capital                                                                                                                                                                                                        | 422,002                      | 236,492                      |
| Accumulated other comprehensive loss                                                                                                                                                                                              | (68)                         | (179)                        |
| Accumulated deficit                                                                                                                                                                                                               | (316,623)                    | (217,564)                    |
| Total stockholders' equity                                                                                                                                                                                                        | <u>105,344</u>               | <u>18,775</u>                |
| Total liabilities and stockholders' equity                                                                                                                                                                                        | <u>\$ 248,254</u>            | <u>\$ 159,127</u>            |

**AERIE PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**(Unaudited)**

(in thousands, except share and per share data)

|                                                                          | THREE MONTHS ENDED<br>DECEMBER 31, |                    | TWELVE MONTHS ENDED<br>DECEMBER 31, |                    |
|--------------------------------------------------------------------------|------------------------------------|--------------------|-------------------------------------|--------------------|
|                                                                          | 2016                               | 2015               | 2016                                | 2015               |
| <b>Operating expenses</b>                                                |                                    |                    |                                     |                    |
| General and administrative                                               | \$ (14,664)                        | \$ (7,648)         | \$ (44,478)                         | \$ (30,635)        |
| Research and development                                                 | (14,093)                           | (12,302)           | (52,394)                            | (44,451)           |
| Loss from operations                                                     | (28,757)                           | (19,950)           | (96,872)                            | (75,086)           |
| Other income (expense), net                                              | (504)                              | (512)              | (1,994)                             | 862                |
| Net loss before income taxes                                             | (29,261)                           | (20,462)           | (98,866)                            | (74,224)           |
| Income tax expense                                                       | (61)                               | 85                 | (193)                               | (139)              |
| Net loss                                                                 | <u>\$ (29,322)</u>                 | <u>\$ (20,377)</u> | <u>\$ (99,059)</u>                  | <u>\$ (74,363)</u> |
| Net loss attributable to common stockholders—basic and diluted           | <u>\$ (29,322)</u>                 | <u>\$ (20,377)</u> | <u>\$ (99,059)</u>                  | <u>\$ (74,363)</u> |
| Net loss per share attributable to common stockholders—basic and diluted | <u>\$ (0.87)</u>                   | <u>\$ (0.76)</u>   | <u>\$ (3.40)</u>                    | <u>\$ (2.88)</u>   |
| Weighted average number of common shares outstanding—basic and diluted   | <u>33,613,375</u>                  | <u>26,593,158</u>  | <u>29,135,583</u>                   | <u>25,781,230</u>  |
| Net loss                                                                 | (29,322)                           | (20,377)           | (99,059)                            | (74,363)           |
| Unrealized (loss) gain on available-for-sale investments                 | (55)                               | (147)              | 111                                 | (72)               |
| Comprehensive loss                                                       | <u>\$ (29,377)</u>                 | <u>\$ (20,524)</u> | <u>\$ (98,948)</u>                  | <u>\$ (74,435)</u> |

**Aerie Pharmaceuticals, Inc.**  
**Reconciliation of GAAP Net Loss to Adjusted Net Loss**  
**(Unaudited)**  
(in thousands)

|                                                                          | <b>THREE MONTHS ENDED<br/>DECEMBER 31,</b> |                    | <b>TWELVE MONTHS ENDED<br/>DECEMBER 31,</b> |                    |
|--------------------------------------------------------------------------|--------------------------------------------|--------------------|---------------------------------------------|--------------------|
|                                                                          | <b>2016</b>                                | <b>2015</b>        | <b>2016</b>                                 | <b>2015</b>        |
| <b>Net loss attributable to common stockholders – basic and diluted:</b> |                                            |                    |                                             |                    |
| Net loss attributable to common stockholders – basic and diluted (GAAP)  | \$ (29,322)                                | \$ (20,377)        | \$ (99,059)                                 | \$ (74,363)        |
| <b>Adjustments:</b>                                                      |                                            |                    |                                             |                    |
| Stock-based compensation (a)                                             | 5,280                                      | 3,412              | 16,794                                      | 12,945             |
| <b>Adjusted Net loss</b>                                                 | <b>\$ (24,042)</b>                         | <b>\$ (16,965)</b> | <b>\$ (82,265)</b>                          | <b>\$ (61,418)</b> |
| <b>Operating expenses:</b>                                               |                                            |                    |                                             |                    |
| <b>General and administrative expense:</b>                               |                                            |                    |                                             |                    |
| General and administrative expense (GAAP)                                | \$ (14,664)                                | \$ (7,648)         | \$ (44,478)                                 | \$ (30,635)        |
| <b>Adjustments:</b>                                                      |                                            |                    |                                             |                    |
| Stock-based compensation (a)                                             | 3,718                                      | 2,603              | 13,013                                      | 10,445             |
| <b>Adjusted general and administrative expense</b>                       | <b>\$ (10,946)</b>                         | <b>\$ (5,045)</b>  | <b>\$ (31,465)</b>                          | <b>\$ (20,190)</b> |
| <b>Research and development expense:</b>                                 |                                            |                    |                                             |                    |
| Research and development expense (GAAP)                                  | \$ (14,093)                                | \$ (12,302)        | \$ (52,394)                                 | \$ (44,451)        |
| <b>Adjustments:</b>                                                      |                                            |                    |                                             |                    |
| Stock-based compensation (a)                                             | 1,562                                      | 809                | 3,781                                       | 2,500              |
| <b>Adjusted research and development expense</b>                         | <b>\$ (12,531)</b>                         | <b>\$ (11,493)</b> | <b>\$ (48,613)</b>                          | <b>\$ (41,951)</b> |
| Operating expenses (GAAP)                                                | \$ (28,757)                                | \$ (19,950)        | \$ (96,872)                                 | \$ (75,086)        |
| <b>Adjustments:</b>                                                      |                                            |                    |                                             |                    |
| Stock-based compensation (a)                                             | 5,280                                      | 3,412              | 16,794                                      | 12,945             |
| <b>Adjusted operating expenses</b>                                       | <b>\$ (23,477)</b>                         | <b>\$ (16,538)</b> | <b>\$ (80,078)</b>                          | <b>\$ (62,141)</b> |
| <b>Other income (expense):</b>                                           |                                            |                    |                                             |                    |
| Other income (expense) (GAAP)                                            | \$ (504)                                   | \$ (512)           | \$ (1,994)                                  | \$ 862             |
| <b>Adjustments:</b>                                                      |                                            |                    |                                             |                    |
|                                                                          | —                                          | —                  | —                                           | —                  |
| <b>Adjusted other income (expense)</b>                                   | <b>\$ (504)</b>                            | <b>\$ (512)</b>    | <b>\$ (1,994)</b>                           | <b>\$ 862</b>      |

**Aerie Pharmaceuticals, Inc.**  
**Reconciliation of GAAP Net Loss Per Share to Adjusted Net Loss Per Share**  
**(Unaudited)**

|                                                                                    | THREE MONTHS ENDED<br>DECEMBER 31, |                   | TWELVE MONTHS ENDED<br>DECEMBER 31, |                   |
|------------------------------------------------------------------------------------|------------------------------------|-------------------|-------------------------------------|-------------------|
|                                                                                    | 2016                               | 2015              | 2016                                | 2015              |
| <b>Net loss per share attributable to common stockholders – basic and diluted:</b> |                                    |                   |                                     |                   |
| Net loss per share attributable to common stockholders – basic and diluted (GAAP)  | \$ (0.87)                          | \$ (0.76)         | \$ (3.40)                           | \$ (2.88)         |
| <b>Adjustments:</b>                                                                |                                    |                   |                                     |                   |
| Stock-based compensation (a)                                                       | 0.15                               | 0.12              | 0.58                                | 0.50              |
| <b>Adjusted Net loss per share</b>                                                 | <b>\$ (0.72)</b>                   | <b>\$ (0.64)</b>  | <b>\$ (2.82)</b>                    | <b>\$ (2.38)</b>  |
| <b>Weighted average number of common shares outstanding – basic and diluted</b>    | <b>33,613,375</b>                  | <b>26,593,158</b> | <b>29,135,583</b>                   | <b>25,781,230</b> |

Aerie is providing adjusted information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the Company's performance.

This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP.

Explanation of adjustments:

**(a) Stock-based compensation:** Excludes non-cash stock-based compensation.

Contacts

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or

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