UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36152

Aerie Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-3109565**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

4301 Emperor Boulevard, Suite 400
Durham, North Carolina 27703
(919) 237-5300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of Each Class	Ticker Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	**AERI**	**NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2019, based upon the closing price of $29.55 of the registrant's common stock as reported on The NASDAQ Global Market, was $1,334,440,206.

As of February 14, 2020, the registrant had 46,428,456 shares of common stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement (the "Proxy Statement") for the 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission (the "SEC") within 120 days of the registrant's fiscal year ended December 31, 2019.

TABLE OF CONTENTS

Unless otherwise indicated or the context requires, the terms “Aerie,” “Company,” “we,” “us” and “our” refer to Aerie Pharmaceuticals, Inc. and its subsidiaries. References to “approved products” means products approved by the U.S. Food and Drug Administration (“FDA”) or other regulatory authorities; references to “product candidates” means products that are in development but not yet approved by the FDA or other regulatory authorities; references to “future product candidates” means products that have not yet been developed.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “would,” “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 appear in a number of places throughout this report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the sales of Rhopressa® (netarsudil ophthalmic solution) 0.02% (“Rhopressa®”) or of Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (“Rocklatan®”), in the United States, and the potential future sales in the United States of any current or future product candidates, if approved;

- the potential future sales in jurisdictions outside of the United States of Rhopressa®, named Rhokiinsa® (netarsudil ophthalmic solution) 0.02% (“Rhokiinsa®”) in Europe, or Rocklatan®, named Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (“Roclanda®”) in Europe, or their equivalents, and those of any current or future product candidates;

- our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States;

- third-party payer coverage and reimbursement for our approved products and product candidates and any future product candidates, if approved;

- the glaucoma patient market size and the rate and degree of market adoption of our approved products and product candidates and any future product candidates, if approved, by eye-care professionals and patients;

- the timing, cost or other aspects of the commercial launch of our approved products and product candidates and any future product candidates, if approved;

- the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our product candidates and any future product candidates, including statements regarding the timing of initiation and completion of the studies and trials;

- our expectations regarding the effectiveness of our approved products, product candidates and any future product candidates and our expectations regarding the results of any clinical trials and preclinical studies;

- the timing of and our ability to request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our approved products, product candidates and any future product candidates in the United States, Europe, Japan and elsewhere, including the expected timing of, and regulatory and/or other review of, filings for such approved products, product candidates and any future product candidates;

- our expectations related to the use of proceeds from our financing activities;

- our estimates regarding anticipated operating expenses and capital requirements and our needs for additional financing;

- our plans to pursue development of additional product candidates and technologies in ophthalmology, including development of our approved products or product candidates for additional indications, and our preclinical retinal programs and other therapeutic opportunities;

- the potential advantages of our approved products, product candidates and any future product candidates;
- our ability to protect our proprietary technology and enforce our intellectual property rights;
- our expectations regarding collaborations, licensing, acquisitions and strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies; and
- our stated objective of building a major ophthalmic pharmaceutical company.

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 Part I, Item 1A of this report and elsewhere in this report.

In particular, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our product candidates or any future product candidates in the United States, and there can be no assurance that we will receive FDA approval for our product candidates or any future product candidates. In addition, neither the European Commission ("EC") grant of a centralised marketing authorisation for Rhokiinsa® nor the European Medicines Agency ("EMA") acceptance of the Marketing Authorisation Application ("MAA") for Roclanda® constitutes an EC grant of a centralised marketing authorisation for Roclanda® and there can be no assurance that Roclanda® will receive approval by the EMA. FDA approval of Rhopressa® and Rocklatan® do not constitute regulatory approval of these products in jurisdictions outside of the United States and there is no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such jurisdictions. In addition, the preclinical research discussed in this report 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 report, and we may suspend or discontinue research programs at any time for any reason.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that forward-looking statements are not guarantees of future performance and that 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 report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate, are consistent with the forward-looking statements contained in this report, they may not be predictive of results or developments in future periods.

Any forward-looking statements that we make in this report speak only as of the date of this report. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether the result of new information, future events or otherwise, after the date of this report.

PART I

ITEM 1. BUSINESS

Overview

We are an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. Our strategy is to successfully commercialize our U.S. Food and Drug Administration ("FDA") approved products, Rhopressa® (netarsudil ophthalmic solution) 0.02% ("Rhopressa®") and Rocklatan® (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% ("Rocklatan®") in the United States. We have a commercial team responsible for sales of Rhopressa® and Rocklatan® that includes approximately 100 sales representatives targeting eye-care professionals throughout the United States.

Rhopressa® is a once-daily eye drop designed to reduce elevated intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension. The active ingredient in Rhopressa®, netarsudil, is an Aerie-owned Rho kinase ("ROCK") inhibitor. We believe that Rhopressa® represents the first of a new drug class for reducing IOP in patients with glaucoma in over 20 years.

Rocklatan® is a once-daily fixed-dose combination of Rhopressa® and latanoprost, the most commonly prescribed drug for the treatment of patients with open-angle glaucoma. We believe, based on our clinical data, that Rocklatan® has the potential to provide a greater IOP-reducing effect than any currently marketed glaucoma medication, and we believe that Rocklatan® competes with both prostaglandin analog ("PGA") and non-PGA therapies and may over time become the product of choice for patients requiring maximal IOP reduction, including those with higher IOPs and those who present with significant disease progression despite using currently available therapies.

Both Rhopressa® and Rocklatan® are being sold to national and regional U.S. pharmaceutical distributors, and patients have access to them through pharmacies across the United States.

Outside the United States

Our strategy also includes developing our business opportunities outside the United States, including obtaining regulatory approval in Europe and Japan for Rhopressa® and Rocklatan®.

In Europe, Rhokiinsa® (marketed as Rhopressa® in the United States) was granted a centralised marketing authorisation by the European Commission ("EC") in November 2019 and the Marketing Authorisation Application ("MAA") for Roclanda® (marketed as Rocklatan® in the United States) was accepted by the European Medicines Agency ("EMA") in December 2019. To optimize the commercial opportunity, we may launch Roclanda®, if approved, before Rhokiinsa® in Europe as the European market is oriented more toward fixed-dose combination products. The Phase 3 registration trial for Roclanda®, named Mercury 3, commenced in Europe during the third quarter of 2017. Mercury 3 is designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe of bimatoprost, a PGA, and timolol, a beta blocker. If successful, Mercury 3 is expected to improve the commercialization prospects of Roclanda® in Europe; it is not required for regulatory approval. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. We currently expect to read out topline 90-day efficacy data for the trial in the second half of 2020. We will continue to evaluate the commercial prospects for Rhokiinsa® and Roclanda® in Europe based on the timing and substance of the Mercury 3 data and other market conditions.

In Japan, we plan to pursue regulatory approval for Rhopressa® and Rocklatan®. With respect to the clinical progress of Rhopressa® in Japan, we completed a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a successful Phase 2 clinical trial conducted in Japan. These studies were designed to meet the requirements of Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") for potential regulatory submission of Rhopressa® in Japan. Topline results of the Phase 2 trial indicated positive efficacy and tolerability in the patient set. Clinical trials for Rocklatan® have not yet begun. We expect to move forward with plans for Phase 3 initiation in Japan for Rhopressa®, along with exploring collaboration with a potential partner in Japan to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, and will continue to explore other potential opportunities elsewhere in Eastern Asia.

Glaucoma Product Manufacturing

We currently use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States. In the second quarter of 2019, we completed the build-out of our own manufacturing plant in Athlone, Ireland, for additional commercial production of Rhopressa® and Rocklatan®. In January 2020, we received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the New Drug Application ("NDA") Prior Approval Supplement ("PAS"), which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. The manufacturing plant is expected to begin production of commercial supplies of Rocklatan® in the first quarter of 2020. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the Athlone manufacturing plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®.

Pipeline Opportunities

We also seek to enhance our longer-term commercial potential by identifying and advancing additional product candidates through our internal discovery efforts, our entry into potential research collaborations or in-licensing arrangements or our acquisition of additional ophthalmic products, technologies or product candidates that complement our current product portfolio.

We recently acquired Avizorex Pharma S.L. ("Avizorex"), a Spanish ophthalmic pharmaceutical company, developing therapeutics for the treatment of dry eye disease. Avizorex completed a Phase 2a study in dry eye subjects in 2019 for its lead product candidate AVX-012. The active ingredient in AVX-012 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates ocular surface wetness and blink rate. We plan to initiate a larger Phase 2b study in late 2020.

We are developing two sustained-release implants focused on retinal diseases, AR-1105 and AR-13503 SR. AR-1105 is a dexamethasone steroid implant, for which we completed enrollment in a Phase 2 clinical trial in patients with macular edema due to retinal vein occlusion ("RVO"). We are also developing AR-13503, an Aerie-owned ROCK and Protein kinase C inhibitor with potential in the treatment of diabetic macular edema ("DME"), wet age-related macular degeneration (age-related macular degeneration, "AMD") and related diseases of the retina, potentially as an adjunct to current standard of care anti-vascular endothelial growth factor (vascular endothelial growth factor, "VEGF") therapies. AR-13503 is the active ingredient in our AR-13503 SR implant. We have initiated a first-in-human clinical study for AR-13503 SR.

We own the worldwide rights to all indications for Rhopressa® and Rocklatan®. We have patent protection for Rhopressa® and Rocklatan® in the United States through early 2034 and internationally through 2030, and have filed for patent protection in the United States and internationally through 2037. In addition, through the acquisition of Avizorex, we are the exclusive licensee through 2031 of issued U.S. patents and pending patent applications internationally, which provide patent protection for AVX-012. Furthermore, we have an allowed U.S. patent application for AR-1105 in the United States, which upon issuance will provide patent protection to 2036, and have also filed for patent protection internationally through 2036. We also have patent protection for AR-13503 in the United States and internationally, which extends to 2030, and have filed for patent protection in the United States and internationally through dates ranging from 2030 to 2037. Our intellectual property portfolio contains patents and pending patent applications related to composition of matter, pharmaceutical compositions, methods of use and synthetic methods.

Our Strategy

Our goal is to become a leader in the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. We believe Rhopressa® and Rocklatan® have the potential to address many of the unmet medical needs in the glaucoma market, AVX-012 in the dry eye market, and clinical implants AR-1105 and AR-13503 SR in the retinal disease market. Key elements of our strategy are to:

Successfully commercialize Rhopressa® and Rocklatan® in the United States. We own worldwide rights to all indications for Rhopressa® and Rocklatan® and we intend to retain our commercialization rights in the United States. Rhopressa® is a first in class ROCK inhibitor designed to reduce IOP in patients with open-angle glaucoma or ocular hypertension. Rocklatan® is a fixed dose combination of Rhopressa® and latanoprost. We launched Rhopressa® in the United States at the end of April 2018 and Rocklatan® in the United States in May 2019. Our sales organization is targeting eye-care professionals throughout the United States. We have already obtained substantial formulary coverage for our glaucoma products under commercial plans and Medicare Part D plans.

Advance the development of Rhopressa® and Rocklatan® in jurisdictions outside the United States to regulatory approval and commercialize in Europe, depending on the overall pricing environment in that region, while securing a potential partner in Japan. Our strategy includes developing our business opportunities in jurisdictions outside of the United States, including obtaining regulatory approval in Europe and Japan for Rhopressa® and Rocklatan®. In Europe, the EC granted a centralised marketing authorisation for Rhokiinsa® (marketed as Rhopressa® in the United States) in November 2019 and we submitted an MAA for Roclanda® (marketed as Rocklatan® in the United States), which was accepted by the EMA. With respect to Rocklatan®, we commenced the Mercury 3 Phase 3 clinical trial in Europe during the third quarter of 2017, which is designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe of bimatoprost, a PGA, and timolol, a beta blocker. If successful, Mercury 3 is expected to improve our commercialization prospects in Europe; it is not needed for regulatory approval. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. We currently expect to read out topline 90-day efficacy data for the trial in the second half of 2020. In November 2019, we submitted the MAA for Roclanda® with the EMA. The MAA for Roclanda® was accepted for review by the EMA in December 2019, and an opinion from the Committee for Medicinal Products for Human Use ("CHMP") is expected in the fourth quarter of 2020. Since Roclanda® is a fixed-dose combination product that includes Rhokiinsa®, the MAA submission for Roclanda® was predicated on the receipt of a centralised marketing authorisation for Rhokiinsa®. We will continue to evaluate the commercial opportunities in Europe for Roclanda® and Rhokiinsa® based on the timing and substance of the Mercury 3 data and other market conditions.

We currently plan to partner for further development and ultimate commercialization of Rhopressa® and Rocklatan® in Japan, if approved, and will continue to explore other potential opportunities elsewhere in Eastern Asia. We completed a Phase 1 clinical trial and a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, which were designed to support meeting the requirements of Japan's PMDA for potential regulatory submission of Rhopressa® in Japan. In July 2019, we also completed enrollment of the Phase 2 clinical trial in Japan and successful topline results were released in November 2019. The study was designed in accordance with the requirements of the PMDA on Japanese patients to support subsequent Phase 3 registration trials that are also expected to be conducted in Japan. The results of the Phase 2 clinical trial indicated positive efficacy and tolerability among the patient set. Clinical trials for Rocklatan® have not yet begun. We expect to move forward with plans for Phase 3 initiation in Japan for Rhopressa®, along with exploring collaboration with a potential partner in Japan to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, and will continue to explore other potential opportunities elsewhere in Eastern Asia.

Continue to leverage and strengthen our intellectual property portfolio. We believe we have a strong intellectual property position relating to Rhopressa® and Rocklatan®. Our intellectual property portfolio contains U.S. and foreign patents and pending U.S. and foreign patent applications related to composition of matter, pharmaceutical compositions, methods of use and synthetic methods. We have patent protection for Rhopressa® and Rocklatan® in the United States, which extends through early 2034, and internationally through 2030, and have also filed for patent protection in the United States and internationally through 2037. In addition, through the acquisition of Avizorex, we are the exclusive licensee through 2031 of issued U.S. patents and pending patent applications internationally, which provide patent protection for AVX-012. Furthermore, we have an allowed U.S patent application for AR-1105 in the United States, which upon issuance will provide patent protection to 2036, and have also filed for patent protection internationally through 2036. We also have patent protection for AR-13503 in the United States and internationally, which extends to 2030, and have filed for patent protection in the United States and internationally through dates ranging from 2030 to 2037.

Expand our product candidate portfolio and pipeline through internal discovery efforts, research collaboration arrangements and in-licensing or acquisitions of additional product candidates, products or technologies. We continue to seek to discover and develop new compounds in our research laboratories focused on ophthalmic opportunities. In addition, we may enter into additional research collaborations or license arrangements or complete additional acquisitions to broaden our presence in ophthalmology, as we continually explore and discuss potential additional opportunities for new ophthalmic products, delivery alternatives and new therapeutic areas. For example, through business development activities, we have acquired from Avizorex the clinical-stage dry eye product candidate AVX-012, for which we plan to conduct a Phase 2b study in late 2020. The U.S. dry eye disease market was approximately $1.5 billion in 2018. Through business development activities, we have also acquired the worldwide ophthalmic rights to a bio-erodible polymer technology from DSM, a global science-based company headquartered in the Netherlands, and PRINT® (Particle Replication in Non-wetting Templates) implant manufacturing technology from Envisia Therapeutics, Inc. ("Envisia"). With these, we have created a unique sustained-release ophthalmology platform that, at a minimum, allows for the progression of our sustained-release retinal implant program but we believe may have the potential for more applications. We are currently developing two sustained-release implants focused on retinal diseases, AR-1105 and AR-13503 SR, for which we commenced clinical trials in 2019. We believe there is a need in the current retinal disease treatment paradigm for new treatment pathways and less frequent injections. The U.S. retinal disease market was approximately $6 billion in 2018.

Our Products, Product Candidates and Pipeline

Rhopressa®, our first FDA-approved product, has demonstrated that it reduces IOP through ROCK inhibition. Using this mechanism of action ("MOA"), Rhopressa® increases the outflow of aqueous humor through the trabecular meshwork ("TM"), which accounts for approximately 80% of fluid drainage from the healthy eye and is the diseased tissue responsible for elevated IOP in glaucoma. Our second FDA-approved product, once-daily Rocklatan®, a fixed-dose combination of Rhopressa® and latanoprost, reduces IOP through the same MOA as Rhopressa® and through a second MOA, utilizing the ability of latanoprost to increase the outflow of aqueous humor through the uveoscleral pathway, the eye's secondary drain. Both Rhopressa® and Rocklatan® are taken once-daily in the evening and have shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

AVX-012 is a product candidate we recently acquired for the treatment of dry eye disease. The active ingredient in AVX-012 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates ocular surface wetness and blink rate. Positive results from a Phase 2a study support the therapeutic potential of AVX-012 to treat signs and symptoms of dry eye.

Our other product candidates include AR-13503 SR, a ROCK and Protein kinase C inhibitor sustained-release implant with potential in the treatment of DME, wet AMD and other diseases of the retina, and AR-1105, a dexamethasone steroid implant being developed for the potential treatment of macular edema due to RVO or diabetic retinopathy. Both product candidates are miniaturized bio-erodible sustained-release implants that are designed to be injected intravitreally every six months.

We discovered and developed the active ingredient in Rhopressa® and Rocklatan®, netarsudil, and AR-13503 internally through a rational drug design approach that coupled medicinal chemistry with high content screening of compounds in proprietary cell-based assays. We selected and formulated netarsudil for preclinical *in vivo* testing following a detailed characterization of over 3,000 synthesized ROCK inhibitors, a number that has since grown to approximately 4,000.

The following table summarizes each of our current product, product candidate and preclinical molecules, their MOA(s) and their status, as well as our intellectual property rights.

Name and Mechanism		Status	Intellectual Property Rights
Rhopressa® (Rhokiinsa® in Europe)	ROCK inhibitor	**U.S.:** Marketed; launched in April 2018 **Europe:** Centralised marketing authorisation granted in November 2019 **Japan:** Phase 2	Wholly-Owned
Rocklatan® (Roclanda® in Europe)	ROCK inhibitor and latanoprost, a PGA	**U.S.:** Marketed; launched in May 2019 **Europe:** MAA accepted by the EMA in December 2019	Wholly-Owned
AVX-012	TRPM8 agonist	**U.S.:** Expect to initiate Phase 2b clinical study in late 2020	Wholly-Owned; acquired from Avizorex
AR-1105 implant	dexamethasone steroid	**U.S.:** Phase 2 clinical trial initiated Q1 2019; completed enrollment in October 2019	Wholly-Owned; acquired from Envisia
AR-13503 SR implant	ROCK and Protein kinase inhibitor	**U.S.:** First-in-human clinical study commenced in Q3 2019	Wholly-Owned

Rhopressa®

Rhopressa® is the first of a new class of glaucoma drug products that was discovered by our scientists. It was approved by the FDA in December 2017 for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension. It was

also granted a centralised marketing authorisation by the EC in November 2019. Our key target markets outside the United States include Europe and Japan.

The active ingredient in Rhopressa®, netarsudil, is an Aerie-owned ROCK inhibitor. ROCK is a protein kinase, which is an enzyme that modifies other proteins by chemically adding phosphate groups to them. Specifically, ROCK regulates actin and myosin, which are proteins that are responsible for cellular contraction. ROCK activity also promotes the production of extracellular matrix proteins. ROCK inhibitors block cell contraction in the TM outflow pathway and reduce the production of extracellular matrix, thereby improving TM fluid outflow and consequently reducing IOP.

Rhopressa® is competing primarily in the adjunctive therapy market, which represents approximately one-half of the U.S. glaucoma prescription market and totaled approximately 35 million prescriptions in 2018 according to IQVIA. Initial indications point to healthcare professionals prescribing Rhopressa® as a concomitant therapy to prostaglandins or non-PGA medications when additional IOP reduction is desired. We believe Rhopressa® is primarily competing with other non-PGA products, due to its targeting of the diseased TM, its demonstrated ability to reduce IOP at consistent levels across tested baselines, its preferred once-daily dosing relative to other currently marketed non-PGA products, and its safety profile. Currently marketed therapies that are used adjunctively to PGAs are older generation products that are generally dosed between two and three times a day, have MOA(s) focused on reducing fluid production, often have lower efficacy levels and have systemic side effects. We believe that Rhopressa® may also become a preferred therapy where PGAs are contraindicated, for patients who do not respond to PGAs and for patients who choose to avoid the cosmetic issues associated with PGA products. In November 2019, we released topline data from our Phase 4 Multi-center Open-label Study (“MOST”) trial, which observed Rhopressa® efficacy in various real-world clinical settings, including as both an adjunctive product and monotherapy. The results indicated positive IOP reduction in all settings along with a favorable tolerability profile.

Rhopressa® in the United States

We launched Rhopressa® in the United States at the end of April 2018. Rhopressa® is being sold to national and regional U.S. pharmaceutical distributors, and patients have access to Rhopressa® through pharmacies across the United States. We have obtained formulary coverage for Rhopressa® for the majority of lives covered under commercial and Medicare Part D plans.

Rhopressa® Outside of the United States

In Europe, in November 2019, the EC granted a centralised marketing authorisation for Rhokiinsa®. This follows the CHMP adopting a positive opinion recommending approval of the MAA for Rhokiinsa® in September 2019.

In support of a potential regulatory submission for Rhopressa® in Japan, we conducted a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a successful Phase 2 clinical trial conducted in Japan. In July 2019, we completed enrollment of a Phase 2 clinical trial in Japan and topline results were released in November 2019. These studies were designed to meet the requirements of the PMDA on Japanese patients in Japan to support subsequent Phase 3 registration trials that are also expected to be conducted in Japan. Topline results of the Phase 2 clinical trial indicated positive efficacy and tolerability in the patient set. We plan to move forward with plans for Phase 3 initiation in Japan for Rhopressa®, along with exploring collaboration with a potential partner in Japan to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, and will continue to explore other potential opportunities elsewhere in Eastern Asia.

Rocklatan®

Rocklatan® is a once-daily fixed-dose combination of Rhopressa® and latanoprost, the most widely-prescribed drug for the treatment of patients with open-angle glaucoma or ocular hypertension, and was approved by the FDA in March 2019. We believe that Rocklatan® has the potential to provide a greater IOP-reducing effect than any currently marketed glaucoma medication. Therefore, we believe that Rocklatan® competes with both PGA and non-PGA therapies for patients requiring maximal IOP reduction, including those with higher IOPs and those who present with significant disease progression despite use of currently available therapies.

Rocklatan® in the United States

We launched Rocklatan® in the United States in May 2019. Rocklatan® is now being sold to national and regional U.S. pharmaceutical distributors, and patients have access to Rocklatan® through pharmacies across the United States.

Rocklatan® Outside of the United States

In Europe, the clinical trials Mercury 1 and Mercury 2 represent the basis for European approval of Roclanda®. We also initiated a third Phase 3 registration trial for Roclanda®, named Mercury 3, in Europe during the third quarter of 2017. Mercury 3, a six-month efficacy and safety trial, is designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe consisting of bimatoprost (a PGA) and timolol (a beta blocker). If successful, Mercury 3 is expected to improve our commercialization prospects in Europe; it is not required for regulatory approval. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. Patients are being evaluated with maximum baseline IOPs ranging from above 20 mmHg to below 36 mmHg. We currently expect to read out topline 90-day efficacy data for the Mercury 3 trial in the second half of 2020. In December 2019, the MAA for Roclanda® was accepted by the EMA. An opinion from the CHMP is expected in the fourth quarter of 2020. Since Roclanda® is a fixed-dose combination product that includes Rhokiinsa®, the MAA submission for Roclanda® was predicated on the receipt of a centralised marketing authorisation for Rhokiinsa®, which the EC granted in November 2019. In Japan, clinical trials for Rocklatan® have not yet begun.

Product Candidates

To complement our internal research through business development opportunities, we acquired from Avizorex the clinical-stage dry eye product candidate AVX-012. Furthermore, we have also acquired worldwide ophthalmic rights to a bio-erodible polymer technology from DSM and PRINT® implant manufacturing technology, which is a proprietary technology capable of creating precisely-engineered sustained-release products utilizing fully-scalable manufacturing processes, from Envisia. Using these technologies, we have created a sustained-release ophthalmology platform and are currently developing two sustained-release implants focused on retinal diseases, AR-1105 and AR-13503 SR, and in the future we believe this technology may be useful as we explore additional sustained-release applications.

AVX-012 (TRPM8 agonist)

In December 2019, we acquired Avizorex, a Spanish ophthalmic pharmaceutical company, developing therapeutics for the treatment of dry eye disease. Avizorex completed a Phase 2a study in dry eye subjects in 2019 for its lead product candidate AVX-012. The active ingredient in AVX-012 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates ocular surface wetness and blink rate. By stimulating these processes in a physiological manner, TRPM8 agonists have the potential to restore tear film stability and reduce discomfort in patients with dry eye. Positive results from the Phase 2a study support the therapeutic potential of AVX-012 to treat signs and symptoms of dry eye. We are planning to initiate a larger Phase 2b study in late 2020.

AR-1105 Implant (dexamethasone steroid)

In October 2017, we acquired the rights to use PRINT® technology in ophthalmology and certain other assets from Envisia. In addition, we acquired Envisia's intellectual property rights relating to a preclinical dexamethasone steroid implant using a bio-erodible polymer-based drug delivery system that comprised of a blend of different poly D, L-lactic-co-glycolic acid ("PLGA") polymers and PRINT® technology for the potential treatment of macular edema due to RVO and diabetic retinopathy, which we refer to as AR-1105. The Investigational New Drug application ("IND") for this sustained-release implant was submitted in December 2018. In January 2019, we announced that the FDA reviewed the IND for AR-1105 and it is now in effect. We initiated a Phase 2 clinical trial of AR-1105 in patients with macular edema due to RVO during March 2019 and completed enrollment in October 2019.

AR-13503 SR Implant (ROCK and Protein kinase inhibitor)

Our owned preclinical small molecule, AR-13503, is a ROCK and Protein kinase C inhibitor and is the active ingredient in our AR-13503 sustained-release implant. AR-13503 SR has potential for the treatment of DME, wet AMD and other diseases of the retina. AR-13503, which is the active metabolite of Rhopressa®, has been shown to reduce lesion size in an *in vivo* preclinical model of wet AMD at levels similar to the current market-leading wet AMD anti-VEGF product. When used in combination preclinically with the market leading anti-VEGF product, AR-13503 produced greater lesion size reduction than the anti-VEGF product alone in a model of proliferative DR. Pending additional studies, AR-13503 may have the potential to provide an entirely new mechanism and pathway to treat DME, wet AMD and related diseases of the retina, potentially as an adjunctive therapy to current anti-VEGF therapies.

Since AR-13503 is a small molecule with a short half-life when injected into the back of the eye, and the aforementioned diseases are located in the back of the eye, a delivery mechanism was needed to deliver the molecule to the back of the eye for a sustained delivery period.

Using our licensed technology from DSM, AR-13503 has been combined with a polyesteramide polymer to produce an injectable, thin fiber implant that is minute in size. Preclinical experiments with the AR-13503 SR implant have demonstrated linear, sustained elution rates over several months and achievement of target retinal drug concentrations. The IND for AR-13503 SR became effective in April 2019, allowing us to initiate human studies in the treatment of neovascular age-related macular degeneration ("nAMD") and DME. We initiated a first-in-human clinical study for AR-13503 SR in the third quarter of 2019.

Pipeline Opportunities

We are also preliminarily evaluating use of the PRINT® technology platform for sustained-release of therapies for other ophthalmic indications. We commenced operation of our current Good Manufacturing Practices ("cGMP")-validated manufacturing facility for production of ophthalmic implants using PRINT® technology in our Durham, North Carolina, facility in October 2018.

We may continue to enter into research collaboration arrangements, license, acquire or develop additional product candidates and technologies to broaden our presence in ophthalmology, and we continually explore and discuss potential additional opportunities for new ophthalmic products, delivery alternatives and new therapeutic areas with potential partners and on our own.

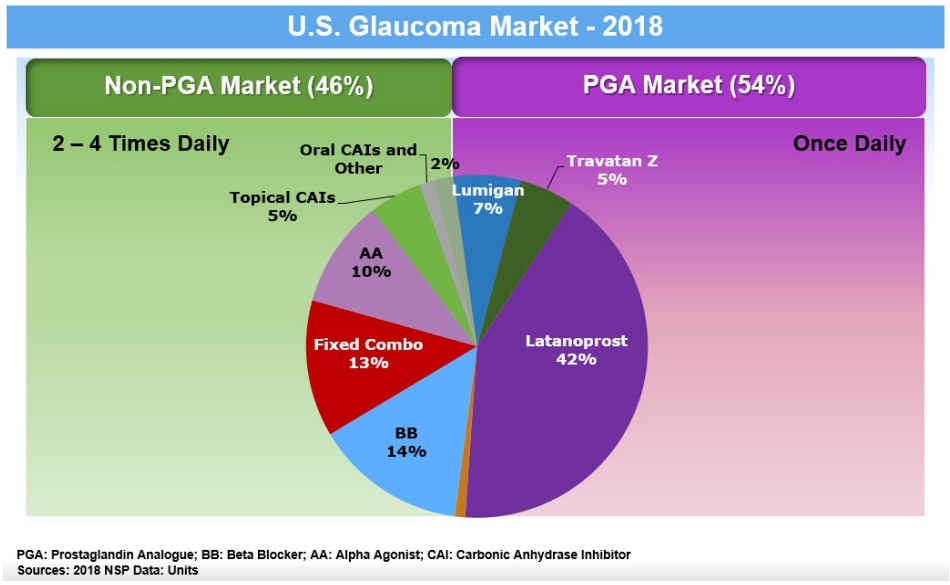
We own over 4,000 ROCK inhibitor molecules, some of which have additional features including the inhibition of other kinases such as Janus kinase and those in the IκB family and we evaluate this library on an ongoing basis for additional development opportunities. Early stage evaluations of these molecules are underway for other ophthalmic indications. We continue to evaluate outside business development opportunities to provide access to technologies developed outside of Aerie to complement our internal research.

Glaucoma Overview

Glaucoma Market Overview

Glaucoma is one of the largest segments in the global ophthalmic market. In 2018, branded and generic glaucoma product sales were approximately $5.0 billion in the United States, Europe and Japan in aggregate, according to IQVIA. Prescription volume for glaucoma products in the United States alone was 35 million, representing 52 million bottles in 2018, and is expected to grow, driven in large part by the aging population.

The PGA and non-PGA market segments each represent approximately one-half of the prescription volume in the United States glaucoma market, as shown in the following chart, which is based on IQVIA data.



According to the National Eye Institute, it is estimated that over 2.7 million people in the United States suffer from glaucoma, a number that is expected to reach approximately 4.3 million by 2030. Furthermore, The Eye Diseases Prevalence Research Group has estimated that only half of the U.S. glaucoma sufferers know that they have the disease. Glaucoma is a progressive and highly individualized disease, in which elevated levels of IOP are associated with damage to the optic nerve, resulting in irreversible vision loss and potentially blindness. Patients may suffer the adverse effects of glaucoma across a wide range of IOP levels. There are multiple factors that can contribute to an individual developing glaucoma, including, but not limited to, age, family history and ethnicity. Glaucoma is treated by the reduction of IOP, which has been shown to slow the progression of vision loss. In a healthy eye, fluid is continuously produced and drained in order to maintain pressure equilibrium and provide nutrients to the eye tissue. The FDA recognizes sustained reduction of IOP as the primary clinical endpoint for the approval of drugs to treat patients with glaucoma and ocular hypertension. The primary drainage mechanism of the eye is the TM, which accounts for approximately 80% of fluid drainage in a healthy eye, while the secondary drainage mechanism, the uveoscleral pathway, is responsible for the remaining drainage. In glaucoma patients, damage to the TM results in insufficient drainage of fluid from the eye, which causes increased IOP and damage to the optic nerve.

Once glaucoma develops, it is a chronic condition that requires life-long treatment. The initial treatment for glaucoma patients is typically the use of prescription eye drops. PGAs have become the most widely prescribed glaucoma drug class. The most frequently prescribed PGA is once-daily latanoprost. The most commonly prescribed non-PGA drugs belong to the beta blocker class. The most frequently prescribed beta blocker is twice-daily timolol. Other non-PGA drug classes include the alpha agonists and carbonic anhydrase inhibitors. When PGA monotherapy is insufficient to control IOP or contraindicated due to concerns about side effects, non-PGA products are used either as add-on therapy to the PGA or as an alternative monotherapy. It is estimated that up to 50% of glaucoma patients receiving PGA monotherapy require add-on therapy within two years of initial prescription of such PGA monotherapy to maintain adequate control of IOP.

We believe there are significant unmet needs in the glaucoma market as is evident by the degree of use of multiple therapies to treat patients with the disease and understand that eye-care professionals are eager for new therapy choices, as we have seen with the early success of the Rhopressa® and Rocklatan® U.S. commercial launches. PGAs have side effects, contraindications and reduced efficacy in patients with low to moderately elevated IOPs relative to patients with higher IOPs. Other currently marketed non-PGAs are less efficacious than PGAs, have more serious and a greater number of side effects and contraindications, and require multiple daily doses. As a result, we believe there is a significant unmet need in both the PGA and non-PGA market segments, each of which represents approximately one-half of the U.S. and European glaucoma market based on prescription volumes, according to IQVIA. Despite the limitations of existing glaucoma drugs, Xalatan® (latanoprost), the best-selling PGA, together with Xalacom®, its fixed-dose combination with a beta blocker, which is not available in the United States, generated peak annual global revenues of approximately $1.7 billion prior to the introduction of their generic equivalents, and the most commonly prescribed non-PGA drugs each generated peak annual global revenues of over $400 million prior to the introduction of their generic equivalents. Rhopressa® is the first of a new class of glaucoma drug products

and may be prescribed by eye-care professionals as a preferred adjunctive therapy for patients taking PGAs, due to its IOP-reducing ability, more convenient dosing and better tolerability profile compared to other currently marketed non-PGA adjunctive products. Rocklatan®, a fixed-dose combination of Rhopressa® and latanoprost, has the potential to provide a greater IOP-reducing effect than any currently marketed glaucoma medication. Therefore, we believe that Rocklatan® competes with both PGA and non-PGA therapies for patients requiring maximal IOP reduction, including those with higher IOPs and those who present with significant disease progression despite use of currently available therapies.

Glaucoma Medical Overview

Glaucoma is generally characterized by relatively high IOP as a result of impaired drainage of fluid, known as aqueous humor, from the eye. The FDA recognizes sustained reduction of IOP, measured in terms of mmHg, as the primary clinical endpoint for regulatory approval, making clinical trials for this indication relatively straight-forward due to easily measured objective parameters.

In a healthy eye, aqueous humor is continuously produced and drained from the eye in order to maintain pressure equilibrium and provide micronutrients to various tissues in the eye. An insufficient drainage of fluid can increase IOP above normal levels, which can eventually cause damage to the optic nerve. The normal range of IOP is generally between 10 and 21 mmHg. Several studies have demonstrated that the significant majority of glaucoma patients have IOPs between 21 and 26 mmHg at the time of diagnosis. Once damaged, the optic nerve cannot regenerate and thus damage to vision is permanent.

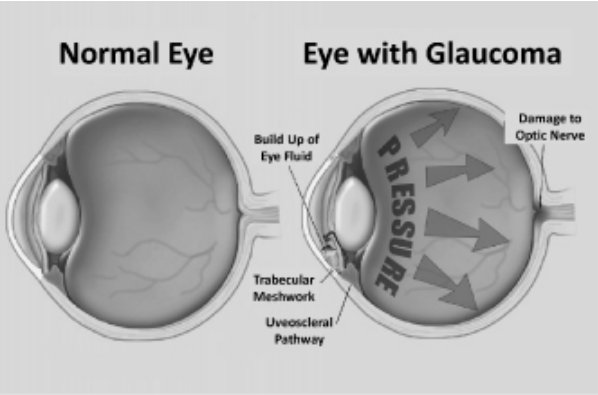
The most common form of glaucoma is open-angle glaucoma, which is characterized by abnormally high IOP as a result of impaired drainage of fluid from the eye's primary drain, the TM. Open-angle glaucoma is a progressive disease leading to vision loss and blindness for some patients as a result of irreversible damage to the optic nerve.

Studies of the disease have demonstrated that reducing IOP in patients with glaucoma can help slow or halt further damage to the optic nerve and help preserve vision. Once diagnosed, glaucoma requires life-long treatment to maintain IOP at lower levels based on the individual patient's risk of disease progression. Ophthalmologists will routinely determine a target IOP, which represents the desired IOP level to achieve with glaucoma therapy for an individual patient. Should the disease progress even once the initial target IOP is reached, further reduction of IOP has been shown to help in preventing additional damage to the optic nerve and further vision loss. This may require reducing IOP until it is in the so-called "low normal range" of 12 mmHg to 14 mmHg to protect the optic nerve from further damage.

There are multiple factors that can contribute to an individual developing open-angle glaucoma, including, but not limited to, age, family history and ethnicity. For example, there generally is a higher incidence and severity of the disease in African-American and Hispanic populations.

Some patients with high IOP are diagnosed with a condition known as ocular hypertension. Patients with ocular hypertension have high IOP without the loss of visual fields or observable damage to the optic nerve and are at an increased risk of developing glaucoma. These patients are commonly treated in the same manner as glaucoma patients.

The following diagram illustrates how increased IOP eventually leads to increased pressure on the optic nerve, resulting in gradual loss of vision and ultimately visual disability and blindness.



The ciliary body in the eye is the tissue that produces aqueous humor, the production of which is commonly referred to as fluid inflow. The fluid leaves the eye primarily through the TM, the process of which is commonly referred to as fluid outflow. The healthy eye maintains a state of IOP homeostasis through a constant physiological process of aqueous humor production and

drainage. The deteriorating function of the TM in glaucoma leads to increased resistance to fluid outflow and higher IOP. There is also a secondary drain for the fluid in the eye known as the uveoscleral pathway, which is typically responsible for approximately 20% of fluid drainage.

In addition to aqueous humor production and drainage through the TM and uveoscleral pathway, episcleral venous pressure ("EVP") plays a significant role in the regulation of IOP. EVP represents the pressure of the blood in the episcleral veins of the eye which are the site of drainage of eye fluid into the bloodstream. Historical studies have shown that EVP accounts for approximately 10 mmHg of IOP, or approximately one-half of IOP in patients with pressures near the normotensive level of 21 mmHg, and approximately one-third of IOP in patients with pressures of 24 mmHg to 30 mmHg. When EVP is reduced, aqueous humor is able to flow more freely from the eye.

Patients are diagnosed through measurements of IOP using Goldmann applanation tonometry, the standard device used by clinicians to measure IOP, along with an evaluation of visual fields and observing the appearance of the optic nerve. These tests are routinely carried out by eye-care professionals. The initial treatment for patients diagnosed with open-angle glaucoma or ocular hypertension is typically a PGA eye drop. PGAs are designed to reduce IOP by increasing outflow through the eye's secondary fluid drain. An eye-care professional will then measure a patient's response to the drug over the first few months. It has been shown that up to 50% of glaucoma patients require more than one drug to treat their IOP. This may occur as early as three to six months after initiating treatment with a PGA. The eye-care professionals may then add a second drug from one of the non-PGA classes, to be used together with the initial drug, or switch to a fixed-dose combination of two drugs in a single eye drop, or select an alternative single treatment. The reason so many patients eventually need more than one drug is generally considered to be a reflection of the progressive nature of the disease at the TM.

In severe glaucoma cases, patients may need to undergo an invasive surgical procedure. Trabeculectomy is the most common glaucoma-related surgical procedure, also referred to as filtration surgery, in which a piece of tissue in the drainage angle of the eye is removed, creating an opening to the outside of the eye. The opening is partially covered with a scleral flap, the white part of the eye, and the conjunctiva, the thin membrane covering the sclera. This new opening allows fluid to drain out of the eye, bypassing the clogged drainage channels of the TM to maintain a reduced IOP. There are also laser surgeries which apply laser energy to the eye's drainage tissue to improve the outflow of fluid. Devices called shunts are used in glaucoma surgery to divert fluid in a controlled manner from the inside of the eye to the subconjunctival space bypassing the blocked TM. Generally, the shunts reduce IOP to the extent that the use of drops can be reduced, but often not completely eliminated. Many patients continue to require eye drops even following surgery.

Dry Eye

Dry eye is a multifactorial, symptomatic disorder of the ocular surface and tear film. Dry eye has been associated with either decreased tear production, increased tear evaporation, or a combination of both. Symptoms of dry eye include ocular discomfort, dryness, and visual disturbance. Dry eye has been shown to contribute to difficulties with everyday activities, including reading, using a computer and driving. Artificial tears the are the most common initial treatment for dry eye disease, but artificial tears often fail to adequately address the signs and symptoms of dry eye.

The U.S. dry eye disease market was approximately $1.5 billion in 2018. It is estimated that there are approximately 30 million dry eye sufferers in the United States with approximately 10 percent currently being treated. Currently marketed prescription products often lack efficacy and also have a significant number of treatment burdens, including significant instillation site discomfort, delayed onset of efficacy up to twelve weeks, taste altering effects, and hence relatively low persistence rates. We believe that the dry eye space remains a very large and underserved market. These unmet needs generated our interest in proceeding with the acquisition of Avizorex, a Spanish ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease. AVX-012 has a novel MOA whereby corneal TRPM8 receptors are modulated, improving signs of dry eye by stimulating basal tear production, and symptoms of dry eye by providing a cooling sensation upon instillation.

Retinal Diseases

AMD is the leading cause of irreversible vision loss in individuals over 55 years of age in developed countries. Clinically, it manifests in two forms: wet AMD and dry AMD. Wet AMD is responsible for a rapid and substantial vision decline characterized by abnormal growth and leakage of blood vessels that breaks through the Bruch's membrane into the subretinal pigment epithelium space and/or the subretinal space, leading to exudation, hemorrhage, retinal edema, pigment epithelial detachment and fibrous scarring.

DR is the leading cause of vision loss among working age individuals in developed countries and DME is a common cause of vision loss associated with DR. DME occurs due to retinal microvasculature damage, increase in vascular permeability and loss of blood-retinal barrier leading to interstitial fluid accumulation in the retina, particularly in the region of the macula.

In both diseases, wet AMD and DME, vascular permeability, angiogenesis and inflammation play an important role and VEGF has shown to be a key mediator that has been found to be upregulated. Currently, the standard of care for treating wet AMD and DME is intravitreal ("IVT") injection of VEGF inhibitors (anti-VEGF). In addition, alternative therapeutic approaches for DME are directed towards stopping vascular leakage using laser photocoagulation and IVT injection of corticosteroids.

Existing anti-VEGF agents have similar safety and efficacy profiles. Three are the most widely used: bevacizumab, ranibizumab and aflibercept. Although anti-VEGF agents have shown a well-established efficacy profile in wet AMD and DME, a downside of these treatments is that some patients have poor response, experience a loss of efficacy after repeated injections over time or require frequent injections to maintain complete resolution of the exudation/edema. Thus, the need for alternative treatment options with prolonged treatment duration to reduce treatment burden of repeat injections and different mechanism of action to target refractory or non-response to anti-VEGF agents leaves a considerable unmet need. We are developing AR-13503 SR implant to address these unmet needs.

RVO is the second-most common sight-threatening vascular disorder of the retina after DR. Current estimates put global prevalence at approximately 16 million people affected with the disease in one or both eyes and around 520 new cases per million are reported each year. RVO is the result of thrombus formation in the central, hemi-central or branch retinal vein, often due to compression by adjacent artherosclerotic retinal arteries or vasculitis. The two main complications resulting from RVO are macular edema and retinal ischemia leading to retinal or iris neovascularization. Macular edema is a non-specific response of the retina to a variety of insults and involves the breakdown of the blood-retina barrier at the capillary endothelium, resulting in increased vascular permeability and subsequent leakage of fluids into the adjacent retinal tissues and significant visual disturbances. This reduction in vision may be reversible in the short-term, but chronic macular edema causes irreversible damage to the retina and permanent vision loss. Current options for treating macular edema depend upon the cause and severity of the condition. In the case of RVO, the goal is to reduce the amount of fluid leakage and decrease the edema, thus leading to improved visual acuity. Argon laser photocoagulation was used for many years to treat macular edema associated with branch RVO, but was less effective in the treatment of central RVO, and was not successful in all patients.

Within the last 10 years, IVT pharmacotherapy has revolutionized the therapeutic options for macular edema-associated retinal vascular diseases. Two classes of medication are currently approved to treat macular edema following RVO; corticosteroids (e.g., dexamethasone IVT implant, OZURDEX) and anti-VEGF agents (e.g., ranibizumab, LUCENTIS®, aflibercept, EYLEA®). While both classes have demonstrated efficacy in RVO patients, the treatment burden remains high, with the anti-VEGFs typically requiring monthly or bi-monthly IVT injections and the dexamethasone implant typically requiring injections approximately once every three months. A corticosteroid implant that remained effective for a longer duration would provide the benefit of reducing the treatment burden on patients while treating the inflammatory components of macular edema that are not addressed by inhibition of VEGF. Additionally, if the dose of corticosteroid could be reduced without compromising efficacy, then there exists the potential for reduced corticosteroid-related adverse events such as cataract formation and increased IOP. We are developing AR-1105, a dexamethasone IVT implant, to address these unmet needs.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our experience and scientific knowledge provide us with competitive advantages, we face competition from established branded and generic pharmaceutical companies, for example, Bausch Health Companies Inc., Novartis International AG, Allergan, Inc., Santen Inc. and smaller biotechnology and pharmaceutical companies as well as from academic institutions, government agencies and private and public research institutions, which may in the future develop products or technologies to treat glaucoma or other diseases of the eye. Products that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that the key competitive factors affecting the success of Rhopressa® and Rocklatan®, are likely to be efficacy and their respective MOA(s), safety, convenience, price, tolerability and the availability of reimbursement from government and other third-party payers.

We currently expect to compete directly against companies producing existing and future glaucoma treatment products. The most commonly approved classes of eye drops to reduce IOP in glaucoma are discussed below:

PGA Drug Class

- **Prostaglandin Analogues ("PGAs").** Most PGAs are once-daily dosed eye drops generally prescribed as the initial drug to reduce IOP by increasing fluid outflow through the eye's secondary drain. PGAs represent approximately one-half of the U.S. and European prescription volume for the treatment of glaucoma.

  Xalatan® (latanoprost), the best-selling PGA, together with Xalacom®, its fixed-dose combination with a beta blocker, which is not available in the United States, had worldwide peak sales of approximately $1.7 billion before its patent expired in 2012, according to publicly reported sales. The adverse effects of PGAs include conjunctival hyperemia, or eye redness, irreversible change in iris color, discoloration of the skin around the eyes, and droopiness of eyelids caused by the loss of orbital fat. PGAs should be used with caution in patients with a history of intraocular inflammation.

Non-PGA Drug Class

- **Beta Blockers.** Beta blockers, with their MOA designed to inhibit aqueous production, are one of the oldest approved drugs for the reduction of IOP. The most commonly used drug in this class is timolol. Beta blockers are less effective than PGAs in terms of IOP reduction and are typically used twice daily. Beta blockers are the most commonly used non-PGA drug. They are used as an initially prescribed monotherapy and as an adjunctive therapy to PGAs when the efficacy of PGAs is insufficient. Beta blocker eye drops have contraindications in their label as a result of systemic exposure from topical application of the eye drops, potentially leading to cardio-pulmonary events such as bronchospasm, arrhythmia and heart failure.
- **Topical Carbonic Anhydrase Inhibitors.** Carbonic anhydrase inhibitors, with their MOA designed to inhibit aqueous production, are less effective than PGAs and are required to be dosed three times daily in order to obtain the desired IOP reduction. In published clinical studies of carbonic anhydrase inhibitors, the most frequently reported adverse events reported were blurred vision and bitter, sour or unusual taste. Carbonic anhydrase inhibitors are sulfonamides and, as such, systemic exposure increases risk of adverse responses such as Stevens Johnson syndrome and blood dyscrasias.
- **Alpha Agonists.** Alpha agonists, with their MOA designed to inhibit aqueous production plus their effect on uveoscleral outflow, are less effective than PGAs and need to be dosed three times daily in order to obtain the desired IOP reduction. In clinical studies, the most frequently reported adverse reactions that occurred in individuals receiving brimonidine ophthalmic solution, a commonly prescribed alpha agonist, included allergic conjunctivitis, conjunctival hyperemia, eye pruritus, burning sensation, conjunctival folliculosis, hypertension, ocular allergic reaction, oral dryness and visual disturbance.

Despite their modest efficacy, safety and tolerability profiles, the requirement for two to three doses per day, and the fact that they do not target the diseased tissue in glaucoma, beta blocker, carbonic anhydrase inhibitor and alpha agonist products account for up to one-half of the total prescription volume for the treatment of glaucoma based on historical prescription patterns, with beta blocker timolol being the most widely prescribed non-PGA drug. This is driven by the PGA products not being sufficiently effective as monotherapy for up to half of all glaucoma patients. Fixed-dose combination glaucoma products are also currently marketed in the United States, including Cosopt, the combination of a beta blocker with a carbonic anhydrase inhibitor, and Combigan, the combination of a beta blocker with an alpha agonist. There are no fixed-dose combinations of PGAs with other glaucoma drugs currently available in the United States.

New eye drops for the treatment of glaucoma continue to be developed by our competitors. The following table outlines publicly disclosed development programs for the treatment of glaucoma of which we are aware:

New MOA(s)

Brand	MOA / Dosing	Status
Rhopressa® (Aerie AR-13324)	ROCK inhibitor (qd)	**U.S.:** Marketed; launched in April 2018 **Europe:** Centralised marketing authorisation granted in November 2019 **Japan:** Phase 2
Rocklatan® (Aerie PG324)	ROCK inhibitor + PGA (qd)	**U.S.:** Marketed; launched in May 2019 **Europe:** MAA accepted by the EMA in December 2019

New PGAs[1]

Brand	MOA / Dosing	Status
Vyzulta™ (Bausch)	NO donating latanoprost (qd)	U.S.: Marketed
Xelpros™ (Sun)	Latanoprost, without BAK (qd)	U.S.: Marketed
DE-117 (Santen)	EP2 agonist (qd)	U.S.: Phase 3 Japan: launched in November 2018
DE-126 (Santen)	FP/EP3 agonist (qd)	U.S. and Japan: Phase 2b
NCX-470 (Nicox)	NO donating bimatoprost (qd)	U.S.: Phase 2

[1]*Not usable as add-on therapy to current PGAs.*

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Early-stage companies are also developing treatments for glaucoma, retinal diseases and other diseases of the eye and may prove to be significant competitors. We expect that our competitors will continue to develop new treatments for glaucoma, retinal diseases and other diseases of the eye, which may include eye drops, oral treatments, surgical procedures, implantable devices or laser treatments. Alternative treatments beyond eye drops continue to develop.

Early-stage companies may also compete through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific, commercial and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer adverse effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Our industry is highly competitive and is currently dominated by generic drugs, such as latanoprost and timolol, in the case of glaucoma treatment, and additional products are expected to become available on a generic basis over the coming years. Our ability to compete may be affected because in many cases insurers or other third-party payers encourage the use of generic products. Further, surgical advances, including devices and implants designed to reduce IOP, may have a longer-term effect on the glaucoma eye drop market.

Sales and Marketing

We are commercializing Rhopressa® and Rocklatan® in the United States with our own focused, specialized sales force. For the launch of Rhopressa®, we hired a commercial team that includes approximately 100 sales representatives targeting eye-care professionals throughout the United States. This sales force is also responsible for sales of Rocklatan®.

We have obtained formulary coverage for Rhopressa® and have made significant progress in contracting for formulary coverage for Rocklatan®, with U.S. payers for both commercial and Medicare Part D prescription drug plans.

Outside of the United States we may, if commercially viable, commercialize Rhokiinsa® and, if we obtain regulatory approval, Roclanda® in Europe. We are exploring collaboration with a potential partner in Japan.

Major Customers

For the year ended December 31, 2019, a significant percentage of our sales of Rhopressa® were to three large wholesale drug distributors. Sales to McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation accounted for 36.5%, 33.3% and 28.0% of total revenues, respectively, for the year then ended.

Manufacturing

We currently rely on our third-party manufacturers to produce the API and final drug product for Rhopressa® and Rocklatan® and we may rely on third-party manufacturers for our current and future product candidates. Our current contract manufacturers produce commercial supplies of Rhopressa® and Rocklatan®.

The commercial production of the final drug product is ultimately expected to be supported by a combination of internal and outsourced manufacturing. In addition to our current contract manufacturers, we have also obtained FDA approval for an additional Rhopressa® drug product contract manufacturer in the first quarter of 2019, which began to supply commercial product in the second quarter of 2019. Further, we have obtained FDA approval for an additional API contract manufacturer, which began to supply commercial API in the second quarter of 2019. We have also received approval of an additional Rocklatan® drug product contract manufacturer in January 2020. Latanoprost, used in the manufacture of Rocklatan®, is available in commercial quantities from multiple reputable third-party manufacturers.

We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities. However, should a supplier or manufacturer on which we have relied to produce Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current or future product candidate provides us with a faulty product or such product is later recalled, we would likely experience reputational harm, delays and additional costs, each of which could be significant.

In the second quarter of 2019, we completed the build-out of our own manufacturing plant in Athlone, Ireland, for additional commercial production of Rocklatan® and Rhopressa®. In January 2020, we received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the PAS, which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. The manufacturing plant is expected to produce commercial supplies of Rocklatan® in the first quarter of 2020. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the Athlone manufacturing plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®.

As demand for Athlone sourced products grows, we may need to continue to use product sourced from our contract manufacturers when the manufacturing plant in Athlone, Ireland, is fully operational. We need to continue to hire and train qualified employees to staff this facility. The management and operation of a pharmaceutical manufacturing facility requires the implementation and development of procedures that are compliant with the quality and other regulations dictated by regulatory authorities in the jurisdictions for which product is produced. Failure to maintain such compliance could cause us to experience delays in production, reputational harm and could negatively affect our commercial operations.

We expect third-party manufacturers to be capable of providing sufficient quantities of Rhopressa® and Rocklatan® to meet our anticipated clinical and commercial demands. If our existing third-party suppliers should become unavailable to us for any reason, we believe that there are a number of potential replacements, although we could experience a delay in our ability to obtain alternative suppliers.

Intellectual Property

We have obtained patent protection for Rhopressa® and Rocklatan® (patent protection for Rocklatan® includes patent protection we have secured for Rhopressa®), in the United States and foreign jurisdictions, including in, but not limited to, Europe and Asia, and will seek and are seeking patent protection in additional foreign jurisdictions from time to time as we deem appropriate. We intend to maintain and defend our patent rights to protect our technology, inventions, processes and

improvements that are commercially important to the development of our business. Our existing patents or patents we obtain in the future may not be commercially useful in protecting our technology. In addition, our patents may not issue on any of our pending patent applications or patent applications we file in the future. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. For a more comprehensive discussion of the risks related to our intellectual property, see "Risk Factors—Risks Related to Intellectual Property."

Our intellectual property consists of issued patents, and pending patent applications for compositions of matter, pharmaceutical formulations, methods of use, medical devices and synthetic methods. We have patent protection for Rhopressa® and Rocklatan® in the United States through at least 2034. Additionally, we hold patents for composition of matter and method of use in certain foreign jurisdictions for Rhopressa® and Rocklatan® through 2030 and have filed for patent protection in the United States and internationally through 2037.

With respect to our product candidates, through the acquisition of Avizorex, we are the exclusive licensee through 2031 of issued U.S. patents and applications pending internationally, which provide protection for AVX-012. We have also filed for patent protection for AR-1105 internationally through 2036. On October 30, 2019, the United States Patent and Trademark issued a Notice of Allowance of a pending U.S. patent application, which upon issuance will provide protection for AR-1105 to 2036. Furthermore, we have patent protection for AR-13503 in the United States and internationally, which extends to 2030, and have filed for patent protection in the United States and internationally through dates ranging from 2030 to 2037.

We also hold patents and have pending patent applications for other ROCK inhibitor molecules.

The following table summarizes the status of our patent portfolio as of December 31, 2019 setting forth the number of existing issued patents and pending patent applications, as well as their respective estimated expiration date ranges:

Country	Number of Issued Patents	Number of Pending Patents	Estimated Expiration Date Range
United States	31	22	2026 - 2039
Australia	7	10	2026 - 2038
Brazil	0	4	2036 - 2038
Canada	4	10	2026 - 2038
China	0	10	2034 - 2038
Europe	55[(1)]	11	2026 - 2039[(1)]
Hong Kong	1	11	2030 - 2039
India	0	4	2035 - 2038
Japan	5	12	2026 - 2037
Mexico	0	4	2026 - 2038
Patent Cooperation Treaty	0	2	2020 - 2021
Singapore	0	3	2036 - 2038
South Korea	0	5	2035 - 2038

(1) Includes patent protection in Belgium (3 issued patents), France (9 issued patents), Germany (9 issued patents), Great Britain (9 issued patents), Ireland (1 issued patent), Italy (9 issued patents), Netherlands (3 issued patents), Spain (9 issued patents) and Switzerland (3 issued patents).

(2) All of the European patents have the same expiration date range in the individual countries of 2026 - 2039, with the exception of Ireland, which has one issued patent expiring in 2030.

Aerie®, Rhopressa® and Rocklatan® are registered U.S. trademarks of ours. In Europe, Rhokiinsa® and Roclanda® are registered trademarks of ours. We also have other pending trademark applications and registered trademarks in the United States and foreign jurisdictions.

Regulatory Matters

FDA Regulation and Marketing Approval

In the United States, the FDA regulates drugs under the FDCA and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions and non-approval of product candidates. These sanctions could include the imposition by the FDA or an institutional review board ("IRB") of a clinical hold on trials, the FDA's refusal to approve pending applications or related supplements, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties or criminal prosecution. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the research, clinical development, manufacture and marketing of pharmaceutical products.

These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of our products. Our drugs must be approved by the FDA through the NDA process before they may be legally marketed in the United States. See "—*The NDA Approval Process*" below.

The process required by the FDA before drugs may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices or other applicable regulations;
- submission of an IND, which allows clinical trials to begin unless the FDA objects within 30 days;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses conducted in accordance with FDA regulations, Good Clinical Practices ("GCP"), which are international ethical and scientific quality standards meant to assure the rights, safety and well-being of trial participants are protected and to define the roles of clinical trial sponsors, investigators, administrators, and monitors;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of an NDA, which must occur before a drug can be marketed or sold.

IND and Clinical Trials

Prior to commencing the first clinical trial, an initial IND, which contains the results of preclinical tests along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA raises concerns or questions about the conduct of the clinical trial within the 30-day time period. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each trial subject. Regulatory authorities, including the FDA, an IRB, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements.

For purposes of NDA approval, human clinical trials are typically conducted in sequential phases that may overlap:

- Phase 1—the drug is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. These trials may also provide early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

- Phase 2—trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 registration trials.
- Phase 3—when Phase 2 evaluations demonstrate that a dosage range of the product appears effective and has an acceptable safety profile, and provide sufficient information for the design of Phase 3 registration trials, Phase 3 registration trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

An investigational drug product that is a combination of two different drugs in the same dosage form must comply with an additional rule that requires that each component make a contribution to the claimed effects of the drug product. This typically requires larger studies that test the drug against each of its components. In addition, typically, if a drug product is intended to treat a chronic disease, as is the case with our products, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The NDA Approval Process

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment (currently exceeding $2.9 million for fiscal year 2020) unless a waiver or exemption applies. The application must include all relevant data available from pertinent non-clinical, preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meetings to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 registration trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the identity, strength, quality and purity of the final

drugs. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life.

The results of product development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. An NDA must also contain data to assess the safety and effectiveness of the product for the claimed indication in all relevant pediatric populations. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it files them. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA files it. The FDA has 60 days from its receipt of an NDA to conduct an initial review to determine whether the application will be filed based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. If the NDA submission is filed, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA has agreed to specific performance goals on the review of NDAs and seeks to review standard NDAs in 12 months from submission of the NDA. The review process may be extended by the FDA for three additional months to consider certain late submitted information or information intended to clarify information already provided in the submission. After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, non-clinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 trials may confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency after approval. The FDA has recently taken the position that under this authority it can require studies with efficacy endpoints in certain circumstances, if, for example, such a study is appropriate to further assess whether a potential lack of expected pharmacological effect, including reduced effectiveness, may result in a serious adverse drug experience. See "*—Post-Marketing Requirements*" below.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy ("REMS") from manufacturers to ensure that the benefits of a drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA. Based on statutory standards, elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the NDA approval, and in some cases if consensus is not obtained until after the PDUFA review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, including relevant pediatric data, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product or problems the extent or severity of which were unknown may result in restrictions on the product or even complete withdrawal of the product from the market. We cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Adverse Event Reporting

The FDA requires reporting of certain information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use, require labeling changes, and, potentially, withdrawal or suspension of the product from the market.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, a portion of a product’s U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the “Orange Book”) and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA’s acceptance or approval of certain competitor applications.

Patent Term Extension

Patent Term Extension (“PTE”) in the United States can compensate for lost patent grant time during product development and the regulatory review process for a patent that covers a new product or its use. This PTE period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. PTEs that can be obtained are for up to five years beyond the expiration of the patent or 14 years from the date of product approval, whichever is earlier. Only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant’s product or method of using the product. Upon approval of a drug, each of the patents identified in the application for the drug are then published in the FDA’s Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (“ANDA”). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to

submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been filed with and accepted by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDCA, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity ("NCE"). A drug is entitled to NCE exclusivity if it contains a drug substance no active moiety of which has been previously approved by the FDA. This means that, in the case of a fixed-dose combination product, the FDA makes the NCE exclusivity determination for each drug substance in the drug product and not for the drug product as a whole. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. For a drug that has been previously approved by the FDA, the FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the new conditions of use and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include in a lengthy review process.

Advertising

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("PDMA"), a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. Unless the products were

packaged prior to November 27, 2018, the DSCSA requires product identifiers (i.e., serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

Manufacturing

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. We currently rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, the applicant under an approved NDA is subject to an annual program fee, currently exceeding $325,000 per prescription drug product for fiscal year 2020.

Post-Approval Testing

The FDA also may require post-marketing testing, also known as Phase 4 testing, REMS to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, withdrawal of approval, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Reimbursement, Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Federal Anti-Kickback Statute, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and similar state laws. Pricing and rebate programs must be considered in price reports in order to comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive regulatory approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-government payers.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of our products, if any such products or the condition that it is intended to treat is the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our products. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our potential products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Federal Anti-Kickback Statute, the Federal False Claims Act, and other state and federal laws and regulations. The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions, and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices and/or our future relationships with eye-care professionals might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we have developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The Federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or

promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,000 and $25,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed in "*—Patient Protection and Affordable Care Act*" below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Numerous U.S. federal and state laws, including state security breach notification laws, state health information privacy laws and U.S. federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information, are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, which imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," such as independent contractors or agents of covered entities that receive or obtain protected health information with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates. In addition, HITECH also gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing these actions. As a result of HIPAA, we could be subject to criminal penalties if we obtain and/or disclose individually identifiable health information from a HIPAA-covered entity, including healthcare providers, in a manner that is not authorized or permitted by HIPAA. In addition, many U.S. states and foreign governments have enacted comparable laws addressing the privacy and security of health information, such as the General Data Protection Regulation (the "GDPR") enacted by the EU, some of which are more stringent than HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to disrupt our operations, including recently enacted laws in a majority of states requiring security breach notification. If there are any violations of these laws, we could face significant administrative and monetary sanctions as well as reputational damage, which may have a material adverse effect on our business.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Government Programs for Marketed Drugs

Medicaid, the 340B Drug Pricing Program, and Medicare

Federal law requires that a pharmaceutical manufacturer, as a condition of having its products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. This federal requirement is effectuated through a Medicaid drug rebate agreement between the manufacturer and the Secretary of Health and Human Services. CMS administers the Medicaid drug rebate agreements, which provide, among other things, that the drug manufacturer will pay rebates to each state Medicaid agency on a quarterly basis and report certain price information on a monthly and quarterly basis. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs. For innovator products, that is, drugs that are marketed under approved NDAs, the basic rebate amount is the greater of 23.1% of the average manufacturer price ("AMP") for the quarter or the difference between such AMP and the best price for that same quarter. The AMP is the weighted average of prices paid to the manufacturer (1) directly by retail community pharmacies and (2) by wholesalers for drugs distributed to retail community pharmacies. The best price is essentially the lowest price available to non-governmental entities. Innovator products are also subject to an additional rebate that is based on the amount, if any, by which the product's current AMP has increased over the baseline AMP, which is the AMP for the first full quarter after launch, adjusted for inflation. For non-innovator products, generally generic drugs marketed under approved abbreviated new drug applications, the basic rebate amount is 13% of the AMP for the quarter. Non-innovator products are also subject to an additional rebate. The additional rebate is similar to that discussed above for innovator products, except that the baseline AMP quarter is the fifth full quarter after launch (for non-innovator multiple source drugs launched on April 1, 2013 or later) or the third quarter of 2014 (for those launched before April 1, 2013).

The terms of participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drugs under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain safety net healthcare providers no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid drug rebate program, discussed above. Manufacturers are required to report pricing information to the Health Resources and Services Administration ("HRSA") on a quarterly basis. HRSA has also issued regulations relating to the calculation of the ceiling price as well as imposition of civil monetary penalties for each instance of knowingly and intentionally overcharging a 340B covered entity.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs, such as injectable products, that are administered "incident to" a physician service and are not generally self-administered. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. As with the Medicaid drug rebate program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Medicare Part D beneficiaries have a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare does not cover their prescription drug costs, known as the coverage gap. However, by 2020, Medicare Part D beneficiaries will pay 25% of drug costs after they reach the initial coverage limit - the same percentage they were responsible for before they reached that limit - thereby closing the coverage gap. The cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of a drug approved under an NDA is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare beneficiaries in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D.

Federal Contracting/Pricing Requirements

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs, available to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration. The law also requires manufacturers to offer deeply discounted FSS contract pricing for purchases of their covered drugs by the Department of

Veterans Affairs, the Department of Defense ("DoD"), the Coast Guard, and the Public Health Service (including the Indian Health Service) in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. FSS pricing to those four federal agencies for covered drugs must be no more than the Federal Ceiling Price ("FCP"), which is at least 24% below the Non-Federal Average Manufacturer Price ("Non-FAMP") for the prior year. The Non-FAMP is the average price for covered drugs sold to wholesalers or other middlemen, net of any price reductions.

The accuracy of a manufacturer's reported Non-FAMPs, FCPs, or FSS contract prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for civil monetary penalties of $100,000 per incorrect item. Finally, manufacturers are required to disclose in FSS contract proposals all commercial pricing that is equal to or less than the proposed FSS pricing, and subsequent to award of an FSS contract, manufacturers are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

Tricare Retail Pharmacy Network Program

The DoD provides pharmacy benefits to current and retired military service members and their families through the Tricare healthcare program. When a Tricare beneficiary obtains a prescription drug through a retail pharmacy, the DoD reimburses the pharmacy at the retail price for the drug rather than procuring it from the manufacturer at the discounted FCP discussed above. In order for the DoD to realize discounted prices for covered drugs (generally drugs approved under NDAs), federal law requires manufacturers to pay refunds on utilization of their covered drugs sold to Tricare beneficiaries through retail pharmacies in DoD's Tricare network. These refunds are generally the difference between the Non-FAMP and the FCP and are due on a quarterly basis. Absent an agreement from the manufacturer to provide such refunds, DoD will designate the manufacturer's products as Tier 3 (non-formulary) and require that beneficiaries obtain prior authorization in order for the products to be dispensed at a Tricare retail network pharmacy. However, refunds are due whether or not the manufacturer has entered into such an agreement.

Branded Pharmaceutical Fee

A branded pharmaceutical fee is imposed on manufacturers and importers of branded prescription drugs, generally drugs approved under NDAs. In each year between 2011 and 2018, the aggregate fee for all such manufacturers will range from $2.5 billion to $4.1 billion, and then will remain at $2.8 billion in 2019 and subsequent years. This annual fee is apportioned among the participating companies based on each company's sales of qualifying products to or utilization by certain U.S. government programs during the preceding calendar year. The fee is not deductible for U.S. federal income tax purposes. Utilization of generic drugs, generally drugs approved under ANDAs, is not included in a manufacturer's sales used to calculate its portion of the fee.

Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act ("PPACA") was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- As discussed above, effective in 2010, PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefits. CMS expanded Medicaid rebate liability to the territories of the United States as well, effective April 1, 2020. In addition, PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS, beginning in April 2016, also provided for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.
- Effective in 2010, PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible

entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication.

- Effective in 2011, PPACA imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., “donut hole”). The Bipartisan Budget Act of 2018 increased the manufacturer’s subsidy under this program from 50% to 70% of the negotiated price, beginning in 2019.
- Effective in 2011, PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- PPACA requires pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any “transfer of value” made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Effective January 1, 2022, we will also be required to report on transfers of value to, among others, physician assistants and nurse practitioners or clinical nurse specialists. The information reported each year is made publicly available on a searchable website.
- As of 2010, a Patient-Centered Outcomes Research Institute was established pursuant to PPACA to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- PPACA created the Independent Payment Advisory Board, which has the authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

There have been ongoing discussions within the U.S. federal government regarding the future of PPACA. There is uncertainty with respect to the impact these changes, if any, may have, and any changes likely will take time to unfold.

European Union

European Union Drug Development

In the EU, our products and product candidates will also be subject to extensive regulatory requirements. Regulatory laws for pharmaceuticals are largely harmonized throughout the EU, so that applicable EU law is most significant and national laws have less importance. As in the United States, medicinal products can only be marketed if a centralised marketing authorisation from the competent regulatory agencies has been obtained, and the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Phases 1 to 3 of clinical trials in humans are comparable to those regulated in the United States, and GCP requirements in the EU for these studies follow internationally accepted standards.

Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trial regulatory framework for pharmaceuticals by setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (“NCA”) and one or more Ethics Committees (“ECs”). All suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and ECs of the Member State where they occurred. All clinical trials will have to conform to current GCP guidelines issued by the EU and the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, in particular when the results of such trials are being used in marketing authorisation procedures, and audits by EU inspectors on regulatory conformance of such clinical trials are likely.

In 2014, the new EU Clinical Trial Regulation 546/2014 was enacted (the “Regulation”). When it becomes applicable (expected in 2021), it will govern all newly-commenced clinical trials. The new Regulation aims to make more uniform and

streamline the clinical trials authorisation process, ensure consistent rules for conducting clinical trials throughout the EU, increase the efficiency of clinical trials, and increase the transparency of authorization, conduct and results of clinical trials. All clinical trials initiated before the Regulation becomes effective remain subject to the Clinical Trials Directive of 2001.

Generally, in the European Economic Area ("EEA"), for every product candidate, a pediatric investigation plan ("PIP") will have to be submitted and approval be obtained, in addition to clinical trials conducted in adults. The clinical studies that sponsoring companies must carry out on children are to be set out in detail in the PIP. In most cases, the PIP will become a commitment when applying for a marketing authorisation for a product candidate. A PIP may entail significant cost.

European Union Drug Review Approval

In the EEA, which is currently comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorisation ("MA") which is comparable to an NDA in the United States. There are two types of marketing authorisations in the EEA: the Centralised MA, which is issued by the European Commission through the Centralized Procedure based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP"), a body of the EMA, and which is valid throughout the entire territory of the EEA; and the National MA, which is issued by the competent authorities of each Member State of the EEA and only authorizes marketing in that Member State's national territory and not in the EEA as a whole.

The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. The National MA is for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a national MA in all the Member States where the authorization was sought. Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

On November 19, 2019, we received a marketing authorisation for Rhokiinsa® valid throughout the European Commission based on a positive opinion of EMA's CHMP issued in September 2019. In December 2019, we filed an application with the EMA for a centralised MA for Roclanda®. The EMA is responsible for the validation and scientific evaluation of the application but the European Commission will decide upon our application. The EMA's CHMP will carry out a scientific assessment of the application and will give a recommendation on whether the medicine should be authorized or not. A favorable opinion is accompanied by a draft summary of the product's characteristics, the package leaflet and the proposed text for the packaging.

The time limit for the evaluation procedure is 210 days, subject to extensions if additional questions need to be addressed. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission to start the decision-making phase. Within 15 days a draft implementing decision is sent by the Commission to the Standing Committee on Medicinal Products for Human Use, allowing for its scrutiny by EU countries. These have 15 days to return their linguistic comments, and 22 days for substantial ones. Once a favorable opinion is reached, the draft decision is adopted via an empowerment procedure. The adoption of the decision should take place within 67 days of the opinion of the EMA. The Commission's Secretariat-General then notifies the marketing authorisation holder of the decision. The decision is subsequently published in the Community Register. In practice, the procedure is expected to take at least one year.

Marketing authorisations are initially valid for five years. Applications for renewal must be made to the EMA at least six months before this five-year period expires.

Files Required for Obtaining an EU Marketing Authorisation

Similar to the United States, applications for MAs in the EU must be supported by an extensive dossier that shows the product candidate has the required quality, efficacy and safety suitable for the intended use, and additional administrative documents. The content and format of the dossier must follow the so-called Common Technical Document ("CTD") format. Amongst other things, the applicant must submit all relevant data from pharmaceutical, pre-clinical and clinical trials, and all relevant

information as regards the composition, quality and manufacturing process of the product. These requirements are laid down in applicable EU legislation and very detailed EMA guidelines.

In the course of the MAA process, an inspection of the veracity and the compliance of the clinical trials that form the basis of the MAA may be conducted by EU inspectors. If it turns out that a clinical trial does not meet GCP and other applicable regulatory standards, it may not serve as a basis for proving efficacy and safety of the product at issue.

Also, the manufacturing sites for the active ingredients of the product candidate may be inspected by the EU in order to establish that the manufacturing indeed complies with cGMP standards.

Applicants are responsible for ensuring the safety profile of their medicine is adequately characterized at the time of submitting their MAA. Applicants are required to submit a risk management plan as part of their MAA. Risk management plans describe existing knowledge on the safety of a medicine and future pharmacovigilance activities designed to further study or monitor the product's safety. Part of that plan will be that a qualified person responsible for pharmacovigilance is being retained.

Post-approval Obligations of an MA Holder in the EU

Even after approval of a product candidate by the EC, an MA holder will face various ongoing actions and obligations and must ensure that it has a suitable organization in place that is able to meet these obligations.

Reportable suspected adverse events must be reported to competent authorities via EudraVigilance, a centralized European information system of suspected adverse reactions to medicines. EudraVigilance will re-route the case safety reports to EU member states. The EMA will make the reports of individual cases of suspected adverse reactions also available to the WHO Uppsala Monitoring Centre. Patients and healthcare professionals will continue to report adverse reactions to national competent authorities.

For public health reasons, the EMA may require the MA holder to provide additional data post-authorization, as necessary to provide additional data about the safety and, in certain cases, the efficacy or quality of authorized medicinal products.

The EMA is responsible for harmonizing and coordinating pharmacovigilance inspections at EU level, which involves, among others:

- Preparing a risk-based program of routine pharmacovigilance inspections in relation to centrally authorised products.
- Preparing and developing guidance on pharmacovigilance inspections.
- Coordinating advice on the interpretation of pharmacovigilance requirements and related technical issues.

The EMA is also responsible for coordinating inspections to verify compliance with cGMP, GCP, good laboratory practice and good pharmacovigilance practice, and any other aspects of the supervision of authorized medicinal products.

Member States and the Commission must inform other member states, the EMA and the Commission if concerns result from the evaluation of data from pharmacovigilance activities. This may result in the suspension or revocation of the marketing authorisation.

Member states have systems in place which aim at preventing dangerous medicinal products from reaching the patient and cover the receipt and handling of notifications of suspected falsified medicines or quality defects. Rapid alerts must be sent to all member states and a recall may be initiated if such medicines have already reached patients.

An MA holder must:

- Continuously operate a pharmacovigilance system, part of which requires a permanently and continuously available appropriately qualified person responsible for pharmacovigilance.
- Establish a risk management system, take account of scientific and technical progress and adapt accordingly, and continuously provide the competent authorities with information which might involve amendment of its marketing authorisation.
- Inform the competent authorities of positive and negative results in clinical trials or studies and any defects, and on request have at its disposal details regarding, for example, the volume of sales.

- Ensure that a package information leaflet is made available on request from patients' organizations, in formats appropriate for the blind and partially-sighted.
- Inform the EMA of changes related to the placement of the medicinal product on the market, for example withdrawal or suspension.

Data Exclusivity and Similar Protection in the EU

An innovator company enjoys a period of “data exclusivity” during which its preclinical and clinical trials data may not be referenced in the regulatory filings of another company (typically a generic company) for the same drug substance.

The period of data exclusivity in Europe has been harmonized as eight years from the date of first authorization in Europe. There is an additional period of two years of “market exclusivity”. This is the period of time during which a generic company may not market an equivalent generic version of the originator's pharmaceutical product (although their application for authorization may be processed during this period, such that they are in a position to market their product on the expiry of this additional two-year period).

After that period of a total of 10 years, generic companies can market their “essentially similar” products by referencing the innovator’s data, unless the innovator product qualifies for a further one year of exclusivity. This additional one year may be obtained if the innovator company is granted an MA for a significant new indication for the relevant medicinal product within the first eight years of its marketing. In such a situation, the generic companies can only market their copy products after 11 years from the grant of the innovator company's initial MA.

In addition, the innovator company may be eligible to receive a Supplementary Protection Certificate (“SPC”). This is an intellectual property right that serves as an extension to a patent right, comparable to a PTE in the U.S. SPCs aim to offset the loss of patent protection for pharmaceutical products that occurs due to the compulsory lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

An SPC can extend an eligible patent right for a maximum of five years. An additional six-month extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a PIP, as outlined above.

Manufacture of pharmaceuticals in the EU

We are currently completing our manufacturing plant in Athlone, Ireland, where our products are planned to be filled in sterile conditions. As a manufacturer of pharmaceutical products in the EU, we will be subject to extensive EU and national legislation that intends to ensure that only safe products will come into circulation. As a manufacturer, we will have to comply with GMP.

Current GMP describes the minimum standard that medicines manufacturers must meet in their production processes. The EMA coordinates inspections to verify compliance with these standards and plays a key role in harmonizing GMP activities at EU level. GMP requires that medicines:

- are of consistent high quality;
- are appropriate for their intended use;
- meet the requirements of the marketing authorisation or clinical trial authorization.

GMP in the EU is based on several EU regulations and directives, as well as on extensive EMA guidance. These GMP guidelines provide interpretation of GMP principles and guidelines, supplemented by a series of annexes that modify or augment the detailed guidelines for certain types of product, or provide more specific guidance on a particular topic.

Manufacturers and importers located in the EU must hold an authorization issued by the national competent authority of the Member State where they carry out these activities. They must show that they comply with EU GMP to obtain a manufacturing authorisation.

In the EU, national competent authorities are responsible for inspecting manufacturing sites located within their own territories. Competent authorities plan routine inspections following a risk-based approach, or if there is suspicion of non-compliance. After inspecting a manufacturing site, EU competent authorities issue a GMP certificate or a non-compliance statement, which is entered in a publicly available database (EudraGMDP).

Reimbursement in the EU

The EU does not have a centralized healthcare system. Healthcare is provided through very different systems at the national level. Most EU citizens have government-sponsored healthcare coverage. Constant budgeting pressures and the jurisdictional divide may lead to delayed or restricted patient access. Generally, the reimbursement prices must be negotiated with national healthcare carriers on a state-by-state process. Therefore, the receipt of a marketing authorisation will not be equivalent to full market access in all EU member states. Reimbursement prices may depend on the level of innovation and improvement of patient care that the product brings about, as evaluated, e.g., by semi-public bodies like National Institute for Health and Care Excellence ("NICE") in the United Kingdom or Institute for Quality and Efficiency in Health Care ("IQWiG") in Germany. It may take one to two years from the issuance of a marketing authorisation before market access in all EU member states with full reimbursement is achieved, if at all.

EU and national laws impose a number of restrictions on pricing. Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products ("Transparency Directive") aims to ensure the transparency of national pricing and reimbursement. It sets procedural requirements to help monitor national decisions and their compatibility with pharmaceutical trade in the EU internal market. For example, member states must ensure that decisions on prices are made within a certain timeframe and communicated to the applicant with a statement of reason based on objective and verifiable criteria. Member states must also ensure that such decisions are open to judicial review.

Another important restriction on pricing is Article 102 of the Treaty on the Functioning of the European Union ("TFEU"), which prohibits dominant pharmaceutical companies from abusing this dominance in their relevant markets.

EU Privacy Laws

The GDPR came into effect in the European Union on May 25, 2018 and has changed the way that personal data can be held and processed. Non-compliance can lead to substantial fines, amounting to up to 4% of annual global revenue or €20 million, whichever is greater.

The GDPR expands and formalizes many rights that existed under former laws. It also requires that organizations inventory their data and document the legal basis for processing personal information. Further, the GDPR provides EU data subjects with rights they may exercise in connection with their data such as the "right to be forgotten".

Generally, personal data of third parties must only be held and used by a company (the "Data Controller") when covered by an informed consent of the person concerned, or by a legitimate and vital interest, as defined in the GDPR. Any consent must be informed, freely given and specific, and, if applicable, also include the right to transfer personal data to a country outside of the EU. The Data Controller is responsible for GDPR compliance, but can outsource certain tasks to third parties, so-called "Data Processors". Affected third parties must be informed in some detail on the storage and use of their data, e.g. as clinical trial subjects, or as prescribers, and have the right to deny their consent.

It is important for companies to ensure they have a nominated data protection officer. They must also brief and train their staff, so they are aware and aligned. Companies should keep records of their approach to GDPR and how they have prepared for it. Preparation should also extend to a response in the event of an access request or complaint from a data subject, or with regards to a GDPR breach.

Brexit

The United Kingdom ("UK") left the EU on January 31, 2020 ("Brexit"), with a transition period up to December 31, 2020 in which the *status quo* will be largely unchanged. As one of the Brexit consequences, the EMA has relocated from London to Amsterdam. This has led to a significant reduction of the EMA workforce, which has resulted in significant delays in its administrative procedures. Pursuant to Article 45 of the Withdrawal Agreement between the EU and the UK, the UK and EU member states will share with each other MA dossiers pending at the end of the transition period, i.e. up to December 31, 2020 to enable review by the other in accordance with respective regulation. This procedure may apply to Roclanda® if our MAA is still pending on December 31, 2020.

The UK Medicines and Healthcare products Regulatory Authority ("MHRA") has issued guidance to the effect that products having an EU centralised marketing authorisation as of the UK withdrawal date, i.e. on January 31, 2020, will be grandfathered in the UK. To this effect and subject to the completion of an administrative process, such EU marketing authorisation will be converted by the MHRA into a national UK product license. Therefore, we expect Rhokiinsa® will continue to be authorised in the UK.

Subject to pending negotiations between the UK and EU of their exit agreement, there could be an impact to our business in the UK, which cannot be determined at this time.

Japan

Right of Reference

In Japan, clinical trial data collected for obtaining an approval in foreign countries can be used for obtaining an approval for a drug in accordance with the requirements stipulated in the notification by Ministry of Health, Labor and Welfare (the "MHLW"). The collection of such clinical data and drafting of the submission must meet the requirements under the normal Japanese regulations (Article 43 of the Enforcement Regulations of Pharmaceuticals and Medical Devices Law). The clinical trial data are required to include (i) pharmacodynamics, dose response, efficacy and safety in the foreign countries, (ii) clinical test data clearly exhibiting dose response, efficacy and safety (planned and performed in accordance with Japan rules, such as the Ministerial Ordinance on Good Clinical Practice for Drugs, and GCP; well-managed and using proper test controls; and using proper endpoints, and (iii) pharmacodynamics characteristic in the Japanese population. Further, the MHLW usually requests that a company submit bridging data from testing that is performed in Japan so that the clinical test data in foreign countries are demonstrated to be able to be generalized to the Japanese population. Generally, when the bridging data demonstrate that the dose response, efficacy and safety in Japan are similar to those in the foreign countries, the MHLW recognizes that the test results in the foreign countries can be generalized to the Japanese population. When the dose of the Japanese population in the bridging data is different from that of the test in the foreign countries, the MHLW will request that a company submit pharmacodynamics test results. When the number of samples in the bridging study or studies is limited, the MHLW will request that a company further submit test data demonstrating safety. When the bridging data cannot demonstrate efficacy and safety, the MHLW will request that a company submit clinical test results for the Japanese population.

Obtaining Approval

In practice, there are three basic ways for a non-Japanese company to obtain approval for pharmaceuticals manufactured overseas:

- Option 1—establish a Japanese corporation that obtains the necessary approvals and licenses. This provides the most durable presence in Japan. It also entails high initial time and expense (including hiring staff) and must be done in compliance with the provisions of the Pharmaceuticals and Medical Devices Law.
- Option 2—designate an existing Japanese company to obtain the necessary approvals and licenses. The manufacturing/sales approval for the drug will be registered in the Japanese company's name. This can raise potential problems if the overseas company does not strictly control the Japanese approval holder.
- Option 3—use the designated marketing approval holder ("DMAH") system under Article 19-2 of the Pharmaceuticals and Medical Devices Law and select a Japanese company approved by the MHLW to act as a DMAH. This option provides several benefits, including the manufacturing/sales approval being held directly by the non-Japanese company. In addition, the costs for obtaining/maintaining drug approval are lower than in the first two options. Since the approval is under the non-Japanese company's name, there are fewer concerns about the Japanese company acting on its own. If there are problems with the DMAH, the non-Japanese company can designate another company as the DMAH. Compared with the first option, the costs for a DMAH are lower, since there is no need to establish a new company. DMAHs are authorized by the MHLW, licensed for manufacture/sales of pharmaceuticals and provide full support in the drug approval process.

Japan Privacy Laws

Japan has regulatory provisions for privacy protection for personal information, including of patients in clinical trials. Most importantly, the Act on the Protection of Personal Information covers the protection of personal information. Personal information as used in the Act means information about a living individual that can identify the specific individual by name, date of birth or other description contained in such information (including such information as will allow easy reference to other information and will thereby enable the identification of the specific individual).

Pharmaceutical companies in Japan typically adopt their own internal privacy policies based on this law. The requirements tend to be general and leave a good deal of discretion to individual companies, but typically pharmaceutical companies establish policies covering appropriate safeguarding of personal information, prior consent for disclosure, and protection of personal data from leaks or other unauthorized access or disclosure.

The Clinical Research Act establishing clinical research guidelines, similarly, requires persons conducting clinical studies to obtain informed consent of participants and protect participants' personal data.

Other Countries

In addition to regulations in the United States, the EU, Japan, and potentially the UK, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our potential products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. In addition, the requirements governing the conduct of clinical trials, commercial sales, product licensing, pricing and reimbursement vary greatly from country to country.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. In addition, our international operations and relationships with partners, collaborators, contract research organizations, vendors and other agents are subject to anti-corruption and anti-bribery laws and regulations, including the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits U.S. companies and their representatives from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Failure to comply with the FCPA, or similar applicable laws and regulations in other countries, could expose us and our personnel to civil and criminal sanctions. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

We had approximately 380 full-time employees as of December 31, 2019. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Corporate Citizenship

We are dedicated to the principles of environmental stewardship, social responsibility, and good corporate governance. We consider these to be among our most important values and so integrate them in our ongoing and strategic activities.

As it relates to the environment and sustainability, we employ green processes, materials, practices, equipment and technologies where possible throughout our operations to foster conservation and reduce waste. We minimize energy consumption using various power-saving technologies designed to consume electrical power only when needed. The majority of our office space in the U.S. is Leadership in Energy and Environmental Design("LEED") certified, our new manufacturing plant in Athlone, Ireland is LEED silver certified, and both our manufacturing plant in Athlone, Ireland and our implant manufacturing facility in Durham, North Carolina, were built from end-to-end with sustainability and good manufacturing practices in mind. We have also instituted environmentally conscious programs into the work environment for our employees by implementing recycling and composting programs, offering water dispensers to reduce plastic bottle waste, and providing electric automobile charging stations in our employee parking areas, as examples.

From a social responsibility perspective, even though we have not yet attained profitability as a company, we have donated tens of thousands of dollars to causes that we believe are important to society. These donations were directed to support glaucoma research, providing free eye care to indigent patients in the United States and beyond, a national educational symposium for glaucoma patients, supporting women in ophthalmology, and other donations to causes of interest to areas beyond our immediate scope, such as for needy children in Harlem, New York.

We also strive to be socially conscious in our practices. We support diversity in our hiring practices and follow a management philosophy that integrates social responsibility and the highest governance standards. Our Audit Committee of the Board of Directors has consistently received very high ratings for independence and competency, and our most recent stockholder vote on executive compensation practices received nearly 95% support. As we continue to build our company, we will continue to keep the environment, our social responsibility and governance considerations at top of mind.

Corporate and Available Information

Our principal executive offices are located at 4301 Emperor Boulevard, Suite 400, Durham, North Carolina 27703 and our telephone number is (919) 237-5300. We were incorporated in Delaware in June 2005. Our internet address is www.aeriepharma.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our SEC reports can be accessed through the Investors section of our website. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at http://www.sec.gov. The information found on our website is not incorporated by reference into this report or any other report we file with or furnish to the SEC.

ITEM 1A. RISK FACTORS

We operate in an industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our common stock to decline.

Risks Related to Development, Regulatory Approval and Commercialization

We depend substantially on the success of our products, Rhopressa® and Rocklatan®. If we are unable to successfully commercialize Rhopressa® or Rocklatan®, or experience significant delays in doing so, our business will be materially harmed.

Our business and the ability to generate revenue related to product sales depend on the successful commercialization of our products Rhopressa®, which began in April 2018, and Rocklatan®, which began in May 2019, and the successful development, regulatory approval and commercialization of any current or future product candidates for the treatment of patients with open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. Rhopressa® and Rocklatan® have been approved by the FDA in the United States, and the EC has granted a centralised marketing authorisation for Rhopressa® for the EU (where it will be marketed as Rhokiinsa®), but they have not received regulatory approval in any other jurisdiction and no sales can be made in any such jurisdiction unless such approval occurs. We have invested a significant portion of our efforts and financial resources in the development of Rhopressa® and Rocklatan®, and our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize these products. The success of Rhopressa®, Rocklatan® and any current or future product candidates depends on several factors, including:

- successfully completing clinical trials;
- receiving and maintaining regulatory approvals from applicable regulatory authorities;
- developing and maintaining effective sales, marketing and distribution capabilities;
- establishing adequate internal manufacturing capacity or arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- establishing commercial markets;
- obtaining coverage and reimbursement from third-party payers; and
- successfully competing with other products.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize Rhopressa®, Rocklatan® or any current or future product candidates, which could materially harm our business, and we may not be able to earn sufficient revenues and cash flows to continue our operations.

The commercial success of Rhopressa® and Rocklatan® and any current or future product candidates, if approved, will depend on the degree of market acceptance among eye-care professionals, patients, patient advocacy groups, healthcare payers and the medical community.

Commercial activities began in the United States in April 2018 for Rhopressa® and in May 2019 for Rocklatan®. Our sales force is working to gain market acceptance among eye-care professionals, patients, patient advocacy groups, healthcare payers, including pharmacy benefit managers, and the medical community. The commercial success of these products in the United States will depend on the degree of such market acceptance. Similarly, if Rhopressa® is approved in jurisdictions outside the United States and the EU, if Rocklatan® is approved in any jurisdictions outside the United States and any current or future product candidates are approved in any jurisdiction in which they may receive approval, those products may not gain market acceptance among eye-care professionals, patients, patient advocacy groups, healthcare payers, including pharmacy benefit managers, and the medical community in such jurisdictions. There are a number of available therapies marketed for the treatment of open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. Some of these drugs are branded and subject to patent protection, but most others, including latanoprost and many beta blockers, in the case of glaucoma treatment, are available on a generic basis. Many of these approved drugs are well-established therapies and are widely accepted by eye-care professionals, patients and third-party payers. Insurers and other third-party payers may also encourage the use of generic products, either in preference to or prior to the use of brand therapies. The degree of market acceptance of Rhopressa® and Rocklatan® and any current or future product candidates, if approved, will depend on a number

of factors, including:

- the market price, affordability and patient out-of-pocket costs, relative to other available products, which are predominantly generics;
- the possibility that third-party payers will not give favorable positions on their formularies or will place restrictions on their use, including through use of step therapy or prior authorization programs;
- the timing of market introduction;
- their effectiveness as compared with currently available products, including eye drops and other technologies such as sustained-release inserts and devices;
- eye-care professional willingness to prescribe and patient willingness to adopt them in place of current therapies;
- varying patient characteristics including demographic factors such as age, health, race and economic status;
- changes in the standard of care for the targeted indications;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in labeling;
- limitations in the approved clinical indications and MOA(s);
- our success in demonstrating their benefits including relative convenience and ease of initiation, prescription and administration;
- the strength of our selling, marketing and distribution capabilities;
- the quality of our relationships with eye-care professionals, patient advocacy groups, third-party payers and the medical community;
- the continuous availability of quality manufactured products;
- sufficient third-party coverage or reimbursement; and
- the degree to which the products are subject to material product liability claims.

As we have done with Rhopressa® and Rocklatan®, it is possible that we may find it necessary or desirable to provide rebates on current or future product candidates, if approved, to customers or third-party payers or to implement patient assistance programs, including co-pay assistance programs, which could affect our profitability. In addition, we do not know how eye-care professionals, patients and third-party payers will continue to respond to the pricing of Rhopressa® and Rocklatan® in the United States or how they will respond to their pricing in jurisdictions outside the United States, or the pricing of any current or future product candidates in any jurisdiction, if approved.

The market opportunities for our currently marketed or potential products, if approved, are difficult to precisely estimate. Our estimates of these market opportunities in the United States, the potential market opportunity for Rhokiinsa® in the EC and the potential market opportunity in jurisdictions outside the United States for any current or future product candidates, if approved, include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. For example, the Mercury 3 results for Roclanda® are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. While we believe that our internal assumptions are reasonable, independent sources have not verified all of our assumptions. If any of these assumptions prove to be inaccurate and the actual market for any of our products post-regulatory approval is smaller than we expect or if we fail to maintain market acceptance or fail to achieve market acceptance, our potential product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

If we fail to obtain and sustain an adequate level of coverage and reimbursement for Rhopressa® or Rocklatan® or any current or future product candidates, if approved, by third-party payers, potential future sales would be materially adversely affected.

The course of treatment for patients with open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye includes primarily older drugs, and the leading products for the treatment of open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye currently in the market, including latanoprost and timolol, in the case of glaucoma treatment, are available as generic drugs. Therefore, there will be no commercially viable market for Rhopressa® or Rocklatan® or any current or future product candidates, if approved, without adequate coverage and reimbursement from third-party payers, and any

reimbursement policy may be affected by future healthcare reform measures. We have obtained formulary coverage for the majority of lives covered under commercial plans and Medicare Part D plans for Rhopressa® in the United States and are gaining incremental coverage for Rocklatan®. We cannot be certain that those levels of coverage will continue to increase, or that we will be able to maintain those levels of coverage. Further, we cannot be certain that adequate coverage and reimbursement will be available for either of our products in jurisdictions outside the United States or for any current or future product candidates, if approved. Additionally, even if there is a commercially viable market, if the level of coverage or reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payers, such as government or private healthcare insurers and pharmacy benefit managers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. A current trend in the United States healthcare industry is toward cost containment. Large public and private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payers, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payers limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payers may limit the covered indications. Cost-control initiatives in the U.S. healthcare industry could decrease the price we have established for Rhopressa®, Rocklatan® or any current or future product candidates, if approved, which could result in product revenues being lower than anticipated. Our products are currently priced higher than existing generic drugs and consistently with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payers may not be willing to reimburse for Rhopressa® or Rocklatan® or any current or future product candidates, if approved, which would significantly reduce the likelihood of them gaining market acceptance. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted.

We believe that U.S. third-party payers consider the efficacy, cost effectiveness, safety and tolerability of Rhopressa® and Rocklatan® and will consider such factors of any current or future product candidates, if approved, and whether use of any such products should be a covered benefit under its health plan in determining whether to approve coverage and reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not maintain approval for reimbursement of Rhopressa® or we do not receive approval for reimbursement of Rocklatan® or any current or future product candidates, if approved, from third-party payers on a timely or satisfactory basis or if pricing is set at unsatisfactory levels. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business could be materially adversely affected if Part D prescription drug plans were to limit access to or deny or limit reimbursement of any of our approved products.

Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of any of our products, if approved by the appropriate regulatory authorities, to other available therapies. If the prices for any of our products, if approved by the appropriate regulatory authorities, decrease or if governmental and other third-party payers do not provide adequate coverage and reimbursement levels, our revenue, potential for future cash flows and prospects for profitability will suffer. Also, we may not be able to launch the product uniformly throughout the EU but may have to commence commercial operations on a country-by-country basis, which could complicate the launching process and negatively affect our sales.

We face competition from established branded and generic pharmaceutical companies and if our competitors are able to develop and market products that are preferred over our products, our commercial opportunity will be reduced or eliminated.

The development and commercialization of new drug products is highly competitive. We face competition from established branded and generic pharmaceutical companies and smaller biotechnology and pharmaceutical companies, as well as from academic institutions, government agencies and private and public research institutions, which may in the future develop products to treat patients with open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye. We currently compete directly against companies producing existing and future glaucoma treatment products. To the extent we develop proprietary compounds for use beyond glaucoma, we will face competition from companies, academic institutions, government agencies and private and public research institutions operating in such new therapeutic areas.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Early-stage companies are also developing treatments for open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye and may prove to be significant competitors. In September 2018, Sun Pharmaceuticals Industries Ltd. received FDA approval for a PGA indicated for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension. We expect that our competitors will continue to develop new treatments for open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye, which may include eye drops, oral treatments, surgical procedures, implantable devices or laser treatments. Alternative treatments beyond eye drops continue to develop. For example, although surgical procedures are currently used in severe cases, less invasive procedures are currently under development and we expect that we will compete with other companies that develop implantable devices or other products or procedures for use in the treatment of open-angle glaucoma, dry eye, retinal diseases and other diseases of the eye.

Other early-stage companies may also compete through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer adverse effects, are more convenient or are less expensive than any products that we may develop. In addition, competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

In addition, our ability to compete may be affected because in many cases insurers or other third-party payers encourage the use of generic products. Ophthalmology is currently dominated by generic drugs, such as latanoprost and timolol, in the case of glaucoma treatment, and additional products are expected to become available on a generic basis over the coming years. Our current products are priced at a premium over competitive generic products and consistent with other branded glaucoma drugs. Our ability to compete effectively will depend upon, among other things, our ability to:

- successfully complete clinical trials and obtain all requisite regulatory approvals in a timely and cost-effective manner;
- obtain and maintain patent protection and non-patent exclusivity in all current and potential commercial jurisdictions for our products;
- attract and retain key personnel;
- develop effective manufacturing capabilities in our manufacturing plant in Athlone, Ireland, and continue to build an effective selling and marketing infrastructure;
- demonstrate the advantages of our products compared to alternative therapies, including, in the case of Rhopressa® and Rocklatan®, other currently marketed PGA and non-PGA products;
- identify and develop additional product candidates to expand our current product portfolio;
- compete against other products with fewer contraindications; and
- obtain and sustain adequate coverage and reimbursement from third-party payers.

If our competitors market products that are more effective, safer, have fewer side effects or are less expensive than our products or that reach the market sooner than any of our current or future product candidates, if approved, we may not achieve commercial success.

If we are unable to establish a direct sales force in jurisdictions outside the United States, our business may be harmed.

We have no experience selling, marketing or distributing any drug product in any jurisdictions outside the United States, and we currently are evaluating a commercially-oriented presence in jurisdictions outside the United States. Other companies have experienced unsuccessful product launches and failed to meet expectations of market potential, including companies with significantly more experience and resources than us, and there can be no guarantee that we will successfully launch any product in any jurisdictions outside the United States. To achieve commercial success for our products in jurisdictions outside the United States, we must either develop a sales and marketing organization in such jurisdictions or outsource these functions to third parties. We are currently evaluating the commercialization and profit potential of Rhokiinsa® and Roclanda® in Europe and expect to partner for Japan. If we do pursue a direct sales and marketing strategy in a jurisdiction, we would incur significant additional expenses and commit significant additional time and management resources if we were to establish and train a sales force to market and sell our products in jurisdictions outside the United States. We may not be able to successfully establish these capabilities on our expected timing or at all despite these additional expenditures.

Factors that may inhibit our efforts to successfully establish a sales force in jurisdictions outside the United States include:

- an inability to compete with other pharmaceutical companies to recruit, hire, train and retain adequate numbers of effective sales and marketing personnel with requisite knowledge of our target market;
- an inability to effectively manage a geographically dispersed sales and marketing organization in such jurisdictions;
- the inability of sales personnel to obtain access to adequate numbers of eye-care professionals to prescribe any future approved products;
- failure to adhere to regulatory requirements governing the sale of products in any jurisdiction;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- a delay in bringing products to market after efforts to hire and train our sales force have already commenced.

In the event we are unable to successfully market and promote our products, our business may be harmed.

Outside the United States, we have only obtained regulatory approval for Rhopressa® in Europe and have not obtained regulatory approval outside the United States for Rocklatan®.

Rhopressa® has received regulatory approval in the United States and the EU and Rocklatan® has received regulatory approval in the United States. We do not yet have any products that have received regulatory approval in any jurisdictions outside the United States and the EU. We cannot guarantee that we will ever have any other marketable products. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval to market each product from the FDA and cannot commercialize product candidates in the EU without first obtaining regulatory approval to market each product; similarly, we cannot commercialize product candidates outside of the United States and the EU without obtaining regulatory approval from comparable foreign regulatory authorities.

With respect to approval of Rhopressa® outside the United States, in the fourth quarter of 2019, the EC granted a centralised marketing authorisation. Rhopressa® will be marketed under the name Rhokiinsa® in the EC. With respect to the clinical progress of Rhopressa® in Japan, we completed a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a successful Phase 2 clinical trial conducted in Japan. These studies were designed to meet the requirements of Japan's PMDA for potential regulatory submission of Rhopressa® in Japan. Topline results of the Phase 2 trial indicated positive efficacy and tolerability in the patient set. We expect to move forward with plans for Phase 3 initiation in Japan for Rhopressa®.

We cannot predict how long it will take to obtain approval in Japan and whether our clinical trials ultimately will be successful. We will need to ensure that all clinical trials in Japan comply with all applicable regulations. Any failure to fully comply with Japanese regulations could result in the regulatory authorities requesting corrections or requiring new clinical trials be conducted, which could cause delay in obtaining the approval.

With regard to Rocklatan® in jurisdictions outside the United States, in December 2019, the EMA accepted our MAA for Rocklatan®, which will be marketed under the name Roclanda® in the EU, if approved. In addition, we initiated a third Phase 3 registration trial for Roclanda®, named Mercury 3. Mercury 3 is not required for regulatory approval, but, if successful, is expected to improve our commercialization prospects in the EU. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. Clinical trials for Rocklatan® have not yet begun in Japan.

We cannot predict whether ongoing trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date. FDA approval of any of our products does not constitute assurance that we will receive FDA approval for any current or future product candidates. Likewise, the EC grant of a centralised marketing authorisation for Rhokiinsa® and EMA acceptance of our MAA for Roclanda® do not constitute regulatory approval of Roclanda® in the EU, and there can be no assurance that we will receive regulatory approval for any of our products in jurisdictions outside the United States and the EU.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, have specific requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and

obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. Even if Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® and any current or future product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications, or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical studies or surveillance as conditions of approval. Following any approval for commercial sale of any products we may develop, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, will be subject to additional review and approval by the FDA and other regulatory authorities. Also, regulatory approval for Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current or future product candidates, if approved, may be withdrawn. If we are unable to obtain regulatory approval for Rhopressa® outside the United States and the EU, for Rocklatan® outside the United States or any current or future product candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other product candidate in the future.

Regulatory approval may be substantially delayed or may not be obtained for our products in jurisdictions outside the United States or for any current or future product candidates in any jurisdiction if regulatory authorities require additional time or studies to assess the safety and efficacy.

We may be unable to initiate or complete development of our products in jurisdictions outside the United States on schedule, if at all. If applicable regulatory authorities require additional time or studies to assess the safety or efficacy of any of our products or current or future product candidates, we may require funding beyond the amounts currently on our balance sheet. In addition, in the event of any unforeseen costs or other business decisions, we may not have or be able to obtain adequate funding to complete the necessary steps for approval of any of our products or current or future product candidates. Preclinical studies and clinical trials required to demonstrate the quality, safety and efficacy of drug products are time consuming and expensive and together take several years or more to complete. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, Europe, Japan or other markets may result from many factors, including:

- our inability to obtain sufficient funds required for a clinical trial;
- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- regulatory questions regarding interpretations of data and results and the emergence of new information regarding product candidates or other products;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the applicable regulators regarding the scope or design of our clinical trials;
- our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in our clinical trials;
- our inability to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding the effectiveness or safety of product candidates during clinical trials;
- any determination that a clinical trial or product candidate presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to reach agreements on acceptable terms with prospective contract research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- our inability to identify and maintain a sufficient number of sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by any of our product candidates;
- our inability to obtain approval from IRBs to conduct clinical trials at their respective sites;
- the failure of a third party to comply with applicable regulatory requirements, including site inspections and inspection readiness;
- our inability to timely manufacture or obtain from third parties sufficient quantities or quality of the product candidate or other materials required for a clinical trial; and
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that are initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for that product candidate, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

The UK left the EU as of January 31, 2020, with a transitional period up to December 31, 2020. As one of the Brexit consequences, the EMA has relocated from London to Amsterdam. This has led to a significant reduction of the EMA workforce, which has resulted in significant delays in its administrative procedures. Pursuant to the Withdrawal Agreement between the EU and the UK, the UK and the EU member states will share with each other marketing authorization dossiers pending at the end of the transition period, i.e. up to December 31, 2020, to enable review by the other in accordance with respective regulation. This procedure may apply to Roclanda® if our MAA is still pending as of that date. The UK MHRA has issued guidance to the effect that pharmaceuticals having an EU centralised marketing authorisation as of the UK withdrawal date, i.e. on January 31, 2020, will be grandfathered in the UK and, subject to the completion of an administrative process, such EU centralised marketing authorisation will be converted by the MHRA into a national UK product license. Therefore, we expect that Rhokiinsa® will continue to be authorised in the UK. Whether or not such grandfathering will apply for Roclanda® is unclear and may depend on how fast we can receive an EU marketing authorisation, if at all.

If Brexit results in market access delays in Europe or the requirement for additional marketing approvals, our business may be materially harmed.

The failure by the U.S. Congress to timely approve a budget for the federal government and its agencies, including the FDA, could have a material adverse effect on our business.

On an annual basis, the U.S. Congress must approve budgets that govern spending by the federal agencies, including the FDA. If Congress cannot agree on a budget, or if the President vetoes a budget approved by Congress, then the federal government may be shut down and non-essential federal employees, including many FDA employees, may be furloughed. Such a shutdown would prevent the FDA from performing many of its duties, which are crucial to our business. For example, on December 22, 2018, due to a lapse in appropriations for the federal government, most of the federal government was shut down, including many functions of the FDA, and most federal employees were furloughed for several weeks. Any future government shutdown could affect, among other things, the FDA approval process of one or more of our current or future product candidates, or the ability of the FDA to inspect a manufacturing facility supporting our business, each of which could have a material adverse effect on our business.

Failure can occur at any stage of clinical development. If the clinical trials are unsuccessful, we could be required to abandon development.

A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of preclinical testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, adverse events may occur or other risks may be discovered in Phase 3 registration trials that may cause us to suspend or terminate our clinical trials. In some instances, there can be significant

variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the patient populations and the rates of dropout among clinical trial participants. Our future clinical trial results therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for Rhopressa® in jurisdictions outside the United States and the EU and Rocklatan® in jurisdictions outside the United States or for any current or future product candidates in any jurisdiction.

Flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced or after data results have been obtained. We have limited experience in designing clinical trials and may be unable to design and execute clinical trials to support regulatory approval. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. Further, regulatory agencies, IRBs or data safety monitoring boards may at any time order the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Since our inception, we have not voluntarily or involuntarily suspended or terminated a clinical trial due to unacceptable safety risks to participants.

If the results of any of our clinical trials do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of our product candidates will be materially adversely affected. Moreover, preclinical and clinical data are often susceptible to varying interpretations, analyses and entry criteria, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, including longer term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials or earlier stage testing have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound. Our ongoing clinical trials for regulatory approvals in jurisdictions outside the United States may not produce the results that we expect and remain subject to the risks associated with clinical drug development as indicated above.

The breadth of the labeling of any product or product candidate, if approved, will depend upon providing evidence of such product's MOA(s) that is satisfactory to the applicable regulatory authority. Failure to do so will limit the types of claims we will be able to make in our product marketing and labeling. For example, based on the results of our preclinical and clinical studies, we believed Rhopressa® reduced IOP through additional MOAs; however, Rhopressa® received FDA approval for only one MOA, ROCK inhibition or the mechanism by which Rhopressa® increases outflow of aqueous humor through the Trabecular Meshwork ("TM") of the eye, as reflected in the Rhopressa® product labeling.

We may experience numerous unforeseen events that could cause our clinical trials to be unsuccessful, delayed, suspended or terminated, or which could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or implement a clinical hold;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we estimate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may elect or be required to suspend or terminate clinical trials based on a finding that the participants are being exposed to health risks;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- product candidates may have undesirable adverse effects or other unexpected characteristics.

If we elect or are required to suspend or terminate a clinical trial, our commercial prospects will be adversely impacted and our ability to generate product revenues may be delayed or eliminated.

Rhopressa®, Rocklatan® or any current or future product candidates may have undesirable or adverse effects, which may result in the delay, denial or withdrawal of regulatory approval or may require our products to be taken off the market, require them to include safety warnings or otherwise limit their sales after regulatory approval is received.

Unforeseen adverse effects from Rhopressa®, Rocklatan® or any current or future product candidates could arise either during clinical development or, even after approval, after the approved product has been marketed. To date, the main tolerability finding of Rhopressa® has been mild conjunctival hyperemia, or eye redness. In our Phase 3 registration trials, some patients also experienced conjunctival hemorrhages, or petechiae, corneal verticillata, blurry vision, and decreased visual acuity as adverse events. Rocklatan® combines Rhopressa® with latanoprost. To date, the main tolerability finding of Rocklatan® has also been mild conjunctival hyperemia. In our Phase 3 registration trials, some patients also experienced conjunctival hemorrhage, eye pruritus, increased lacrimation, reduced visual acuity, blepharitis, punctate keratitis and corneal disorder as adverse events. The main adverse effects of latanoprost include conjunctival hyperemia, irreversible change in iris color, discoloration of the skin around the eyes and droopiness of eyelids caused by the loss of orbital fat.

While the FDA granted approval of Rhopressa® and Rocklatan® based on the data included in their respective NDAs, we do not know whether the results when a larger number of patients in broader populations are exposed to the products, including results related to safety and efficacy, will be consistent with the results from our earlier clinical studies that served as the basis of FDA approval. New data relating to Rhopressa® or Rocklatan®, including from any adverse event reports or any negative results during clinical development for additional indications, may emerge at any time.

Any undesirable or adverse effects that may be caused by any such products or product candidates could interrupt, delay or halt clinical trials and could result in the delay, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from successfully commercializing Rhopressa® or Rocklatan® or any current or future product candidates, if approved, and generating or continuing to generate revenues from their sale. In addition, if we or others identify undesirable or adverse effects caused by Rhopressa®, Rocklatan® or any current or future product candidates after regulatory approval we could face one or more of the following consequences:

- regulatory authorities may re-review the product and impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication, or other safety labeling changes;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (“REMS”);
- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may seize the product;
- we may be required to change the way that the product is promoted or administered, conduct additional clinical trials or recall such product;
- we may be subject to litigation or product liability claims fines, injunctions or criminal penalties; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating or continuing to generate revenues from its sale.

We currently have no international commercial operations. We intend to explore the licensing of commercialization rights or other forms of collaboration outside of the United States and we have developed internal manufacturing capabilities in Ireland, both of which will expose us to additional risks of conducting business in international markets.

Markets outside of the United States are a component of our growth strategy. If we fail to successfully commercialize, obtain licenses or enter into collaboration arrangements with selling parties, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. As part of this strategy, in March 2015 and April 2015, we formed Aerie Limited and Aerie Ireland Limited, respectively. Additionally, in January 2017, we commenced establishment of our own manufacturing plant in Athlone, Ireland, which is expected to begin production of commercial supplies of Rocklatan® in the first quarter of 2020. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®. We will continue to evaluate the

commercial prospects for Rhokiinsa® and Roclanda® in Europe based on the timing and substance of the Mercury 3 data for Roclanda® and other market conditions. We also opened an office in Dublin in 2015, in Tokyo in October 2018 and in London in 2019 to assist with our expected international expansion. International operations and business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into or expand collaboration or licensing arrangements with third parties in connection with our international sales, marketing, manufacturing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of product candidates;
- changes in a specific country's or region's political and cultural climate or economic condition or changes in governmental regulations and laws;
- differing regulatory requirements for drug approvals, manufacturing and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- changes in tariffs, trade barriers and other regulatory requirements including those governing data privacy;
- divergent environmental laws and regulations;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences (including the tax reform law that was enacted in the United States in December 2017) that create uncertainty with respect to the tax impact on our business operations and profitability;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, tsunamis, floods, hurricanes and fires.

These and other risks may materially adversely affect our business, results of operations, financial condition or ability to attain or sustain revenue from international markets.

If we are found in violation of U.S. federal or state "fraud and abuse" laws or other healthcare laws and regulations, we may be required to pay a penalty and/or be suspended from participation in U.S. federal or state healthcare programs, which may adversely affect our business, financial condition and results of operation.

In the United States, our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription

of a particular drug for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the Federal Anti-Kickback Statute.

- The Federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Many states have similar false claims laws. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks have resulted in the submission of false claims to governmental healthcare programs.
- Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the Federal False Claims Act as well as under the false claims laws of several states.

In addition, certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, are required to report annually to CMS information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website. Effective January 1, 2022, transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives must also be reported.

Many states have adopted laws similar to the Federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Furthermore, the government purchasing and reimbursement programs include remedies such as the obligation to correct reported prices and pay additional rebates (depending on the direction of the correction) or pay restitution to the extent the government overpaid for covered drugs, In addition, federal law provides for civil monetary penalties for conduct such as failure to provide required information, late submission of required information, false information, and knowingly and intentionally overcharging a 340B covered entity.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. Were this to occur, our business, financial condition and results of operations and cash flows may be materially adversely affected.

Existing and future legislation may increase the difficulty and cost of commercializing our potential products and may affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our potential products, restrict or regulate post-marketing activities and affect our ability to profitably sell our potential products for which we obtain regulatory approval. Government elections in the jurisdictions in which we operate could affect the changes and proposed changes regarding the healthcare system. For example, the presidential and congressional elections in the United States in 2020 could affect the legislative and other proposals.

In the United States, the Medicare Modernization Act ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that are covered in any therapeutic class under the Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act ("PPACA") added provisions to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other things, PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price. There have been efforts by the Trump Administration and Congress to seek to repeal all or portions of PPACA. For example, the Tax Cuts and Jobs Act ("Tax Act") was enacted in 2017, which includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

In addition, the Trump Administration has indicated an intent to address prescription drug pricing and recent Congressional hearings have brought increased public attention to the costs of prescription drugs. The Trump Administration has made a number of proposals that are in early stages. Numerous bills have been introduced in Congress by members of both parties seeking to reduce drug prices using a variety of approaches. These actions and the uncertainty about the future of the PPACA and healthcare laws are likely to continue the downward pressure on pharmaceutical pricing and increase our regulatory burdens and operating costs. While we currently do not believe the implementation of any such initiatives would negatively impact our net sales or operating margins, these initiatives are in early stages.

Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether agencies such as the FDA or Centers for Medicare and Medicaid Services will issue new guidance or interpretations, whether existing guidance or interpretations will be changed, or what the impact of such changes on our sales and promotional activities for our approved products or the marketing approvals of our potential products may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and Rhopressa® or Rocklatan® or any current or future product candidates, if approved, could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory

approval is withdrawn, the value of our company and our operating results will be materially adversely affected. Additionally, if we are unable to continue to generate revenues from our product sales, our potential for achieving profitability will be diminished and the need to raise capital to fund our operations will be increased.

Rhopressa® and Rocklatan® and any current or future product candidates, if approved, subject us to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties.

Rhopressa® and Rocklatan® are, and any current or future product candidates, if approved, will be, subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping, submission of safety and other post-market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturing facilities are required to comply with extensive FDA and EMA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current good manufacturing requirements ("cGMP") requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work are required to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We are also required to report certain adverse reactions and production problems, if any, to the FDA and the EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion. Promotional communications with respect to prescription drugs also are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Accordingly, we may not promote any product for indications, uses or claims for which they are not approved, even though physicians may prescribe them for those uses. If we want to expand any such indications for which we may market a product, we will need to obtain additional regulatory approvals, which may not be granted.

If a regulatory agency discovers previously unknown problems with Rhopressa® or Rocklatan® or any current or future product candidates, if approved, such as adverse events of unanticipated severity or frequency, or problems with the facility where such product is manufactured, or disagrees with the promotion, marketing or labeling of such product, or finds that we have engaged in the promotion of off-label use, it may impose restrictions on that product or us, including requiring withdrawal of that product from the market. If either of our products fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- require product recalls;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our potential future collaborators to enter into a consent decree or permanent injunction, which can include shutdown of manufacturing facilities, imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties or pursue criminal prosecution;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or by our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

We may not be able to identify additional therapeutic opportunities for Rhopressa®, Rocklatan® or any current or future product candidates or to expand our portfolio of product candidates.

We continue to explore other therapeutic opportunities in ophthalmology through internal research programs and from time to time we may explore such opportunities through research collaboration arrangements or acquisitions and may seek to commercialize a portfolio of new ophthalmic drugs or technologies in addition to Rhopressa® and Rocklatan®. For example, in 2017, we entered into a collaboration arrangement with DSM, which was expanded in the third quarter of 2018, and acquired the rights to certain assets from Envisia, both of which are expected to support the development of our ongoing preclinical retinal programs. In addition to our preclinical retinal programs, we are conducting preclinical studies to evaluate potential additional indications for Rhopressa® and potentially Rocklatan®. In 2019, we acquired Avizorex, an ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease. Our clinical operations to date have been

limited to developing product candidates for the treatment of glaucoma and ocular hypertension, and there can be no assurance that we will successfully develop, license or acquire any drugs or technologies in new therapeutic areas or at all.

Preclinical studies require additional research and development, which in some cases may include significant preclinical, clinical and other testing, prior to initiating clinical development or seeking regulatory approval to market new indications, technologies and/or product candidates. Accordingly, these additional indications, technologies and product candidates will not be commercially available for a number of years, if at all. In particular, although we are currently exploring additional indications for Rhopressa®, we cannot guarantee that we will pursue or receive the regulatory approvals required to promote Rhopressa® for any additional indications. Failure to receive such approvals will prevent us from promoting and commercializing Rhopressa® beyond its currently approved indication.

Research programs, including through collaboration arrangements, to pursue the development of Rhopressa®, Rocklatan® and any current or future product candidates for additional indications and to identify new product candidates, technologies, therapeutic areas and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential additional indications, technologies, therapeutic areas and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential additional indications, technologies, therapeutic areas and/or product candidates;
- potential additional indications, technologies, therapeutic areas or product candidates may, after further study, fail to demonstrate efficacy sufficient to warrant further clinical development;
- potential technologies or product candidates may, after further study, be shown to be ineffective or have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities or to develop suitable potential product candidates or technologies, whether through internal research programs, research collaboration arrangements or acquisitions, than we possess, thereby limiting our ability to diversify and expand our product portfolio.

We are also focused on furthering the development of our current and future product candidates focused on retinal diseases and dry eye disease. Through business development activities, in 2017 we acquired worldwide ophthalmic rights to a bio-erodible polymer technology from DSM and PRINT® implant manufacturing technology, which is a proprietary technology capable of creating precisely-engineered sustained-release products utilizing fully-scalable manufacturing processes, from Envisia. Using these technologies, we have created a sustained-release ophthalmology platform and are currently developing two sustained-release implants focused on retinal diseases, AR-1105, a dexamethasone IVT implant, and AR-13503, a ROCK/Protein kinase C inhibitor. In March 2019, we initiated a Phase 2 clinical trial of AR-1105 in patients with macular edema due to retinal vein occlusion. In August 2019, we initiated a Phase 2 clinical trial of AR-13503 SR in patients with neovascular age-related macular degeneration or diabetic macular edema. We acquired Avizorex in 2019 and are planning to initiate a Phase 2b study on AVX-012 in late 2020. The decision whether to pursue, and the timing of, any additional preclinical research programs is subject to a number of factors and we may suspend or discontinue research programs at any time.

In addition, because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify or develop additional therapeutic opportunities for Rhopressa®, Rocklatan® or any current or future product candidates or any uses for our existing proprietary compounds beyond glaucoma or to develop suitable potential product candidates or technologies through internal research programs, research collaboration arrangements or acquisitions, which could materially adversely affect our future growth and prospects.

Rhopressa® and Rocklatan® are designed to treat patients with open-angle glaucoma or ocular hypertension, and the success or failure of either of them could impact sales of the other or other potential ROCK inhibitor products in the future.

Rhopressa® and Rocklatan® are designed to be once-daily dosed ROCK inhibitor eye drops to be applied topically to reduce IOP for the treatment of glaucoma or ocular hypertension. While we believe there is space for both Rhopressa® and Rocklatan®, we cannot guarantee that cannibalization of sales will not occur in the future. While increased sales for one of Rhopressa® or Rocklatan® may negatively impact sales for the other, our commercialization strategy is unique for each. Because each of Rhopressa® and Rocklatan® are ROCK inhibitor eye drops designed to treat patients with glaucoma or ocular hypertension, any

challenges or failures with respect to either of Rhopressa® and Rocklatan® could negatively impact sales or the public perception of the other or any other potential ROCK inhibitor products we may develop in the future.

Risks Related to Manufacturing

We anticipate continued reliance on third-party manufacturers for the development and commercialization of Rhopressa®, Rocklatan® and any current or future product candidates in accordance with manufacturing regulations, beyond our recent progress in internal manufacturing capabilities.

With respect to the commercial production of Rhopressa® and Rocklatan®, we currently have contractual relationships for finished product manufacturing with two vendors and are outsourcing the production of the API. To the extent we terminate our existing supplier arrangements in the future and seek to enter into arrangements with alternative suppliers, we might experience a delay in our ability to obtain our clinical or commercial supplies.

Reliance on third-party manufacturers entails risks, including:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over Rhopressa® or Rocklatan® or any current or future product candidates, if approved, or otherwise do not satisfactorily perform according to the terms of their agreements with us;
- delays in obtaining regulatory approval for Rhopressa® and/or Rocklatan® outside the United States or any current or future product candidates, if our third-party manufacturers fail to satisfy or comply with regulatory requirements;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- product loss due to contamination, equipment failure or improper installation or operation of equipment or operator error;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

For example, in October 2016, we were required to withdraw the initial submission of our NDA for Rhopressa® due to a contract manufacturer of our drug product not being prepared for pre-approval inspection by the FDA. We resubmitted the Rhopressa® NDA in February 2017 upon receiving confirmation from the contract manufacturer that it was prepared for FDA inspection and the Rhopressa® NDA was subsequently approved in December 2017.

In addition, our manufacturers may not perform as agreed or may not remain in the contract manufacturing business. In the event of a natural disaster, business failure, strike or other difficulty, we may be unable to replace a third-party manufacturer in a timely manner and the production of Rhopressa®, Rocklatan® or any current or future product candidates could be interrupted, resulting in delays and additional costs. We may also have to incur other charges and expenses for products that fail to meet specifications and undertake remediation efforts.

In January 2017, we commenced establishment of our own manufacturing plant in Athlone, Ireland. This is our first manufacturing plant, which is expected to begin production of commercial supplies of Rocklatan® in the first quarter of 2020. In January 2020, we received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the PAS, which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. We expect FDA approval to produce commercial supplies of Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the Athlone manufacturing plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®. However, there can be no assurance that we will be able to successfully manufacture our final drug product on a commercial scale or in accordance with manufacturing regulations. See "*—We have limited experience developing manufacturing facilities or manufacturing Rhopressa® or Rocklatan®, and we cannot assure you that we will be able to develop our manufacturing plant or manufacture Rhopressa® or Rocklatan® at full capacity and in compliance with regulations at a cost or in quantities necessary to make them commercially viable.*" If our manufacturing operations fail to achieve regulatory approval or to effectively produce commercial supplies of Rhopressa® or Rocklatan® or any current or future product candidates, if approved, or until such time we are capable of developing internal manufacturing capabilities, we will be required to rely solely on third-party manufacturers to meet our commercial manufacturing needs, which may materially adversely affect our business, results of operations or financial

condition.

We commenced operation of our cGMP-validated manufacturing facility for production of ophthalmic implants using the proprietary PRINT® technology platform in the fourth quarter of 2018. This facility is not being used to produce commercial supplies of Rhopressa® or Rocklatan®.

If we or third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before we or a third party can begin commercial manufacture of Rhopressa® or Rocklatan® or any current or future product candidates, if approved, we or the third party must obtain regulatory approval of our or their manufacturing facilities, processes and quality systems. If our third-party manufacturers do not have a cGMP compliance status acceptable to the FDA, approval of any NDA that includes those third-party manufacturers will be delayed.

Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, we or any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost-effective manner. We or certain of our contract manufacturers may fail to satisfy or comply with manufacturing regulations. If we or our contract manufacturers do not have a compliance status acceptable to the FDA, regulatory approval and/or commercial supply of the active pharmaceutical ingredients of Rhopressa® or Rocklatan® or any current or future product candidates, if approved, will be significantly delayed and may result in significant additional costs.

In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities, before and after product approval, and must comply with cGMP. We or our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If we or a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions and criminal or civil prosecution. These possible sanctions could materially adversely affect our reputation, financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA or other regulatory review and/or approval of the manufacturing process and procedures in accordance with the FDA's regulations or comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch or commercial production of a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

We have limited experience developing manufacturing facilities or manufacturing Rhopressa® or Rocklatan®, and we cannot assure you that we will be able to develop our manufacturing plant or manufacture Rhopressa® or Rocklatan® at full capacity and in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

In January 2020, we received FDA approval to produce Rocklatan® at the Athlone manufacturing plant for commercial distribution in the United States and expect to begin production of commercial supplies of Rocklatan® for the United States in the first quarter of 2020. This approval follows a successful pre-approval inspection of the plant and FDA review of the PAS, which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the Athlone manufacturing plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®. We have limited experience in developing manufacturing facilities or manufacturing drug products. As the Athlone plant output commences and expands, per unit costs will suffer until the proper capacity levels are achieved, thus generating a unit cost that is higher than we currently have with our contract manufacturers.

The development of manufacturing facilities and the manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and

expense in conducting validation studies. There can be no assurance that we will obtain permission or approval from the FDA and other regulatory authorities to allow the plant to manufacture Rhopressa® for export to the United States and other markets.

Our manufacturing operations and those of our third-party suppliers are subject to environmental, health and safety laws and regulations concerning, among other things, the use, storage, generation, handling, transportation and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, exposure to hazardous substances and emissions or discharges into the air or water. Violations of these laws and regulations can result in significant business interruptions and/or civil and criminal penalties. New laws and regulations, violations of or amendments to existing laws or regulations, or stricter enforcement of existing requirements, could require us to incur material costs, subject us to new or increased liabilities, and cause disruptions to our manufacturing activities that could be material.

Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced regulations. If we are unable to effectively produce commercial supplies of Rhopressa® and Rocklatan®, we will be required to rely on a third-party manufacturer to meet our commercial manufacturing needs, which may materially adversely affect our business, results of operations and financial condition. See "*—We anticipate continued reliance on third-party manufacturers for the development and commercialization of Rhopressa®, Rocklatan® and any current or future product candidates in accordance with manufacturing regulations, beyond our recent progress in internal manufacturing capabilities*."

Any of these risks could entail higher costs, cause us to delay production and may result in our being unable to effectively support commercialization of Rhopressa® and Rocklatan®. Furthermore, if we fail to deliver the required commercial quantities of product on a timely basis, and at commercially reasonable prices and acceptable quality, we would likely be unable to meet demand, if any, for Rhopressa® and Rocklatan® and we would lose potential revenues.

Production at our suppliers' facilities could be disrupted for a variety of reasons, which could prevent us from producing enough of our products to maintain our sales and satisfy our customers' demands.

A disruption in production at our suppliers' facilities could have a material adverse effect on our business. Disruptions or interruptions of production or operations could occur for many reasons, including accidents, unplanned maintenance or other manufacturing problems, cyber security incidents, terrorism, acts of war or political unrest, disease or public health crises, strikes or other labor unrest, transportation interruption or other unforeseen events as a result of weather, fire, natural disasters or otherwise. Additional facilities with sufficient capacity or capabilities may not be available, may cost substantially more or may take a significant time to start production due to the need for FDA approval, each of which could negatively affect our business and financial performance. If one of our key suppliers is unable to produce our products or raw materials for an extended period of time, our sales may be reduced by the shortfall caused by the disruption and we may not be able to meet our customers' needs, which may materially adversely affect our business and financial performance.

For example, in December 2019, a strain of coronavirus was reported to have surfaced in Wuhan, China, which has and is continuing to spread throughout China and other parts of the world. We maintain a supply chain structure that presently allows us to avoid the current coronavirus outbreak. We also maintain a limited supply of starting materials in house. However, the future impact of this outbreak is highly uncertain and cannot be predicted. If the coronavirus spreads to other regions, including to India or Ireland, or if the duration of the disruption is longer than anticipated, our business and financial performance could be adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have recently begun commercializing Rhopressa® and Rocklatan®, have limited revenue and may never become profitable.

We have a limited operating history and began commercializing our first product Rhopressa® in the United States in April 2018, and our second product Rocklatan® in the United States in May 2019. We have never been profitable and only have two products approved for commercial sale. Even though we received FDA approval, began commercial sales for these two products in the United States and received the centralised marketing authorisation for Rhokiinsa® by the EC, we are still in the process of obtaining additional regulatory approvals in jurisdictions outside the United States and there is no guarantee that either product will be approved in any such jurisdictions.

Our ability to generate product revenue depends on a number of factors, including our ability to:

- maintain an acceptable price for each of Rhopressa® and Rocklatan® in the United States;

- set acceptable net prices for our glaucoma products outside the United States that allow for adequate profitability, in a stand-alone or partnered environment;
- set an acceptable price for any current or future product candidates, if approved, and obtain adequate coverage and reimbursement from third-party payers;
- manufacture or obtain commercial quantities of Rhopressa® and Rocklatan® and any current or future product candidates, if approved, at acceptable cost levels;
- successfully market and sell Rhopressa® and Rocklatan® and any current or future product candidates, if approved, in the United States and other jurisdictions; and
- successfully complete clinical development, and receive regulatory approval, for our current and any future product candidates.

Our net product revenue may be impacted by the accuracy of our estimates for discounts and allowances, in which estimates for reserves are based on current contractual and statutory requirements, invoices from CMS for the company funded portion of the coverage gap, known market events and trends, industry data, forecasted customer mix and lagged claims. In addition, because of the numerous risks and uncertainties associated with product development, commercialization and manufacturing, we are unable to precisely predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations for a number of reasons, including if we are required by the FDA or other regulatory authorities to perform studies in addition to those that we currently anticipate. Even though we have begun commercial sales of Rhopressa® and Rocklatan®, we are still incurring and anticipate continuing to incur significant costs associated with commercialization activities.

Our ability to become and remain profitable depends on our ability to generate revenue. Although we have generated revenues from the sales of our products, even if we were able to continue to generate revenues from our products and to generate revenues from current or future product candidates, if approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could materially impair our ability to raise capital, expand our business or continue our operations.

We have incurred net losses since inception and anticipate that we will continue to incur net losses until such a time when Rhopressa® and Rocklatan® are commercially successful, if at all.

We have incurred losses in each year since our inception in June 2005. Our net losses were $199.6 million, $232.6 million and $145.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $896.0 million.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have devoted the majority of our historical financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the sale of equity securities and issuance of convertible debt, including the completion of our initial public offering (“IPO”) in October 2013, the issuance of $125.0 million aggregate principal amount of convertible notes (the “2014 Convertible Notes”) to Deerfield in September 2014, which were converted into shares of common stock in July 2018, the issuance of $316.25 million of 1.50% convertible notes due 2024 (the “Convertible Notes”) in September 2019, and the issuance and sale of common stock pursuant to our registration statements on Form S-3 and prior “at-the-market” sales agreements. Our products will continue to require significant marketing efforts and substantial investment to maintain and increase revenues. Any current or future product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenue.

We expect our research and development expenses to continue to be significant in connection with our ongoing and planned activities. In addition, as we have now launched Rhopressa® and Rocklatan®, we have incurred and expect to continue to incur increased manufacturing, selling and marketing expenses. As a result, we expect to continue to incur operating losses until our products generate adequate commercial revenue to render Aerie profitable. These losses have had and will continue to have a material adverse effect on our stockholders’ equity, financial position, cash flows and working capital.

We may need to obtain additional financing to fund our operations and, if we are unable to obtain such financing, we may be unable to complete the development and commercialization of Rhopressa®, Rocklatan® or any current or future product candidates.

Our operations have consumed substantial amounts of cash since inception. In October 2013, we received net proceeds from our IPO of approximately $68.3 million, after deducting underwriting discounts and commissions and expenses. Since our IPO through December 31, 2019, we have raised additional net proceeds of approximately $122.9 million from the issuance of the 2014 Convertible Notes, which were converted into shares of common stock in July 2018, approximately $308.3 million from the issuance of the Convertible Notes and approximately $487.7 million through the issuance and sale of common stock under our shelf registration statements on Form S-3 and prior "at-the-market" sales agreements.

We may need to obtain additional financing to fund our future operations. Additionally, we may need to obtain additional financing to conduct additional trials for the approval of Rhopressa® and Rocklatan® in additional jurisdictions or any current or future product candidates, and for completing the development of any additional product candidates or technologies and executing our international expansion strategy. Moreover, our fixed expenses, such as rent and other contractual commitments, are substantial and are expected to increase in the future, and we also expect to incur increased expenses as we expand our employment base.

Our future funding requirements will depend on many factors, including, but not limited to:

- the amount of sales and other revenues from Rhopressa® and Rocklatan® and any current or future product candidates, if approved, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- selling and marketing costs associated with Rhopressa® and Rocklatan® and any current or future product candidates, if approved, including the cost and timing of expanding our marketing and sales capabilities;
- our commercial success with our commercialized products and any current or future product candidates, if approved;
- the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates or technologies;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities;
- the time and cost necessary to establish internal manufacturing capabilities or arrangements with third-party manufacturers;
- costs of any new business strategies;
- the costs of operating as a public company;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We believe that our existing cash and cash equivalents, investments and expected cash flows will be sufficient to support the product commercialization of Rhopressa® and Rocklatan® through at least the next twelve months. We also intend to use these funds for general corporate purposes, including our clinical, regulatory and commercialization efforts beyond the United States, further development of other potential pipeline opportunities including activities to support execution of our dry eye and retina programs, our external business development efforts and our manufacturing activities, including the operation of our own manufacturing plant in Ireland.

Until we can generate a sufficient amount of revenue, we may need to finance future cash needs through additional financings or other available sources. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization or manufacturing efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or

licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on a number of assumptions that may prove to be incorrect and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the Convertible Notes.

As of December 31, 2019, we had $316.25 million in principal amount of indebtedness as a result of the issuance of the Convertible Notes. We may also incur additional indebtedness to meet future financing needs. Interest payments, fees, covenants and restrictions under agreements governing our current or future indebtedness, including the indenture governing the Convertible Notes, could have important consequences, including the following:

- impairing our ability to successfully continue to commercialize Rhopressa® or Rocklatan® and commercialize any current or future product candidates, which would prevent us from generating a source of revenue and becoming profitable;
- limiting our ability to obtain additional financing on satisfactory terms to fund our working capital requirements, capital expenditures, potential acquisitions, debt obligations and other general corporate requirements, and making it more difficult for us to satisfy our obligations with respect to any such additional financing;
- increasing our vulnerability to general economic downturns, competition and industry conditions, which could place us at a competitive disadvantage compared to our competitors with no debt obligations or with debt obligations on more favorable terms;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business; and
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the Convertible Notes.

The occurrence of any one of these events could have an adverse effect on our business, financial condition, operating results or cash flows and ability to satisfy our obligations under the indenture governing the Convertible Notes and any other indebtedness.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Notes, and our cash needs may increase in the future. In addition, the agreements governing indebtedness that we may incur in the future may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

We may be unable to raise the funds necessary to repurchase the Convertible Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and the terms of our then-existing borrowing arrangements may limit our ability to repurchase the Convertible Notes or pay cash upon their conversion.

Noteholders may require us to repurchase their Convertible Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing any of our then-existing borrowing arrangements may restrict our ability to repurchase the Convertible Notes or pay the cash amounts due upon conversion. If we fail to repurchase Convertible Notes or

to pay the cash amounts due upon conversion when required, we will be in default under the indenture governing the Convertible Notes and may be in default under any other then-existing borrowing arrangements. A default under the indenture governing the Convertible Notes or the fundamental change itself could also lead to a default under any of our then-existing agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the Convertible Notes and any other then-existing indebtedness.

The accounting method for the Convertible Notes could adversely affect our reported financial condition and results.

The accounting method for reflecting the Convertible Notes on our balance sheet, accruing interest expense for the Convertible Notes and reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition.

In accordance with ASC Topic 470, *Debt*, the initial liability carrying amount of the Convertible Notes is the fair value of a similar debt instrument that does not have a conversion feature, valued using our cost of capital for straight, unconvertible debt. We reflect the difference of approximately $128.4 million between the net proceeds from the Convertible Notes and the initial carrying amount as a debt discount for accounting purposes, which is being amortized into interest expense over the term of the Convertible Notes. In addition, the debt issuance costs relating to the Convertible Notes were allocated to debt and equity components in proportion to the allocation of proceeds. Issuance costs of $5.5 million were recorded as debt issuance costs in the net carrying value of Convertible Notes. The debt issuance costs are amortized on an effective interest basis over the term of the Convertible Notes. The remaining issuance costs of $3.7 million were recorded as additional paid-in capital and such amounts are not subject to amortization. As a result of this amortization, the interest expense that we expect to recognize for the Convertible Notes for accounting purposes will be greater than the cash interest payments we will pay on the Convertible Notes, which will result in lower reported income or higher reported loss. The lower reported income or higher reported loss resulting from this accounting treatment could depress the trading price of our common stock.

In addition, because we intend to settle conversions by paying the conversion value in cash up to the principal amount being converted, with the potential of any excess in shares of common stock, we expect to be eligible to use the treasury stock method to reflect the shares underlying the Convertible Notes in our diluted earnings per share. Under this method, if the conversion value of the Convertible Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the Convertible Notes were converted and that we issued shares of our common stock to settle the excess. However, if reflecting the Convertible Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Convertible Notes does not exceed their principal amount for a reporting period, then the shares of common stock underlying the Convertible Notes will not be reflected in our diluted earnings per share. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method and/or under what conditions the treasury stock method would remain available for convertible debt instruments (such as the Convertible Notes). If we are unable or otherwise elect not to use the treasury stock method in accounting for the shares of common stock issuable upon conversion of the Convertible Notes, then our diluted earnings (net loss) per share of common stock could be adversely affected. For example, in July 2019, the Financial Accounting Standards Board published an exposure draft proposing to amend these accounting standards to eliminate the treasury stock method for convertible instruments and instead require application of the “if-converted” method. Under that method, if it is adopted, diluted earnings per share would generally be calculated assuming that all the Convertible Notes were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may reduce our reported diluted earnings per share. Furthermore, if any of the conditions to the convertibility of the Convertible Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Convertible Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their Convertible Notes and could materially reduce our reported working capital.

The capped call transactions may affect the value of our common stock.

In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain option counterparties. The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Convertible Notes and/or offset any cash payments we are required to make in excess of the aggregate principal amount of converted Convertible Notes, as the case may be, with such reduction and/or offset subject to a cap. The option counterparties or their respective affiliates are expected to modify their hedge positions from time to time by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock, the Convertible Notes or other securities or instruments of ours (if any) in secondary market transactions prior to the maturity of the Convertible Notes (and are likely to do so during any observation period related to a conversion of Convertible Notes or following any issuance of

a notice of redemption with respect to the Convertible Notes). Any of these activities could adversely affect the market price of our common stock.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the market price of the shares of our common stock.

We are subject to counterparty risk with respect to the capped call transactions.

The counterparties to the capped call transactions are financial institutions, and we are subject to the risk that one or more of the counterparties may default or otherwise fail to perform, or may exercise certain rights to terminate, their obligations under the capped call transactions. Our exposure to the credit risk of the option counterparties is not secured by any collateral. Global economic conditions have in the past resulted in the actual or perceived failure or financial difficulties of many financial institutions. If any option counterparty becomes subject to proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at the time under any capped call transactions with that option counterparty. Our exposure will depend on many factors but, generally, our exposure will increase if the market price or the volatility of our common stock increases. In addition, upon a default or other failure to perform, or a termination of obligations, by a counterparty, the counterparty may fail to deliver the shares of common stock required to be delivered to us under the capped call transactions and we may suffer adverse tax consequences or experience more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the counterparties.

We may sell additional debt or equity securities at any time, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, business strategies and growth, or if we decide based on ongoing forecast updates, new strategic initiatives, market conditions or for other reasons that additional financings are desirable or needed, we may sell additional debt or equity securities, which would result in dilution to all of our stockholders or impose restrictive covenants that adversely impact our business. In September 2016, our automatic shelf registration statement on Form S-3 became effective upon filing with the SEC, pursuant to which we may offer an unlimited amount of common stock from time to time, and, through the date of this report, we have issued and sold approximately 7.4 million shares of common stock pursuant to such shelf registration statement. Although our existing shelf registration statement on Form S-3 expired on September 15, 2019, for so long as we remain a well-known seasoned issuer we will be able to file a new automatic shelf registration statement covering our equity or debt securities. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.

We were incorporated and commenced active operations in the second quarter of 2005. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our product candidates and advancing Rhopressa® and Rocklatan® to FDA approval and commercial launch. We have not yet demonstrated our ability to successfully manufacture a widely-sold commercial scale product. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a relatively new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We have recently transitioned from a company with solely a product development focus to a company capable of supporting commercial and manufacturing activities and we may not be successful with these endeavors.

Determining our income tax rate is complex and subject to uncertainty.

The computation of income tax provisions is complex, as it is based on the laws of federal, state, local and non-U.S. taxing jurisdictions and requires significant judgment on the application of complicated rules governing accounting for tax provisions under U.S. GAAP. Our provision for income tax can be materially impacted, for example, by the geographical mix of our profits and losses, changes in our business, such as internal restructuring and acquisitions, changes in tax laws and accounting guidance and other regulatory, legislative or judicial developments, transfer pricing policies, tax audit determinations, changes in our uncertain tax positions, changes in our capital structure and leverage, changes to our transfer pricing practices, tax deductions attributed to equity and other compensation and limitations on such deductions and changes in our need for a valuation allowance for deferred tax assets. In addition, relevant taxing authorities may disagree with our determinations as to

the income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates and reduced cash flows than otherwise would be expected. For these reasons, our actual income taxes may be materially different than our provision for income tax.

Our ability to use our net operating loss carryforwards may be limited.

If we experience an "ownership change" for purposes of Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), or similar state provisions, we may be subject to annual limits on our ability to utilize net operating loss carryforwards. An ownership change is, as a general matter, triggered by sales or acquisitions of our stock in excess of 50% on a cumulative basis during a three-year period by persons owning 5% or more of our total equity value.

As of December 31, 2019, we had U.S. federal and state net operating losses ("NOLs") of approximately $495.6 million and $510.3 million, respectively. If not utilized, federal NOLs that arose before 2018 and state NOLs begin to expire at various dates beginning in 2031 and 2024, respectively. Federal NOLs that arose on or after January 1, 2018 can be carried forward indefinitely to be utilized against future income, but can only be used to offset a maximum of 80% of our federal taxable income in any year. Our federal and state NOLs are included as deferred tax assets and have been fully offset by a valuation allowance as of December 31, 2019. As of December 31, 2019, we also had foreign NOLs of $68.1 million which are available solely to offset taxable income of our foreign subsidiaries, subject to any applicable limitations under foreign law.

Changes to the United States tax laws could materially impact our financial position and results of operations.

In December 2017, the Tax Act was signed into law. The Tax Act makes extensive changes to the U.S. tax laws and includes provisions that, among other things, reduce the U.S. corporate tax rate, repeal the corporate alternative minimum tax ("AMT") and refund certain existing AMT credits over several years, introduce a capital investment deduction, limit the interest deduction, limit the use of net operating losses to offset future taxable income, limit the deduction for compensation paid to certain executive officers and make extensive changes to the U.S. international tax system, including the taxation of foreign earnings of U.S. multinational corporations. Further, due to the expansion of our international business activities, changes enacted in the Tax Act with respect to the U.S. taxation of such activities may increase our worldwide effective tax rate and adversely affect our financial position and results of operations. The U.S. Treasury Department has released regulations implementing the Tax Act and is expected to release additional regulations and the U.S. tax laws may be further amended in the future. The Tax Act is complex and far-reaching and we cannot predict with certainty the resulting impact its enactment will have on us.

Our international operations subject us to potentially adverse tax consequences.

We generally conduct our international operations through wholly-owned subsidiaries and report our taxable income, if any, in various jurisdictions worldwide based upon our business operations in those jurisdictions. Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with any of our determinations including as to the income and expenses attributable to specific jurisdictions and the statutory domiciles of our intellectual property. If such a disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates and reduced cash flows.

In addition, jurisdictions outside the United States could challenge aspects of the Tax Act or implement reactionary legislation or regulations that could adversely affect us and/or negate or minimize any favorable impact that we may derive from the Tax Act in the future.

Risks Related to Our Reliance on Third Parties

We currently depend on third parties to conduct some of the operations of our clinical trials and other portions of our operations, and we may not be able to control their work as effectively as if we performed these functions ourselves.

We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to oversee and conduct our clinical trials and to perform the related data collection and analysis. We expect to rely on these third parties to conduct clinical trials of any current or future product candidates that we develop. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. In addition, any CRO that we retain will be subject to the FDA's regulatory requirements or similar foreign standards and we do not have control over compliance with these regulations by these providers. Our agreements with third-party service providers are on a trial-by-trial and project-by-project bases. Typically, we may terminate the agreements with notice and are responsible for the third party's

incurred costs. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. We also rely on other third parties to store and distribute drug supplies for our clinical trials and commercial supply. Any performance failure on the part of our third-party vendors could delay, as applicable, clinical development, regulatory approval or commercialization of Rhopressa®, Rocklatan® or any current or future product candidates, producing additional losses and depriving us of potential product revenue.

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities, and we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan, the protocols for the trial and the FDA's regulations and international standards, referred to as GCP requirements, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial participants are protected. Preclinical studies must also be conducted in compliance with the Animal Welfare Act requirements. Managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers.

Furthermore, these third parties may produce or manufacture competing drugs or may have relationships with other entities, some of which may be our competitors. The use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

If these third parties do not successfully carry out their contractual duties or obligations and meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols according to regulatory requirements or for other reasons, our financial results and the commercial prospects for Rhopressa® and Rocklatan® and any current or future product candidates, if approved, could be harmed, our costs could increase and our ability to obtain regulatory approval (as applicable) and commence product sales could be delayed.

If we fail to manage an effective distribution process in the United States or establish an effective distribution process in jurisdictions outside the United States, our business may be adversely affected.

We have established the infrastructure necessary for distributing pharmaceutical products in which third-party logistics wholesalers warehouse Rhopressa® and Rocklatan® and distribute them to pharmacies and will need to establish such infrastructures in jurisdictions outside the United States. This distribution network requires significant coordination with our sales and marketing and finance organizations, and the failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively manage the distribution process, the continued commercialization of our products could be disrupted or the commercial launch and sales of Rhopressa® and Rocklatan® in jurisdictions outside the United States, in any such case, or any current or future product candidates, if approved, will be delayed or severely compromised and our results of operations may be harmed.

Any collaboration arrangement that we may enter into may not be successful, which could adversely affect our ability to develop and commercialize any current or future product candidates or technologies or to enter new therapeutic areas.

We continually explore and discuss additional opportunities for new ophthalmic products, delivery alternatives and new therapeutic areas with potential partners and on our own. We may seek collaboration arrangements with pharmaceutical or biotechnology companies or universities for the development or commercialization of our current and potential current or future product candidates or technologies. For example, in 2017, we entered into a collaborative research, development and licensing agreement with DSM, which was expanded in the third quarter of 2018. Part of our globalization strategy is to partner in Japan. We will face, to the extent that we decide to enter into additional collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are often complicated and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements and the terms of such arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate and/or technology, we can expect to relinquish some or all of the control over the future success of that product candidate and/or technology to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Accordingly, there can be no assurance that any collaboration or licensing arrangement or similar strategic transaction we enter into will result in the benefits that we anticipate.

Disagreements between parties to a collaboration arrangement regarding research, clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate or technology and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the

parties has final decision-making authority. In addition, collaborators may not pursue development and commercialization of our preclinical molecules or product candidates or may elect not to continue or renew development or commercialization programs based on our results, changes in their strategic focus due to the acquisition of competitive products or technologies, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration may adversely affect us financially and could harm our business reputation.

Risks Related to Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any future licensee's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We believe we will be able to obtain, through prosecution of our current pending patent applications, adequate patent protection for our proprietary drug technology. If we are compelled to spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed. If we are unable to effectively protect the intellectual property that we own, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our competitive business position and harm our business prospects. Our patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

The patent positions of pharmaceutical products are often complex and uncertain. The standards of patentability as well as the breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or create uncertainty. In addition, publication of information related to our current product and potential products may prevent us from obtaining or enforcing patents relating to such product and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Our intellectual property includes issued patents and pending patent applications for compositions of matter, pharmaceutical formulations, methods of use, medical devices and synthetic methods. As of December 31, 2019, we owned 46 patents and have 21 pending patent applications in the United States and certain foreign jurisdictions for Rhopressa® and Rocklatan®. Patent protection for Rocklatan® includes the U.S. patents that cover Rhopressa®. The patents cover composition of matter and method of use. As of December 31, 2019, we owned and had pending patent applications in the United States and certain foreign jurisdictions for our product candidates. Our exclusive license regarding AVX-012 provides us with exclusive rights in patents covering AVX-012 and its use in treating dry-eye in the United States and pending patent applications internationally. Furthermore, as of December 31, 2019, for AR-1105 we had two pending patent applications in the United States and eight pending patent applications internationally. One of the U.S. pending patent applications has been allowed. With respect to AR-13503, as of December 31, 2019, we owned 37 patent applications and had 15 pending patent applications internationally for AR-13503. See "Business—Intellectual Property" for further information about our issued patents and patent applications.

Patents that we own or may license in the future do not necessarily ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- our patents may not be broad or strong enough to prevent competition from other products that are identical or similar to Rhopressa® and Rocklatan®;
- there can be no assurance that the term of a patent can be extended under the provisions of Patent Term Extension ("PTE") afforded by U.S. law or similar provisions in foreign countries, where available;
- our issued patents and patents that we may obtain in the future may not prevent generic entry into the markets for Rhopressa® and Rocklatan®;
- we do not currently own or control foreign patents issued outside of Australia, Canada, Europe and Japan that would prevent generic entry into those markets for Rhopressa® and Rocklatan®;

- we may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if our patents are challenged, a court of competent jurisdiction could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our patents that adversely affects the scope of our patent rights;
- a court of competent jurisdiction could determine that a competitor's technology or product does not infringe our patents; and
- our patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of Rhopressa® and/or Rocklatan® by submitting ANDAs to the FDA in which our competitors claim that our patents are invalid, unenforceable and/or not infringed. In addition, our competitors may file patent applications that may have an impact on our ability to make, use and sell products that contain Rhopressa® or Rocklatan®. Should such a competitor's patent application(s) issue, it is possible the competitor will allege that our making, using or selling of products containing Rhopressa® or Rocklatan® infringes such issued patents. In such circumstances, we may need to challenge such pending applications or issued patents, or perhaps come to a financial arrangement with the competitor.

Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency having competent jurisdiction may find our patents invalid and/or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In that regard, third parties may challenge our patents in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

A significant portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents. If our pending patent applications fail to issue our business will be adversely affected.

Our commercial success will depend significantly on maintaining and expanding patent protection for Rhopressa® and Rocklatan® and any current or future product candidates, as well as successfully defending our current and future patents against third-party challenges. As of December 31, 2019, we owned 108 patents and have 114 pending patent applications in the United States and certain foreign jurisdictions relating to Rhopressa®, Rocklatan® and our previously discontinued product candidates and other proprietary technology. See "Business—Intellectual Property" included elsewhere in this report for further information about our issued patents and patent applications. Our issued patents include 46 patents for composition of matter and method of use covering Rhopressa® in the United States and certain foreign jurisdictions. These patents also cover Rocklatan® to the extent that Rhopressa® forms a part of Rocklatan®. The remainder of our portfolio is made up of patents covering previously discontinued product candidates and other proprietary technology and pending patent applications that have not yet been issued by the U.S. Patent and Trademark Office (the "USPTO"), or any other jurisdiction that covers Rhopressa®, Rocklatan® or our previously discontinued product candidates or other proprietary technology.

There can be no assurance that our pending patent applications will result in issued patents in the United States or foreign jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or enforceability, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our products.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. It may be difficult for us to stop the infringement of our patents or the misappropriation of these intellectual property rights in any foreign jurisdictions. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and disrupt the commercialization of or increase the costs of commercializing Rhopressa® or Rocklatan® or any current or future product candidates, if approved.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. If patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. There could be issued patents of which we are not aware that Rhopressa®, Rocklatan® or any current product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates or methods either do not infringe the claims of the relevant patent or that the patent claims asserted are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates, if approved, unless we acquire or obtain a license under the applicable patents or until the patents expire. We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing

technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing one or more of our current products and potential products or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities, biotechnology companies or other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the intellectual property and other proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property, including trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with members of our senior management, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal by the FDA to increase disclosure and make data more accessible to the public, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

Any lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely impact the price of our common stock.

We may be required to initiate litigation to enforce or defend our intellectual property. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically

last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings, and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common stock.

We will need to obtain regulatory approval of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

We assigned the trade names Rhopressa® and Rocklatan® to our now FDA-approved products. In 2019, the EC granted a centralised marketing authorisation for Rhopressa®, which will be marketed under the trade name Rhokiinsa®. Any other names we intend to use for our current or any future product candidates will require approval from the FDA and applicable non-U.S. regulatory authorities regardless of whether we have secured a formal trademark registration from the USPTO or applicable non-U.S. regulatory authorities. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. Regulatory authorities outside the United States conduct their own investigations. If the FDA or applicable non-U.S. authorities object to any of our proposed product names for any current or future product candidates, we may be required to adopt an alternative trade name. In 2018, the EMA approved the name Roclanda® for Rocklatan® in the EU. A trademark application for Roclanda® was filed in the EU on October 25, 2018, and this mark was successfully registered in the EU on March 4, 2019.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our patents and obtaining data exclusivity for Rhopressa®, Rocklatan®, Rhokiinsa® or any current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for Rhopressa® and Rocklatan® and any current or future product candidates, one or more of our U.S. patents may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. PTEs, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for PTE is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for PTE. A PTE application pursuant to 35 USC §156 (section 156) was filed February 8, 2018 seeking an extension of U.S. patent number 8,394,826 (the "'826 patent"). The '826 patent covers Rhopressa® and Rocklatan®, and is presently expected to expire November 20, 2030, though the date may be extended if the '826 patent PTE application is granted. To date there have been two official substantive actions on the '826 patent PTE application. On September 18, 2018 the USPTO confirmed that '826 patent is eligible for PTE under section 156. On May 13, 2019 the FDA confirmed that Rhopressa® was subject to the required FDA approval and that the PTE application was filed timely. We expect the FDA and USPTO will complete the PTE application review in late 2020; however, it is not possible to predict with certainty when the PTE will become official, if at all.

Risks Related to Our Business Operations and Industry

We depend upon our key personnel and our ability to attract and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. We are highly dependent on our senior management team and our scientific founders, as well as the other principal members of our management and scientific teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any

member of our senior management or scientific team or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of Vicente Anido, Jr., our Chairman of the Board of Directors and Chief Executive Officer, Thomas A. Mitro, our President and Chief Operating Officer, Richard J. Rubino, our Chief Financial Officer, Casey C. Kopczynski, our Chief Scientific Officer, David A. Hollander, our Chief Research & Development Officer, John LaRocca, our General Counsel, or Kathleen McGinley, our Vice President of Human Resources and Corporate Services, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not currently carry "key person" insurance on the lives of members of executive management. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We have increased the size of our organization, and we may experience difficulties in managing our growth.

We have increased the size of our organization. We have approximately 380 full-time employees as of December 31, 2019 compared to 353 full-time employees as of December 31, 2018, and may expand further as we scale-up our manufacturing plant in Ireland.

Our growth has imposed significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate new employees. Our future financial performance and our ability to commercialize Rhopressa® and Rocklatan® and any current or future product candidates, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our research programs, clinical trials and the regulatory process effectively;
- manage the operation of our manufacturing plant and the manufacturing of Rhopressa®, Rocklatan® and any current or future product candidates for clinical and commercial use;
- integrate current and additional management, administrative, financial, manufacturing and sales and marketing personnel;
- hire additional personnel necessary to effectively commercialize and manufacture Rhopressa® and Rocklatan® and any current or future product candidates, if approved;
- continue to develop and maintain our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Product candidates that we may acquire or develop in the future may be intended for patient populations that are large. In order to continue development and marketing of these product candidates, if approved, we would need to significantly expand our operations. Our staff, financial resources, systems, procedures or controls may be inadequate to support our operations and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third parties.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in

controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business may be negatively impacted by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute Rhopressa® or Rocklatan® or any current or future product candidates, if approved. Similarly, these macroeconomic factors could affect the ability of our contract manufacturers, sole-source or single-source suppliers, collaboration partners or licensees to remain in business or otherwise develop, manufacture or supply product. Failure by any of them to remain in business could affect our ability to manufacture Rhopressa® or Rocklatan® or any current or future product candidates, if approved, or develop additional product candidates or technologies.

A significant portion of our revenue currently comes from a limited number of distributors, and any decrease in revenue from these distributors could harm our business.

A significant portion of our revenue comes from a limited number of distributors. In the year ended December 31, 2019, three distributors represented approximately 36.5%, 33.3% and 28.0% of total revenues. We further expect that a significant portion of our revenue will continue to depend on sales to a limited number of distributors in the foreseeable future. We do not have long-term commitments from our distributors to carry our products, and any of our distributors may from quarter to quarter comprise a significant concentration of our revenues. Our dependence on a few distributors could expose us to the risk of substantial losses if any single large distributor stops purchasing our products, purchases a lower quantity of our products or goes out of business and we cannot find substitute distributors on equivalent terms without delays, if at all. While we may be able to shift our business to one of our other existing distributors or to a new distributor, there may be disruption in the interim. In addition, any reduction in the prices we receive for our products could adversely impact our revenues and financial condition. If we lose our relationship with any of our significant distributors, we could experience delays in the distribution of our products and could also experience declines in our revenues which in turn could materially adversely affect our business, results of operations or financial condition.

If we engage in acquisitions or licenses in the future, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions or licenses.

We may attempt to acquire or license businesses, technologies, services, products or product candidates in the future that we believe are a strategic fit with our business. For example, in October 2017, we acquired the rights to use PRINT® technology and certain other assets from Envisia. Further, in August 2018 we entered into an Amended and Restated Collaborative Research, Development, and License Agreement with DSM, which provides for (i) a worldwide exclusive license for all ophthalmic indications to DSM's polyesteramide polymer technology, (ii) continuation of the collaborative research initiatives through the end of 2020, including the transfer of DSM's formulation technology to Aerie during that time and (iii) access to a preclinical latanoprost implant. Additionally, in late 2019 we acquired Avizorex, an ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease. We have no present agreement regarding any material acquisitions. However, if we do undertake any acquisitions or additional licenses, the process of integrating an acquired or licensed business, technology, service, product or product candidate into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions or licenses could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions or licenses could also result in the incurrence of debt, actual or contingent liabilities or the amortization of expenses related to intangible assets, any of which could adversely affect our operating results.

We have limited experience identifying, negotiating and implementing acquisitions or licenses of additional businesses, technologies, services, products or product candidates, which is a lengthy and complex process. The market for acquiring or licensing businesses, technologies, services, products or product candidates is intensely competitive, and other companies,

including some with substantially greater financial, marketing and sales resources, may also pursue strategies to acquire or license businesses, technologies, products or product candidates that we may consider attractive. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

We have limited resources to identify and execute the acquisition or licensing of additional businesses, technologies, services, products, or product candidates and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire or license the rights to additional businesses, technologies, services, products or product candidates on terms that we find acceptable, or at all. In particular, any product candidate that we acquire or license may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Business interruptions could delay the development of our potential products and our manufacturing activities, and could disrupt our potential sales.

Our principal executive office and research facility is located in Durham, North Carolina, our regulatory, commercial support and other administrative activities are located in Irvine, California, and our clinical, finance and legal operations are located in Bedminster, New Jersey. We also lease space for a manufacturing plant in Athlone, Ireland and small offices in Malta, Ireland, the United Kingdom and Japan. We are vulnerable to natural disasters, such as severe storms, and other adverse events that could disrupt our operations. We carry limited insurance for natural disasters and other adverse events, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our business and operations would suffer in the event of system failures, cyber-attacks or other security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, sales force, collaborators and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, ransomware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusions, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, supplier, collaboration partner or other third party with whom we do business may attempt to obtain such information and may purposefully or inadvertently cause a breach involving such information. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs, manufacturing activities and/or commercialization efforts, damage our reputation, provide competitors with valuable information and subject us to additional liabilities, including criminal penalties and civil sanctions. We have not been subject to cyber-attacks or other cyber incidents to date which, individually or in the aggregate, have been material to our business, but the actions we take to prevent or detect the risk of cyber incidents and protect our information technology networks and infrastructure may be insufficient to prevent or detect a major cyber-attack or other cyber incident in the future.

In addition, there is a risk created by our lack of redundancy across our systems and if any of these events were to occur, this could result in a loss of materials that would be difficult to replace, such as proprietary information including intellectual property and business information and/or customer, supplier, employee, business partner and, in certain instances, patient personally identifiable information. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture Rhopressa® and Rocklatan®, and similar events relating to their systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the commercialization of Rhopressa® and Rocklatan® and the further development of any current or future product candidates could be delayed.

Our actual or perceived failure to comply with U.S. federal, state, and foreign governmental regulations and other legal obligations related to privacy, data protection and information security could harm our reputation and business.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information, data about our clinical participants, suppliers and business partners and personally identifiable information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Any access, disclosure or other loss of information could result in legal claims or proceedings, disruption of our operations and damage to our reputation, all of which could materially adversely affect our business. In addition, we are subject to various U.S. federal and state and international privacy and security regulations. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many U.S. states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. With our increasing international presence, we are also subject to the laws of jurisdictions outside the United States. Privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements, which could increase the costs incurred by us in complying with such laws.

The EU member states, Switzerland, Japan and other countries have established, or are in the process of establishing, legal frameworks for privacy and data security that impose significant compliance obligations with which our customers, our vendors or we must comply. For example, the EU General Data Protection Regulation (the "GDPR"), which became effective on May 25, 2018, imposes strict requirements on data controllers and processors of personal data. The GDPR is wide-ranging in scope and imposes numerous requirements, including requirements relating to processing sensitive data (including health, biometric and genetic information), obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. In addition, the GDPR grants individuals an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU, including to the United States and other regions.

The GDPR introduced new fines and penalties for a breach of requirements, which may result in significant fines of up to 4% of annual global revenues, or €20.0 million, whichever is greater. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, in particular as regards data processing in the context of clinical trials. As a result of the implementation of the GDPR, we were required to put in place additional mechanisms to ensure compliance with the new data protection rules, although there is a risk that the measures will not be implemented correctly or that individuals within our business will not be fully compliant with the new procedures. If there are any breaches of these measures, we could face significant administrative and monetary sanctions as well as reputational damage, which may have a material adverse effect on our business.

Our disclosure controls and procedures and our systems to implement such disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If product liability lawsuits are successfully brought against us, our insurance may be inadequate and we may incur substantial liability.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates. We face an additional risk from our commercial sales of Rhopressa® and Rocklatan® and will face further risk to the extent we commercialize any current or future product candidates, if approved. We maintain primary product liability insurance and excess product liability insurance that cover our clinical trials, and we have and plan to maintain insurance against product liability lawsuits for commercial sale of Rhopressa® and Rocklatan® and any current or future product candidates, if approved. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been unpredictable.

Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with our clinical trials or commercial use of Rhopressa® or Rocklatan® or any current or future product candidates, if approved, for which our insurance coverage may not be adequate, and the cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial.

For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Rhopressa® or Rocklatan® or any current or future product candidates, if approved. Regardless of the merits or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for Rhopressa® or Rocklatan® or any current or future product candidates, if approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend resulting litigation;
- diversion of management and scientific resources from our business operations;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We increased our insurance coverage when each of Rhopressa® and Rocklatan® received FDA approval. However, the product liability insurance we will need to maintain in connection with the continued commercial sales of Rhopressa® and Rocklatan® and any current or future product candidates if and when they receive regulatory approval, may be unavailable in adequate amounts or at a reasonable cost. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could inhibit the continued commercial production and sale of Rhopressa® or Rocklatan® or any current or future product candidates if and when they obtain regulatory approval, which could materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

Additionally, we do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our financial position, cash flows and results of operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been, and may continue to be, highly volatile.

Our stock price has been volatile and is likely to continue to be volatile. The following factors, in addition to other factors described elsewhere in this "Risk Factors" section, may have a significant impact on the market price of our common stock:

- the success of our commercial launch of Rhopressa® and Rocklatan® in the United States, including associated sales volumes, revenues and profitability;

- overall company profitability and ability to generate positive cash flows, and elimination of the additional costs associated with financing overhang;
- our ability to maintain adequate product supply to meet demand at an acceptable per unit cost;
- our ability to obtain regulatory approval in jurisdictions outside the United States;
- the results of our testing and clinical trials;
- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationships with manufacturers, suppliers, licensees or collaboration partners;
- the results of our efforts to develop, acquire or license additional product candidates or technologies;
- variations in the level of expenses related to Rhopressa®, Rocklatan® or preclinical and clinical development programs;
- changes in laws or regulations;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual versus expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the capital markets;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In addition, the stock market, in general, and pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, any decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

Any securities litigation could result in substantial damages and may divert management's time and attention from our business.

A putative securities class action lawsuit was filed against us and certain of our officers and directors in 2015, which has now concluded. If our stock price experiences volatility, we may be the subject of additional securities litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Monitoring and defending against legal actions is time-consuming for our management and detracts from our ability to fully focus on our business activities. Any adverse determination in litigation could also subject us to significant liabilities.

Certain of our existing stockholders, executive officers and directors own a significant percentage of our common stock and may be able to influence or control matters submitted to our stockholders for approval.

Our officers and directors, and stockholders who own more than 5% of our outstanding common stock, beneficially own approximately 48.6% of our common stock as of December 31, 2019. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in

companies with ownership concentration. Some of our stockholders may be able to influence or determine matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders.

This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that other stockholders may feel are in their best interest, and certain of our existing stockholders may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Additionally, under certain circumstances, our amended and restated certificate of incorporation renounces any interest or expectancy that we have in, or in being offered an opportunity to participate in, corporate opportunities that are presented to certain entities or their affiliates and certain other related parties (whether or not any such person is our director). These provisions will apply even if the opportunity is one that we might reasonably have pursued or had the ability or desire to pursue if granted the opportunity to do so.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our stock, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will continue to cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our stock, or provide more favorable relative recommendations about our competitors, our stock price could decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not intend to declare cash dividends on our shares of common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, we expect that only appreciation of the price of our common stock, if any, will provide a return to investors for the foreseeable future.

The requirements associated with being a public company require significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”), the listing requirements of The Nasdaq Global Market, and other applicable securities rules and regulations. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and The Nasdaq Global Market may also impose various additional requirements on public companies. We have made, and will continue to make, changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to continue to meet our reporting obligations. However, the measures we take may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

We are subject to Section 404(b) of the Sarbanes-Oxley Act (“Section 404”), which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting, among other additional requirements. Compliance with Section 404 is costly and time consuming for management and could result in the detection of internal control deficiencies. Moreover, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis, and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal

controls over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our common stock to fall. Any failure to file accurate and timely quarterly and annual reports that we are required to file with the SEC under the Exchange Act could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our bylaws, as well as provisions of the Delaware General Corporation Law ("DGCL"), could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- establishing a classified board of directors such that not all members of the board are elected at one time;
- allowing the authorized number of our directors to be changed only by resolution of our board of directors;
- limiting the removal of directors by the stockholders;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- requiring the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal our bylaws.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive office and research facility is located in Durham, North Carolina, our regulatory, commercial support and other administrative activities are located in Irvine, California, and our clinical, finance and legal operations are located in Bedminster, New Jersey. We also lease space for a manufacturing plant in Athlone, Ireland. Our Durham, North Carolina, facility consists of approximately 61,000 square feet of laboratory and office space under leases that expire between June 2020 and June 2024 and our Irvine, California, location consists of approximately 37,300 square feet of office space under a lease that expires in January 2022. We terminated our previous lease and entered into a lease for our new Bedminster, New Jersey, location, which consists of approximately 34,000 square feet of office space under a lease that expires in October 2029. Our manufacturing plant in Athlone, Ireland, consists of approximately 30,000 square feet of interior floor space and is under lease through at least September 2027. We may require additional space and facilities as our business expands.

ITEM 3. LEGAL PROCEEDINGS

We may periodically become subject to legal proceedings and claims arising in connection with our business. We are not a party to any known litigation, are not aware of any material unasserted claims and do not have contingency reserves established for any litigation liabilities.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

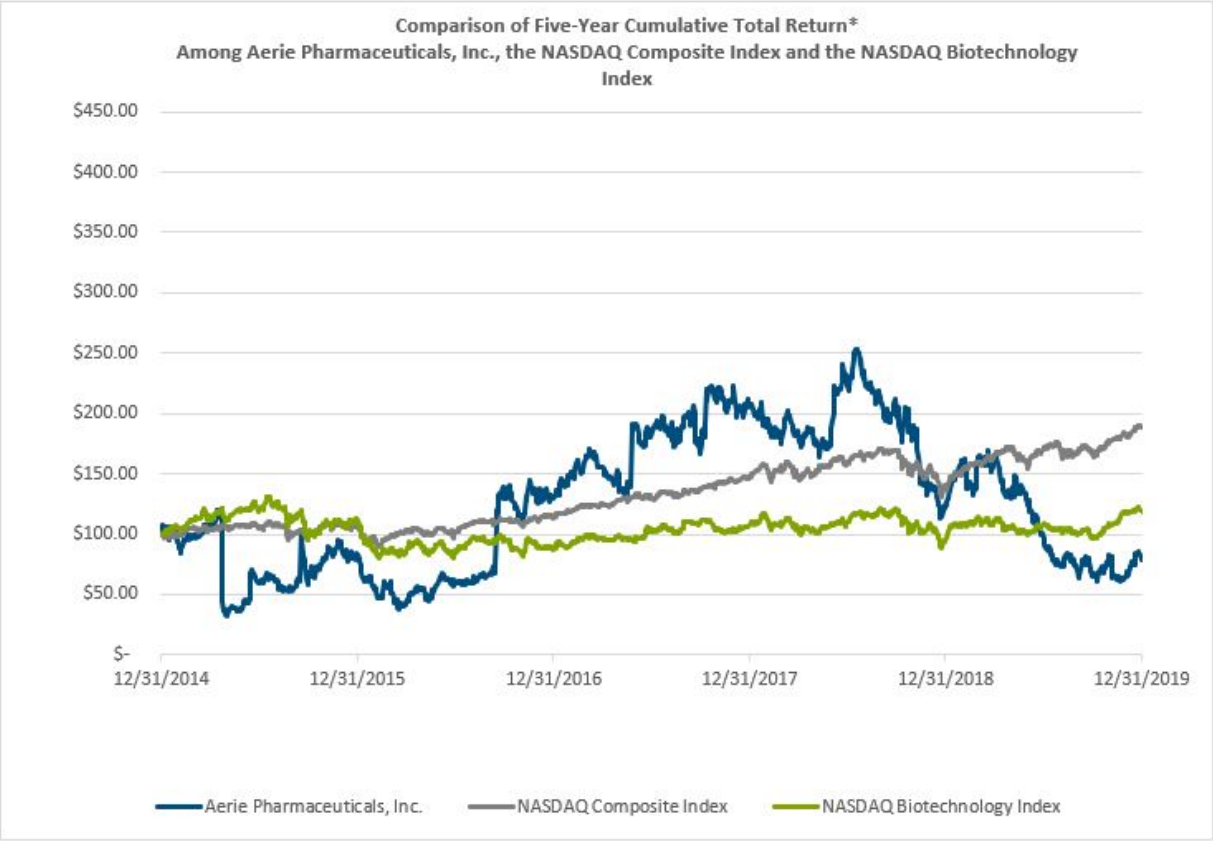
Our common stock is traded on The Nasdaq Global Market under the symbol "AERI."

Stockholders

As of February 14, 2020, we had 46,428,456 shares of common stock outstanding held by approximately 253 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Stock Performance Graph

The following graph illustrates a comparison of the five-year cumulative total stockholder return on our common stock since December 31, 2014 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2014, in our common stock and in each index. It also assumes reinvestment of dividends, if any. Historical stockholder return shown is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



**This performance graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.*

Dividend Policy

We have not declared or paid any cash dividends on our capital stock in the last two fiscal years. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. In addition, the terms of our current and any future debt agreements may preclude us from paying dividends. As a result, we anticipate that only appreciation of the price of our common stock, if any, will provide a return to investors for at least the foreseeable future.

Purchase of Equity Securities

We did not purchase any of our equity securities during the period covered by this report.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth our selected financial data for the periods and as of the dates indicated. You should read the following selected financial data together with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report and our audited consolidated financial statements and the accompanying notes included elsewhere in this report. We have derived the statements of operations data for the years ended December 31, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this report. We have derived the statements of operations data for the years ended December 31, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016 and 2015 from our audited consolidated financial statements not included in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	YEAR ENDED DECEMBER 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
Product revenues, net [1]	$ 69,888	$ 24,181	$ —	$ —	$ —
Total revenues, net	69,888	24,181	—	—	—
Costs and expenses:					
Cost of goods sold	4,833	641	—	—	—
Selling, general and administrative	138,402	120,614	56,905	34,706	30,635
Pre-approval commercial manufacturing	22,767	26,545	16,710	9,772	—
Research and development	91,378	86,123	72,078	52,394	44,451
Total costs and expenses	257,380	233,923	145,693	96,872	75,086
Loss from operations	(187,492)	(209,742)	(145,693)	(96,872)	(75,086)
Other income (expense), net [2]	(12,179)	(22,824)	(1,170)	(1,994)	862
Loss before income taxes	(199,671)	(232,566)	(146,863)	(98,866)	(74,224)
Income tax expense (benefit)	(90)	3	(1,758)	193	139
Net loss	$ (199,581)	$ (232,569)	$ (145,105)	$ (99,059)	$ (74,363)
Net loss per common share—basic and diluted	$ (4.39)	$ (5.58)	$ (4.11)	$ (3.40)	$ (2.88)
Weighted average number of common shares outstanding—basic and diluted	45,427,154	41,663,958	35,324,472	29,135,583	25,781,230

(1) We launched our first product, Rhopressa®, in the United States in April 2018 and commenced generating product revenues in the second quarter of 2018. We launched Rocklatan® in the United States in May 2019 and commenced generating product revenues in the second quarter of 2019.

(2) Includes interest expense related to the amortization of issuance costs and fees incurred on the July 2018 and May 2019 tranches of the credit facility, which was terminated in September 2019, as well as the stated interest and amortization of debt discount and issuance costs related to the Convertible Notes.

	AS OF DECEMBER 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 143,940	$ 202,818	$ 197,569	$ 197,945	$ 91,060
Total Investments	165,250	—	52,086	35,717	59,310
Short-term	165,250	—	52,086	35,717	45,502
Long-term	—	—	—	—	13,808
Total assets	452,608	285,044	290,276	248,254	159,127
Convertible notes, net	188,651	—	123,845	123,539	123,236
Total stockholders' equity	166,950	227,806	135,599	105,344	18,775

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis should be read in conjunction with our audited financial statements and related notes that appear elsewhere in this Annual Report on Form 10-K. This management's discussion and analysis contains forward-looking statements that involve risks and uncertainties. Please see "Special Note Regarding Forward-Looking Statements" for additional factors relating to such statements, and see "Risk Factors" in Part I, Item 1A of this report for a discussion of certain risk factors applicable to our business, financial condition and results of operations. Past operating results are not necessarily indicative of operating results in any future periods. We have applied the FAST Act Modernization and Simplification of Regulation S-K, which limits the discussion to the two most recent fiscal years. Refer to Item 7. of our Form 10-K issued on March 1, 2019 for prior year discussion related to fiscal 2017.

Overview

We are an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. Our strategy is to successfully commercialize our FDA-approved products, Rhopressa® and Rocklatan®, in the United States. We have a commercial team that is responsible for sales of Rhopressa® and Rocklatan® that includes approximately 100 sales representatives targeting eye-care professionals throughout the United States.

Our strategy also includes developing our business opportunities outside of the United States, including obtaining regulatory approval in Europe and Japan for Rhopressa® and Rocklatan®. In Europe, Rhokiinsa® was granted a centralised marketing authorisation by the EC in November 2019 and the MAA for Roclanda® was accepted by the EMA in December 2019. To optimize the commercial opportunity, we may launch Roclanda®, if approved, before Rhokiinsa® in Europe as the European market is oriented more toward fixed-dose combination products. The Phase 3 registration trial for Roclanda®, named Mercury 3, commenced in Europe during the third quarter of 2017 and we currently expect to read out topline 90-day efficacy data for the trial in the second half of 2020, as discussed in "*—Products"* below. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe.

In Japan, we plan to pursue regulatory approval for Rhopressa® and Rocklatan®. With respect to the clinical progress of Rhopressa® in Japan, we completed a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a successful Phase 2 conducted in Japan. Topline results of the Phase 2 trial indicated positive efficacy and tolerability in the patient set. Clinical trials for Rocklatan® have not yet begun. We expect to move forward with plans for Phase 3 initiation in Japan, along with exploring collaboration with a potential partner in Japan for Rhopressa® to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, as discussed in "*—Products"* below.

We currently use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States. In the second quarter of 2019, we completed the build-out of our own manufacturing plant in Athlone, Ireland, for further commercial production of Rhopressa® and Rocklatan®. In January 2020, we received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the PAS, which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. The manufacturing plant is expected to begin production of commercial supplies of Rocklatan® in the first quarter of 2020. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. We also anticipate the Athlone manufacturing plant to have the capacity to produce Rhokiinsa® and, if approved, Roclanda®.

We also seek to enhance our longer-term commercial potential by identifying and advancing additional product candidates through our internal discovery efforts, our entry into potential research collaborations or in-licensing arrangements or our acquisition of additional ophthalmic products or technologies or product candidates that complement our current product portfolio. As discussed in "*—Product Candidates"* below, some examples include our collaboration with DSM, whereby we have access to their bio-erodible polymer technology, our acquisition of assets from Envisia, designed to advance our progress in developing potential future sustained-release product candidates to treat retinal diseases and our acquisition of Avizorex, which expands our footprint in ophthalmology by developing therapeutics for the treatment of dry eye disease.

We own the worldwide rights to all indications for Rhopressa® and Rocklatan®. We have patent protection for Rhopressa® and Rocklatan® in the United States through early 2034 and internationally through 2030, and have filed for patent protection in the United States and internationally through 2037. In addition, through the acquisition of Avizorex, we are the exclusive licensee through 2031 of issued U.S. patents and pending patent applications internationally, which provide patent protection for AVX-012. Furthermore, we have an allowed U.S. patent application for AR-1105 in the United States, which upon issuance

will provide patent protection to 2036, and have also filed for patent protection internationally through 2036. We also have patent protection for AR-13503 in the United States and internationally, which extends to 2030, and have filed for patent protection in the United States and internationally through dates ranging from 2030 to 2037. Our intellectual property portfolio contains patents and pending patent applications related to composition of matter, pharmaceutical compositions, methods of use, and synthetic methods.

Products, Product Candidates and Pipeline Opportunities

Products

Rhopressa®, our first FDA-approved product, has demonstrated that it reduces IOP through ROCK inhibition. Using this MOA, Rhopressa® increases the outflow of aqueous humor through the TM, which accounts for approximately 80% of fluid drainage from the healthy eye and is the diseased tissue responsible for elevated IOP in glaucoma. Our second FDA approved product, once-daily Rocklatan®, a fixed-dose combination of Rhopressa® and latanoprost, reduces IOP through the same MOA as Rhopressa® and through a second MOA, utilizing the ability of latanoprost to increase the outflow of aqueous humor through the uveoscleral pathway, the eye's secondary drain. Both Rhopressa® and Rocklatan® are taken once-daily in the evening and have shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

Rhopressa®

Rhopressa® is a once-daily eye drop designed to reduce elevated IOP in patients with open-angle glaucoma or ocular hypertension. The active ingredient in Rhopressa®, netarsudil, is an Aerie-owned ROCK inhibitor. We believe that Rhopressa® represents the first of a new drug class for reducing IOP in patients with glaucoma in over 20 years. Rhopressa® is competing primarily in the adjunctive therapy market, which represents approximately one-half of the U.S. glaucoma prescription market, according to IQVIA. Initial indications point to healthcare professionals prescribing Rhopressa® as a concomitant therapy to prostaglandins or non-PGA medications when additional IOP reduction is desired. We believe Rhopressa® is primarily competing with other non-PGA products, due to its targeting of the diseased TM, its demonstrated ability to reduce IOP at consistent levels across tested baselines, its preferred once-daily dosing relative to other currently marketed non-PGA products and its safety profile. Currently marketed therapies that are used adjunctively to PGAs are older generation products that are generally dosed between two and three times a day, have MOA(s) focused on reducing fluid production, often have lower efficacy levels and have systemic side effects. We believe that Rhopressa® may also become a preferred therapy where PGAs are contraindicated, for patients who do not respond to PGAs and for patients who choose to avoid the cosmetic issues associated with PGA products. In November 2019, we released topline data from our Phase 4 MOST trial, which observed Rhopressa® efficacy in various real-world clinical settings, including as an adjunctive product or monotherapy. The results indicated positive IOP reduction in all settings along with a favorable tolerability profile.

Rhopressa® in the United States

We launched Rhopressa® in the United States at the end of April 2018. Rhopressa® is being sold to national and regional U.S. pharmaceutical distributors, and patients have access to Rhopressa® through pharmacies across the United States. We have obtained formulary coverage for Rhopressa® for the majority of lives covered under commercial and Medicare Part D plans.

Rhopressa® Outside of the United States

In Europe, in November 2019, the EC granted a centralised marketing authorisation for Rhokiinsa®. This follows the CHMP adopting a positive opinion recommending approval of the MAA for Rhokiinsa® in September 2019.

In support of a potential regulatory submission for Rhopressa® in Japan, we conducted a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a successful Phase 2 clinical trial conducted in Japan. In July 2019, we completed enrollment of a Phase 2 clinical trial in Japan and topline results were released in November 2019. These studies were designed in accordance with the requirements of the PMDA on Japanese patients in Japan to support subsequent Phase 3 registration trials that are also expected to be conducted in Japan. Topline results of the Phase 2 clinical trial indicated positive efficacy and tolerability results for the patient set. We expect to move forward with plans for Phase 3 initiation in Japan for Rhopressa®, along with exploring collaboration with a potential partner in Japan to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, and will continue to explore other potential opportunities elsewhere in Eastern Asia.

Rocklatan®

Rocklatan® is a once-daily fixed-dose combination of Rhopressa® and latanoprost, the most widely-prescribed drug for the treatment of patients with open-angle glaucoma or ocular hypertension, and was approved by the FDA in March 2019. We believe that Rocklatan® has the potential to provide a greater IOP-reducing effect than any currently marketed glaucoma medication. Therefore, we believe that Rocklatan® competes with both PGA and non-PGA therapies for patients requiring maximal IOP reduction, including those with higher IOPs and those who present with significant disease progression despite using currently available therapies.

Rocklatan® in the United States

We launched Rocklatan® in the United States in May 2019. Rocklatan® is now being sold to national and regional U.S. pharmaceutical distributors, and patients have access to Rocklatan® through pharmacies across the United States.

Rocklatan® Outside of the United States

In Europe, the clinical trials Mercury 1 and Mercury 2 represent the basis for European approval of Roclanda®. We also initiated a third Phase 3 registration trial for Roclanda®, named Mercury 3, in Europe during the third quarter of 2017. Mercury 3, a six-month efficacy and safety trial, is designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe consisting of bimatoprost (a PGA) and timolol (a beta blocker). If successful, Mercury 3 is expected to improve our commercialization prospects in Europe; it is not required for regulatory approval. The Mercury 3 results are expected to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. We currently expect to read out topline 90-day efficacy data for the trial in the second half of 2020. In December 2019, the MAA for Roclanda® was accepted by the EMA. An opinion from the CHMP is expected in the fourth quarter of 2020. Since Roclanda® is a fixed-dose combination product that includes Rhokiinsa®, the MAA submission for Roclanda® was predicated on the receipt of a centralised marketing authorisation for Rhokiinsa®, which the EC granted in November 2019. In Japan, clinical trials for Rocklatan® have not yet begun.

Product Candidates

To complement our internal research through business development opportunities, we acquired from Avizorex the clinical-stage dry eye product candidate AVX-012. Furthermore, we have also acquired worldwide ophthalmic rights to a bio-erodible polymer technology from DSM and PRINT® implant manufacturing technology, which is a proprietary technology capable of creating precisely-engineered sustained-release products utilizing fully-scalable manufacturing processes, from Envisia. Using these technologies, we have created a sustained-release ophthalmology platform and are currently developing two sustained-release implants focused on retinal diseases, AR-1105 and AR-13503 SR, and in the future we believe this technology may be useful as we explore additional sustained-release applications.

AVX-012 (TRPM8 receptor)

In December 2019, we acquired Avizorex, a Spanish ophthalmic pharmaceutical company, developing therapeutics for the treatment of dry eye disease. Avizorex completed a Phase 2a study in dry eye subjects in 2019 for its lead product candidate AVX-012. The active ingredient in AVX-012 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates ocular surface wetness and blink rate. By stimulating these processes in a physiological manner, TRPM8 agonists have the potential to restore tear film stability and reduce discomfort in patients with dry eye. Positive results from the Phase 2a study support the therapeutic potential of AVX-012 to treat signs and symptoms of dry eye. We are planning to initiate a larger Phase 2b study in late 2020.

AR-1105 Implant (dexamethasone steroid)

In October 2017, we acquired the rights to use PRINT® technology in ophthalmology and certain other assets from Envisia. In addition, we acquired Envisia's intellectual property rights relating to a preclinical dexamethasone steroid implant using a biodegradable polymer-based drug delivery system that comprised of a blend of different PLGA polymers and PRINT® technology for the potential treatment of macular edema due to RVO and diabetic retinopathy, which we refer to as AR-1105. We submitted the IND for AR-1105 in December 2018. In January 2019, we announced that the FDA reviewed the IND for AR-1105 and it is now in effect. We initiated a Phase 2 clinical trial of AR-1105 in patients with macular edema due to RVO during March 2019 and completed enrollment in October 2019.

AR-13503 SR Implant (ROCK and Protein kinase inhibitor)

Our owned clinical small molecule, AR-13503, is a ROCK and Protein kinase C inhibitor and is the active ingredient in our AR-13503 sustained-release implant. AR-13503 SR has potential for the treatment of DME, wet AMD and other diseases of the retina. AR-13503, which has the same active metabolite as Rhopressa®, has been shown to reduce lesion size in an *in vivo* preclinical model of wet AMD at levels similar to the current market-leading wet AMD anti-VEGF product. When used in combination preclinically with the market-leading anti-VEGF product, AR-13503 produced greater lesion size reduction than the anti-VEGF product alone in a model of proliferative DR. Pending additional studies, AR-13503 may have the potential to provide an entirely new mechanism and pathway to treat DME, wet AMD and related diseases of the retina, potentially as an adjunctive therapy to current anti-VEGF therapies.

Since AR-13503 is a small molecule with a short half-life when injected into the back of the eye, and the aforementioned diseases are located in the back of the eye, a delivery mechanism was needed to deliver the molecule to the back of the eye for a sustained delivery period.

Using our licensed technology from DSM, AR-13503 has been combined with a polyesteramide polymer to produce an injectable, thin fiber implant that is minute in size. Preclinical experiments with the AR-13503 SR implant have demonstrated linear, sustained elution rates over several months and achievement of target retinal drug concentrations. The IND for AR-13503 SR became effective in April 2019, allowing us to initiate human studies in the treatment of nAMD and DME. We initiated a first-in-human clinical study for AR-13503 SR in the third quarter of 2019.

Pipeline Opportunities

We are also preliminarily evaluating use of the PRINT® technology platform for sustained-release of therapies for other ophthalmic indications. We commenced operation of our cGMP-validated manufacturing facility for production of ophthalmic implants using PRINT® technology in our Durham, North Carolina, facility in October 2018.

We may continue to enter into research collaboration arrangements, license, acquire or develop additional product candidates and technologies to broaden our presence in ophthalmology, and we continually explore and discuss potential additional opportunities for new ophthalmic products, delivery alternatives and new therapeutic areas with potential partners and on our own.

We own over 4,000 ROCK inhibitor molecules, some of which have additional features including the inhibition of other kinases such as Janus kinase and those in the IκB family and we evaluate this library on an ongoing basis for additional development opportunities. Early stage evaluations of these molecules are underway for other ophthalmic indications. We continue to evaluate outside business development opportunities to provide access to technologies developed outside of Aerie to complement our internal research.

Financial Overview

Our cash and cash equivalents and investments totaled $309.2 million as of December 31, 2019. We believe that our cash and cash equivalents and investments and projected cash flows from revenues will provide sufficient resources for our current ongoing needs through at least the next twelve months, though there may be need for additional financing activity as we continue to grow. See “—Liquidity and Capital Resources” below and Note 10 to our consolidated financial statements included elsewhere in this report for further discussion.

We have incurred net losses since our inception in June 2005. Until 2018, when we commenced commercial operations, our business activities were primarily limited to developing product candidates, raising capital and performing research and development activities. As of December 31, 2019, we had an accumulated deficit of $896.0 million. We recorded net losses of $199.6 million, $232.6 million and $145.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our capital resources and business efforts are largely focused on activities relating to the commercialization of Rhopressa® and Rocklatan®, advancing our product candidates and pipeline, international expansion and completion of construction of our manufacturing plant in Athlone, Ireland. We expect to continue to incur operating losses until our products generate adequate commercial revenue to render Aerie profitable. If we do not successfully commercialize Rhopressa®, Rocklatan® or any current or future product candidates, if approved, we may be unable to generate adequate product revenues to achieve such profitability. We may be required to obtain further funding through debt or equity offerings or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on

acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs or commercialization or manufacturing efforts.

Product Revenues, Net

We launched Rhopressa® in the United States in late April 2018 and commenced generating product revenues from sales of Rhopressa® in the second quarter of 2018. We launched Rocklatan® in the United States on May 1, 2019 and commenced generating product revenues from sales of Rocklatan® in the second quarter of 2019. Our product revenues are recorded net of provisions relating to estimates for (i) trade discounts and allowances, such as discounts for prompt payment and distributor fees, (ii) estimated rebates to Third-party Payers, estimated payments for Medicare Part D prescription drug program coverage gap (commonly called the "donut hole"), patient co-pay program coupon utilization, chargebacks and other discount programs and (iii) reserves for expected product returns. These estimates reflect current contractual and statutory requirements, known market events and trends, industry data, forecasted customer mix and lagged claims. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which may have an impact on earnings in the period of adjustment.

We will not generate any revenue from any current or future product candidates unless and until we obtain regulatory approval and commercialize such products.

Cost of Goods Sold

Cost of goods sold consists of direct and indirect costs to procure and manufacture product sold, including third-party manufacturing costs. Prior to receiving FDA approval, these costs for Rhopressa® and Rocklatan® were expensed as pre-approval commercial manufacturing expenses (as defined below). We began capitalizing inventory costs for Rhopressa® and Rocklatan® after receipt of FDA approval, and in January 2020, we received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. We expect FDA approval to produce Rhopressa® at our Athlone plant by the end of 2020. The manufacturing plant is expected to begin production of commercial supplies of Rocklatan® in the first quarter of 2020 and Rhopressa® in late 2020. Cost of goods sold in 2020 will continue to be favorably impacted by sales of Rhopressa® and Rocklatan® inventory that was expensed prior to FDA approval; however, we do not expect the impact to be material. Further, we expect cost of goods sold in 2020 to be unfavorably impacted by the production of inventory at our Athlone plant as production volumes ramp up towards capacity levels over time.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and stock-based compensation for all officers and employees in general management, sales and marketing, finance and administration. Other significant expenses include selling and marketing expenses, facilities expenses, shipping and handling costs and professional fees for audit, tax, legal and other services.

Pre-approval Commercial Manufacturing Expenses

Pre-approval commercial manufacturing expenses consist of costs incurred for commercial-related manufacturing activities for Rhopressa® and Rocklatan® prior to FDA approval. These costs include those associated with the manufacturing of inventory in anticipation of commercial launch, expenses associated with the establishment of both our manufacturing plant in Athlone, Ireland, and our additional API and drug product contract manufacturers, as well as employee-related expenses, which includes salaries, benefits and stock-based compensation for commercial-related manufacturing personnel prior to regulatory approval.

We obtained regulatory approval for the commercial production of Rocklatan® in early 2020 in our Athlone, Ireland, plant as well as approval for our additional API and drug product contract manufacturers during 2019 and early 2020. Accordingly, we expect that our pre-approval commercial manufacturing expenses will decrease in 2020 as compared to 2019, as the cost of commercial product produced by these manufacturers following regulatory approval will be capitalized as inventory.

Research and Development Expenses

We expense research and development costs to operations as incurred. Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense for research and development personnel;

- expenses incurred under agreements with CROs, contract manufacturing organizations and service providers that assist in conducting clinical trials and preclinical studies;
- costs associated with any collaboration arrangements, licenses or acquisitions of preclinical molecules, product candidates or technologies;
- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations; and
- depreciation expense for assets used in research and development activities.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with research institutions, consultants and CROs that assist in conducting and managing clinical trials. We accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If future timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis. Historically, such modifications have not been material.

Other (Expense) Income, Net

Other (expense) income primarily includes interest expense, interest income, foreign exchange gains and losses, and other income and expense. Interest expense consists of interest expense under the Convertible Notes and the 2014 Convertible Notes, including the amortization of debt discounts and issuance costs incurred prior to the conversion of the 2014 Convertible Notes on July 23, 2018. Interest expense also includes the amortization of issuance costs and commitment fees incurred on the credit facility entered into on July 23, 2018. Interest income primarily consists of interest earned on our cash, cash equivalents and investments, and amortization of premium and accretion of discount on our investments. Foreign exchange gains and losses are primarily due to the remeasurement of our Euro-denominated liability related to our build-to-suit lease obligation, which is held by a subsidiary with a U.S. dollar functional currency. Other expense includes the value of additional shares of Aerie common stock issued to complete the conversion of the 2014 Convertible Notes in July 2018. See Note 10 to our consolidated financial statements included elsewhere in this report for additional information.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and related disclosures. We evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of revenue recognition, leases, acquisitions, stock-based compensation and fair value measurements. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this report. The following accounting policies are the most critical in fully understanding and evaluating our reported financial results and affect significant judgments and estimates that we use in the preparation of our financial statements.

Revenue Recognition

Revenue transactions are accounted for under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). In accordance with ASC Topic 606, we recognize revenue when our customers obtain control of our product for an amount that reflects the consideration we expect to receive from our customers in exchange for that product. To determine revenue recognition for contracts that are determined to be in scope of ASC Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services transferred to our customer. Once the contract is determined to be within the scope of ASC

Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

Aerie's customers include a limited number of national and select regional wholesalers (the "distributors"). These distributors subsequently resell the product, primarily to retail pharmacies that dispense the product to patients. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that would have been recognized is one year or less or the amount is immaterial. Product affordability for the patient drives consumer acceptance, and this is generally managed through coverage by third-party payers, such as government or private healthcare insurers and pharmacy benefit managers ("Third-party Payers") and such product may be subject to rebates and discounts payable directly to those Third-party Payers.

Net product revenues for the year ended December 31, 2019, were derived from sales of Rhopressa® and Rocklatan® in the United States. Product revenue is recorded net of trade discounts, allowances, rebates, chargebacks, estimated returns and other incentives, discussed below. These reserves are classified as either reductions of accounts receivable or as current liabilities. Amounts billed or invoiced are included in accounts receivable, net on the consolidated balance sheet. We did not have any contract assets (unbilled receivables) at December 31, 2019, as customer invoicing generally occurs before or at the time of revenue recognition. We did not have any contract liabilities at December 31, 2019, as we did not receive payments in advance of fulfilling our performance obligations to our customers.

Net product revenue is typically recognized when the distributors obtain control of our product, which occurs at a point in time, typically upon delivery of Rhopressa® to the distributors. For the year ended December 31, 2019, three distributors accounted for 36.5%, 33.3% and 28.0% of total revenues, respectively. We evaluate the creditworthiness of each of our distributors to determine whether it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. We do not assess whether a contract has a significant financing component if the expectation is such that the period between the transfer of the promised goods to the customer and the receipt of payment will be less than one year. Standard credit terms do not exceed 75 days.

We calculate our net product revenue based on the wholesale acquisition cost that we charge our distributors for Rhopressa® and Rocklatan® less provisions for (i) trade discounts and allowances, such as discounts for prompt payment and distributor fees, (ii) estimated rebates to Third-party Payers, estimated payments for Medicare Part D prescription drug program coverage gap (commonly called the "donut hole"), patient co-pay program coupon utilization, chargebacks and other discount programs and (iii) reserves for expected product returns. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, known market events and trends, industry data, forecasted customer mix and lagged claims. Provisions for revenue reserves reduced product revenues by $105.9 million and $19.6 million in aggregate for the years ended December 31, 2019 and 2018, respectively, a significant portion of which related to commercial and Medicare Part D rebates. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net product revenues only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment.

Trade Discounts and Allowances: We generally provide discounts on sales of Rhopressa® and Rocklatan® to our distributors for prompt payment and pay fees for distribution services and for certain data that distributors provide to us. We expect our distributors to earn these discounts and fees, and accordingly deduct the full amount of these discounts and fees from our gross product revenues at the time such revenues are recognized.

Rebates, Chargebacks and Other Discounts: We contract with Third-party Payers for coverage and reimbursement of Rhopressa® and Rocklatan®. We estimate the rebates and chargebacks we expect to be obligated to provide to Third-party Payers and deduct these estimated amounts from our gross product revenue at the time the revenue is recognized. We estimate the rebates and chargebacks that we expect to be obligated to provide to Third-party Payers based upon (i) our contracts and negotiations with these Third-party Payers, (ii) estimates regarding the payer mix for Rhopressa® and Rocklatan® based on third-party data and utilization, (iii) inventory held by distributors and (iv) estimates of inventory held at the retail channel. Other discounts include our co-pay assistance programs for commercially-insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to pay associated with product that has been recognized as revenue.

Product Returns: We estimate the amount of Rhopressa® and Rocklatan® that will be returned and deduct these estimated amounts from our gross revenue at the time the revenue is recognized. We currently estimate product returns based on historical

industry information regarding rates for comparable pharmaceutical products and product portfolios, the estimated remaining shelf life of Rhopressa® and Rocklatan® shipped to distributors, and contractual agreements with our distributors intended to limit the amount of inventory they maintain. Reporting from the distributors includes distributor sales and inventory held by distributors, which provide us with visibility into the distribution channel to determine when product would be eligible to be returned.

Leases

We adopted Accounting Standards Update ("ASU") 2016-02, *Leases* ("ASC Topic 842") effective January 1, 2019. Under this new lease standard, practically all leases with lease terms in excess of one year are required to be recognized on the balance sheet as right-of-use assets and corresponding lease liabilities. Significant assumptions utilized in recognizing the right-of-use asset and corresponding liability included the expected lease term and the incremental borrowing rate. The expected lease term includes both contractual lease periods and, as applicable, extensions of the lease term when we have determined the exercise of the option to extend is reasonably certain to occur. The incremental borrowing rate was utilized to discount lease payments over the expected term given our operating leases do not provide an implicit rate. We estimated the incremental borrowing rate to reflect the profile of secured borrowing over the expected term of the leases. In addition, significant judgment was utilized in determining the impact of our build-to-suit lease for our manufacturing plant in Athlone, Ireland, upon adoption of ASC Topic 842, for which we concluded we were the owner of the leased space for accounting purposes. As a result, we maintained our previous accounting for our build-to-suit asset and liability upon adoption of ASC Topic 842, which was discounted at the implicit rate of the facility obligation.

The standard has been implemented using the optional transitional method and we elected to utilize certain practical expedients. In electing the optional transition method, we were required to recognize and measure operating leases existing at, or entered into after, the adoption date. We utilized an incremental borrowing rate on the adoption date to determine the present value of the remaining operating lease assets and liabilities. Prior period results have not been restated. See Note 2 to our consolidated financial statements included elsewhere in this report for further discussion.

Acquisitions

We evaluate acquisitions to determine whether the acquisition is a business combination or an acquisition of assets under ASC Topic 805: *Business Combinations* ("ASC Topic 805"). Business combinations are accounted for using the acquisition method of accounting, whereby assets acquired and liabilities assumed are recorded as of the acquisition date at their respective fair values and any excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill. In an asset acquisition that does not constitute a business, no goodwill is recognized, and the net assets acquired are generally recorded at cost. In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), effective for us beginning on January 1, 2018. The ASU clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The new standard was effective for us beginning on January 1, 2018; however, we elected to early adopt this ASU as of July 1, 2017. Under ASC Topic 805, including the provisions of ASU 2017-01, the October 4, 2017 transaction to acquire assets from Envisia was determined to meet the criteria of an asset acquisition rather than a business combination, resulting in a $24.8 million charge to research and development expense on the consolidated statement of operations and comprehensive loss in the three months ended December 31, 2017 for acquired in-process research and development ("IPR&D"). The December 2019 transaction to acquire Avizorex was determined to meet the criteria of an asset acquisition rather than a business combination, resulting in a $10.2 million charge to research and development expense on the consolidated statement of operations and comprehensive loss in the three months ended December 31, 2019 for acquired IPR&D. Significant judgment is required in estimating the fair value of intangible assets and in a determination of whether an acquisition is a business combination or an acquisition of assets. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management but are inherently uncertain.

Stock-Based Compensation

We recognize compensation costs related to stock options granted to employees ratably over the requisite service period, which in most cases is the vesting period of the award for employees, based on the estimated fair value of the awards on the date of grant. Compensation expense for options granted to non-employees is determined as the fair value of consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of the awards granted to non-employees is remeasured each period until the related service is complete. The fair value of restricted stock awards ("RSAs") and restricted stock units ("RSU"), including restricted stock awards with non-market performance and service conditions ("PSAs"), are determined based on the fair value of our common stock on the date of grant. Compensation expense

related to RSAs and RSUs are recognized ratably over the vesting period. As the PSAs have multiple performance conditions, compensation expense is recognized for each vesting tranche over the respective requisite service period of each tranche if and when we deem it probable that the performance conditions will be satisfied. Compensation expense for stock purchase rights under our employee stock purchase plan is measured and recognized on the date that we become obligated to issue shares of our common stock and is based on the difference between the fair value of our common stock and the purchase price on such date. The fair value of the stock appreciation rights ("SARs") is estimated using the Black-Scholes option pricing model and is marked to market through stock-based compensation expense. SARs are liability-based awards as they may only be settled in cash.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

Determining the appropriate fair value measurement of stock-based awards requires the use of subjective assumptions. We estimate the fair value of options to purchase common stock using the Black-Scholes option pricing model, which is affected by our common stock fair values as well as assumptions regarding a number of other subjective variables. These other variables include the expected term of the options, our expected stock price volatility over the expected term of the options, risk-free interest rates and expected dividends.

We estimate the fair value of stock options at the grant date using the following assumptions:

- *Fair Value of our Common Stock.* The fair value for our underlying common stock is determined using the closing price on the date of grant as reported on The Nasdaq Global Market.
- *Volatility*. We calculate expected volatility based on our historical volatility in combination with reported data for a selected group of similar publicly traded companies, or guideline peer group, for which the relevant historical information is available. We selected representative companies from the pharmaceutical industry with similar characteristics to us, including stage of product development and commercialization.
- *Expected Term*. We used the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, as we do not have sufficient historical exercise and post-vesting termination data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The midpoint between the vesting date and the maximum contractual expiration date is used as the expected term under this method.
- *Risk-free Rate*. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to exercise.
- *Forfeiture*. Forfeitures are recognized in the period in which they occur. Prior to 2017, forfeitures were estimated such that we only recognized expense for the shares expected to vest, and adjustments were made if actual forfeitures differed from those estimates.
- *Dividend Yield*. Except for a one-time cash dividend related to the spin-off of certain non-core intellectual property that occurred in 2012, we have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Key weighted average assumptions utilized in the fair value calculation for the underlying common stock as of December 31, 2019, 2018 and 2017 appear in the table below.

	YEAR ENDED DECEMBER 31,		
	2019	2018	2017
Expected term (years)	6.0	6.0	6.0
Expected stock price volatility	74%	78%	84%
Risk-free interest rate	1.9%	2.7%	2.0%
Dividend yield	—	—	—

Fair Value Measurements

We record certain financial assets and liabilities at fair value based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. In September 2019, we issued an aggregate principal amount of $316.25 million of

Convertible Notes. The estimated fair value of the liability component of the Convertible Notes was determined based on a discounted cash flow analysis and a binomial lattice model. The valuation required the use of Level 3 unobservable inputs and subjective assumptions, including but not limited to the stock price volatility and bond yield. The use of alternative market assumptions and estimation methodologies could have had an effect on these estimates of fair value. See Note 10 to our consolidated financial statements included elsewhere in this report for additional information.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes the results of our operations for the years ended December 31, 2019 and 2018:

	YEAR ENDED DECEMBER 31,			
	2019	2018	CHANGE	% CHANGE
	(in thousands, except percentages)			
Product revenues, net	$ 69,888	$ 24,181	$ 45,707	*
Total revenues, net	69,888	24,181	45,707	*
Costs and expenses:				
Cost of goods sold	4,833	641	4,192	*
Selling, general and administrative expenses	138,402	120,614	17,788	15 %
Pre-approval commercial manufacturing	22,767	26,545	(3,778)	(14)%
Research and development expenses	91,378	86,123	5,255	6 %
Total costs and expenses	257,380	233,923	23,457	10 %
Loss from operations	(187,492)	(209,742)	22,250	(11)%
Other (expense) income, net	(12,179)	(22,824)	10,645	*
Loss before income taxes	$ (199,671)	$ (232,566)	$ 32,895	(14)%

**Percentage not meaningful*

Product revenues, net

Product revenues, net was $69.9 million and $24.2 million for the years ended December 31, 2019 and 2018, respectively. Revenues recorded during the year ended December 31, 2019 relate to sales of Rhopressa® and Rocklatan®, which we launched in the United States in late April 2018 and in early May 2019, respectively. Revenues recorded during the year ended December 31, 2018 relate to the sales of Rhopressa®, which was our first product to receive regulatory approval. We did not generate any revenues prior to the second quarter of 2018.

Cost of goods sold

Cost of goods sold was $4.8 million for the year ended December 31, 2019. Our gross margin percentage of 93.1% was favorably impacted during the year ended December 31, 2019 by product sales with certain materials produced prior to FDA approval and therefore expensed in prior periods. If inventory sold during the year ended December 31, 2019 was valued at cost, our gross margin for the period then ended would have been 92.1%. Further, our gross margin for the year ended December 31, 2019 was unfavorably impacted by approximately 2.1% primarily due to excess inventory write-off.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $17.8 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This increase was primarily associated with the expansion of our employee base to support the growth of our operations, as well as sales and marketing expenses incurred in connection with our commercial launches of Rhopressa® and Rocklatan®.

Employee-related expenses increased by $10.7 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018 primarily due to increased headcount as a result of expanding our sales force in 2018 to support our commercial launches of Rhopressa® and Rocklatan® in the United States. Employee-related expenses also included an increase

in stock-based compensation expense of $4.0 million. Selling and marketing expenses increased by $4.4 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018 related to our commercialization of Rhopressa® and Rocklatan®, which we launched in the United States in late April 2018 and in early May 2019, respectively.

Pre-approval commercial manufacturing expenses

Pre-approval commercial manufacturing expenses decreased by $3.8 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. Expenses were lower due to the receipt of regulatory approval of our API and drug product contract manufacturers, which began to supply commercial API and product, respectively, in the second quarter of 2019, as the cost of commercial API and product, respectively, produced by these manufacturers following regulatory approval were capitalized as inventory. These costs were partially offset by an increase of costs related to our manufacturing plant in Ireland, of which we completed the build-out in the second quarter of 2019.

Research and development expenses

Research and development expenses increased by $5.3 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This increase is primarily comprised of $10.2 million of expense related to the acquisition of Avizorex and an increase of $5.1 million of employee-related expenses, including stock-based compensation. These increased expenses were partially offset by a decrease of $9.0 million related to our expanded collaboration agreement with DSM, of which $6.0 million was paid to DSM upon execution of the agreement in July 2018.

Research and development activities for the year ended December 31, 2019 were comprised primarily of clinical expenses related to Rocklatan® and retinal studies associated with AR-1105 and AR-13503, as well as the Phase 2 clinical trial in Japan for Rhopressa®. Research and development expenses for Rhopressa® totaled $8.9 million and $10.7 million for the years ended December 31, 2019 and 2018, respectively. The $1.8 million decrease in expenses for Rhopressa® for the year ended December 31, 2019 as compared to the year ended December 31, 2018 primarily related to costs incurred in 2018 in connection with the MAA in Europe. Research and development expenses for Rocklatan® totaled $8.4 million and $6.3 million for the years ended December 31, 2019 and 2018, respectively. The $2.1 million increase in expenses for Rocklatan® for the year ended December 31, 2019 as compared to the year ended December 31, 2018 primarily relate to costs incurred in 2019 related to the Mercury 3 registration trial in Europe.

Other (expense) income, net

Other (expense) income, net consists of the following:

	YEAR ENDED DECEMBER 31			
	2019	2018	CHANGE	% CHANGE
	(in thousands, except percentages)			
Interest income	$ 2,970	$ 3,429	$ (459)	(13)%
Interest expense	(15,255)	(2,531)	(12,724)	*
Other income (expense)	106	(23,722)	23,828	*
Other (expense) income, net	$ (12,179)	$ (22,824)	$ 10,645	*

**Percentage not meaningful*

Other (expense) income, net changed by $10.6 million in decreased net expense for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The change was primarily related to the value of the additional 329,124 shares of Aerie common stock issued to Deerfield in the amount of $24.1 million, which was recorded as other expense during the third quarter of 2018 in connection with the induced conversion of the entire outstanding principal amount of the 2014 Convertible Notes in July 2018. In addition, interest expense increased by $12.7 million, primarily due to the amortization of issuance costs and fees incurred on the July 2018 and May 2019 tranches of the credit facility, which was terminated in September 2019, as well as the stated interest and amortization of debt discount and issuance costs related to the Convertible Notes. This increase in interest expense was partially offset by costs incurred in the prior year for debt discount and issuance costs related to our 2014 Convertible Notes through the date of conversion in July 2018 and amortization of issuance costs and fees incurred on the July 2018 tranche of the credit facility.

Liquidity and Capital Resources

Since our inception, we have funded operations primarily through the sale of equity securities and the issuance of convertible notes. We commenced generating product revenues related to sales of Rhopressa® in the second quarter of 2018 and Rocklatan® in the second quarter of 2019. We have incurred losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses until such a time when our products are commercially successful, if at all. We will not generate any revenue from any current or future product candidates unless and until we obtain regulatory approval and commercialize such products.

Sources of Liquidity

Since our initial public offering in October 2013, we have:

- issued $125.0 million aggregate principal amount of the 2014 Convertible Notes, which was subsequently converted into shares of Aerie's common stock in July 2018;
- issued approximately 11.0 million shares of our common stock through December 31, 2017, for which we received net proceeds of approximately $351.3 million, after deducting fees and expenses. This includes approximately $207.7 million of net proceeds from our prior "at-the-market" sales agreements, of which approximately $61.1 million were received during the year ended December 31, 2017, and approximately $143.6 million of net proceeds from the issuance of shares of our common stock pursuant to underwriting agreements, related to registered public offerings, of which approximately $72.7 million were received during the year ended December 31, 2017;
- issued approximately 2.3 million additional shares of our common stock during the year ended December 31, 2018, for which we received net proceeds of approximately $136.4 million, after deducting fees and expenses. This includes approximately $62.3 million of net proceeds from our "at-the-market" sales agreement ("ATM") and approximately $74.1 million of net proceeds from the issuance of shares of our common stock pursuant to an underwriting agreement, dated January 23, 2018, related to a registered public offering;
- commenced generating product revenues related to sales of Rhopressa® in the second quarter of 2018 and Rocklatan® in the second quarter of 2019. Product revenues, net amounted to $69.9 million and $24.2 million for the years ended December 31, 2019 and 2018, respectively. Accounts receivable, net amounted to $38.4 million and $2.7 million as of December 31, 2019 and 2018, respectively; and
- issued $316.25 million aggregate principal amount of Convertible Notes.

As of December 31, 2019, our principal sources of liquidity were our cash and cash equivalents and investments, which totaled approximately $309.2 million. In September 2019, we issued an aggregate principal amount of $316.25 million of the Convertible Notes and simultaneously terminated our credit facility. See Note 10 to our consolidated financial statements included elsewhere in this report for additional information. We believe that our cash and cash equivalents and investments and projected cash flows from revenues will provide sufficient resources for our current ongoing needs through at least the next twelve months. See "—*Operating Capital Requirements*."

Cash Flows

The following table summarizes our sources and uses of cash:

	YEAR ENDED DECEMBER 31,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (150,430)	$ (152,576)	$ (93,213)
Investing activities	(183,247)	20,789	(42,807)
Financing activities	274,799	137,036	135,644
Net increase (decrease) in cash and cash equivalents	$ (58,878)	$ 5,249	$ (376)

Operating Activities

During the year ended December 31, 2019, net cash used in operating activities of $150.4 million related to a net loss of $199.6 million, adjusted for non-cash items of $73.1 million primarily related to stock-based compensation expense, amortization and accretion and depreciation, partially offset by a net cash outflow of $24.0 million related to changes in operating assets and liabilities.

During the year ended December 31, 2018, net cash used in operating activities of $152.6 million related to a net loss of $232.6 million, adjusted for non-cash items of $66.6 million primarily related to stock-based compensation expense, induced conversion of the 2014 Convertible Notes in July 2018, amortization and accretion and depreciation, partially offset by a net cash inflow of $13.4 million related to changes in operating assets and liabilities.

During the year ended December 31, 2017, net cash used in operating activities of $93.2 million related to a net loss of $145.1 million, adjusted for non-cash items of $53.2 million primarily related to stock-based compensation expense, acquisition of Envisia assets expensed to research and development and depreciation, partially offset by a net cash outflow of $1.3 million related to changes in operating assets and liabilities.

Investing Activities

During the year ended December 31, 2019, our investing activities used net cash of $183.2 million primarily related to purchases of available-for-sale investments of $165.5 million, purchases of property, plant and equipment of $10.0 million, primarily related to the completion of the build-out of our manufacturing plant in Ireland and $7.8 million related to the acquisition of Avizorex.

During the year ended December 31, 2018, our investing activities provided net cash of $20.8 million primarily related to purchases of available-for-sale investments of $56.2 million, purchases of property, plant and equipment of $31.3 million, primarily related to the build-out of our manufacturing plant in Ireland, which were partially offset by sales and maturities of investments of $108.3 million.

During the year ended December 31, 2017, our investing activities used net cash of $42.8 million primarily related to purchases of available-for-sale investments of $104.5 million and purchases of property, plant and equipment of $16.0 million to support the growth of our operations and a $10.5 million cash payment for the acquisition of assets from Envisia, which were partially offset by sales and maturities of investments of $88.2 million.

Financing Activities

During the years ended December 31, 2019, 2018 and 2017, our financing activities provided net cash of $274.8 million, $137.0 million and $135.6 million, respectively. The net cash provided by financing activities during the year ended December 31, 2019 was primarily related to the $308.3 million of net proceeds from the issuance of Convertible Notes, partially offset by $32.9 million payment in premiums for the capped call options. The net cash provided by financing activities during the years ended December 31, 2018 and 2017 was primarily related to the issuance and sale of common stock under our prior “at-the-market” sales agreements and under underwriting agreements related to registered public offerings, from which we received net proceeds of approximately $136.0 million and $134.2 million, respectively.

Operating Capital Requirements

We expect to incur ongoing operating losses until such a time when Rhopressa® or Rocklatan® or any other product, if approved in the future, generates adequate revenues to render Aerie profitable.

Our principal liquidity requirements are for: working capital; operating expenses including for commercialization and manufacturing activities; expenses associated with developing our pipeline opportunities, including pursuing strategic growth opportunities; costs associated with executing our international expansion strategy, including clinical and potential commercialization activities in Europe and Japan; contractual obligations; and capital expenditures.

We believe that our cash and cash equivalents and investments and projected cash flows from revenues will provide sufficient resources to support our operations through at least the next twelve months. We are required to make semi-annual interest payments in cash in arrears on the Convertible Notes at a rate of 1.50% per annum on April 1 and October 1 of each year, beginning on April 1, 2020.

Our future funding requirements will depend on many factors, including, but not limited to the following:

- commercial performance of Rhopressa® and Rocklatan® or any current or future product candidates, if approved;
- costs of commercialization activities for Rhopressa® and Rocklatan® and any current or future product candidates, if approved;
- costs of building inventory to support sales growth and other associated working capital needs;
- costs, timing and outcome of seeking regulatory approval;
- timing and costs of our ongoing and future clinical trials and preclinical studies including those related to our international expansion;
- costs of any follow-on development or products, including the exploration and/or development of any additional indications or additional opportunities for new ophthalmic product candidates, delivery alternatives and new therapeutic areas;
- terms and timing of any acquisitions, collaborations or other arrangements;
- costs related to the Convertible Notes; and
- costs related to filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims.

We based our projections on assumptions that may prove to be incorrect or unreliable or may change due to circumstances beyond our control, and as a result, we may consume our available capital resources earlier than we originally projected. Accordingly, we may be required to obtain further funding through debt or equity offerings or other sources. If such funding is required, we cannot guarantee that it will be available to us on favorable terms, if at all.

Income Taxes and Net Operating Loss Carryforwards

We have incurred significant NOLs since our inception in June 2005. We expect to continue to incur NOLs until such a time when Rhopressa® or Rocklatan® or any other product, if approved in the future, generates adequate revenues to render Aerie profitable. We launched Rhopressa® in the United States at the end of April 2018 and Rocklatan® in May 2019. As a result, we commenced generating product revenues related to sales of Rhopressa® in the second quarter of 2018 and Rocklatan® in the second quarter of 2019; however, we did not generate taxable income in 2018 or 2019. The NOLs may be utilized to offset taxable income generated in the future.

As of December 31, 2019, we had federal and state NOL carryforwards of approximately $495.6 million and $510.3 million, respectively. Federal NOLs that arose prior to 2018 and state NOLs will begin to expire at various dates beginning in 2031 and 2024, respectively. Federal NOLs that arose on or after January 1, 2018, can be carried forward indefinitely to be utilized against future income, but can only be used to offset a maximum of 80% of our federal taxable income in any year. As of December 31, 2018, we had foreign NOL carryforwards of $68.1 million, which are available solely to offset taxable income of our foreign subsidiaries, subject to any applicable limitations under foreign law.

NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. State NOLs and tax credit carryforwards may be subject to similar limitations under state laws.

In December 2017, the Tax Act was signed into law and enacted significant changes to the Internal Revenue Code of 1986, as amended. This new tax legislation, among other changes, reduced the federal corporate income tax rate from 35% to 21% effective January 1, 2018. Under U.S. GAAP, deferred tax assets and liabilities are required to be revalued during the period in which the new tax legislation is enacted, which resulted in the remeasurement of our federal deferred tax assets and liabilities as of December 31, 2017 to reflect the effects of the enacted changes in tax rate. As we provide a full valuation allowance on our net deferred tax assets, there was no impact to income tax expense in our consolidated statement of operations and comprehensive loss for the year ended December 31, 2017 as a result of the remeasurement. The Tax Act also repealed the corporate AMT for tax years beginning after December 31, 2017 and provides that existing AMT credit carryovers are refundable in tax years beginning after December 31, 2017. We have approximately $1.1 million of AMT credit carryovers that

we expect to be fully refunded between 2020 and 2022. The Tax Act also limits various business deductions, including the interest deduction, modifies the maximum deduction of NOLs and includes various international tax provisions. Many provisions in the Tax Act were generally effective in tax years beginning in 2018, and we will continue to analyze additional information and guidance related to certain aspects of the Tax Act in assessing the potential impact on Aerie in the future.

Indebtedness

In September 2019, we issued an aggregate principal amount of $316.25 million of Convertible Notes and simultaneously terminated the credit facility. No funds were drawn on the credit facility at the time of termination.

The Convertible Notes are senior, unsecured obligations with interest payable semi-annually in cash in arrears at a rate of 1.50% per annum on April 1 and October 1 of each year, beginning on April 1, 2020. The Convertible Notes will mature on October 1, 2024 unless they are redeemed, repurchased or converted prior to such date. Prior to April 1, 2024, the Convertible Notes will be convertible at the option of holders only during certain periods and upon satisfaction of certain conditions. On and after April 1, 2024, the Convertible Notes will be convertible at the option of the holders any time until the close of business on the second scheduled trading day immediately preceding the maturity date. Upon conversion, the Convertible Notes may be settled in shares of our common stock, cash or a combination, thereof, at our election. We currently intend to settle the principal and interest amounts of the Convertible Notes in cash. See Note 10 to our consolidated financial statements appearing elsewhere in this report for more information.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2019:

	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	MORE THAN 5 YEARS
			(in thousands)		
Lease obligations[1]	$ 24,826	$ 5,738	$ 5,893	$ 3,341	$ 9,854
Convertible Notes[2]	316,250	—		316,250	—
Purchase obligations[3]	24,929	7,357	14,906	2,666	—
	$ 366,005	$ 13,095	$ 20,799	$ 322,257	$ 9,854

(1) Our lease obligations are primarily related to our principal executive office and research facility in Durham, North Carolina, and corporate offices in Bedminster, New Jersey, Irvine, California and other foreign offices. Additionally, the table reflects rental payments related to a lease agreement we entered into in January 2017 for a new manufacturing plant in Athlone, Ireland, under which we are leasing approximately 30,000 square feet of interior floor space. We completed the build-out of our manufacturing plant in the second quarter of 2019. We are permitted to terminate the lease agreement beginning in September 2027. Obligations denominated in foreign currencies have been translated to U.S. dollars at the foreign exchange rates in effect at December 31, 2019.

(2) In September 2019, we issued Convertible Notes, which mature on October 1, 2024 and bear interest at a rate of 1.50% per annum. Refer to Note 10 to our consolidated financial statements included elsewhere in this report for further information.

(3) Purchase obligations primarily include non-cancelable commitments under our contract manufacturing agreements.

We have agreements with third-parties with contingent milestone payments that are potentially payable by us, as more fully described in Note 1 to our consolidated financial statements appearing elsewhere in this report, which are not reflected in the table above. These payments are contingent upon achieving certain development and/or regulatory milestones that may or may not ever be achieved. Therefore, our requirement to make such payments in the future, if at all, as well as the timing of any such payments is highly uncertain.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC regulations.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this report regarding the impact of certain recent accounting pronouncements on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Given the short-term nature of our cash and cash equivalents and investments, we do not believe that a change in market interest rates would have a material impact on our financial condition or results of operations. We do not currently engage in any hedging activities against changes in interest rates.

We face market risks attributable to fluctuations in foreign currency exchange rates and exposure on the remeasurement of foreign currency-denominated monetary assets or liabilities into U.S. dollars. In particular, our operations and subsidiary in Ireland may enter into certain obligations or transactions in Euros or other foreign currencies but has a U.S. dollar functional currency. We do not currently have a foreign currency hedging program. To date and during the year ended December 31, 2019, foreign currency exposure and foreign currency financial instruments have not been material.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning at page F-1 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)), as of the end of the period covered by this report. Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, the disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in conformity with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to the information set forth in the sections titled “Nominees for Election as Directors,” “Information About Our Executive Officers,” “Directors Continuing in Office,” “Delinquent Section 16(a) Reports,” “Code of Business Conduct and Ethics” and “Information about the Board of Directors and Corporate Governance - Audit Committee” in our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Compensation,” “Director Compensation” and “Information about the Board of Directors and Corporate Governance - Compensation Committee Interlocks and Insider Participation” in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to the information set forth in the sections titled “Securities Authorized for Issuance under Equity Compensation Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the information set forth in the sections titled “Board of Directors’ Independence” and “Transactions with Related Persons” in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the information set forth in the section titled “Independent Registered Public Accounting Firm Fees and Services” in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The financial statement schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

See “Index to Consolidated Financial Statements” beginning on page F-1 of this report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because the required information is not present, or not present in amounts sufficient to require submission of the schedules, or because the required information is provided in the financial statements or notes thereto.

(a)(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit Index attached hereto and are incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

EXHIBIT NO.	EXHIBIT DESCRIPTION
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on October 31, 2013).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on October 31, 2013).
4.1	Indenture, dated as of September 9, 2019, by and between Aerie Pharmaceuticals, Inc. and Wilmington Trust, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on September 10, 2019 (File No. 001-36152)).
4.2	Form of 1.50% Convertible Senior Note due 2024 (included within the Indenture filed as Exhibit 4.1 and incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on September 10, 2019 (File No. 001-36152)).
4.3*	Description of the Registrant's Securities.
10.1	Form of Aerie Pharmaceuticals, Inc. Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.2	Aerie Pharmaceuticals, Inc. Second Amended and Restated Omnibus Incentive Plan (incorporated by reference to the appendix to the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-36152) filed on April 27, 2018).
10.3	Form of Aerie Pharmaceuticals, Inc. Incentive Stock Option Agreement (Cliff Vesting) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on February 24, 2015).
10.4	Form of Aerie Pharmaceuticals, Inc. Incentive Stock Option Agreement (Monthly Vesting) (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on February 24, 2015).
10.5	Form of Aerie Pharmaceuticals, Inc. Restricted Stock Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on February 24, 2015).
10.6	Form of Aerie Pharmaceuticals, Inc. Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on March 19, 2014).
10.7	Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of July 13, 2005 (incorporated by reference to Exhibit 10.5 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.8	First Amendment of Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of February 19, 2008 (incorporated by reference to Exhibit 10.6 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.9	Second Amendment of Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of December 3, 2009 (incorporated by reference to Exhibit 10.7 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.10	Third Amendment of Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of February 23, 2011 (incorporated by reference to Exhibit 10.8 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.11	Fourth Amendment of Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of August 9, 2013 (incorporated by reference to Exhibit 10.9 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.12	Fifth Amendment of Aerie Pharmaceuticals, Inc. 2005 Stock Option Plan, dated as of September 16, 2013 (incorporated by reference to Exhibit 10.10 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).

10.13	Form of Indemnification Agreement for officers and directors (incorporated by reference to Exhibit 10.19 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 21, 2013).
10.14	Employment Agreement, dated as of September 20, 2013, by and between Aerie Pharmaceuticals, Inc. and Vicente Anido, Jr., Ph.D. (incorporated by reference to Exhibit 10.18 to the Registrant's Form S-1 Registration Statement (File No. 333-191219) filed on October 3, 2013).
10.15	Amended and Restated Employment Agreement, dated July 25, 2017, by and between Aerie Pharmaceuticals, Inc. and Vicente Anido, Jr., Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on July 26, 2017).
10.16	Amended and Restated Employment Agreement, dated as of December 18, 2013, between Aerie Pharmaceuticals, Inc. and Thomas Mitro (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on December 20, 2013).
10.16.1	Amendment to Amended and Restated Employment Agreement, dated as of March 6, 2017, by and between Aerie Pharmaceuticals, Inc. and Thomas Mitro (incorporated by reference to Exhibit 10.16.1 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
10.17	Amended and Restated Employment Agreement, dated as of December 18, 2013, between Aerie Pharmaceuticals, Inc. and Richard Rubino (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on December 20, 2013).
10.17.1	Amendment to Amended and Restated Employment Agreement, dated as of March 6, 2017, by and between Aerie Pharmaceuticals, Inc. and Richard Rubino (incorporated by reference to Exhibit 10.17.1 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
10.18	Employment Agreement, dated as of December 18, 2013, between Aerie Pharmaceuticals, Inc. and Casey Kopczynski (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-36152) filed on December 20, 2013).
10.18.1	Amendment to Employment Agreement, dated as of March 6, 2017, by and between Aerie Pharmaceuticals, Inc. and Casey Kopczynski (incorporated by reference to Exhibit 10.18.1 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
10.19	Aerie Pharmaceuticals, Inc. Second Amended & Restated Inducement Award Plan (incorporated by reference to Exhibit 4.2 to the Registrant's Form S-8 Registration Statement (File No. 333-223364) filed on March 1, 2018).
10.20	Form of Aerie Pharmaceuticals, Inc. Inducement Award Plan Nonqualified Stock Option Agreement (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
10.21	Form of Aerie Pharmaceuticals, Inc. Inducement Award Plan Restricted Stock Agreement (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
10.22	Employment Agreement, dated as of January 19, 2018, by and between Aerie Pharmaceuticals, Inc. and John LaRocca (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36152) filed on May 9, 2018).
10.23*	Employment Agreement, dated as of October 7, 2019, by and between Aerie Pharmaceuticals, Inc. and David Hollander.
10.24	Form of Capped Call Transaction Confirmation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 10-Q filed on November 7, 2019 (File No. 001-36152)).
10.25	Form of Additional Capped Call Transaction Confirmation (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 10-Q filed on November 7, 2019 (File No. 001-36152)).
10.26†	Contract Manufacturing Supply Agreement, dated as of December 9, 2014, by and between Bausch & Lomb Incorporated and Aerie Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 10-Q (File No. 001-36152) filed on November 7, 2018).

10.27†	First Amendment to Contract Manufacturing Supply Agreement, dated as of May 31, 2018, by and between Bausch & Lomb Incorporated, Aerie Pharmaceuticals, Inc. and Aerie Distribution Incorporated (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 10-Q (File No. 001-36152) filed on November 7, 2018).
10.28†	Second Amendment to Contract Manufacturing Supply Agreement, dated as of August 15, 2018, by and between Bausch & Lomb Incorporated, Aerie Pharmaceuticals, Inc. and Aerie Distribution Incorporated (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 10-Q (File No. 001-36152) filed on November 7, 2018).
10.29†	Manufacture and Supply Agreement, dated as of January 1, 2018, by and between Cayman Chemical Company, Incorporated and Aerie Distribution, Incorporated (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 10-Q (File No. 001-36152) filed on November 7, 2018).
10.30*	Form of Aerie Pharmaceuticals, Inc. Restricted Stock Unit Award Agreement.
10.31*	Amendment to Aerie Pharmaceuticals, Inc. Second Amended & Restated Inducement Award Plan.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on March 9, 2017).
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
32.1***	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2***	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	Inline XBRL Instance Document.
101.SCH**	Inline XBRL Taxonomy Extension Schema Document.
101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Database.
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104*	Cover Page Interactive Data File.

† Certain portions of this exhibit have been omitted and separately filed with the SEC pursuant to a request for confidential treatment which has been granted by the SEC.

* Filed herewith.

** Attached as Exhibit 101 to this report are the following formatted in Inline XBRL (Extensible Business Reporting Language):

(i) Consolidated Balance Sheets at December 31, 2019 and 2018, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019, 2018 and 2017 (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019, 2018 and 2017 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017 and (v) Notes to Consolidated Financial Statements.

*** Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AERIE PHARMACEUTICALS, INC.

Date: February 24, 2020

By: /S/ VICENTE ANIDO, JR., PH.D.
Vicente Anido, Jr., Ph.D.
Chief Executive Officer, Chairman of the Board

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/S/ VICENTE ANIDO, JR., PH.D. Vicente Anido, Jr., Ph.D.	Chief Executive Officer, Chairman of the Board (Principal Executive Officer)	February 24, 2020
/S/ RICHARD J. RUBINO Richard J. Rubino	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 24, 2020
/S/ GERALD D. CAGLE, PH.D. Gerald D. Cagle, Ph.D.	Director	February 24, 2020
/S/ RICHARD CROARKIN Richard Croarkin	Director	February 24, 2020
/S/ MECHIEL M. DU TOIT Mechiel M. du Toit	Director	February 24, 2020
/S/ MURRAY A. GOLDBERG Murray A. Goldberg	Director	February 24, 2020
/S/ DAVID W. GRYSKA David W. Gryska	Director	February 24, 2020
/S/ BENJAMIN F. MCGRAW III, PHARM. D. Benjamin F. McGraw III, Pharm. D.	Director	February 24, 2020
/S/ JULIE MCHUGH Julie McHugh	Director	February 24, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

AERIE PHARMACEUTICALS, INC.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Aerie Pharmaceuticals, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Aerie Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases as of January 1, 2019.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to

permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Provisions for Revenue Reserves - Commercial and Medicare Part D Rebates

As described in Notes 2 and 3 to the consolidated financial statements, product revenues are recorded net of provisions for (i) trade discounts and allowances, such as discounts for prompt payment and distributor fees, (ii) estimated rebates to third-party payers, estimated payments for Medicare Part D prescription drug program coverage gap, patient co-pay program coupon utilization, chargebacks and other discount programs, and (iii) reserves for expected product returns. Management estimates the rebates and chargebacks it expects to be obligated to provide to third-party payers and deducts these estimated amounts from its gross product revenue at the time the revenue is recognized. Provisions for revenue reserves reduced product revenues by $105.9 million in aggregate for the year ended December 31, 2019, a significant portion of which related to commercial and Medicare Part D rebates. Management estimates the rebates and chargebacks based on contractual and statutory requirements, known market events and trends, industry data, forecasted customer mix, and lagged claims.

The principal considerations for our determination that performing procedures relating to provisions for revenue reserves - commercial and Medicare Part D rebates is a critical audit matter are there was significant judgment by management due to the significant measurement uncertainty involved in developing the provisions, as the estimate is based on significant assumptions related to forecasted customer mix and lagged claims. This in turn led to a high degree of auditor judgment, subjectivity, and effort in applying procedures relating to these assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to rebates for the commercial and Medicare Part D programs, including controls over the assumptions used to estimate the provisions for these rebates. These procedures also included, among others, developing an independent estimate of the commercial and Medicare Part D rebates by utilizing third-party data on forecasted customer mix, the terms of the specific rebate programs, and the trend of lagged claims. The independent estimate was compared to the rebates recorded by management to evaluate the reasonableness of management's estimate. Additionally, these procedures included testing a sample of actual rebate claims paid and evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

Valuation of and Accounting for Convertible Notes Transactions at Issuance

As described in Notes 2 and 10 to the consolidated financial statements, in September 2019, the Company issued convertible notes with an aggregate principal amount of $316.25 million to qualified institutional buyers. Management separately accounts for the liability and equity components of convertible notes transactions that can be settled in cash by allocating the proceeds from issuance between the liability component and the embedded conversion option in accordance with accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the proceeds from the convertible debt issuance and the amount measured as the liability component is recorded as the equity component with a corresponding discount recorded on the debt. Additionally, in September 2019, the Company bought capped call options from financial institutions for a total of $32.9 million in premiums to minimize the impact of potential dilution of the Company's

common stock upon conversion of its convertible notes. The capped call options meet the definition of a derivative, however, qualify for derivative scope exception for instruments indexed to a company's own stock. Accordingly, the premiums for the capped call options were recorded as additional paid-in capital on the Company's consolidated balance sheet as the options are settleable in Aerie common stock at the election of the Company. As disclosed by management, the estimated fair value of the liability component of the convertible notes was $187.9 million at the time of issuance, and was determined based on a discounted cash flow analysis and a binomial lattice model. The valuation required the use of Level 3 unobservable inputs and subjective assumptions, including but not limited to the stock price volatility and bond yield. The equity component was approximately $128.4 million at the time of issuance and its fair value is not remeasured as long as it continues to meet the conditions for equity classification.

The principal considerations for our determination that performing procedures relating to the valuation of and accounting for convertible notes transactions at issuance is a critical audit matter are there was significant judgment by management to determine the accounting for the embedded conversion and capped call options, which included allocating the proceeds from issuance between the liability component and the embedded conversion option in accordance with accounting for convertible debt instruments that may be settled in cash, and the determination of whether the capped call options met the definition of a derivative and qualified for derivative scope exception for instruments indexed to a company's own stock. There was also significant judgment by management to estimate the fair value of the convertible notes due to the use of a discounted cash flow analysis and binomial lattice model, which included significant assumptions related to the stock price volatility and bond yield. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence obtained related to the valuation and accounting for the convertible notes transactions, and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the valuation of the convertible notes transactions, including controls over the management's valuation method, significant assumptions, and data, and controls relating to the accounting for the convertible notes transactions, including controls over the review and documentation of related technical accounting guidance considered. These procedures also included, among others, (i) reading the convertible notes transactions agreements, and (ii) the involvement of professionals with specialized skill and knowledge to assist in evaluating the appropriateness of the accounting for the convertible notes, and to assist in developing an independent range of values for the convertible notes and comparison of management's estimate to the independently developed range. Developing the independent estimate involved evaluating the binomial lattice model used by management, including relevant data and related significant assumptions such as bond yield, and independently developing the stock price volatility significant assumptions.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 24, 2020

We have served as the Company's auditor since 2011.

AERIE PHARMACEUTICALS, INC.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	DECEMBER 31,	
	2019	**2018**
Assets		
Current assets		
Cash and cash equivalents	$ 143,940	$ 202,818
Short-term investments	165,250	—
Accounts receivable, net	38,354	2,715
Inventory	21,054	10,112
Prepaid expenses and other current assets	7,744	4,530
Total current assets	376,342	220,175
Property, plant and equipment, net	58,147	60,525
Operating lease right-of-use assets	16,523	—
Other assets	1,596	4,344
Total assets	$ 452,608	$ 285,044
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 12,770	$ 12,403
Accrued expenses and other current liabilities	65,376	38,381
Operating lease liabilities	5,502	—
Total current liabilities	83,648	50,784
Convertible notes, net	188,651	—
Long-term operating lease liabilities	12,102	—
Other non-current liabilities	1,257	6,454
Total liabilities	285,658	57,238
Commitments and contingencies (Note 14)		
Stockholders' equity		
Preferred stock, $0.001 par value; 15,000,000 shares authorized as of December 31, 2019 and December 31, 2018; None issued and outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2019 and December 31, 2018; 46,464,669 and 45,478,883 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	46	45
Additional paid-in capital	1,062,996	924,180
Accumulated other comprehensive loss	(92)	—
Accumulated deficit	(896,000)	(696,419)
Total stockholders' equity	166,950	227,806
Total liabilities and stockholders' equity	$ 452,608	$ 285,044

The accompanying notes are an integral part of these consolidated financial statements.

AERIE PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,		
	2019	**2018**	**2017**
Product revenues, net	$ 69,888	$ 24,181	$ —
Total revenues, net	69,888	24,181	—
Costs and expenses:			
Cost of goods sold	4,833	641	—
Selling, general and administrative	138,402	120,614	56,905
Pre-approval commercial manufacturing	22,767	26,545	16,710
Research and development	91,378	86,123	72,078
Total costs and expenses	257,380	233,923	145,693
Loss from operations	(187,492)	(209,742)	(145,693)
Other (expense) income, net	(12,179)	(22,824)	(1,170)
Loss before income taxes	(199,671)	(232,566)	(146,863)
Income tax (benefit) expense	(90)	3	(1,758)
Net loss	$ (199,581)	$ (232,569)	$ (145,105)
Net loss per common share—basic and diluted	$ (4.39)	$ (5.58)	$ (4.11)
Weighted average number of common shares outstanding—basic and diluted	45,427,154	41,663,958	35,324,472
Net loss	$ (199,581)	$ (232,569)	$ (145,105)
Unrealized (loss) gain on available-for-sale investments	(92)	28	40
Comprehensive loss	$ (199,673)	$ (232,541)	$ (145,065)

The accompanying notes are an integral part of these consolidated financial statements.

AERIE PHARMACEUTICALS, INC.

Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT				
Balances at December 31, 2016	33,458,607	$ 33	$ 422,002	$ (68)	$ (316,623)	$ 105,344
Issuance of common stock, net of discounts, commissions and expenses of $3,458	2,506,387	2	133,810	—	—	133,812
Issuance of common stock upon exercise of stock purchase rights	27,953	—	1,050	—	—	1,050
Issuance of common stock upon exercise of stock options	201,592	1	827	—	—	828
Issuance of common stock for restricted stock awards, net	489,952	1	(751)	—	—	(750)
Shares issued for asset acquisition	263,146	—	14,302	—	—	14,302
Stock-based compensation	—	—	26,078	—	—	26,078
Other comprehensive income	—	—	—	40	—	40
Net loss	—	—	—	—	(145,105)	(145,105)
Balances at December 31, 2017	36,947,637	37	597,318	(28)	(461,728)	135,599
Cumulative effect adjustment from adoption of ASU 2016-16	—	—	—	—	(2,122)	(2,122)
Issuance of common stock, net of commissions and expenses of $1,345	2,313,824	2	136,443	—	—	136,445
Issuance of common stock upon exercise of stock purchase rights	34,193	—	1,401	—	—	1,401
Issuance of common stock upon exercise of stock options and warrants	597,777	1	4,250	—	—	4,251
Issuance of common stock for restricted stock awards, net	216,005	—	(2,172)	—	—	(2,172)
Issuance of shares upon conversion of 2014 Convertible Notes	5,369,447	5	148,078	—	—	148,083
Stock-based compensation	—	—	38,862	—	—	38,862
Other comprehensive income	—	—	—	28	—	28
Net loss	—	—	—	—	(232,569)	(232,569)
Balances at December 31, 2018	45,478,883	45	924,180	—	(696,419)	227,806
Issuance of common stock upon exercise of stock options and warrants	612,759	—	3,140	—	—	3,140
Issuance of common stock upon exercise of stock purchase rights	42,611	—	979	—	—	979
Issuance of common stock for restricted stock awards, net	330,416	1	(2,630)	—	—	(2,629)
Stock-based compensation	—	—	45,551	—	—	45,551
Other comprehensive loss	—	—	—	(92)	—	(92)
Equity component of Convertible Notes, net of issuance costs of $3,725	—	—	124,666	—	—	124,666
Payment for capped call share options	—	—	(32,890)	—	—	(32,890)
Net loss	—	—	—	—	(199,581)	(199,581)
Balances at December 31, 2019	46,464,669	$ 46	$ 1,062,996	$ (92)	$ (896,000)	$ 166,950

The accompanying notes are an integral part of these consolidated financial statements.

AERIE PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows
(in thousands)

	YEAR ENDED DECEMBER 31,		
	2019	**2018**	**2017**
Cash flows from operating activities			
Net loss	$ (199,581)	$ (232,569)	$ (145,105)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	5,138	2,442	1,410
Amortization and accretion	12,976	1,646	315
Acquisition of assets expensed to research and development	10,171	—	24,802
Stock-based compensation	45,093	38,728	26,078
Induced conversion of 2014 Convertible Notes	—	24,059	—
Other non-cash	(271)	(270)	601
Changes in operating assets and liabilities			
Accounts receivable, net	(35,639)	(2,715)	—
Inventory	(10,257)	(9,689)	—
Prepaid, current and other assets	(2,144)	(791)	(2,239)
Accounts payable, accrued expenses and other current liabilities	28,766	26,583	925
Operating lease liabilities	(4,682)	—	—
Net cash used in operating activities	(150,430)	(152,576)	(93,213)
Cash flows from investing activities			
Acquisition of assets	(7,835)	—	(10,500)
Purchase of available-for-sale investments	(165,454)	(56,195)	(104,490)
Proceeds from sales and maturities of investments	—	108,297	88,153
Purchase of property, plant and equipment	(9,958)	(31,313)	(15,970)
Net cash (used in) provided by investing activities	(183,247)	20,789	(42,807)
Cash flows from financing activities			
Proceeds from sale of common stock, net	—	135,972	134,215
Proceeds related to issuance of stock for stock-based compensation arrangements, net	684	3,630	1,429
Proceeds from exercise of warrants	761	—	—
Proceeds from convertible notes, net of issuance costs	308,349	—	—
Payments of issuance costs	(1,769)	(1,883)	—
Payment for capped call options	(32,890)	—	—
Other financing	(336)	(683)	—
Net cash provided by financing activities	274,799	137,036	135,644
Net change in cash and cash equivalents	(58,878)	5,249	(376)
Cash and cash equivalents, at beginning of period	202,818	197,569	197,945
Cash and cash equivalents, at end of period	$ 143,940	$ 202,818	$ 197,569
Supplemental disclosures			
Cash paid for interest	$ 6,496	$ 1,774	$ 2,188
Non-cash investing and financing activities:			
Conversion of convertible notes to common stock (Note 10)	$ —	$ 148,078	$ —
Equity issued for Envisia Asset Acquisition	$ —	$ —	$ 14,302
Liabilities incurred from Avizorex Asset Acquisition	$ 1,186	$ —	$ —
Purchases of property, plant and equipment in accounts payable and accrued expense and other current liabilities	$ 771	$ 3,526	$ 4,176
Acquisition of capital lease obligation	$ —	$ —	$ 689
Deferred costs from the sale of common stock	$ —	$ —	$ 403
Build-to-suit lease transaction (Note 7)			

The accompanying notes are an integral part of these consolidated financial statements.

1. The Company

Aerie Pharmaceuticals, Inc. ("Aerie"), with its wholly-owned subsidiaries, Aerie Distribution, Inc., Aerie Pharmaceuticals Limited and Aerie Pharmaceuticals Ireland Limited ("Aerie Distribution," "Aerie Limited" and "Aerie Ireland Limited," respectively, together with Aerie, the "Company"), is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. The Company has its principal executive offices in Durham, North Carolina, and operates as one business segment.

The Company has two U.S. Food and Drug Administration ("FDA") approved products, Rhopressa® (netarsudil ophthalmic solution) 0.02% ("Rhopressa®") and Rocklatan® (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% ("Rocklatan®"). Rhopressa® is a once-daily eye drop designed to reduce elevated intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension. Rocklatan® is a once-daily fixed-dose combination of Rhopressa® and latanoprost, the most widely-prescribed drug for the treatment of patients with open-angle glaucoma. The Company is commercializing Rhopressa®, which was launched in the United States at the end of April 2018, and Rocklatan®, which was launched in the United States in May 2019. In November 2019, the Company released topline data from its Phase 4 Multi-center Open-label Study ("MOST"), which observed Rhopressa® efficacy in various real-world clinical settings, including as an adjunctive product and monotherapy. The results indicated positive IOP reduction in all settings, along with a favorable tolerability profile. In addition to actively promoting the products in the United States, the Company is pursuing its strategy to obtain regulatory approval for Rhopressa® and Rocklatan® in Europe and Japan. Rhopressa® and, if approved, Rocklatan® will be marketed under the names Rhokiinsa® and Roclanda®, respectively, in Europe.

In Europe, Rhokiinsa® was granted a centralised marketing authorisation by the European Commission ("EC") in November 2019 and the Marketing Authorisation Application ("MAA") for Roclanda® was accepted by the European Medicines Agency ("EMA") in December 2019. The Phase 3 registration trial for Roclanda®, named Mercury 3, is a six-month efficacy and safety trial designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe of bimatoprost (a PGA), and timolol (a beta blocker). If successful, Mercury 3 is expected to improve the commercialization prospects of Roclanda® in Europe; it is not required for regulatory approval. The Mercury 3 results are expected to be an important determinant as the Company evaluates the commercialization and profitability potential of Rhokiinsa® and Roclanda® in Europe. The Company currently expects to read out topline 90-day efficacy data for the trial in the second half of 2020.

In Japan, with respect to the clinical progress of Rhopressa®, the Company completed a Phase 1 clinical trial, a successful pilot Phase 2 clinical study in the United States on Japanese and Japanese-American subjects, as well as a Phase 2 clinical trial conducted in Japan. These studies were designed to meet the requirements of Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") for potential regulatory submission of Rhopressa® in Japan. Topline results of the Phase 2 trial indicated positive efficacy and tolerability in the patient set. Clinical trials for Rocklatan® have not yet begun. The Company expects to move forward with plans for Phase 3 initiation in Japan for Rhopressa®, along with exploring collaboration with a potential partner in Japan to advance the Company's clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan, and will continue to explore other potential opportunities elsewhere in Eastern Asia.

The Company is also focused on furthering the development of its product candidates focused on dry eye and retinal diseases, particularly AVX-012, AR-1105 and AR-13503 SR, described below. The Company acquired Avizorex Pharma S.L. ("Avizorex"), a Spanish ophthalmic pharmaceutical company, developing therapeutics for the treatment of dry eye disease. The active ingredient in AVX-012 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates ocular surface wetness and blink rate. The Company is planning to initiate a large Phase 2b study in late 2020.

The Company has also acquired worldwide ophthalmic rights to a bio-erodible polymer technology from DSM, a global science-based company headquartered in the Netherlands, and PRINT® (Particle Replication in Non-wetting Templates) implant manufacturing technology, which is a proprietary technology capable of creating precisely-engineered sustained-release products utilizing fully-scalable manufacturing processes, from Envisia Therapeutics Inc. ("Envisia"). Using these technologies, the Company has created a sustained-release ophthalmology platform and is currently developing two sustained-release implants focused on retinal diseases, AR-1105 and AR-13503 SR. AR-1105 is a dexamethasone steroid implant, for which the Company has completed enrollment in a Phase 2 clinical trial in patients with macular edema due to retinal vein occlusion ("RVO"). The Company is also developing AR-13503, a ROCK and Protein kinase C inhibitor that is the active ingredient in the AR-13503 sustained-release implant. The Investigational New Drug application ("IND") for AR-13503 SR

became effective in April 2019, allowing the Company to initiate human studies in the treatment of neovascular age-related macular degeneration ("nAMD") and diabetic macular edema ("DME"). The Company initiated a first-in human clinical study for AR-13503 SR in the third quarter of 2019.

In November 2019, the Company entered into a Share Purchase Agreement (the "Agreement") with Avizorex, under which the Company acquired Avizorex, including its lead product candidate AVX-012, for which Avizorex completed a Phase 2a study in dry eye subjects in 2019. The consideration given for the Avizorex acquisition was $10.2 million. Additionally, the Company agreed to make potential milestone payments of up to an aggregate of $69.0 million, contingent upon the achievement of certain clinical and product regulatory approvals, plus royalties on net sales of any approved products from Avizorex's development pipeline. Under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 805: *Business Combinations* ("ASC Topic 805"), including the provisions of Accounting Standards Update ("ASU") 2017-01, the Company accounted for the transaction as an asset acquisition rather than a business combination, and expensed $10.2 million of acquired in-process research and development ("IPR&D") to research and development in the consolidated statement of operations and comprehensive loss during the three months ended December 31, 2019. In addition, any milestone payments will be recognized only once the contingency is resolved and such amounts are payable.

In October 2017, the Company entered into an Asset Purchase Agreement (the "Envisia Agreement") with Envisia to acquire the rights to use PRINT® technology in ophthalmology, as well as rights relating to a preclinical dexamethasone steroid implant for the potential treatment of RVO and DME that utilizes the PRINT® technology, referred to as AR-1105. Under the terms of the Envisia Agreement, the Company (a) made an upfront cash payment of $10.5 million and issued 263,146 shares of Aerie's common stock valued at approximately $14.3 million and (b) agreed to make potential milestone payments of up to an aggregate of $45.0 million, contingent upon the achievement of certain product regulatory approvals. Under the provisions of ASC Topic 805, including the provisions of ASU 2017-01 (see Note 2), the Company accounted for the transaction as an asset acquisition rather than a business combination, and expensed $24.8 million of acquired IPR&D to research and development in the consolidated statement of operations and comprehensive loss during the three months ended December 31, 2017. In addition, any milestone payments will be recognized only once the contingency is resolved and such amounts are payable.

In July 2017, the Company entered into a collaborative research, development and licensing agreement with DSM, which included an option to license DSM's bio-erodible polymer implant technology for sustained delivery of certain Aerie compounds to treat ophthalmic diseases. This technology uses polyesteramide polymers to produce an injectable, thin fiber that is minute in size. On August 1, 2018, the Company entered into an Amended and Restated Collaborative Research, Development, and License Agreement with DSM (the "Collaboration Agreement"), which provides for (i) a worldwide exclusive license for all ophthalmic indications to DSM's polyesteramide polymer technology, (ii) continuation of the collaborative research initiatives through the end of 2020, including the transfer of DSM's formulation technology to Aerie during that time and (iii) access to a preclinical latanoprost implant. Aerie paid $6.0 million to DSM upon execution of the Collaboration Agreement, with an additional $9.0 million payable to DSM through the end of 2020. As a result, $9.6 million related to the expanded collaboration agreement with DSM was expensed to research and development expense during the year ended December 31, 2018, which included the upfront payment of $6.0 million. The Collaboration Agreement includes contingent payments of up to $75.0 million that may be due to DSM upon the achievement of certain development and regulatory milestones. In addition, pursuant to the Collaboration Agreement, a $3.0 million milestone payment was made during the year ended December 31, 2018 upon the completion of certain manufacturing technology transfer activities. Aerie would also pay royalties to DSM when products are commercialized under this Collaboration Agreement, if any.

The Company commenced generating product revenues related to the sales in the United States of Rhopressa® in the second quarter of 2018 and Rocklatan® in the second quarter of 2019. The Company's activities prior to the commercial launch of Rhopressa® had primarily consisted of developing product candidates, raising capital and performing research and development activities. The Company has incurred losses and experienced negative operating cash flows since inception. The Company had previously funded its operations primarily through the sale of equity securities (Note 12) and issuance of convertible notes (Note 10) prior to generating product revenues. In September 2019, the Company issued an aggregate principal amount of $316.25 million of 1.50% convertible senior notes due 2024 (the "Convertible Notes") and simultaneously terminated its $200 million senior secured delayed draw term loan facility (the "credit facility"). See Note 10 for additional information.

If the Company does not successfully commercialize Rhopressa® and Rocklatan® or any current or future product candidates, if approved, it may not generate sufficient cash flows and may be unable to achieve profitability. Accordingly, the Company may be required to obtain further funding through debt or equity offerings or other sources. Adequate additional funding may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on acceptable terms, it may be forced to delay, reduce or eliminate its research and development programs or commercialization and manufacturing efforts.

2. Significant Accounting Policies

Basis of Presentation and Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of Aerie and its wholly-owned subsidiaries. All intercompany accounts, transactions and profits have been eliminated in consolidation. Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of income and expenses during the reporting periods. Significant items subject to such estimates and assumptions include revenue recognition, acquisitions, stock-based compensation and fair value measurements. Actual results could differ from the Company's estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and investments. The Company's cash and cash equivalents, which include short-term highly liquid investments with original maturities of three months or less, are held at several financial institutions. The Company's investment policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper, money market instruments, and certain qualifying money market mutual funds, and places restrictions on credit ratings, maturities, and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments to the extent recorded on the consolidated balance sheet.

The Company relies on its third-party manufacturers to produce the active pharmaceutical ingredient ("API") and final drug product for Rhopressa® and Rocklatan® and may rely on third-party manufacturers for its current and future product candidates. In addition to the current contract manufacturers, the Company obtained FDA approval for an additional Rhopressa® drug product contract manufacturer in the first quarter of 2019, which began to supply commercial product in the second quarter of 2019. Further, the Company has obtained FDA approval for an additional API contract manufacturer, which began to supply commercial API in the second quarter of 2019. The Company has also received approval of an additional Rocklatan® drug product contract manufacturer in January 2020.

In addition, the Company has established its own manufacturing plant in Athlone, Ireland, for future commercial production of Rocklatan® and Rhopressa®, if approved, and thereafter, potentially Rhokiinsa® and, if approved, Roclanda®. In January 2020, the Company received FDA approval to produce Rocklatan® at the Athlone plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the New Drug Application ("NDA") Prior Approval Supplement ("PAS"), which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. The Company expects FDA approval to produce Rhopressa® at the Athlone plant by the end of 2020. The Company expects to continue to use product sourced from the contract manufacturers in addition to the manufacturing plant in Athlone, Ireland.

Revenue Recognition

The Company accounts for its revenue transactions under FASB ASC Topic 606, *Revenue from Contracts with Customers*. In accordance with ASC Topic 606, the Company recognizes revenues when its customers obtain control of its product for an amount that reflects the consideration it expects to receive from its customers in exchange for that product. To determine revenue recognition for contracts that are determined to be in scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine

the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when such performance obligation is satisfied.

Aerie's customers include a limited number of national and select regional wholesalers (the "distributors"). These distributors subsequently resell the product, primarily to retail pharmacies that dispense the product to patients. Net product revenue is typically recognized when distributors obtain control of the Company's products, which occurs at a point in time, typically upon delivery of product to the distributors. The Company evaluates the creditworthiness of each of its distributors to determine whether it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. The Company does not assess whether a contract has a significant financing component if the expectation is such that the period between the transfer of the promised goods to the customer and the receipt of payment will be less than one year. Standard credit terms do not exceed 75 days. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that would have been recognized is one year or less or the amount is immaterial. Shipping and handling costs related to the Company's product sales are included in selling, general and administrative expenses.

The Company's net product revenues through December 31, 2019 were generated through sales of Rhopressa®, which was commercially launched in the United States at the end of April 2018, and sales of Rocklatan®, which was commercially launched in the United States in May 2019. Product revenue is recorded net of trade discounts, allowances, commercial and government rebates, co-pay program coupons, chargebacks, U.S. government funding requirements for the coverage gap (commonly called the "donut hole") portion of the Medicare Part D program and estimated returns and other incentives. These reserves are classified as either reductions of accounts receivable or as current liabilities. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, known market events and trends, industry data, forecasted customer mix and lagged claims. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net product revenues only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment. See Note 3 for additional information.

Cash Equivalents

The Company's cash and cash equivalents are held at several financial institutions. The Company considers money market accounts and short-term highly liquid investments with original maturities of three months or less to be cash equivalents.

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out ("FIFO") method. The Company analyzes its inventory levels at least quarterly and writes down inventory that is expected to expire prior to being sold, inventory in excess of expected sales requirements and inventory that fails to meet commercial sale specifications, with a corresponding charge to cost of goods sold. The determination of whether inventory costs will be realizable requires estimates by management of future expected inventory requirements based on sales forecasts. If actual net realizable value is less than the estimated amount or if actual market conditions are less favorable than the Company's projections, additional inventory write-downs may be required. Charges for inventory write-downs are not reversed if it is later determined that the product is saleable.

Prior to the date the Company obtains regulatory approval for its product candidates or its manufacturing facilities such as its manufacturing plant in Athlone, Ireland, manufacturing costs related to commercial production are expensed as pre-approval commercial manufacturing expense on the consolidated statements of operations and comprehensive loss. Once regulatory approval is obtained, the Company capitalizes such costs as inventory on the consolidated balance sheets.

Property, Plant and Equipment, Net

Property, plant and equipment is recorded at historical cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. Construction-in-progress reflects amounts incurred for property, plant or equipment construction or improvements that have not been yet placed in service and are not depreciated or amortized, which primarily

relates to the completion of the build-out of the Company's manufacturing plant in Ireland. Repairs and maintenance are expensed when incurred. Upon retirement or sale, the cost of the assets disposed of and the related accumulated depreciation are removed from the accounts, and any resulting gain or loss is included in the determination of net loss.

Estimated useful lives by major asset category are as follows:

Manufacturing equipment	10 years
Laboratory equipment	7 years
Furniture and fixtures	5 years
Software, computer and other equipment	3 years
Leasehold improvements	Lower of estimated useful life or term of lease

Leases

The Company determines if an arrangement is a lease at inception. For each lease, the lease term is determined at the commencement date and includes renewal options and termination options when it is reasonably certain that the Company will exercise that option. Operating leases with lease terms greater than one year are included in operating lease right-of-use ("ROU") assets and current and long-term operating lease liabilities in the Company's consolidated balance sheets.

Operating lease ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term using an estimated rate of interest the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The operating lease ROU assets are based on the liability adjusted for any prepaid or deferred rent and lease incentives. The incremental borrowing rate was utilized to discount lease payments over the expected term given that the Company's operating leases do not provide an implicit rate. The Company estimates the incremental borrowing rate to reflect the profile of secured borrowing over the expected term of the leases based on the information available at the later of the date of adoption or the lease commencement date. Rent expense for the operating lease is recognized on a straight-line basis over the lease term.

The Company's lease agreements have lease and non-lease components, which are generally accounted for as a single lease component. Non-lease components include lease operating expenses, which are variable costs under the Company's current leases. For vehicle leases, the Company accounts for the lease and non-lease components as a single lease component and applies a portfolio approach to effectively account for the operating lease ROU assets and liabilities.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount of an asset or asset group to estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. For the years ended December 31, 2019, 2018 and 2017, no such impairment losses have been recorded by the Company.

Acquisitions

The Company evaluates acquisitions to determine whether the acquisition is a business combination or an acquisition of assets under ASC Topic 805. Business combinations are accounted for using the acquisition method of accounting, whereby assets acquired and liabilities assumed are recorded as of the acquisition date at their respective fair values and excess of the fair value of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill. In an asset acquisition that does not constitute a business, no goodwill is recognized, and the net assets acquired are generally recorded at cost. Significant judgment is required in estimating the fair value of intangible assets and in a determination of whether an acquisition is a business combination or an acquisition of assets. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but are inherently uncertain.

The consolidated financial statements as of and for the years ended December 31, 2019 and December 31, 2017 include the impact of the acquisition of assets from Avizorex and Envisia, respectively (see Note 1 for additional information).

Research and Development Costs

Research and development costs are charged to expense as incurred and include, but are not limited to:

- employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations ("CROs"), contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies;
- costs associated with any collaboration arrangements, licenses or acquisitions of preclinical molecules, product candidates or technologies;
- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations; and
- depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate. No material adjustments to these estimates have been recorded in these consolidated financial statements.

Research and development costs also include the cost of IPR&D projects acquired as part of an asset acquisition that have no alternative future use. Milestone payments due to third parties in connection with research and development activities prior to regulatory approval are expensed as incurred, while milestone payments due to third parties upon, or subsequent to, regulatory approval are capitalized and amortized over the estimate useful life.

Stock-Based Compensation

Stock-based compensation for awards granted to employees and non-employees is measured at grant date, based on the estimated fair value of the award. The Company estimates the fair value of options to purchase common stock and stock appreciation rights ("SARs") using a Black-Scholes option pricing model. The Black-Scholes option pricing model utilizes assumptions including expected term, volatility, a risk-free interest rate and an expected dividend yield. The Company utilized the guidance set forth in the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin 107, *Share-Based Payment* ("SAB 107"), to determine the expected term of options, as it does not have sufficient historical exercise and post-vesting termination data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. The simplified method utilizes the midpoint between the vesting date and the maximum contractual expiration date as the expected term. Volatility is based on the historical volatility of the Company as well as several public entities that are similar to the Company. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term. The Company uses an expected dividend yield of zero as it does not expect to pay cash dividends for the foreseeable future. Upon issuance and at each reporting period, the fair value of each SARs award is estimated using the Black-Scholes option pricing model and is marked to market through stock-based compensation expense. SARs are liability-based awards as they may only be settled in cash.

The fair value of restricted stock awards ("RSAs") and restricted stock units ("RSUs"), including restricted stock awards with non-market performance and service conditions ("PSAs") are determined based on the fair value of Aerie's common stock on the date of grant. Compensation expense related to RSAs and RSUs are recognized ratably over the vesting period. As the PSAs have multiple performance conditions, compensation expense is recognized for each vesting tranche over the respective requisite service period of each tranche if and when the Company's management deems it probable that the performance conditions will be satisfied. Stock-based compensation related to stock options, RSAs, RSUs and PSAs is expensed on a straight-line basis over the relevant vesting period, although the Company may recognize a cumulative true-up adjustment related to PSAs once a condition becomes probable of being satisfied if the related service period had commenced in a prior period. All stock-based compensation expense is recorded between selling, general and administrative, pre-approval commercial manufacturing and research and development costs in the consolidated statements of operations and comprehensive loss based upon the underlying employees' roles within the Company. The Company accounts for forfeitures as they occur.

Investments

The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase. The Company's investments are classified as available-for-sale in accordance with ASC Topic 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its consolidated balance sheets. Investments are classified as long-term assets on the consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments in debt securities are recorded at fair value, with unrealized gains or losses included in comprehensive loss on the consolidated statements of operations and comprehensive loss and in accumulated other comprehensive loss on the consolidated balance sheets. Realized gains and losses, interest income earned on the Company's cash, cash equivalents and investments, and amortization or accretion of discounts and premiums on investments are included within other income (expense), net. Interest income was $3.0 million, $3.4 million and $1.8 million for the years ended December 31, 2019, 2018 and 2017, respectively. Realized gains and losses are determined using the specific identification method and are included as a component of other income (expense), net. Realized gains or losses were immaterial for the years ended December 31, 2019, 2018 and 2017.

The Company reviews investments in debt securities for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. The Company did not recognize any impairments on its investments during the years ended December 31, 2019, 2018 or 2017.

Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures*. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1—Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.
- Level 2—Other inputs that are directly or indirectly observable in the marketplace.
- Level 3—Unobservable inputs that are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company's cash equivalents are carried at fair value according to the fair value hierarchy described above. The Company's investments were valued utilizing Level 2 inputs and the Convertible Notes were valued utilizing Level 2 inputs as of December 31, 2019. There were no transfers between the different levels of the fair value hierarchy in 2019 or in 2018.

Convertible Notes Transaction

The Company separately accounts for the liability and equity components of convertible notes transactions that can be settled in cash by allocating the proceeds from issuance between the liability component and the embedded conversion option in accordance with accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the proceeds from the convertible debt issuance and the amount measured as the liability component is recorded as the equity component with a corresponding discount recorded on the debt. The Company recognizes amortization of the resulting discount using the effective interest method as interest expense on the consolidated statements of operations and comprehensive loss. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The Company allocates issuance costs incurred to the liability and equity components. Issuance costs attributable to the liability component are amortized to expense over the respective term of the convertible notes, and issuance costs attributable to the equity component are netted with the respective equity component in additional paid-in capital.

In September 2019, the Company bought capped call options from financial institutions to minimize the impact of potential dilution of Aerie common stock upon conversion of the Convertible Notes. The capped call options meet the definition of a

derivative in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"), however, qualify for derivative scope exception under ASC 815 for instruments indexed to a company's own stock. Accordingly, the premiums for the capped call options were recorded as additional paid-in capital on the Company's consolidated balance sheet as the options are settleable in Aerie common stock at the election of the Company. See Note 10 for additional information.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss includes changes in stockholders' equity that are excluded from net income (loss), specifically changes in unrealized gains and losses on the Company's available-for-sale securities.

Income Taxes

Deferred tax assets or liabilities are recorded for temporary differences between financial statement and tax basis of assets and liabilities, using enacted rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. The Company has provided a full valuation allowance on its deferred tax assets that consist of federal and state net operating losses ("NOLs"), stock-based compensation and tax credits as of December 31, 2019 and 2018 (Note 11). The Company reduced its valuation allowance during the year ended December 31, 2017 for federal alternative minimum tax ("AMT") credit carryforwards that became fully refundable under the Tax Act (defined herein). See Note 11 for additional information.

As of December 31, 2019 and 2018, the Company had no uncertain tax positions. The Company recognizes the impact of an uncertain tax position in the consolidated financial statements only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. The Company did not recognize interest or penalties on uncertain tax positions for the years ended December 31, 2019, 2018 or 2017.

Adoption of New Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC Topic 842"). ASC Topic 842 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months on the balance sheet. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASC Topic 842 is effective for financial statements issued for annual and interim periods beginning on January 1, 2019. The Company has elected the optional transition method that provided the option to use the effective date of ASC Topic 842 as the date of initial application on transition. Accordingly, the Company did not adjust comparative periods or make the new required lease disclosures for periods before the effective date of January 1, 2019. There was no cumulative effect adjustment recognized to accumulated deficit upon adoption. As of the date of adoption of the new leasing standards, the Company recognized an operating lease ROU asset of approximately $17.3 million and a corresponding operating lease liability of approximately $17.9 million, which are included in the consolidated balance sheets. The adoption of the new leasing standards did not have a material impact on the consolidated statements of operations and comprehensive loss.

The Company elected to utilize the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance (i) without reassessing the classification of the operating leases in accordance with ASC Topic 842, (ii) without reassessing whether an existing contract contained a lease and (iii) without reassessing initial direct costs. In addition, the Company elected not to allocate the consideration between lease and non-lease components for its operating leases. The Company also reassessed its lease conclusions for its manufacturing plant in Athlone, Ireland, under ASC Topic 842 since construction was still in progress as of the date of adoption. Upon the reassessment, the Company concluded it was the owner of the leased space for accounting purposes under ASC Topic 842 as of the date of adoption and therefore, maintained its previous build-to-suit lease accounting under the transition guidance of ASC Topic 842.

In August 2018, the FASB issued Accounting Standards Update ("ASU") 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which amends ASC 350-40, *Internal-Use Software*, to include in its scope implementation costs of a cloud computing arrangement that is a service contract. Consequently, the accounting for costs incurred to implement a cloud computing arrangement that is a service arrangement, is aligned with the guidance on capitalizing costs associated with developing or obtaining internal-use software. This ASU is effective for the Company beginning January 1, 2019 and early adoption is permitted. The Company elected to early adopt this standard during the third quarter of 2018, which did not have a material impact on its consolidated financial statements and disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of ASC Topic 718, Compensation—Stock Compensation to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. This ASU was effective for the Company beginning January 1, 2019. The adoption of ASU 2018-07 did not have a material impact on the Company's consolidated financial statements and disclosures. In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("SAB 118") ("ASU 2018-05"), which adds guidance to clarify the treatment of income taxes based on changes enacted in December 2017 in H.R. 1 (referred to herein as the "Tax Act"). ASU 2018-05 incorporates references in ASC Topic 740 to SAB 118, which was issued in December 2017, to address the application of U.S. GAAP in situations when a registrant may not have the necessary information available in reasonable detail to complete the accounting for certain income tax effects. The guidance became effective immediately upon the enactment of the Tax Act in accordance with U.S. GAAP which requires deferred tax assets and liabilities to be revalued during the period in which new tax legislation is enacted. The Company's final impact assessment on the consolidated financial statements did not materially change from its initial estimates.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when changes to the terms or conditions of share-based payment awards must be accounted for as modifications. Under ASU 2017-09, an entity will not apply modification accounting to a share-based payment award if the award's fair value, vesting conditions and classification as an equity or liability instrument are the same immediately before and after the change. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. The guidance became effective for the Company beginning on January 1, 2018. The impact of the adoption of this guidance on its consolidated financial statements would be dependent on future modifications to share-based payment awards, if any.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory* ("ASU 2016-16"), which eliminates the exception to the principle in ASC Topic 740, *Income Taxes*, that generally requires comprehensive recognition of current and deferred income taxes for all intra-entity sales of assets other than inventory. As a result, a reporting entity would recognize the tax expense from the sale of the asset in the seller's tax jurisdiction when the transfer occurs, even though the pre-tax effects of that transaction are eliminated in consolidation. This ASU became effective for the Company on January 1, 2018 and was required to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to accumulated deficit as of the beginning of the period of adoption. At December 31, 2017, the Company had $2.1 million of income tax effects deferred from past intercompany transactions that were recorded as prepaid assets within other assets, net, at December 31, 2017 that were adjusted through accumulated deficit as of January 1, 2018.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"), which provides guidance related to the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. The guidance became effective for the Company beginning on January 1, 2018 and prescribes different transition methods for the various provisions. The adoption of ASU 2016-01 did not have a material impact on its consolidated financial statements and disclosures.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). The standard states that an entity should recognize revenue based on the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The FASB subsequently issued amendments to ASU 2014-09 that had the same effective date of January 1, 2018. The Company did not generate any revenue prior to the three months ended June 30, 2018, and therefore the adoption of ASC Topic 606 did not have an impact on the Company's financial statements for any prior periods or upon adoption. Revenue from sales of Rhopressa®, as well as any other future revenue arrangements, are and will be recognized under the provisions of ASC Topic 606.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The new standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The new standard was effective for the Company beginning on January 1, 2018; however, Aerie elected to early adopt this standard as of July 1, 2017. Under this guidance, the October 4, 2017 transaction to acquire assets from Envisia was determined to meet the criteria of an asset acquisition rather than a business combination resulting in a $24.8 million charge to research and development expense on the consolidated statement of operations and comprehensive loss in the three months ended December 31, 2017. See Note 1 for additional information.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which simplifies the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new ASU also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on January 1, 2021 and prescribes different transition methods for the various provisions. The Company is currently evaluating the impact of ASU 2019-12 on its consolidated financial statements and disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820-10): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which changes the fair value measurement disclosure requirements of ASC Topic 820, *Fair Value Measurements and Disclosures*. Under this ASU, certain disclosure requirements for fair value measurements are eliminated, amended or added. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The guidance is effective for the Company beginning on January 1, 2020 and prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2018-13 to have a material impact on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. Currently, U.S. GAAP delays recognition of the full amount of credit losses until the loss is probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down of the security. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* ("ASU 2018-19"), which clarifies that receivables from operating leases are accounted for using the lease guidance and not as financial instruments. The guidance is effective for the Company beginning on January 1, 2020, with early adoption permitted beginning on January 1, 2019. The new guidance prescribes different transition methods for the various provisions. The Company does not expect the adoption of ASU 2016-13 or ASU 2018-19 to have a material impact on its consolidated financial statements and disclosures.

Net Loss per Common Share

Basic net loss per common share ("Basic EPS") is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities with the exception of warrants for common stock with a $0.05 exercise price, which are exercisable for nominal consideration and are therefore included in the calculation of the weighted-average number of shares of common stock as common stock equivalents. Diluted net loss per share ("Diluted EPS") gives effect to all dilutive potential shares of common stock outstanding during this period. For Diluted EPS, net loss used in calculating Basic EPS may be adjusted for certain items related to the dilutive securities.

For all periods presented, Aerie's potential common stock equivalents have been excluded from the computation of Diluted EPS as their inclusion would have had an anti-dilutive effect.

The potential common stock equivalents that have been excluded from the computation of Diluted EPS consist of the following:

	DECEMBER 31,		
	2019	2018	2017
2014 Convertible Notes	—	—	5,040,323
Outstanding stock options	8,425,551	6,935,119	6,457,343
Stock purchase warrants	4,500	154,500	157,500
Nonvested restricted stock awards	754,415	572,706	447,049
Nonvested restricted stock units	41,811	—	—
Total	9,226,277	7,662,325	12,102,215

3. Revenue Recognition

Net product revenues for the year ended December 31, 2019 were generated from sales of Rhopressa® which was commercially launched in the United States at the end of April 2018, and sales of Rocklatan®, which was commercially launched in the United States in May 2019. For the year ended December 31, 2019, three distributors accounted for 36.5%, 33.3% and 28.0% of total revenues, respectively. For the year ended December 31, 2018, three distributors accounted for 33.9%, 33.3% and 29.7% of total revenues, respectively. The Company commenced generating product revenues related to sales of Rhopressa® in the second quarter of 2018. Product affordability for the patient drives consumer acceptance, and this is generally managed through coverage by third-party payers, such as government or private healthcare insurers and pharmacy benefit managers ("Third-party Payers") and such product may be subject to rebates and discounts payable directly to those Third-party Payers.

Product revenue is recorded net of trade discounts, allowances, rebates, chargebacks, estimated returns and other incentives, discussed below. These reserves are classified as either reductions of accounts receivable or as current liabilities. Amounts billed or invoiced are included in accounts receivable, net on the consolidated balance sheet. The Company did not have any contract assets (unbilled receivables) as of December 31, 2019 or 2018, as customer invoicing generally occurs before or at the time of revenue recognition. The Company did not have any contract liabilities as of December 31, 2019 or 2018, as the Company did not receive payments in advance of fulfilling its performance obligations to its customers. The Company calculates its net product revenue based on the wholesale acquisition cost that the Company charges its Distributors for Rhopressa® less provisions for (i) trade discounts and allowances, such as discounts for prompt payment and Distributor fees, (ii) estimated rebates to Third-party Payers, estimated payments for Medicare Part D prescription drug program coverage gap (commonly called the "donut hole"), patient co-pay program coupon utilization, chargebacks and other discount programs and (iii) reserves for expected product returns. Provisions for revenue reserves reduced product revenues by $105.9 million and $19.6 million in aggregate for the years ended December 31, 2019 and 2018, respectively, a significant portion of which related to commercial and Medicare Part D rebates.

Trade Discounts and Allowances: The Company generally provides discounts on sales of Rhopressa® and Rocklatan® to its distributors for prompt payment and pays fees for distribution services and for certain data that distributors provide to the Company. The Company expects its distributors to earn these discounts and fees, and accordingly deducts the full amount of these discounts and fees from its gross product revenues at the time such revenues are recognized.

Rebates, Chargebacks and Other Discounts: The Company contracts with Third-party Payers for coverage and reimbursement of Rhopressa® and Rocklatan®. The Company estimates the rebates and chargebacks it expects to be obligated to provide to Third-party Payers and deducts these estimated amounts from its gross product revenue at the time the revenue is recognized. The Company estimates the rebates and chargebacks that it expects to be obligated to provide to Third-party Payers based upon (i) the Company's contracts and negotiations with these Third-party Payers, (ii) estimates regarding the payer mix for Rhopressa® and Rocklatan® based on third-party data and utilization, (iii) inventory held by distributors and (iv) estimates of inventory held at the retail channel. Other discounts include the Company's co-pay assistance coupon programs for commercially-insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to pay associated with product that has been recognized as revenue.

Product Returns: The Company estimates the amount of Rhopressa® and Rocklatan® that will be returned and deducts these estimated amounts from its gross revenue at the time the revenue is recognized. The Company currently estimates product returns based on historical industry information regarding rates for comparable pharmaceutical products and product portfolios, the estimated remaining shelf life of Rhopressa® and Rocklatan® shipped to distributors, and contractual agreements with the Company's distributors intended to limit the amount of inventory they maintain. Reporting from the distributors includes distributor sales and inventory held by distributors, which provides the Company with visibility into the distribution channel to determine when product would be eligible to be returned.

4. Investments

Cash and cash equivalents and investments as of December 31, 2019 included the following:

(in thousands)	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
Cash and cash equivalents:				
Cash and cash equivalents	$ 143,940	$ —	$ —	$ 143,940
Total cash and cash equivalents	$ 143,940	$ —	$ —	$ 143,940
Investments:				
Commercial paper (due within 1 year)	$ 64,629	$ —	$ (7)	$ 64,622
Corporate bonds (due within 1 year)	60,640	—	(76)	60,564
U.S. Government and government agencies (due within 1 year)	40,073	—	(9)	40,064
Total investments	$ 165,342	$ —	$ (92)	$ 165,250
Total cash, cash equivalents and investments	$ 309,282	$ —	$ (92)	$ 309,190

Cash, cash equivalents and investments as of December 31, 2018 included the following:

(in thousands)	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
Cash and cash equivalents:				
Cash and cash equivalents	$ 202,818	$ —	$ —	$ 202,818
Total cash and cash equivalents	$ 202,818	$ —	$ —	$ 202,818

5. Fair Value Measurements

The following tables summarize the fair value of financial assets and liabilities that are measured at fair value and the classification by level of input within the fair value hierarchy:

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2019			
(in thousands)	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash and cash equivalents:				
Cash and cash equivalents	$ 133,931	$ 10,009	$ —	$ 143,940
Total cash and cash equivalents:	$ 133,931	$ 10,009	$ —	$ 143,940
Investments:				
Commercial paper	$ —	$ 64,622	$ —	$ 64,622
Corporate bonds	—	60,564	—	60,564
U.S. government and government agencies	—	40,064	—	40,064
Total investments	$ —	$ 165,250	$ —	$ 165,250
Total cash, cash equivalents and investments:	$ 133,931	$ 175,259	$ —	$ 309,190

(in thousands)	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2018			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash and cash equivalents:				
Cash and cash equivalents	$ 202,818	$ —	$ —	$ 202,818
Total cash and cash equivalents:	$ 202,818	$ —	$ —	$ 202,818

The fair value of the Convertible Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices observed in market trading. The market for trading of the Convertible Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the Convertible Notes was $372.9 million at December 31, 2019.

6. Inventory

Inventory consists of the following:

(in thousands)	DECEMBER 31, 2019	DECEMBER 31, 2018
Raw materials	$ 1,400	$ 836
Work-in-process	13,414	6,885
Finished goods	6,240	2,391
Total inventory	$ 21,054	$ 10,112

7. Property, Plant and Equipment, Net

Property, plant and equipment, net consists of the following:

(in thousands)	DECEMBER 31, 2019	DECEMBER 31, 2018
Manufacturing equipment	$ 18,073	$ 2,366
Laboratory equipment	7,525	6,038
Furniture and fixtures	1,648	1,815
Software, computer and other equipment	7,772	2,702
Leasehold improvements	29,720	4,072
Construction-in-progress	3,892	49,057
Property, plant and equipment	68,630	66,050
Less: Accumulated depreciation	(10,483)	(5,525)
Property, plant and equipment, net	$ 58,147	$ 60,525

Depreciation expense was $5.1 million, $2.4 million and $1.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Manufacturing Plant Build-Out

In the second quarter of 2019, the Company completed the build-out on its own manufacturing plant in Athlone, Ireland, for which it leases approximately 30,000 square feet of interior floor space and as such is not the legal owner of the space. However, in accordance with ASC Topic 842, the Company was deemed to be the owner of the leased space prior to completion of construction. Upon completion, the Company performed a sale-leaseback analysis and accounted for the transaction as a sale. The Company therefore derecognized the build-to-suit asset and the corresponding build-to-suit facility lease obligation of approximately $4.4 million as of the completion date. No gain or loss arose from the derecognition. The Company concurrently recognized an operating lease ROU asset and a corresponding operating lease liability related to the leaseback of the facility.

See Note 8 for additional information. The build-to-suit facility lease obligation was approximately $4.5 million as of December 31, 2018. Also, upon completion of the build-out in the second quarter of 2019, amounts previously classified as construction-in-progress related to the manufacturing plant placed into service have been transferred to leasehold improvements and manufacturing equipment and are being amortized in accordance with the Company's policy. See Note 2 for additional information.

8. Leases

The Company has operating leases for corporate offices, research and development facilities, and a fleet of vehicles. The properties primarily relate to the Company's principal executive office and research facility located in Durham, North Carolina, regulatory, commercial support and other administrative activities located in Irvine, California, and clinical, finance and legal operations located in Bedminster, New Jersey. The Durham, North Carolina, facility consists of approximately 61,000 square feet of laboratory and office space under leases that expire between June 2020 and June 2024 and the Irvine, California, location consists of approximately 37,300 square feet of office space under a lease that expires in January 2022. The Company terminated its previous lease and entered into a lease for its new Bedminster, New Jersey, location, which consists of approximately 34,000 square feet of office space under a lease that expires in October 2029. There are also small offices in Malta, Ireland, the United Kingdom and Japan.

The Company is leasing approximately 30,000 square feet of interior floor space in Athlone, Ireland, for its manufacturing plant in Athlone, Ireland, which the Company has concluded is an operating lease upon completion of the build-out in the second quarter of 2019. As a result, the Company concurrently recognized an operating lease ROU asset and a corresponding operating lease liability related to the leaseback of the facility of approximately $2.4 million upon completion of the build-out. The Company is reasonably certain it will remain in the lease through the end of its lease term in 2037, however, the Company is permitted to terminate the lease as early as September 2027.

The Company's operating leases have remaining lease terms of approximately 1 year to 18 years, some of which include options to extend the leases.

Balance sheet information related to leases was as follows:

(in thousands)	DECEMBER 31, 2019
Operating Leases	
Operating lease right-of-use assets	$ 16,523
Operating lease liabilities	$ 5,502
Long-term operating lease liabilities	12,102
Total operating lease liabilities	$ 17,604

The cash paid for amounts included in the measurement of lease liabilities was $4.7 million during the year ended December 31, 2019. The Company's right-of-use assets obtained in exchange for operating lease obligations was $3.1 million during the year ended December 31, 2019.

	DECEMBER 31, 2019
Operating Leases	
Weighted-average remaining lease terms	8 years
Weighted-average discount rate	8%

Maturities of lease liabilities as of December 31, 2019 were as follows:

(in thousands)	OPERATING LEASES
Year Ending December 31,	
2020	$ 5,879
2021	4,074
2022	1,925
2023	1,758
Thereafter	11,551
Total undiscounted lease payments	25,187
Less: present value adjustment	(7,583)
Total lease liabilities	$ 17,604

Lease expense for the Company's operating leases was $5.3 million, including variable lease payments of $1.3 million, for the year ended December 31, 2019, respectively.

Under prior lease guidance, minimum lease payments under operating leases were as follows at December 31, 2018:

(in thousands)	OPERATING LEASES
Year Ending December 31,	
2019	$ 4,283
2020	4,855
2021	4,278
2022	1,643
2023	1,438
Thereafter	6,698
Total minimum lease payments	$ 23,195

Rent expense for the Company's operating leases was $3.8 million and $2.0 million for the years ended December 31, 2018 and 2017, respectively.

9. Accrued Expenses & Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	DECEMBER 31, 2019	DECEMBER 31, 2018
Accrued expenses and other current liabilities:		
Accrued compensation and benefits	$ 11,169	$ 10,438
Accrued consulting and professional fees	3,810	3,927
Accrued research and development [1]	8,734	7,503
Accrued revenue reserves[2]	38,450	10,155
Accrued other[3]	3,213	6,358
Total accrued expenses and other current liabilities	$ 65,376	$ 38,381

(1) Comprised primarily of accruals related to fees for investigative sites, contract research organizations, contract manufacturing organizations and other service providers that assist in conducting preclinical research studies and clinical trials. Also included are liabilities incurred related to the Avizorex acquisition.

(2) Comprised primarily of accruals related to commercial and government rebates as well as returns.
(3) Comprised primarily of accruals related to accrued interest as well as other business-related expenses.

10. Debt

Convertible Notes

In September 2019, the Company issued an aggregate principal amount of $316.25 million of Convertible Notes to qualified institutional buyers pursuant to Rule 144A of the Securities Act of 1933, as amended. The Convertible Notes, governed by an indenture between the Company and a trustee, are senior, unsecured obligations and do not include financial and operating covenants nor any restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by Aerie or any of its subsidiaries. Interest on the Convertible Notes is payable semi-annually in cash in arrears at a rate of 1.50% per annum on April 1 and October 1 of each year, beginning on April 1, 2020. The Convertible Notes will mature on October 1, 2024 unless they are redeemed, repurchased or converted prior to such date. Prior to April 1, 2024, the Convertible Notes will be convertible at the option of holders only during certain periods and upon satisfaction of certain conditions. On and after April 1, 2024, the Convertible Notes will be convertible at the option of the holders any time until the close of business on the second scheduled trading day immediately preceding the maturity date. Upon conversion, the Convertible Notes may be settled in shares of Aerie common stock, cash or a combination, thereof, at the Company's election. The Company intends to settle the principal and interest amounts of the Convertible Notes in cash, and therefore, the Company currently does not expect the conversion to have a dilutive effect on the Company’s earnings per share, as applicable.

The Convertible Notes have an initial conversion rate of 40.04 shares of Aerie common stock per $1,000 principal amount of the Convertible Notes, which will be subject to customary anti-dilution adjustments in certain circumstances. This represents an initial effective conversion price of approximately $24.98 per share, which represents a premium of approximately 35% to the $18.50 per share closing price of Aerie common stock on September 4, 2019, the date the Company priced the offering.

The Company may redeem all or any portion of the Convertible Notes, at its option, on or after October 3, 2022, at a cash redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price of Aerie common stock exceeds 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately before the date the Company provides written notice of redemption; and the trading day immediately before the notice is sent.

Holders of Convertible Notes may require the Company to repurchase their Convertible Notes upon the occurrence of certain events that constitute a fundamental change under the indenture governing the Convertible Notes at a fundamental change repurchase price equal to 100% of the principal amount thereof, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

During the year ended December 31, 2019, the conditions allowing holders of the Convertible Notes to elect to convert had not been met. As of December 31, 2019, the if-converted value of the Convertible Notes did not exceed the principal amount of the Convertible Notes.

In connection with the issuance of the Convertible Notes, the Company incurred debt issuance costs of $9.2 million for the year ended December 31, 2019. In accordance with ASC Topic 470, *Debt*, these costs were allocated to debt and equity components in proportion to the allocation of proceeds. Issuance costs of $5.5 million were recorded as debt issuance costs in the net carrying value of Convertible Notes. The debt issuance costs are amortized on an effective interest basis over the term of the Convertible Notes. The remaining issuance costs of $3.7 million were recorded as additional paid-in capital, net with the equity component and such amounts are not subject to amortization.

The following table summarizes the carrying value of the Convertible Notes as of December 31, 2019:

(in thousands)	**DECEMBER 31, 2019**
Gross proceeds	$ 316,250
Unamortized debt discount and issuance costs	(127,599)
Carrying value	$ 188,651

The estimated fair value of the liability component of the Convertible Notes at the time of issuance was $187.9 million, and was determined based on a discounted cash flow analysis and a binomial lattice model. The valuation required the use of Level 3 unobservable inputs and subjective assumptions, including but not limited to the stock price volatility and bond yield. The equity component of the Convertible Notes was recognized at issuance and represents the difference between the principal amount of the Convertible Notes and the fair value of the liability component of the Convertible Notes at issuance. The equity component was approximately $128.4 million at the time of issuance and its fair value is not remeasured as long as it continues to meet the conditions for equity classification.

Separately, the Company entered into privately negotiated capped call options with financial institutions. The capped call options cover, subject to customary anti-dilution adjustments, the number of shares of Aerie common stock that initially underlie the Convertible Notes. The cap price of the capped call options is $37.00 per share of Aerie common stock, representing a premium of 100% above the closing price of $18.50 per share of Aerie common stock on September 4, 2019, and is subject to certain adjustments under the terms of the capped call options. The capped call options are generally intended to reduce or offset potential dilution to Aerie common stock upon conversion of the Convertible Notes with such reduction and/ or offset, as the case may be, subject to a cap based on the cap price. The Company paid a total of $32.9 million in premiums for the capped call options, which was recorded as additional paid-in capital, using a portion of the gross proceeds from the issuance and sale of the Convertible Notes. The capped call options are excluded from diluted earnings per share because the impact would be anti-dilutive.

Interest expense related to the Convertible Notes, including stated interest and amortization of debt discount and issuance costs, was $7.7 million for the year ended December 31, 2019.

Conversion of 2014 Convertible Notes

On July 23, 2018, Aerie entered into an Exchange and Termination Agreement (the “Exchange and Termination Agreement”) with Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P. and Deerfield Special Situations Fund, L.P. (collectively, the “Holders”). Pursuant to the Exchange and Termination Agreement, (i) the Holders converted the entire outstanding principal amount of the 2014 Convertible Notes into 5,040,323 shares of Aerie common stock (the “Conversion Shares”) in accordance with the terms of the 2014 Convertible Notes, which was recognized in stockholders’ equity, (ii) Aerie issued the Conversion Shares, and (iii) Aerie paid accrued and unpaid interest on the Convertible Notes through July 23, 2018.

In addition, as mutually agreed to with the Holders in order to complete the conversion on the date of the Exchange and Termination Agreement, Aerie issued an additional 329,124 shares of Aerie common stock (the “Additional Shares”) to the Holders. Aerie expensed the value of the Additional Shares in the amount of $24.1 million to other expense during the year ended December 31, 2018.

Credit Facility

In September 2019, the Company terminated its $200 million credit facility with certain entities affiliated with Deerfield Management Company L.P. (“Deerfield”) pursuant to which $100 million of delayed draw term loan commitments were provided by Deerfield in July 2018 (the “July 2018 tranche”) and $100 million of delayed draw term loan commitments were provided by Deerfield in May 2019 (the “May 2019 tranche”). Upon termination, the Company paid aggregate fees of $6.5 million to Deerfield in respect of the fee on undrawn amounts and the exit fee for each of the July 2018 tranche and May 2019 tranche. No funds were drawn under either tranche at the time of termination.

Interest expense was $15.3 million for the year ended December 31, 2019, and included amortization of debt discount and issuance costs related to the Convertible Notes and issuance costs and fees related to the credit facility. Interest expense was $2.5 million for the year ended December 31, 2018, and included amortization of debt discount and issuance costs related to the 2014 Convertible Notes (as defined below) through the date of conversion, as well as issuance costs and fees related to the July 2018 tranche of the credit facility. In July 2018, the entire outstanding principal amount of senior secured convertible notes (the “2014 Convertible Notes”) was converted into shares of Aerie common stock.

11. Income Taxes

The provision for income taxes is based on net loss before income taxes as follows:

(in thousands)	DECEMBER 31, 2019	2018	2017
Net loss before income taxes:			
United States	$ (153,620)	$ (203,230)	$ (133,113)
Non-U.S.	(46,051)	(29,336)	(13,750)
Net loss before income taxes	$ (199,671)	$ (232,566)	$ (146,863)

The components of the provision for income taxes are as follows:

(in thousands, except percentages)	DECEMBER 31, 2019	2018	2017
Provision for income taxes:			
Current:			
United States	$ (90)	$ 3	$ (24)
Non-U.S.	—	—	—
Total	$ (90)	$ 3	$ (24)
Deferred:			
United States	$ —	$ —	$ (1,734)
Non-U.S.	—	—	—
Total	—	—	(1,734)
Provision for income taxes	$ (90)	$ 3	$ (1,758)
Effective tax rate	0.05%	—%	1.20%

Significant components of the Company's net deferred income tax assets as of December 31, 2019 and 2018 consist of the following:

(in thousands)	DECEMBER 31, 2019	2018
Net deferred tax assets:		
Net operating loss carryforwards	$ 142,991	$ 112,375
Stock-based compensation	22,785	17,734
U.S. tax credit carryforwards	10,980	5,996
Envisia asset acquisition	5,476	5,888
Basis difference in intangibles	7,625	—
Convertible Notes	(22,822)	—
Other assets	5,154	2,857
Other liabilities	(1,867)	(1,535)
Valuation allowance	(170,322)	(143,315)
Total net deferred income taxes	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2019, 2018 and 2017 is as follows:

	DECEMBER 31,		
	2019	2018	2017
U.S. federal tax rate	21.00 %	21.00 %	35.00 %
Impact of federal tax legislation	— %	— %	25.82 %
State income taxes, net of federal benefit	4.97 %	4.56 %	7.71 %
Non-taxable foreign loss	(4.44)%	0.09 %	(0.51)%
Stock-based compensation	(1.47)%	1.97 %	(0.02)%
Other	0.98 %	(1.13)%	(2.19)%
Change in valuation allowance	(20.99)%	(26.49)%	(64.61)%
Effective tax rate	0.05 %	— %	1.20 %

The U.S. Tax Cuts and Jobs Act (the “Tax Act”), enacted on December 22, 2017, introduced significant changes to U.S. income tax law, including, among other things, reducing the U.S. statutory tax rate from 35% to 21% beginning in 2018. Under U.S. GAAP, deferred tax assets and liabilities are required to be revalued during the period in which the new tax legislation is enacted. Therefore, the deferred tax assets and liabilities were remeasured as of December 31, 2017, resulting in a reduction of the deferred tax asset balance and corresponding valuation allowance of $34.2 million due to the enacted changes in tax rate. The Tax Act also repealed the corporate AMT for tax years beginning after December 31,2017, and provides that existing AMT credit carryovers are refundable in tax years beginning after December 31, 2017. In March 2019, the IRS issued new guidance related to sequestration on the AMT tax credits. For taxable years beginning after December 31, 2017, refund payments and refund offset transactions due to refundable minimum tax credits will not be reduced due to federal sequestration. The Company has approximately $1.1 million of remaining AMT credit carryovers that are expected to be fully refunded between 2020 and 2022, of which $0.7 million is recorded as a current receivable with the remainder recorded as a non-current receivable within other assets on the consolidated balance sheet as of December 31, 2019.

The Act includes certain anti-deferral and anti-base erosion provisions, including a new minimum tax on global intangible low-taxed income (“GILTI”). The Act subjects the Company to current tax on GILTI of its controlled foreign corporations. Due to current year negative tested income for the Company’s foreign subsidiaries, the Company was not subject to GILTI in 2018 or 2019.

At December 31, 2019, the Company had federal and state NOL carryforwards of approximately $495.6 million and $510.3 million, respectively. If not utilized, federal NOLs that arose prior to 2018 and state NOLs will begin to expire at various dates beginning in 2031 and 2024, respectively. Federal NOLs that arose on or after January 1, 2018 can be carried forward indefinitely against future income, but can only be used to offset a maximum of 80% of the Company’s federal taxable income in any year. As of December 31, 2019, the Company also had foreign NOL carryforwards of $68.1 million, which are available solely to offset taxable income of its foreign subsidiaries, subject to any applicable limitations under foreign law.

Federal NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2019. Such objective evidence limits the ability to consider other subjective evidence, such as projections for future growth. On the basis of this evaluation, as of December 31, 2019, the Company maintains a valuation allowance on all of its deferred tax assets as of December 31, 2019. The amount of deferred tax asset considered realizable, however, could be adjusted if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to other subjective evidence such as projections for growth. As of December 31, 2019, 2018, 2017 and 2016, the Company had a valuation allowance of $170.3 million, $143.3 million, $83.4 million and $56.7 million, respectively. The increase in valuation allowance in 2019 and 2018 of $27.0 million and $59.9 million, respectively, was primarily due to the increase in NOL carryforwards. The increase in valuation allowance in 2017 of $26.7 million was primarily due to the increase in NOL carryforwards, offset by a reduction of the valuation allowance due to the enacted changes in tax rate and federal AMT credit carryforwards, which became fully refundable due to the Tax Act.

The Company does not have any unrecognized tax benefits as of December 31, 2019. The Company is subject to taxation in the United States, Ireland and Malta. As of December 31, 2019, tax years ended December 31, 2015 through December 31, 2018 are open under the statute of limitations and subject to tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS, state, or non-U.S. tax authorities to the extent utilized in a future period.

12. Stockholders' Equity

In September 2019, the Company issued an aggregate principal amount of $316.25 million of Convertible Notes, of which the equity component was approximately $128.4 million at the time of issuance. Separately, the Company entered into privately negotiated capped call options and paid $32.9 million in premiums. Refer to Note 10 for further information regarding the Convertible Notes.

During the year ended December 31, 2018, the Company received net proceeds of approximately $136.4 million through the issue and sale of Aerie's common stock pursuant to an "at-the-market" sales agreements ("ATMs") that commenced in December 2017 and pursuant to an underwriting agreement, dated January 23, 2018, relating to the registered public offering of approximately 1.3 million shares of Aerie's common stock.

During the year ended December 31, 2017, Aerie issued and sold approximately 1.1 million shares of common stock under ATMs entered into in May 2017 and December 2017, and received net proceeds of approximately $61.1 million, after deducting fees and expenses. The Company also entered into an underwriting agreement, dated May 25, 2017, relating to the registered public offering of approximately 1.4 million shares of Aerie's common stock at a price to the public of $53.75 per share, and received net proceeds of approximately $72.7 million, after deducting fees and expenses.

Holders of common stock are entitled to dividends when and if declared by Aerie's Board of Directors subject to prior rights of the holders of any preferred stock. The holder of each share of common stock is entitled to one vote.

Warrants

The Company had 4,500 underlying shares of warrants outstanding as of December 31, 2019, which are all currently exercisable at $5.00 per share and expire in August 2020. As of December 31, 2019 and 2018, all outstanding warrants are classified as equity and are recorded within additional paid-in capital on the consolidated balance sheets. In the fourth quarter of 2019, 298,481 warrants were exercised for shares of Aerie common stock.

13. Stock-based Compensation

Stock-based compensation expense for options granted, RSAs, PSAs, RSUs, SARs and stock purchase rights are reflected in the consolidated statements of operations and comprehensive loss as follows:

	YEAR ENDED DECEMBER 31,		
(in thousands)	**2019**	**2018**	**2017**
Selling, general and administrative	$ 30,463	$ 26,432	$ 18,613
Pre-approval commercial manufacturing	3,634	2,622	1,359
Research and development	10,996	9,674	6,106
Total	$ 45,093	$ 38,728	$ 26,078

As of December 31, 2019, the Company had $72.3 million of unrecognized compensation expense related to options outstanding under its equity plans. This expense is expected to be recognized over a weighted average period of 2.6 years as of December 31, 2019. As of December 31, 2019, the Company had $22.8 million of unrecognized compensation expense, related to unvested RSAs, including PSAs. This cost is expected to be recognized over a weighted average period of 2.7 years as of December 31, 2019.

Equity Plans

The Company maintains three equity compensation plans, the 2005 Aerie Pharmaceutical Stock Plan (the "2005 Plan"), the 2013 Omnibus Incentive Plan (the "2013 Equity Plan"), which was amended and restated as the Aerie Pharmaceuticals, Inc.

Second Amended and Restated Omnibus Incentive Plan (the "Second Amended and Restated Equity Plan"), as described below, and the Aerie Pharmaceuticals, Inc. Inducement Award Plan (the "Inducement Award Plan"), as described below. The 2005 Plan, the Second Amended and Restated Equity Plan and the Inducement Award Plan are referred to collectively as the "Plans."

On October 30, 2013, the effective date of the 2013 Equity Plan, the 2005 Plan was frozen and no additional awards have been or will be made under the 2005 Plan. Any remaining shares available for future grant under the 2005 Plan were allocated to the 2013 Equity Plan. On April 10, 2015, Aerie's stockholders approved the adoption of the Aerie Pharmaceuticals, Inc. Amended and Restated Omnibus Incentive Plan ("Amended and Restated Equity Plan") and no additional awards have been or will be made under the 2013 Equity Plan. Any remaining shares available under the 2013 Equity Plan were allocated to the Amended and Restated Equity Plan.

On June 7, 2018, Aerie's stockholders approved the adoption of the Second Amended and Restated Equity Plan to increase the number of shares issuable under the Plan by 4,500,000. The Second Amended and Restated Equity Plan provides for the granting of up to 10,229,068 equity awards in respect of common stock of Aerie, including equity awards that were previously available for issuance under the 2013 Equity Plan.

On December 7, 2016, Aerie's Board of Directors approved the Inducement Award Plan which provides for the granting of up to 418,000 equity awards in respect of common stock of Aerie and was subsequently amended during the year ended December 31, 2017 to increase the equity awards that may be issued by an additional 874,500 shares. On December 5, 2019, the Inducement Award Plan was further amended by the Company's Board of Directors to increase the number of shares issuable under the plan by 100,000 shares. Awards granted under the Inducement Award Plan are intended to qualify as employment inducement awards under NASDAQ Listing Rule 5635(c)(4).

Options to Purchase Common Stock

Weighted average assumptions utilized in the fair value calculation for options to purchase common stock as of December 31, 2019, 2018 and 2017 are as follows:

	YEAR ENDED DECEMBER 31,		
	2019	2018	2017
Expected term (years)	6.0	6.0	6.0
Expected stock price volatility	74%	78%	84%
Risk-free interest rate	1.9%	2.7%	2.0%
Dividend yield	—%	—%	—%

The following table summarizes the stock option activity under the Plans:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	AGGREGATE INTRINSIC VALUE (000's)
Options outstanding at December 31, 2018	6,935,119	$ 28.96		
Granted	2,252,643	31.37		
Exercised	(287,148)	16.29		
Canceled	(474,572)	46.45		
Expired	(491)	0.41		
Options outstanding at December 31, 2019	8,425,551	$ 29.06	6.7	$ 42,107
Options exercisable at December 31, 2019	5,469,307	$ 24.23	5.5	$ 40,598

The weighted-average fair values of all stock options granted for the years ended December 31, 2019, 2018 and 2017 was $20.70, $38.38, and $35.01, respectively. The aggregate intrinsic value of options exercised for the years ended December 31, 2019, 2018 and 2017 was $4.2 million, $32.0 million and $8.6 million, respectively. The intrinsic value is calculated as the difference between the fair market value at December 31, 2019 and the exercise price per share of the stock options. The fair market value per share of common stock as of December 31, 2019 was $24.17.

The following table provides additional information about stock options that are outstanding and exercisable at December 31, 2019:

EXERCISE PRICE	OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	OPTIONS EXERCISABLE
$0.20 - $10.00	1,454,195	3.5	1,454,195
$10.01 - $20.00	1,067,692	6.5	855,530
$20.01 - $30.00	2,597,369	6.8	1,558,247
$30.01 - $45.00	1,283,424	7.7	698,592
$45.01 - $55.00	1,233,270	8.3	513,798
$55.01 - $73.10	789,601	8.2	388,945
	8,425,551		5,469,307

Restricted Stock Awards

The following table summarizes the RSA, including PSAs, activity under the Plans:

	NUMBER OF SHARES	WEIGHTED AVERAGE FAIR VALUE PER SHARE
Nonvested RSAs at December 31, 2018	572,706	$ 48.18
Granted	519,167	40.07
Vested	(214,276)	45.76
Canceled	(123,182)	49.64
Nonvested RSAs at December 31, 2019	754,415	$ 43.07

The vesting of the RSAs is time and service based with terms of 1 to 4 years. The total fair value of restricted stock vested during the years ended December 31, 2019, 2018 and 2017 was $9.8 million, $5.1 million and $1.3 million, respectively. During the year ended December 31, 2017, the Company granted 98,817 RSAs with non-market performance conditions that vest upon the satisfaction of certain performance conditions and service conditions. During the year ended December 31, 2019, vesting for the remaining PSAs was deemed probable to occur. As of December 31, 2019, 69,171 PSAs were vested.

Restricted Stock Units

As of September 30, 2019, 43,071 nonvested RSAs were cancelled and replaced with a corresponding number of RSUs. The RSUs were issued with the same vesting provisions as the cancelled RSAs. Accordingly, the 43,071 RSUs outstanding at September 30, 2019 were nonvested. As of December 31, 2019, the weighted average fair value per RSU was $19.22, and the associated unrecognized compensation expense totaled $1.9 million. This expense is expected to be recognized over the weighted average period of 2.7 years as of December 31, 2019. As of December 31, 2019, 41,811 RSUs were outstanding.

Stock Appreciation Rights

The following table summarizes the SARs activity under the Plans:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	AGGREGATE INTRINSIC VALUE (000's)
SARs outstanding at December 31, 2018	91,000	$ 53.75		
Granted	113,851	33.73		
Exercised	—	—		
Canceled	(41,835)	46.21		
SARs outstanding at December 31, 2019	163,016	$ 41.70	3.9	$ 25
SARs exercisable at December 31, 2019	18,000	$ 53.68	3.3	$ —

Holders of the SARs are entitled under the terms of the Plans to receive cash payments calculated based on the excess of Aerie's common stock price over the exercise price in their award; consequently, these awards are accounted for as liability-classified awards and the Company measures compensation cost based on their estimated fair value at each reporting date, net of actual forfeitures, if any.

Employee Stock Purchase Plan

The Company maintains the 2013 Employee Stock Purchase Plan (the "Purchase Plan") under which substantially all employees may purchase Aerie's common stock through payroll deductions and lump sum contributions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of the offering periods. Employees may not purchase more than the fair value equivalent of $25,000 of stock during any calendar year. The Purchase Plan provides for the issuance of up to 645,814 shares of Aerie's common stock.

14. Commitments and Contingencies

Milestone Payments

In association with the Avizorex acquisition (see Note 1), contingent milestone payments of up to $69.0 million may be due, subject to achievement of certain product regulatory approvals using the IPR&D assets acquired. Further, in association with the Envisia asset acquisition (see Note 1), contingent milestone payments of up to $45.0 million may be due, subject to achievement of certain product regulatory approvals using the IPR&D assets acquired, if achieved within the 15-year milestone period. Lastly, the Collaboration Agreement with DSM (see Note 1) includes contingent payments of up to $75 million that may be due to DSM upon the achievement of certain development and regulatory milestones. These contingent milestone payments are recognized only when the contingency is resolved (the milestone is achieved) and the consideration is paid or becomes payable. As of December 31, 2019, there were no liabilities recorded relating to potential future milestone payments as the achievement of the related milestones were not met and the timing and likelihood of such milestone payments are not known.

Litigation

The Company may periodically become subject to legal proceedings and claims arising in connection with its business. The Company is not a party to any known litigation, is not aware of any material unasserted claims and does not have contingency reserves established for any litigation liabilities.

15. Segment Information

Aerie has one operating segment: the discovery, development and commercialization of pharmaceutical products that address unmet medical needs, focusing on open-angle glaucoma, dry eye, retinal diseases and potentially other diseases of the eye. The Company's business is managed by a single management team, which reports to the Chief Executive Officer.

The following table presents total long-lived assets by geographic location:

	DECEMBER 31,	
(in thousands)	**2019**	**2018**
United States	$ 9,184	$ 10,393
Ireland	48,963	50,132
Total long-lived assets	$ 58,147	$ 60,525

16. Selected Quarterly Financial Data (Unaudited)

The following table presents selected unaudited quarterly financial information for the years ended December 31, 2019 and 2018. The results for any quarter are not necessarily indicative of future quarterly results and, accordingly, period to period comparisons should not be relied upon as an indication of future performance.

	FOR THE QUARTER ENDED			
(in thousands, except per share amounts)	**DECEMBER 31,**	**SEPTEMBER 30,**	**JUNE 30,**	**MARCH 31,**
2019				
Total revenues, net	$ 24,657	$ 18,544	$ 15,835	$ 10,852
Total costs and expenses	$ 74,595	$ 61,871	$ 61,910	$ 59,004
Net loss	$ (55,064)	$ (49,402)	$ (47,164)	$ (47,951)
Net loss per common share—basic and diluted	$ (1.21)	$ (1.09)	$ (1.04)	$ (1.06)

	DECEMBER 31,	**SEPTEMBER 30,**	**JUNE 30,**	**MARCH 31,**
2018				
Total revenues, net	$ 14,456	$ 7,302	$ 2,423	$ —
Total costs and expenses	$ 66,381	$ 68,640	$ 58,107	$ 40,795
Net loss	$ (51,458)	$ (85,388)	$ (55,024)	$ (40,699)
Net loss per common share—basic and diluted	$ (1.14)	$ (1.96)	$ (1.40)	$ (1.05)

Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934

As of December 31, 2019, Aerie Pharmaceuticals, Inc., a Delaware corporation, had one class of securities registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act"): Common Stock, par value $0.001 per share (the "Common Stock"). The following summary includes a brief description of the Common Stock, as well as certain related additional information. Unless the context requires otherwise, references to "we," "us," "our" and the "Company" refer to Aerie Pharmaceuticals, Inc.

General

Our amended and restated certificate of incorporation authorizes us to issue up to 150,000,000 shares of Common Stock and 15,000,000 shares of preferred stock, par value $0.001 per share. As of December 31, 2019, we had issued and outstanding 46,464,669 shares of Common Stock and no shares of preferred stock.

In addition, as of December 31, 2019, we had outstanding 754,415 shares of restricted stock, options to purchase 8,425,551 shares of Common Stock and warrants to purchase 4,500 shares of Common Stock.

As of December 31, 2019 we had 206 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Common Stock

Holders of Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders (provided that, except as required by law, holders of Common Stock are not entitled to vote on any amendment to our amended and restated certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to our amended and restated certificate of incorporation) and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of Common Stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of Common Stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of Common Stock have no preemptive, subscription, redemption or conversion rights. All outstanding shares of Common Stock are fully paid and non-assessable. The rights, preferences and privileges of holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Stock Options

As of December 31, 2019, options to purchase 8,425,551 shares of Common Stock at a weighted average exercise price of $29.06 per share were outstanding, of which options to purchase 5,469,307 shares of Common Stock were exercisable, at a weighted average exercise price of $24.23 per share.

Warrants

As of December 31, 2019, the following warrants were outstanding:

Number of Underlying Shares	Exercise Price Per Share	Warrant Expiration Date
4,500	$5.00	August 2020

Anti-Takeover Provisions

Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Staggered Board; Removal of Directors

Our amended and restated certificate of incorporation and our amended and restated bylaws divide our board of directors into three classes with staggered three-year terms. In addition, subject to the rights of any outstanding preferred stock, a director may be removed only for cause. Subject to the rights of any outstanding preferred stock, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our amended and restated certificate of incorporation provides that, subject to the rights of any outstanding preferred stock, the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the removal of directors, change to the authorized numbers of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of the Company.

Stockholder Action by Written Consent; Special Meetings

Our amended and restated certificate of incorporation provides that our stockholders may not act by written consent. Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors.

Advance Notice Requirements for Stockholder Proposals

Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (a) by persons who are directors and also officers and (b) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Amendments to Our Bylaws

The DGCL provides generally that the affirmative vote of a majority of the shares presents at any meeting and entitled to vote on a matter is required to amend a corporation's bylaws, unless a corporation's bylaws requires a greater percentage. Our amended and restated bylaws may be amended or repealed by (i) subject to the rights of any outstanding preferred stock, a vote of the majority of the directors present at any regular or special meeting of our board of directors at which a quorum is present, or (ii) the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors.

Corporate Opportunities

To address situations in which officers or directors may have conflicting duties to different corporations, Section 122(17) of the DGCL allows a corporation to renounce, in its certificate of incorporation or by action of its board of directors, any interest or expectancy of the corporation in specified classes or categories of business opportunities. Our amended and restated certificate of incorporation renounces any interest or expectancy in, or in being offered an opportunity to participate in, any business opportunity that may be a corporate opportunity for any of ACP IV, L.P., Clarus Lifesciences II, L.P., Sofinnova Venture Partners VII, L.P. or TPG Funds, L.P. or any of their respective affiliates or any of their or their affiliates' respective partners, members, directors, stockholders, employees or agents (whether or not any such person is our

director), other than someone who is our employee. We do not renounce our interest in any corporate opportunity offered to any such person if such opportunity is offered to such person expressly and solely in his or her capacity as our director.

Limitation on Liability and Indemnification of Officers and Directors

Our amended and restated certificate of incorporation limits the liability of directors to the fullest extent Delaware law permits. The effect of these provisions is to eliminate the rights of the Company and our stockholders, through stockholders' derivative suits on behalf of the Company, to recover monetary damages against a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, our directors will be personally liable to us and our stockholders for any breach of the director's duty of loyalty, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, under Section 174 of the DGCL or for any transaction from which the director derived an improper personal benefit. In addition, our amended and restated certificate of incorporation and bylaws provide that we will indemnify our directors and officers to the fullest extent Delaware law permits. We have entered into indemnification agreements with our current directors and officers. We also maintain directors and officers insurance.

Listing on the Nasdaq Global Market

Our Common Stock is listed on the Nasdaq Global Market under the symbol "AERI."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC.

The foregoing summary does not purport to be complete and is subject to, and qualified in its entirety by, the full text of our amended and restated certificate of incorporation and our amended and restated bylaws. For additional information we encourage you to read: our amended and restated certificate of incorporation and our amended and restated bylaws, both of which are exhibits are exhibits to our Annual Report on Form 10-K; and applicable provisions of the DGCL, including Section 203.

The XXXXXXXXXXXX denotes information that has been redacted.

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "**Agreement**") made as of the 7th of October, 2019 (the "**Effective Date**") is by and between **Aerie Pharmaceuticals, Inc**., a Delaware corporation with principal executive offices at 4301 Emperor Blvd. Suite 400, Durham NC 27703 (the "**Company**"), and **David Hollander**, residing at XXXXXXXXXXXX (the "**Executive**").

W I T N E S S E T H:

WHEREAS, Company desires to employ Executive as its Chief Research & Development Officer; and

WHEREAS, Executive desires to accept such employment and to serve the Company in such capacity, upon the terms and subject to the conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties hereto hereby agree as follows:

1.Employment. The Company agrees to employ Executive, and Executive agrees to be employed by the Company, upon the terms and subject to the conditions of this Agreement.

2. Term. Subject to Sections 8 and 9 hereof, the Company agrees to employ Executive and Executive agrees to be employed by the Company, in each case pursuant to this Agreement, for a period commencing on November 11, 2019 or sooner (the "**Start Date**") and ending on the third anniversary of the Start Date (the "**Initial Term**"). This Agreement will renew automatically for successive one (1) year periods (each, a "**Renewal Period**") unless either party gives notice of non-renewal at least 90 days prior to the end of the Initial Term or the then-current Renewal Period, as applicable (the Initial Term and any Renewal Period are collectively referred to as the "**Term**"). Each additional Renewal Period shall be added to the end of the next scheduled expiration date of the Initial Term or Renewal Period, as applicable, as of the first day after the last day on which notice may be given pursuant to the preceding sentence.

3. Duties; Place of Performance; Etc.

(a) Executive shall serve as Chief Research & Development Officer of the Company and shall report to the Chairman & Chief Executive Officer of the Company (the "**CEO**"). Subject to the direction of the Chairman & CEO and the Board of Directors (the "**Board**"), as applicable, Executive shall have such powers and perform such duties as are reasonably determined by the Chairman & CEO and the Board, but shall be consistent with the duties customarily performed by the Chief Research & Development Officer of a similarly situated company in the United States.

(b) Executive shall devote substantially all of his business time, attention and energies to the business and affairs of the Company and shall use his best efforts to advance the interests of the Company and shall not during the Term be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, which will interfere with the performance by Executive of his duties hereunder or Executive's availability to perform such duties or that will adversely affect, or negatively reflect upon, the Company. Following execution of this Agreement, should Executive be, or desire to become, engaged as a consultant, owner, director officer or advisor of any other venture, Executive must obtain the prior written consent of the Board, which consent may be withheld in the Board's sole discretion.

(c) The duties to be performed by Executive hereunder shall be performed primarily at the offices of the Company or such other place as the Board may authorize; *provided*, *however*, that Executive understands that his duties will require periodic travel, which may be substantial at times.

4. Compensation. As full compensation for the performance by Executive of his duties under this Agreement, the Company shall pay Executive as follows:

(a) Base Salary. The Company shall pay Executive an annual base salary (the "**Base Salary**") equal to Four Hundred and Thirty Thousand Dollars ($430,000), payable in accordance with the Company's normal payroll practices. Executive's Base Salary may be increased at the discretion of the Board but may not be decreased by the Board except as a proportional reduction, as to the salaries of all other officers of the Company at the level of Vice President and above as part of an overall reduction in salaries decided by the Board in good faith as being in the best interests of the Company and its stockholders, and will only be so reduced during such time as all such other executive officer salaries remain so reduced.

(b) Performance Bonus.

(i) During the Term, Executive shall also be eligible to receive an annual cash performance bonus (the "**Performance Bonus**") based on a target equal of fifty percent (50%) of Executive's Base Salary. The actual amount of such Performance Bonus shall be determined by the Board, or a designated committee thereof, and shall be based on the achievement of specific performance objectives to be established by the Chairman & CEO and approved by the Board, or a designated committee thereof, on an annual basis (the "**Performance Goals**"). Executive's Performance Bonus with respect to calendar year 2019 will be One Hundred Eighty-Five Thousand Dollars ($185,000) and will be payable on a date certain in February 2020 (the "**2019 Bonus Payment Date")**. If Executive voluntarily leaves or is terminated for cause within two years of the **2019 Bonus Payment Date**, Executive will pay the Company back the full amount of such Bonus within 10 days of leaving his position.

(ii) During the Term of this Agreement, Executive and the Chairman & CEO shall meet no later than the end of each year to mutually determine Executive's performance objectives for the subsequent calendar year, which objectives shall be approved by the Board, or a designated committee thereof. If Executive and the Chairman & CEO are unable to agree upon such objectives for the relevant year despite mutual good faith efforts to do so, then the objectives will be determined in the good faith discretion by the Chairman & CEO no later than January 15th and will be communicated promptly to Executive in writing after being so determined and will be deemed to have been accepted by Executive.

(iii) Subject to the terms of paragraph 4(b)(i), hereof any Performance Bonus payable to Executive pursuant to this Section 4(b), shall be paid to Executive on or before March 15th of the subsequent calendar year, subject to continued employment through the date of payment.

(c) Withholding. The Company shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts payable to Executive under this Section 4.

(d) Equity Grants.

(i) Stock Options. As soon as practicable after the Start Date, the Company will grant to Executive an option (the "**Initial Option**") pursuant to the Company's Inducement Award Plan (the

"**Inducement Plan**") to purchase 110,000 shares of common stock of the Company (the "**Initial Option Shares**"). The exercise price per share of Executive's Initial Option will be equal to the closing NASDAQ quote on the date that the Initial Option is granted. The Initial Option shall vest, subject to Executive's continued employment, as follows: (A) one-quarter of the Initial Option Shares shall vest and become exercisable on the first anniversary of the Start Date (the "**Initial Vesting Date**") and (B) the balance of the Initial Option Shares shall vest and become exercisable in thirty-six (36) equal monthly installments on each consecutive monthly anniversary of the Initial Vesting Date. The final terms of the Initial Option shall be set forth in an individual option award agreement to be provided to Executive and in the Inducement Plan.

(ii) Restricted Stock. As soon as practicable after the Start Date, the Company will grant to Executive 25,000 shares of restricted common stock of the Company (the "**Restricted Stock**") pursuant to the Inducement Plan. The Restricted Stock shall vest, subject to Executive's continued employment, in four equal annual installments on each of the first four annual anniversaries of the Start Date. The final terms of the Restricted Stock shall be set forth in an individual restricted stock award agreement to be provided to Executive and in the Inducement Plan.

(iii) Additional Equity Grants. During the Term hereof, Executive will be eligible to receive equity incentive awards, which may be in the form of stock options, restricted stock grants or other equity incentive awards under or outside of the Company's Amended and Restated Omnibus Incentive Plan and under any successor equity incentive plans of the Company, as the Board in its sole discretion determines to be appropriate.

(e) Expenses. The Company shall reimburse Executive for all normal, usual and necessary expenses incurred by Executive in furtherance of the business and affairs of the Company, including reasonable travel and entertainment, upon timely receipt by the Company of appropriate vouchers or other proof of Executive's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company.

(f) Insurance.

(i) Executive shall be designated as a named insured on any directors' and officers' liability insurance the Company may have.

(ii) The Company will provide Executive, at the Company's expense, with a life insurance benefit plan with terms and coverage appropriate for Executive's position with the Company, which policy amount shall be equal to no less than one year's Base Salary in effect at the time the policy was acquired. The Company also will provide Executive with medical, dental, vision, short-term and long-term disability plans in accordance with the current Company benefits program.

(g) Executive Benefits. Executive will receive the Company's standard employee benefits package (including health and disability insurance with ninety-five percent (95%) of the cost paid by the Company, participation in the Company's 401(k) plan subject to the terms and conditions thereof) as such package and policies are in effect from time to time, and as such benefits package may be adjusted by the Board in good faith during the Term hereof, as applicable to all employees, which benefits package can be increased, but cannot be decreased unless such decrease is effected in connection with, and is proportional to, an overall reduction in the relevant benefits to all executive officers, and will only be so reduced during such time as all such other relevant executive officer benefits remain so reduced.

(h) Vacation. Executive shall, during the Term, be entitled to four (4) weeks of vacation per annum, in addition to eleven (11) holidays and six (6) sick days provided as part of the Company's benefit programs.

5. Confidential Information and Inventions.

(a) Executive recognizes and acknowledges that in the course of his duties he is likely to receive confidential or proprietary information owned by the Company, its Affiliates or third parties with whom the Company or any such Affiliates has an obligation of confidentiality. Accordingly, during and after the Term, Executive agrees to keep confidential and not disclose or make accessible to any other person or use for any other purpose other than in connection with the fulfillment of his duties under this Agreement, any Confidential and Proprietary Information (as defined below) owned by, or received by or on behalf of, the Company or any of its Affiliates. "**Confidential and Proprietary Information**" shall include, but shall not be limited to, confidential or proprietary scientific or technical information, data, formulas and related concepts, business plans (both current and under development), client lists, promotion and marketing programs, trade secrets, or any other confidential or proprietary business information relating to development programs, costs, revenues, marketing, investments, sales activities, promotions, credit and financial data, manufacturing processes, financing methods, plans or the business and affairs of the Company or of any Affiliate or client of the Company. Additionally, information that, by its nature and content, would be readily recognized by a reasonable person to be proprietary to the Company shall also be deemed Confidential and Proprietary Information. Executive expressly acknowledges the trade secret status of the Confidential and Proprietary Information and that the Confidential and Proprietary Information constitutes a protectable business interest of the Company. Executive agrees not to:

(i) use any such Confidential and Proprietary Information for personal use or for others; and

(ii) permanently remove any Company material or reproductions (including but not limited to writings, correspondence, notes, drafts, records, invoices, technical and business policies, computer programs or disks) thereof from the Company's offices at any time during his employment by the Company, except as required in the execution of Executive's duties to the Company; *provided*, *however*, that Executive shall not be prevented from using or disclosing any Confidential and Proprietary Information:

(A) that Executive can demonstrate was known to him prior to the Effective Date;

(B) that is now, or becomes in the future, available to persons who are not required, by contract or otherwise, to treat such information as confidential unless such persons acquired the Confidential and Proprietary Information through acts or omissions of Executive; or

(C) that Executive is compelled to disclose pursuant to the order of a court or other governmental or legal body having jurisdiction over such matter, provided that (1) Executive shall give Company sufficient advance written notice of such required disclosure to permit it to seek a protective order or other similar order with respect to such Confidential and Proprietary Information, and (2) thereafter Executive shall disclose only the minimum Confidential and Proprietary Information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by the Company.

The Confidential and Proprietary Information that is disclosed pursuant to this paragraph shall remain Confidential and Proprietary Information for all other purposes.

Notwithstanding the foregoing, nothing herein shall preclude Executive's right to communicate, cooperate or file a complaint with any U.S. federal, state or local governmental or law enforcement branch, agency or entity (collectively, a "**Governmental Entity**") with respect to possible violations of any U.S. federal, state or local law or regulation, or otherwise make disclosures to any Governmental Entity, in each case, that are protected under the whistleblower or similar provisions of any such law or regulation; *provided* that in each case such communications and disclosures are consistent with applicable law. In addition, Executive acknowledges that Executive has received notice of the immunity from liability to which Executive is entitled for the disclosure of confidential information or a trade secret to the government or in a court filing as provided by Federal law, as set forth in Exhibit A to this Agreement.

(b) Executive agrees to immediately return to the Company all Company material and reproductions thereof (including but not limited, to writings, correspondence, notes, drafts, records, invoices, technical and business policies, computer programs or disks) in his possession upon request and in any event immediately upon termination of employment.

(c) Except with prior written authorization by the Company, Executive agrees not to disclose or publish any of the Confidential and Proprietary Information, or any confidential, scientific, technical or business information of any other party to whom the Company or any of its Affiliates owes a legal duty of confidence, at any time during or after his employment with the Company.

(d) Executive agrees that all inventions, discoveries, improvements and patentable or copyrightable works, relating to the Company's business ("**Inventions**") initiated, conceived or made by him, either alone or in conjunction with others, during the Term shall be the sole property of the Company to the maximum extent permitted by applicable law and, to the extent permitted by law, shall be "works made for hire" as that term is defined in the United States Copyright Act (17 U.S.C.A., Section 101). The Company shall be the sole owner of all patents, copyrights, trade secret rights, and other intellectual property or other rights in connection therewith. Executive hereby assigns to the Company all right, title and interest he may have or acquire in all such Inventions; *provided*, *however*, that the Board may in its sole discretion agree to waive the Company's rights pursuant to this Section 5(d) with respect to any Invention that is not directly or indirectly related to the Company's business. Executive further agrees to assist the Company in every proper way (but at the Company's expense) to obtain and from time to time enforce patents, copyrights or other rights on such Inventions in any and all countries, and to that end Executive will execute all documents necessary:

(i) to apply for, obtain and vest in the name of the Company alone (unless the Company otherwise directs) letters patent, copyrights or other analogous protection in any country throughout the world and when so obtained or vested to renew and restore the same; and

(ii) to defend any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection.

(e) Executive acknowledges that while performing the services under this Agreement Executive or other employees, agents or advisors of the Company or its Affiliates in the course of their services on behalf of the Company, may locate, identify and/or evaluate molecules, compounds, products and product candidates having commercial potential in the specific segments of the pharmaceutical or biotechnology

research and development industries in which the Company is then operating (the "**Corporate Opportunities**"). Executive understands, acknowledges and agrees that Executive shall not pursue any such Corporate Opportunity for himself or for others unless on behalf of the Company or unless such Corporate Opportunity is first offered to the Company and the Board rejects such Corporate Opportunity. Notwithstanding the foregoing, nothing in this Agreement shall be construed as a limitation of Executive's fiduciary duties as an officer and director of the Company.

(f) The provisions of this Section 5 shall survive any termination of this Agreement.

6. Non-Solicitation; Non-Disparagement.

(a) During the Term and for a period of 12 months thereafter, Executive shall not, directly or indirectly, without the prior written consent of the Company engage in any Prohibited Solicitation. For purposes of this Agreement, a "**Prohibited Solicitation**" shall mean Executive's (i) directly or indirectly hiring, contacting, inducing or soliciting (or assisting any Person to hire, contact, induce or solicit) for employment any person who is, or within six (6) months prior to the date of such hiring, contacting, inducing or soliciting was, an employee of the Company or any of its Affiliates, or (ii) directly or indirectly inducing or soliciting (or assisting any Person to induce or solicit) any customer, client or vendor of, or other person having a business relationship with, the Company or any of its Affiliates to terminate its relationship or otherwise cease doing business in whole or in part with the Company or any of its Affiliates, or directly or indirectly interfering with (or assist any Person to interfere with) any relationship between the Company or any of its Affiliates and any of their respective customers, clients, vendors or any other business contacts.

(b) During the Term and at all times thereafter, (i) Executive agrees he shall not, directly or indirectly, make or encourage any other individual to make any public or private comments, orally or in written form (including, without limitation by e-mail or other electronic transmission), whether or not true, that would "disparage" the Company, or any of its officers, directors, managers, or significant stockholders and (ii) the Company agrees not to issue any public statement that would "disparage" Executive, and shall advise its officers and directors not to make any such statement on the Company's behalf. "Disparaging" statements are those which impugn the character, capabilities, reputation or integrity of the aforesaid individuals or entity or which accuse the aforesaid individuals or entity of acting in violation of any law or governmental regulation or of condoning any such action, or otherwise acting in an unprofessional, dishonest, disreputable, improper, incompetent or negligent manner, but shall not include truthful statements required by due legal process. Notwithstanding the foregoing, nothing in this Agreement shall preclude the parties hereto or their successors from making truthful statements in the proper performance of their jobs or that are required by applicable law, regulation or legal process, and the parties shall not violate this provision in making truthful statements in response to disparaging statements made by the other party.

(c) In the event that Executive materially breaches any provisions of Section 5 or this Section 6, then, in addition to any other rights that the Company may have, the Company shall be entitled to seek injunctive relief to enforce the restrictions contained in such Sections, which injunctive relief shall be in addition to any other rights or remedies available to the Company under the law or in equity.

(d) The right and remedy enumerated in Section 6(c) shall be independent of and shall be in addition to and not in lieu of any other rights and remedies available to the Company at law or in equity. If any of the covenants contained in this Section 6, or any part of any of them, is hereafter construed or adjudicated to be invalid or unenforceable, the same shall not affect the remainder of the covenant or covenants or rights or remedies which shall be given full effect without regard to the invalid portions. If any of the covenants contained in this Section 6 are held to be invalid or unenforceable because of the duration of such

provision or the area covered thereby, the parties agree that the court making such determination shall have the power to reduce the duration and/or area of such provision and in its reduced form such provision shall then be enforceable. No such holding of invalidity or unenforceability in one jurisdiction shall bar or in any way affect the Company's right to the relief provided in this Section 6 or otherwise in the courts of any other state or jurisdiction within the geographical scope of such covenants as to breaches of such covenants in such other respective states or jurisdictions, such covenants being, for this purpose, severable into diverse and independent covenants.

(e) In the event that an actual proceeding is brought in equity to enforce the provisions of Section 5 or this Section 6, Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available. Executive agrees that he shall not raise in any proceeding brought to enforce the provisions of Section 5 or this Section 6 that the covenants contained in such Sections limit his ability to earn a living.

(f) The provisions of this Section 6 shall survive any termination of this Agreement.

7. Representations and Warranties by Executive. Executive hereby represents and warrants to the Company as follows:

(a) Neither the execution or delivery of this Agreement nor the performance by Executive of his duties and other obligations hereunder violate or will violate any statute or law or conflict with or constitute a default or breach of any covenant or obligation, including without limitation any non-competition restrictions, under any prior employment agreement, contract, or other instrument to which Executive is a party or by which he is bound (whether immediately, upon the giving of notice or lapse of time or both).

(b) Executive has the full right, power and legal capacity to enter and deliver this Agreement and to perform his duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of Executive enforceable against him in accordance with its terms. No approvals or consents of any persons or entities are required for Executive to execute and deliver this Agreement or perform his duties and other obligations hereunder.

(c) Executive represents and warrants to the Company that he has not brought and shall not bring with him to the Company, or use in the performance of his responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to Executive prior to his employment with the Company, unless Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Termination. Executive's employment with the Company shall be at-will, and either party may terminate the employment at any time for any reason or no reason at all (subject to applicable notice requirements); *provided*, *however*, that under certain circumstances, Executive may be entitled to receive payments and other benefits from the Company following termination as described in Section 9.

Notwithstanding the foregoing, should Executive voluntarily terminate his employment, Executive shall provide the Company with no less than 30 days' prior written notice, which notice period may be waived or shortened by the Company.

9. Severance.

(a) In the event that Executive's employment is terminated by the Company without Cause, or by Executive for Good Reason (each as hereinafter defined), then, Subject to Section 9(d) and Section 10:

(i) the Company shall pay Executive's accrued but unpaid Base Salary through the date of termination, at the rate in effect at the time of termination, accrued but unused vacation, and reimburse Executive for any unreimbursed business expenses incurred prior to the date of termination;

(ii) the Company shall continue to pay Executive's Base Salary at the rate in effect at the time of termination (without regard to any reduction in Base Salary that served as the basis for a resignation for Good Reason) for a period of 12 months following the date of termination in accordance with the Company's ordinary payroll practice;

(iii) to the extent permitted by applicable healthcare laws and provided that Executive makes a timely election to continue coverage, the Company shall pay directly to the insurance provider the premium for COBRA continuation coverage for Executive and Executive's dependents, less the amount payable by an active employee for such coverage, for a period of 12 months or until he obtains new employment, whichever comes first (the benefits described in this Section 9(a)(iii) shall be referred to as the "**Continued Benefits**"). Notwithstanding the foregoing, in the event that applicable healthcare laws do not permit continuation of coverage, then the Company shall reimburse Executive for the costs of obtaining coverage in an amount not to exceed the coverage amounts paid or payable by Executive immediately prior to the date of termination; and

(iv) the vesting applicable to all Equity Awards granted during the Term shall cease immediately and Executive shall have a period of 90 days to exercise any and all vested Equity Awards, after which time all Equity Awards shall expire; *provided*, *however*, that no such Equity Award that is an option shall be exercisable after the expiration of its maximum term pursuant to the terms thereof.

(b) In the event that Executive's employment is terminated by the Company for Cause, or by Executive other than for Good Reason, then:

(i) the Company shall pay Executive's accrued but unpaid Base Salary through the date of termination, at the rate in effect at the time of termination, accrued but unused vacation, and reimburse Executive for any unreimbursed business expenses incurred prior to the date of termination;

(ii) Executive shall not be entitled to receive any payments or Continued Benefits described in this Section 9;

(iii) Executive shall reimburse the Company for the **2019 Bonus**, as applicable; and

(iv) the vesting applicable to all Equity Awards shall cease immediately and Executive shall have a period of 90 days to exercise any and all vested Equity Awards, after which time all Equity Awards shall expire; *provided*, *however*, that no such Equity Award that is an option shall be exercisable after the expiration of its maximum term pursuant to the terms thereof.

(c) If a Change in Control occurs during the Term and the successor corporation (or a parent or subsidiary of the successor corporation) (1) does not offer Executive employment on terms comparable to Executive's then existing terms of employment with the Company and in connection therewith, Executive terminates employment; or (2) Executive's employment is terminated by such successor corporation without Cause or by Executive for Good Reason, within one-year after the Change in Control, then:

(i) the Company shall pay Executive's accrued but unpaid Base Salary through the date of termination, at the rate in effect at the time of termination, accrued but unused vacation, and reimburse Executive for any unreimbursed business expenses incurred prior to the date of termination;

(ii) the Company shall continue to pay Executive's Base Salary at the rate in effect at the time of termination (without regard to any reduction in Base Salary that served as the basis for a resignation for Good Reason) for a period of 18 months following the date of termination in accordance with the Company's ordinary payroll practice;

(iii) the Company shall pay Executive a Performance Bonus in an amount equal to 1.5 times the greater of (1) the target bonus for the applicable calendar year; and (2) the average of the Performance Bonus received by Executive for the two years immediately preceding termination;

(iv) the Company shall provide the Continued Benefits to Executive for a period of 18 months following the date of termination or until he obtains new employment, whichever comes first; and

(v) All unvested Equity Awards shall immediately vest in full and remain exercisable, if applicable, for a period of 90 calendar days following the date of such termination; *provided*, *however*, that no such Equity Award that is an option shall be exercisable after the expiration of its maximum term pursuant to the terms thereof. In order to give effect to the foregoing provision, notwithstanding anything to the contrary set forth in any agreement governing an Equity Award regarding immediate forfeiture of unvested shares upon termination of service or the duration of post-termination of service exercise periods, following any termination of Executive's employment, none of Executive's equity incentive awards shall terminate with respect to any vested or unvested portion subject to such Equity Award before 90 days following such termination.

(d) This Section 9 sets forth the only obligations of the Company with respect to the termination of Executive's employment with the Company, and Executive acknowledges that, upon the termination of his employment, he shall not be entitled to any payments or benefits which are not explicitly provided in this Section 9. Further, notwithstanding anything to the contrary contained herein, the Company shall have no obligation to pay, and Executive shall have no right to receive, any compensation, benefits or other consideration provided for in this Section 9 (other than any accrued but unpaid Base Salary through the date of termination and any reimbursement of unreimbursed expenses incurred prior to the date of termination) (the "**Payments**") unless Executive executes an agreement in a form satisfactory to the Company (the "**Release Agreement**") releasing the Company from any and all liability in connection with Executive's employment or the termination thereof that becomes effective no later than 60 days following Executive's termination (the "**Release Deadline**"). Except as required by Section 10, the Payments will commence on the first payroll period following the Release Agreement becoming effective; *provided*, that (i) if the Payments (or any portion thereof) constitute "deferred compensation" within the meaning of Section 409A (as defined in Section 10) and (ii) the period commencing on the date of termination and ending on the Release Deadline spans two calendar years, then the Payments (or such portion thereof that constitute "deferred compensation") will commence on the later of the Release Agreement becoming effective and the first payroll date of the Company in the second calendar year. Any portion of the Payments that is delayed due to the application of the preceding sentence shall be made on the date that the Payments commence.

(e) Effective as of the date of any termination of Executive's employment, unless otherwise agreed to by Executive and the Board, upon termination of Executive's employment hereunder for any reason, Executive shall be deemed to have resigned from all offices held at the Company or any subsidiary or other

Affiliate of the Company at the date of such termination, including without limitation the position of General Counsel.

(f) The Company shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts payable to Executive under this Section 9.

(g) The provisions of this Section 9 shall survive any termination of this Agreement.

(h) For purposes of this Agreement, "**Cause**" shall include any of the following:

(i) Executive's willful failure to perform the material duties or obligations hereunder, or willful misconduct by Executive in respect of such duties or obligations, including, without limitation, willful failure, disregard or refusal by Executive to abide by specific, objective and lawful directions received by him in writing constituting an action of the Board, which willful failure, disregard or refusal is not cured by Executive within 30 days following written notice from the Company.

(ii) any willful, intentional or grossly negligent act by Executive having the reasonably foreseeable effect of actually and substantially injuring, whether financial or otherwise, the business or reputation of the Company;

(iii) Executive's indictment of, or plea of nolo contender to, any felony;

(iv) Executive being convicted of a misdemeanor involving moral turpitude that causes, or could reasonably be expected to cause, substantial harm to business or reputation of the Company;

(v) the determination by the Company, after a reasonable and good-faith investigation by the Company following a written allegation by another employee of the Company, that Executive engaged in some form of harassment prohibited by law (including, without limitation, age, sex or race discrimination); provided, however, that Cause shall not exist under this clause (v) unless the Company gives written notice to Executive where such notice describes with particularity the alleged act(s) at issue and has given Executive an opportunity to be heard at a meeting of the Board with or without counsel, and the Board provides Executive with a summary of its findings;

(vi) any conduct on the part of Executive that constitutes a breach of his fiduciary duties to the Company;

(vii) any misappropriation or embezzlement of the property of the Company or its affiliates (whether or not a misdemeanor or felony) by Executive; or

(viii) a material breach by Executive of this Agreement.

(i) For purposes of this Agreement, "**Good Reason**" shall mean:

(i) any material diminution by the Company of Executive's title, duties, reporting or Base Salary, other than as a proportional reduction, consistent with the reductions in the salaries of all other executive officers of the Company at the level of Vice President and above as part of an overall reduction in salaries of executive officers of the Company, which proportional reduction shall remain in effect only for such time as all such other executive officer salaries remain so reduced; or

(ii) a material breach by the Company of Section 4 of this Agreement.

Notwithstanding the foregoing, should Executive wish to terminate this Agreement for Good Reason, he must provide the Company with written notice of such Good Reason within 30 days of the occurrence of such event and reasonably cooperate with the Company in remedying the condition causing Good Reason for a period of not more than 60 days (the **"Cure Period"**). If, following the Cure Period, the condition causing Good Reason remains uncured, a termination of employment by Executive for Good Reason shall be effective on the day following the expiration of such cure period.

(j) For purposes of this Agreement, "**Change in Control**" shall have the meaning set forth in the Plan.

10. Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") and the regulations and other guidance thereunder and any state law of similar effect (collectively, "**Section 409A**") and that are payable in connection with Executive's termination of employment shall not commence unless and until Executive has also incurred a "separation from service" within the meaning of Section 409A, unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A. If Executive is, upon a separation from service, a "specified employee" within the meaning of Section 409A, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the payment of any deferred compensation shall not commence until the earlier to occur of: (i) the date that is six months and one day after Executive's separation from service, or (ii) the date of Executive's death. Any payments that are delayed due to the application of the preceding sentence shall be made on the date that payments commence. For purposes of Section 409A, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

11. Section 280G. Notwithstanding anything to the contrary contained in this Agreement, to the extent that any of the payments and benefits provided for under this Agreement or any other agreement or arrangement between Executive and the Company (collectively, the **"Payments"**) constitute a **"parachute payment"** within the meaning of Section 280G of the Code and (ii) but for this Section 11, would be subject to the excise tax imposed by Section 4999 of the Code, then the Payments shall be payable either (i) in full or (ii) as to such lesser amount which would result in no portion of such Payments being subject to excise tax under Section 4999 of the Code; whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in Executive's receipt on an after-tax basis, of the greatest amount of economic benefits under this Agreement, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. Unless Executive and the Company otherwise agree in writing, any determination required under this Section 11 shall be made in writing by the Company's independent public accountants (the **"Accountants"**), whose reasonable determination shall be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 11, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Sections 280G and 4999 of the Code. Executive and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 11. If a reduction in Payments is necessary so that no portion of the Payments is subject to the excise tax under Section 4999 of the Code, reduction shall occur in the manner that results in the greatest economic benefit to Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro

rata. If this Section 11 is applied to reduce an amount payable to Executive, and the Internal Revenue Service successfully asserts that, despite the reduction, Executive has nonetheless received payments which are in excess of the maximum amount that could have been paid to him without being subjected to any excise tax, then, unless it would be unlawful for the Company make such a loan or similar extension of credit to Executive, Executive may repay such excess amount to the Company though such amount constitutes a loan to Executive made at the date of payment of such excess amount, bearing interest at 120% of the applicable federal rate (as determined under section 1274(d) of the Code in respect of such loan).

12. Miscellaneous.

(a) This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of North Carolina, without giving effect to its principles of conflicts of laws.

(b) Executive will be subject to such indemnification as is provided under the Company's Bylaws.

(c) (c) Any dispute arising out of, or relating to, this Agreement or the breach thereof (other than Sections 5 or 6 hereof), or regarding the interpretation thereof, shall be exclusively decided by binding arbitration conducted in North Carolina in accordance with the rules of the American Arbitration Association (the "**AAA**") then in effect before a single arbitrator appointed in accordance with such rules. Judgment upon any award rendered therein may be entered and enforcement obtained thereon in any court having jurisdiction. The arbitrator shall have authority to grant any form of appropriate relief, whether legal or equitable in nature, including specific performance. Each of the parties agrees that service of process in such arbitration proceedings shall be satisfactorily made upon it if sent by registered mail addressed to it at the address referred to in clause (h) below. The costs of such arbitration shall be borne proportionate to the finding of fault as determined by the arbitrator. Judgment on the arbitration award may be entered by any court of competent jurisdiction.

(d) This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective heirs, legal representatives, successors and assigns.

(e) This Agreement and Executive's rights and obligations hereunder, may not be assigned by Executive. The Company may assign its rights, together with its obligations, hereunder in connection with any sale, transfer or other disposition of all or substantially all of its business or assets provided the assignee entity which succeeds to the Company expressly assumes the Company's obligations hereunder and complies with the terms of this Agreement.

(f) This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the parties hereto.

(g) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

(h) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally or by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the parties at the addresses set forth

on the first page of this Agreement, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, five (5) days after the date of deposit in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this clause (h).

(i) This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

(j) As used in this Agreement, "**Affiliate**" of a specified Person shall mean and include any Person controlling, controlled by or under common control with the specified Person.

(k) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

(l) This Agreement may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

(m) Notwithstanding anything in this Agreement to the contrary, any payments made to Executive herein shall be subject to any recoupment or clawback policy adopted by the Company from time to time and to any requirement of applicable law, regulation or listing standard that requires the Company to recoup or clawback any compensation so paid.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

AERIE PHARMACEUTICALS, INC.

By: /s/ Kathleen McGinley

Name: Kathleen McGinley
Title: Vice President, Human Resources and Corporate Services

EXECUTIVE

By: /s/ David Hollander

Name: David Hollander
Date: 10 October 2019

EXHIBIT A

18 U.S.C. 1833(b) provides:

(1) IMMUNITY—An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that—

(A) is made—

(i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and

(ii) solely for the purpose of reporting or investigating a suspected violation of law; or

(B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(2) USE OF TRADE SECRET INFORMATION IN ANTI-RETALIATION LAWSUIT.—An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual—

(A) files any document containing the trade secret under seal; and

(B) does not disclose the trade secret, except pursuant to court order.

AERIE PHARMACEUTICALS, INC.
SECOND AMENDED & RESTATED OMNIBUS INCENTIVE PLAN
FORM OF RESTRICTED STOCK UNIT AWARD AGREEMENT

THIS AGREEMENT (this "Agreement") effective as of the date of grant set forth on the signature page hereto (the "Date of Grant"), is between Aerie Pharmaceuticals, Inc., a Delaware corporation (together with its successors, the "Company"), and the individual whose name is set forth on the signature page hereto (the "Grantee").

1. Grant of Restricted Stock Units. The Company hereby grants to the Grantee an award (the "Award"), and the Grantee hereby accepts from the Company, the number of Restricted Stock Units set forth on the signature page hereto (subject to adjustment as provided in Section 12.1 of the Aerie Pharmaceuticals, Inc. Second Amended & Restated Omnibus Incentive Plan (the "Plan")), on the terms and conditions set forth in this Agreement and the Plan, a copy of which is being delivered to the Grantee concurrently herewith and is made a part hereof as if fully set forth herein. Subject to the terms of this Agreement, each Restricted Stock Unit represents the right to receive one (1) Share at the time and in the manner set forth in Section 2 hereof. Except as otherwise defined herein, capitalized terms used in this Agreement shall have the same definitions as set forth in the Plan.

2. Vesting and Settlement of the Award.

2.1. Vesting. The Restricted Stock Units granted hereunder shall vest with respect to 25% of the Restricted Stock Units beginning on the first anniversary of the Vesting Commencement Date (set forth on the signature page attached hereto) and to an additional 25% of the Restricted Stock Units on each of the next three anniversaries of the Vesting Commencement Date thereafter (each, a "Vesting Date"), provided that the Grantee continues in employment on each respective Vesting Date.

2.2. Settlement. Within thirty (30) days following the date on which any portion of the Award vests pursuant to Section 2.1 of this Agreement, the Company shall deliver to the Grantee one (1) Share in settlement of each Restricted Stock Unit that becomes vested on a Vesting Date (each such date, a "Payment Date").

3. No Rights as a Stockholder. The Grantee shall have no rights as a stockholder with respect to the Shares covered by the Restricted Stock Units until the effective date of issuance of the Shares and the entry of the Grantee's name as a shareholder of record on the books of the Company following delivery of the Shares in settlement of the Restricted Stock Units.

4. Employment Termination. Except as provided in the next sentence, in the event the Grantee's employment Terminates, the Grantee shall forfeit all Restricted Stock Units that have not yet become vested pursuant to Section 2 hereof. In the event the Grantee's employment is Terminated (i) without Cause or due to death or Disability, the Restricted Stock Units granted hereunder shall vest as to the number of Restricted Stock Units that would have vested on the Vesting Date next following the date of Termination (had the Grantee's employment not been Terminated), multiplied by a fraction, the numerator of which is the total number of whole calendar months the Grantee remained employed by the Company following the Vesting Date immediately preceding the date of Termination, and the denominator of which is twelve (12) or (ii) without Cause in connection with or within the one-year period following a Change in Control, the Restricted Stock Units granted hereunder shall vest with respect to all of the Restricted Stock Units that are not vested as of the date of Termination. Upon the forfeiture of any Restricted Stock Units pursuant to this Section 4, the Grantee shall have no further rights with respect thereto, including the right to the payment of any dividends in respect of such shares that have been deferred pursuant to Section 5.

5. Dividend Equivalent Rights. The Grantee shall be, unless and until such Restricted Stock Units are forfeited pursuant to Section 4 of this Agreement, entitled to the right to receive all dividends or other distributions paid or made with respect to Shares; provided, however, that any entitlement to or payment of dividends or distributions declared or paid on the Restricted Stock Units shall be deferred until such date the Restricted Stock Units in respect of which such dividends or distributions were made vest pursuant to this Agreement. Any such deferred dividends shall be held by the Company for the account of the Grantee and shall be paid to the Grantee, with no interest thereon, as promptly as practicable following the date on which the Restricted Stock Units in respect of which such dividends or distributions were made vest pursuant to this Agreement.

6. Miscellaneous.

6.1. Acknowledgment. The Grantee hereby acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof as the same may be amended from time to time. The Grantee hereby acknowledges that the Grantee has reviewed the Plan and this Agreement and understands the Grantee's rights and obligations thereunder and hereunder. The Grantee also acknowledges that the Grantee has been provided with such information concerning the Company, the Plan, and this Agreement as the Grantee and the Grantee's advisors have requested.

6.2. Resolution of Disputes. Any dispute or disagreement which may arise under, or as a result of, or which may in any way relate to, the interpretation, construction or application of this Agreement shall be determined by the Committee, in good faith, whose determination shall be final, binding, and conclusive for all purposes.

6.3. Governing Law; Compliance with Law; Venue; Service of Process; Waiver of Jury Trials.

(a) Governing Law. This Agreement will be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any applicable principles of conflict of laws that would cause the laws of another State to otherwise govern this Agreement.

(b) Compliance with Law. Notwithstanding anything herein to the contrary, the Company shall not be required to issue shares pursuant to the exercise of any Award granted under this Agreement and the Plan unless such exercise and issuance comply with all applicable laws, including, without limitation, all applicable federal and state securities laws.

6.4. Enforcement. The parties acknowledge and agree that irreparable damage would occur in the event that any of the parties' obligations under this Agreement were not performed in accordance with its specific terms or were otherwise breached. The parties acknowledge and agree that each of the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement. Each of the parties, in such Person's sole discretion, may apply to any court of law or equity of competent jurisdiction for specific performance and/or injunctive relief (without posting a bond or other security) in order to enforce and prevent any violation of the provisions of this Agreement.

6.5. Severability. Whenever possible, each provision or portion of any provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but the invalidity or unenforceability of any provision or portion of any provision of this Agreement in any jurisdiction shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of this Agreement, including that provision or portion of any provision, in any other jurisdiction. In addition, should a court determine that any provision or portion of any provision of this Agreement is not reasonable or valid, either in period of time, geographical area, or otherwise, the parties hereto agree that such provision should be interpreted and enforced to the maximum extent which such court deems reasonable or valid.

6.6. Notice. Unless otherwise provided herein, all notices, requests, and other communications provided for under the terms of this Agreement shall be in writing. Any notice, request, or other communication hereunder shall be sent by (a) personal delivery (including receipted courier service) or overnight delivery service, (b) facsimile during normal business hours, with confirmation of receipt, to the number indicated, (c) reputable commercial overnight delivery service courier, or (d) registered or certified mail, return receipt requested, postage prepaid, and addressed to the intended recipient as set forth below:

(i) If to the Company, to:

Aerie Pharmaceuticals, Inc.
550 Hills Drive, 3rd Floor
Bedminster, New Jersey 07921
Attention: Richard J. Rubino
Facsimile: (908) 470-4329
Telephone: (908) 470-4320

with a copy to:

Fried, Frank, Harris, Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004
Attention: Steven G. Scheinfeld, Esq.
Facsimile: 212-859-4000

(ii) If to the Grantee, at the most recent address or facsimile number contained in the books and records of the Company.

Each such notice, request and other communication will be effective (x) if delivered by hand, overnight courier or registered or certified mail, when such delivery is made at the address specified in this Section 6.6 or (y) if delivered by facsimile, when such facsimile is transmitted to the facsimile number specified in this Section 6.6 and appropriate confirmation is received. Any party may change its facsimile number or its address to which notices, requests, and other communications hereunder are to be delivered by giving the other parties hereto notice in the manner herein set forth.

6.7. Binding Effect; Assignment; Third-Party Beneficiaries. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and any of their respective successors, personal representatives, and permitted assigns who agree in writing to be bound by the terms hereof. Neither this Agreement nor any of the rights, interests, or obligations hereunder shall be assigned by the Grantee without the prior written consent of the Company.

6.8. Amendments and Waivers. This Agreement and any of the provisions hereof may be amended, waived (either generally or in a particular instance and either retroactively or prospectively), modified or supplemented, in whole or in part, only by written agreement signed by the Company, upon approval of the Committee, and by the Grantee; provided, that, the observance of any provision of this Agreement may be waived in writing by the party that will lose the benefit of such provision as a result of such waiver. The waiver by any party hereto of a breach of any provision of this Agreement shall not operate or be construed as a further or continuing waiver of such breach or as a waiver of any other or subsequent breach, except as otherwise explicitly provided for in such waiver. Except as otherwise expressly provided herein, no failure on the part of any party to exercise, and no delay in exercising, any right, power, or remedy hereunder, or otherwise available in respect hereof at law or in equity, shall operate as a waiver thereof, nor shall any single or partial exercise of such right, power, or remedy by such party preclude any other or further exercise thereof or the exercise of any other right, power, or remedy.

6.9. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all such counterparts shall together constitute one and the same instrument.

6.10. Entire Agreement. This Agreement and the Plan constitute the entire agreement, and supersede all prior agreements and understandings, oral and written, between the parties hereto with respect to the Award granted hereby.

6.11. Withholding. The Grantee shall be responsible for the satisfaction of applicable withholding obligations, and the delivery of certificates or evidence of book entry registration representing vested and settled shares to the Grantee shall be subject to the satisfaction of such obligations. The Grantee may elect to satisfy his or her withholding obligations following the Payment Date by surrendering a number of Shares to the Company (including, for the avoidance of doubt, by the Company withholding Shares that would otherwise be delivered pursuant to this Agreement upon the Payment Date) having an aggregate Fair Market Value equal to such withholding obligations. The Grantee agrees to indemnify the Company against any federal, state, and local withholding taxes for which the Company may be liable in connection with the Grantee's acquisition, ownership, or disposition of any Shares.

6.12. No Right to Continued Employment. This Agreement shall not confer upon the Grantee any right with respect to continuance of employment by the Company or any Affiliate, nor shall it interfere in any way with the right of the Company or any Affiliate thereof to terminate the Grantee's employment at any time.

6.13. General Interpretive Principles. Whenever used in this Agreement, except as otherwise expressly provided or unless the context otherwise requires, any noun or pronoun shall be deemed to include the plural as well as the singular and to cover all genders. The headings of the sections, paragraphs, subparagraphs, clauses, and subclauses of this Agreement are for convenience of reference only and shall not in any way affect the meaning or interpretation of any of the provisions hereof. Unless otherwise specified, the terms "hereof," "herein" and similar terms refer to this Agreement as a whole, and references herein to Sections refer to Sections of this Agreement. Words of inclusion shall not be construed as terms of limitation herein, so that references to "include," "includes," and "including" shall not be limiting and shall be regarded as references to non-exclusive and non-characterizing illustrations.

6.14. Signature in Counterparts. This Agreement may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

6.15. Section 409A. The Restricted Stock Units are intended to be exempt from Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be exempt from Section 409A of the Code or, if not exempt, in compliance therewith. Nothing contained herein shall constitute any representation or warranty by the Company regarding compliance with Section 409A of the Code. The Company shall have no obligation to take any action to prevent the assessment of any additional income tax, interest or penalties under Section 409A of the Code on any Person and none of the Company, its Subsidiaries or affiliates, nor any of their respective employees or representatives, shall have any liability to the Grantee with respect thereto.

6.16. Securities Laws. Upon the acquisition of any Shares pursuant to the settlement of the Restricted Stock Units, the Grantee will make such written representations, warranties, and agreements as the Committee may reasonably request in order to

comply with securities laws or with this Agreement. Grantee hereby agrees not to offer, sell or otherwise attempt to dispose of any Shares issued to the Grantee upon settlement of the Restricted Stock Units in any way which would: (x) require the Company to file any registration statement with the Securities and Exchange Commission (or any similar filing under state law or the laws of any other county) or to amend or supplement any such filing or (y) violate or cause the Company to violate the Securities Act, the Exchange Act, or any other Federal, state or local law, or the laws of any other country. The Company reserves the right to place restrictions on any Shares the Grantee may receive as a result of the settlement of the Restricted Stock Units.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, effective as of the Date of Grant.

AERIE PHARMACEUTICALS, INC.

By: __
Name:
Title:

Agreed and acknowledged as
of the Date of Grant:

_____
Name: [_____]

Grantee's Name:	[_____]
Date of Grant:	[_____]
Vesting Commencement Date	[_____]
Number of Shares Subject to the Award:	[_____]

FIRST AMENDMENT
OF THE AERIE PHARMACEUTICALS, INC.
SECOND AMENDED & RESTATED
INDUCEMENT AWARD PLAN

THIS FIRST AMENDMENT of the Aerie Pharmaceuticals, Inc. Second Amended & Restated Inducement Award Plan is dated as of December 5, 2019.

WHEREAS, the Board of Directors of Aerie Pharmaceuticals, Inc. (the "Company") has adopted the Aerie Pharmaceuticals, Inc. Second Amended & Restated Inducement Award Plan (the "Plan"); and

WHEREAS, the Board of Directors deems it to be in the best interest of the Company to amend the Plan as more particularly set forth below.

NOW, THEREFORE, the Plan shall be amended as follows:

The first sentence of Paragraph 4 of the Plan shall be deleted in its entirety and the following substituted in lieu thereof:

Subject to any adjustment as provided in the Plan, the maximum number of Shares that may issued pursuant to Awards granted under the Plan shall not exceed 1,392,500.

IN WITNESS WHEREOF, the undersigned Secretary of the Company certifies that the foregoing First Amendment to the Plan was duly adopted by the Board of Directors.

AERIE PHARMACEUTICALS, INC.

By: /s/ Vicente Anido, Jr., PhD
Name: Vicente Anido, Jr., PhD
Title: Chief Executive Officer

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-228247, 333-223364, 333-221442, 333-219671, 333-216578, 333-216577 and 333-192030) of Aerie Pharmaceuticals, Inc. of our report dated February 24, 2020 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 24, 2020

Exhibit 31.1

CERTIFICATION

I, Vicente Anido, Jr., PhD, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aerie Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2020

/s/ VICENTE ANIDO, JR., PHD

Vicente Anido, Jr., PhD

Chief Executive Officer, Chairman of the Board

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Richard J. Rubino, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aerie Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2020

/s/ RICHARD J. RUBINO

Richard J. Rubino

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Annual Report on Form 10-K of Aerie Pharmaceuticals, Inc., a Delaware corporation (the "Company"), for the fiscal year ended December 31, 2019 (the "Report"), the undersigned, Vicente Anido, Jr., PhD, Chief Executive Officer and Chairman of the Board of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2020

/s/ VICENTE ANIDO, JR., PHD

Vicente Anido, Jr., PhD
Chief Executive Officer, Chairman of the Board
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Annual Report on Form 10-K of Aerie Pharmaceuticals, Inc., a Delaware corporation (the "Company"), for the fiscal year ended December 31, 2019 (the "Report"), the undersigned, Richard J. Rubino, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 24, 2020

/s/ RICHARD J. RUBINO

Richard J. Rubino
Chief Financial Officer
(Principal Financial and Accounting Officer)