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

FORM 8-K

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

Date of Report (Date of earliest event reported): February 25, 2021

Aerie Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36152**	**20-3109565**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

4301 Emperor Boulevard, Suite 400
Durham, North Carolina 27703
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (919) 237-5300

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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Shares of common stock, par value $0.001 per share	AERI	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 25, 2021, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2020 and a general business update. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release dated February 25, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

February 25, 2021

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

Exhibit 99.1

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

2020 Net Revenues of $83.1 Million Increased 19% over 2019

Fourth Quarter Net Revenues of $24.7 Million or $80 Per Bottle

New Sustained Release Pan-VEGF Inhibitor Pipeline Candidate Announced Today

Conference Call and Webcast Today, February 25th, at 5:00 p.m. ET

Durham, N.C. -- (BUSINESS WIRE) -- 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, ocular surface diseases and retinal diseases, today reported financial results for the fourth quarter and year ended December 31, 2020 and provided a general business update.

“Our fourth quarter 2020 net revenues of $24.7 million exceeded third quarter by nearly 23 percent, reflecting strong sequential volume growth in our glaucoma franchise and increased net revenue per bottle. We believe our glaucoma franchise is increasingly benefiting from broader physician awareness of the two product profiles and expanded formulary access. We have recently reduced the fees we pay our wholesalers and continue to refine our payer rebate contracts, and with that we expect our net revenue per bottle to continue increasing as we proceed through 2021. Additionally, we ended 2020 well-funded with cash and investments of over $240 million reflecting stronger revenues, well-controlled operating expenses and the Santen upfront payment. While we are not currently providing full year 2021 financial guidance due to continuing uncertainties surrounding the impact of the ongoing pandemic on ophthalmic practices, based on our volume and net revenue per bottle trajectory, we are comfortable with current consensus analyst estimates,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer.

Dr. Anido added, “With our Santen collaboration agreement now signed and the first Phase 3 trial for Rhopressa® underway in Japan, we are now receiving inbound interest from multiple potential collaborators in Europe, now that we have regulatory approval for both glaucoma products in the region and the positive topline Mercury 3 results in hand. Turning to our pipeline, we have announced a new preclinical implant for the potential treatment of wet age-related macular degeneration and diabetic macular edema, AR-14034, a sustained-release retinal implant containing the pan-VEGF inhibitor axitinib formulated in a unique bio-erodible polymer blend using our exclusive PRINT® technology. We believe, based on the predictability of our PRINT® platform and the formulation capabilities provided by our access to a large variety of polymers, that this preclinical implant may have the potential to provide up to one year of treatment from a single injection with potentially better efficacy than currently available products and product candidates. This is another example of the potential flexibility of our sustained-release ophthalmic platform, and we expect there will be other opportunities for this technology well into the future. Turning to the most advanced product candidates in our pipeline, the Phase 2b clinical trial of AR-15512, our dry eye product candidate, is well underway. We also remain excited about the previously announced topline Phase 2 results for AR-1105, which indicated up to six months of sustained efficacy for patients with macular edema associated with retinal vein occlusion, a significantly differentiated profile for a retinal steroid implant. We are in discussions with both the FDA and EMA to develop a Phase 3 strategy for AR-1105 in the United States and Europe.”

U.S. Glaucoma Franchise Highlights

- Rhopressa® and Rocklatan® generated fourth quarter 2020 net revenues of $24.7 million, equivalent to an average of $80 per bottle. Shipments to wholesalers totaled 307,000 during the fourth quarter of 2020, 18% higher than the 261,000 bottles in the third quarter of 2020. Net revenues for the year ended December 31, 2020 totaled $83.1 million, compared to $69.9 million for the year ended December 31, 2019, reflecting a 19% increase.
- Rhopressa® currently has commercial coverage for 90 percent of lives and market access for 89 percent of lives covered under Medicare Part D plans. Commercial coverage for Rocklatan® represents 89 percent of covered lives. Rocklatan® has market access for 56 percent of Medicare Part D lives and an additional 15 percent of remaining Medicare Part D lives with affordable access through U.S. government funded Low Income Subsidy programs through which co-pays are less than $10 per month.

Pipeline and International Highlights

- A new wet age-related macular degeneration (wAMD) / diabetic macular edema (DME) preclinical implant has been added to Aerie's pipeline. AR-14034 represents a sustained-release implant of axitinib (VEGF A/B/C/D inhibitor) produced with a unique bio-erodible polymer blend using PRINT® technology that may potentially necessitate only one injection to treat a wAMD or DME patient for up to 12 months (refer to the slide presentation posted today in the Events and Presentations page of www.aeriepharma.com).
- Aerie continues to expect topline results of COMET-1, Aerie's Phase 2b clinical trial for its dry eye product candidate, AR-15512, in the third quarter of 2021. COMET-1, which was initiated in October 2020, is powered as a Phase 3 trial.
- Aerie was granted a centralised marketing authorisation in Europe for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (marketed as Rocklatan® in the United States) in January 2021. Aerie continues to prepare for pricing discussions in Germany while evaluating potential collaboration opportunities for Europe.
- Aerie and Santen announced in October 2020 that they executed an exclusive license agreement for the development and commercialization of Rhopressa® and Rocklatan® in Japan and several other Asian countries, and the first Phase 3 clinical trial for Rhopressa® in Japan is underway. The agreement included an upfront payment to Aerie of $50.0 million, with net cash proceeds after withholding taxes of $45.0 million received in the fourth quarter of 2020.
- Aerie continues to evaluate the clinical and regulatory pathways for Phase 3 clinical trials for AR-1105 (dexamethasone steroid implant) in both the U.S. and European markets. This follows the positive Phase 2 results for macular edema due to retinal vein occlusion reported in July 2020, which indicated up to six months of sustained release.

Net cash used in operating activities for the year ended December 31, 2020 on a GAAP basis totaled approximately $64.7 million, resulting in $240.4 million in cash and cash equivalents and investments as of December 31, 2020.

Fourth Quarter 2020 Financial Results

As of December 31, 2020, Aerie had cash and cash equivalents and investments of $240.4 million, including the $45.0 million in net cash proceeds from the Santen collaboration. For the fourth quarter ended December 31, 2020, Aerie reported net product revenues of $24.7 million related to the combined sales of Rhopressa® and Rocklatan®. Aerie reported a GAAP net loss of $46.1 million, or $1.00 net loss per share, compared to a net loss of $55.1 million and $1.21 net loss per share for the fourth quarter of 2019. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 46.0 million and 45.6 million for the fourth quarters of 2020 and 2019, respectively. Total shares outstanding as of December 31, 2020 were 46.8 million.

The $46.1 million net loss for the fourth quarter of 2020 is primarily comprised of $18.1 million of gross profit, including $6.5 million in cost of goods sold, and $53.7 million in total operating expenses, including $35.0 million in selling, general and administrative expenses and $18.7 million in research and development expenses. The cost of goods sold includes $4.6 million in idle capacity costs resulting from the Athlone manufacturing plant having just recently become operational and not yet reaching full capacity. Excluding $9.6 million of stock-based compensation expense, for the fourth quarter of 2020 adjusted cost of goods sold was $5.9 million and adjusted total operating expenses for the fourth quarter of 2020 were $44.8 million, with adjusted selling, general and administrative expenses of $28.4 million and adjusted research and development expenses of $16.5 million. Total adjusted net loss for the fourth quarter of 2020 was $36.5 million and adjusted net loss per share was $0.79.

The $55.1 million net loss for the fourth quarter of 2019 was primarily comprised of $23.0 million of gross profit, including $1.7 million in cost of goods sold, $72.9 million in total operating expenses, including $35.5 million in selling, general and administrative expenses, $6.7 million in pre-approval commercial manufacturing expenses and $30.8 million in research and development expenses. Excluding $11.2 million of stock-based compensation expense, adjusted total operating expenses for the fourth quarter of 2019 were $61.7 million, with adjusted selling, general and administrative expenses of $28.3 million, adjusted pre-approval commercial manufacturing expenses of $5.5 million and adjusted research and development expenses of $28.0 million. Total adjusted net loss for the fourth quarter of 2019 was $43.9 million and adjusted net loss per share was $0.96.

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. In addition, AR-14034 slides will be discussed on the conference call and are posted to Aerie's website. 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 9047298. 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 9047298. The telephone replay will be available until March 5, 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 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 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 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 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, preclinical 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, preclinical implants or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any product candidates 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. In particular, FDA and European Medicines Agency (EMA) approval of Rhopressa® and Rocklatan® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® 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, and there can be no assurance that we will receive FDA approval for our product candidates or any future product candidates. Furthermore, the acceptance of the Investigational New Drug Applications (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 a New Drug Application 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)

	DECEMBER 31,	
	2020	**2019**
Assets		
Current assets		
Cash and cash equivalents	$ 151,570	$ 143,940
Short-term investments	88,794	165,250
Accounts receivable, net	56,022	38,354
Inventory	27,059	21,054
Prepaid expenses and other current assets	8,310	7,744
Total current assets	331,755	376,342
Property, plant and equipment, net	54,260	58,147
Operating lease right-of-use-assets	14,084	16,523
Other assets	1,946	1,596
Total assets	$ 402,045	$ 452,608
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,826	$ 12,770
Accrued expenses and other current liabilities	90,723	65,376
Operating lease liabilities	4,923	5,502
Total current liabilities	104,472	83,648
Convertible notes, net	210,373	188,651
Deferred revenue, non-current	50,858	—
Long-term operating lease liabilities	10,206	12,102
Other non-current liabilities	2,168	1,257
Total liabilities	378,077	285,658
Stockholders' equity		
Common stock	47	46
Additional paid-in capital	1,103,074	1,062,996
Accumulated other comprehensive loss	(52)	(92)
Accumulated deficit	(1,079,101)	(896,000)
Total stockholders' equity	23,968	166,950
Total liabilities and stockholders' equity	$ 402,045	$ 452,608

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2020	2019	2020	2019
Product revenues, net	$ 24,683	$ 24,657	$ 83,138	$ 69,888
Total revenues, net	24,683	24,657	83,138	69,888
Costs and expenses:				
Cost of goods sold	6,534	1,684	25,333	4,833
Selling, general and administrative	35,016	35,467	137,184	138,402
Pre-approval commercial manufacturing	—	6,650	2,304	22,767
Research and development	18,726	30,794	74,007	91,378
Total costs and expenses	60,276	74,595	238,828	257,380
Loss from operations	(35,593)	(49,938)	(155,690)	(187,492)
Other (expense) income, net	(5,266)	(5,126)	(22,166)	(12,179)
Loss before income taxes	(40,859)	(55,064)	(177,856)	(199,671)
Income tax expense (benefit)	5,278	—	5,245	(90)
Net loss	$ (46,137)	$ (55,064)	$ (183,101)	$ (199,581)
Net loss per common share—basic and diluted	$ (1.00)	$ (1.21)	$ (3.99)	$ (4.39)
Weighted average number of common shares outstanding—basic and diluted	45,973,297	45,589,014	45,897,255	45,427,154

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2020	2019	2020	2019
Net loss (GAAP)	$ (46,137)	$ (55,064)	$ (183,101)	$ (199,581)
Add-back: stock-based compensation expense	9,590	11,172	40,095	45,093
Adjusted Net loss	$ (36,547)	$ (43,892)	$ (143,006)	$ (154,488)
Cost of goods sold (GAAP)	$ 6,534	$ 1,684	$ 25,333	$ 4,833
Less: stock-based compensation expense	$ (675)	$ —	$ (2,353)	$ —
Adjusted cost of goods sold	$ 5,859	$ 1,684	$ 22,980	$ 4,833
Selling, general and administrative expenses (GAAP)	$ 35,016	$ 35,467	$ 137,184	$ 138,402
Less: stock-based compensation expense	(6,652)	(7,210)	(27,176)	(30,463)
Adjusted selling, general and administrative expenses	$ 28,364	$ 28,257	$ 110,008	$ 107,939
Pre-approval commercial manufacturing expenses (GAAP)	$ —	$ 6,650	$ 2,304	$ 22,767
Less: stock-based compensation expense	—	(1,144)	(344)	(3,634)
Adjusted pre-approval commercial manufacturing expenses	$ —	$ 5,506	$ 1,960	$ 19,133
Research and development expenses (GAAP)	$ 18,726	$ 30,794	$ 74,007	$ 91,378
Less: stock-based compensation expense	(2,263)	(2,818)	(10,222)	(10,996)
Adjusted research and development expenses	$ 16,463	$ 27,976	$ 63,785	$ 80,382
Total operating expenses (GAAP)	$ 53,742	$ 72,911	$ 213,495	$ 252,547
Less: stock-based compensation expense	(8,915)	(11,172)	(37,742)	(45,093)
Adjusted total operating expenses	$ 44,827	$ 61,739	$ 175,753	$ 207,454

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

	THREE MONTHS ENDED DECEMBER 31,		TWELVE MONTHS ENDED DECEMBER 31,	
	2020	2019	2020	2019
Net loss per common share—basic and diluted (GAAP)	$ (1.00)	$ (1.21)	$ (3.99)	$ (4.39)
Add-back: stock-based compensation expense	0.21	0.25	0.87	0.99
Adjusted Net loss per share—basic and diluted	$ (0.79)	$ (0.96)	$ (3.12)	$ (3.40)
Weighted average number of common shares outstanding—basic and diluted	45,973,297	45,589,014	45,897,255	45,427,154

Contacts

Aerie Pharmaceuticals

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