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, 2020

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2020, based upon the closing price of $14.76 of the registrant's common stock as reported on The NASDAQ Global Market, was $671,924,115.

As of February 19, 2021, the registrant had 46,917,133 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 2021 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, 2020.

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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 “products” mean products approved by the U.S. Food and Drug Administration (“FDA”) or other regulatory authorities; references to “product candidates” mean products that are in development but not yet approved by the FDA or other regulatory authorities; references to “future product candidates” mean 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 broad impact of the coronavirus (“COVID-19”) pandemic on our business;
- 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 product candidates 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 product candidates 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 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 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 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 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 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 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 products or product candidates for additional indications, and our preclinical retinal programs and other therapeutic opportunities;
- the potential advantages of our products, product candidates and any future product candidates;
- our ability to protect our proprietary technology and enforce our intellectual property rights; and
- our expectations regarding existing and future collaborations, licensing, acquisitions and strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies.

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, the European Commission ("EC") grant of a Centralised Marketing Authorisation ("Centralised MA") for Rhokiinsa® and Roclanda® do not constitute European Medicines Agency ("EMA") approval of our product candidates or any future product candidates in Europe, and there can be no assurance that we will receive EMA approval for our product candidates or any future product candidates. FDA and EMA approval of Rhopressa® and Rocklatan® do not constitute regulatory approval of these products in jurisdictions outside of the United States or Europe and there is no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such jurisdictions. In addition, the clinical trials discussed in this report are preliminary and the outcome of such clinical trials 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 clinical trials 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, ocular surface diseases and retinal diseases.

Our strategy is to successfully commercialize our U.S. Food and Drug Administration ("FDA") approved glaucoma franchise products, Rhopressa® (netarsudil ophthalmic solution) 0.02% ("Rhopressa®") and Rocklatan® (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% ("Rocklatan®") in the United States. 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. We have obtained formulary coverage for Rhopressa® and Rocklatan® for the majority of lives covered under commercial plans and Medicare Part D plans. Our commercial team responsible for sales of Rhopressa® and Rocklatan® is targeting eye-care professionals throughout the United States, and with the addition of a contract sales organization and a separate telesales team, we are able to reach over 16,000 eye-care professionals.

U.S. Commercial Products

Rhopressa® is a once-daily eye drop designed to reduce elevated intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension. Rhopressa® is taken in the evening and has shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

The active ingredient in Rhopressa®, netarsudil, is an Aerie-owned Rho kinase ("ROCK") inhibitor. 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. Using this mechanism of action ("MOA"), 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. Rocklatan® is also taken in the evening, and similar to Rhopressa®, has shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

Based on our clinical data, we believe that Rocklatan® has the potential to provide a greater IOP-reducing effect than any glaucoma medication currently marketed in the United States. We also 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.

Outside the United States

Our strategy also includes developing our business opportunities outside the United States, including successfully commercializing Rhopressa® and Rocklatan® in Europe and obtaining regulatory approval in Japan and other countries in Asia, and our globalization plan is well underway.

In Europe, Rhokiinsa® (marketed as Rhopressa® in the United States) was granted a Centralised Marketing Authorisation ("Centralised MA") by the European Commission ("EC") in November 2019. Further, Roclanda® (marketed as Rocklatan® in the United States) was granted a Centralised MA by the EC in January 2021, which followed the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") adopting a positive opinion recommending approval of the Marketing Authorisation Application ("MAA") for Roclanda® in November 2020.

We reported positive interim topline 90-day efficacy data in September 2020 for our Phase 3b clinical trial for Roclanda®, named Mercury 3, which we believe is important to the execution of our strategy in Europe. As a result of the positive Mercury 3 results and the Roclanda® approval in Europe, third parties have expressed interest in a potential commercialization partnership in and potentially beyond Europe. We are currently engaged in discussions with potential partners.

In Japan, we entered into a Collaboration and License Agreement (the "Santen Agreement") with Santen Pharmaceuticals Co., Ltd. ("Santen") in October 2020 to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia. We initiated a Rhopressa® Phase 3 clinical trial in December 2020, the first of three expected Phase 3 clinical trials in Japan. Clinical trials for Rocklatan® have not yet begun.

Glaucoma Product Manufacturing

We have a sterile fill production facility in Athlone, Ireland, for the production of our FDA approved products and clinical supplies with the goal of having the Athlone manufacturing plant supply our ophthalmic products in all markets for which we received regulatory approval and are commercialized. The Athlone manufacturing plant began manufacturing commercial supplies of Rocklatan® in the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. Shipments of commercial supply of Rocklatan® and Rhopressa® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020 and in the fourth quarter of 2020, respectively. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. As the Athlone manufacturing plant commenced operations in 2020, it has not yet reached full capacity. We expect that the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® for the United States as well as the European and Japanese commercial markets. We expect that in 2021 the Athlone manufacturing plant will manufacture most of our needs for Rhopressa® and Rocklatan® in the United States. We may continue to use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States, but at reduced levels compared to before the Athlone manufacturing plant was operational.

Product Candidates and Pipeline

Our strategy also includes enhancing 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.

As discussed in "—*Product Candidates and Pipeline Opportunities*" below, AR-15512 is our product candidate for the treatment of dry eye disease, which we acquired from Avizorex Pharma S.L. ("Avizorex") in late 2019, and for which we initiated a large Phase 2b clinical trial in October 2020. Furthermore, we are developing three sustained-release implants focused on retinal diseases, AR-1105, AR-13503 SR and AR-14034 SR. For AR-1105, we successfully completed a Phase 2 clinical trial for patients with macular edema due to retinal vein occlusion ("RVO") in July 2020, which indicates sustained efficacy of up to six months, an important achievement in validating the potential capabilities of Aerie's sustained release platform. With respect to future plans for AR-1105, we are currently evaluating next steps regarding advancement into a Phase 3 clinical trial along with commercialization prospects in both Europe and the United States. For AR-13503 SR, we initiated a first in-human clinical safety study in the third quarter of 2019 for the treatment of wet age-related macular degeneration (age-related macular degeneration, "AMD") and diabetic macular edema ("DME"), which is currently ongoing. For preclinical AR-14034 SR, we anticipate filing an Investigational New Drug Application ("IND") with the FDA in the second half of 2022 to evaluate its potential as a treatment for wet AMD and DME.

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.

Intellectual Property Portfolio

We own the worldwide rights for Rhopressa® and Rocklatan®. We have patent protection for Rhopressa® and Rocklatan® in the United States and internationally through early 2034, 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 providing patent protection for pharmaceutical compositions comprising AR-15512 and methods of its use for ophthalmic uses. The Avizorex acquisition also enabled us to be the exclusive licensee of pending foreign counterparts to the issued U.S. patents regarding AR-15512. Should these foreign counterparts issue such patents, they will provide patent protection for pharmaceutical compositions in such jurisdictions comprising AR-15512 and methods of its use, including

ophthalmic uses, through 2031. Furthermore, we have an issued U.S. patent covering our AR-1105 implant, which provides patent protection for AR-1105 in the United States through 2036, as well as pending foreign counterparts that upon issuance will provide 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, ocular surface diseases and retinal diseases. We believe Rhopressa® and Rocklatan® have the potential to address many of the unmet medical needs in the glaucoma market, AR-15512 in the ocular surface disease market, and clinical implants AR-1105 and AR-13503 SR and preclinical implant AR-14034 SR in the retinal disease market.

Key elements of our strategy are to:

- ***Successfully commercialize Rhopressa® and Rocklatan® in the United States.***

  Our sales organization, along with the addition of a contract sales organization and telesales team, is targeting approximately 16,000 of the highest prescribing eye-care professionals in the United States, and sales volumes have grown consistently since the launch of each product.

- ***Advance the development of Rhopressa® and Rocklatan® in jurisdictions outside the United States to regulatory approval and commercialize in Europe, Japan and other countries in Asia.***

  In Europe, we reported positive interim topline 90-day efficacy data for Mercury 3, which we deem to be an important determinant as we evaluate the commercialization and profitability potential of Rhokiinsa®, and particularly Roclanda®, in Europe. Roclanda® achieved non-inferiority to a fixed-dose combination in Europe (Ganfort®). As a result we have received interest from third parties interested in a potential collaboration partnership, with whom we are currently engaged, while we are simultaneously preparing on our own for pricing discussions in Germany.

  We entered into the Santen Agreement in October 2020 to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and other countries in Asia. We initiated a Rhopressa® Phase 3 clinical trial in Japan in December 2020. For additional product and trial information see *"—Our Products, Product Candidates and Pipeline"* below.

- ***Supply all clinical and commercial ophthalmic products from the Athlone manufacturing plant for all markets in which we plan to commercialize, while maintaining our secondary suppliers.***

  We have a sterile fill production facility in Athlone, Ireland, for the production of our FDA approved products and clinical supplies with the goal of having the Athlone manufacturing plant supply our ophthalmic products in all markets for which we receive regulatory approval and are commercialized. For additional information see *"—Manufacturing"* below.

- ***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.

  Through business development activities, we have acquired the clinical-stage dry eye product candidate AR-15512 from Avizorex, worldwide ophthalmic rights to a bio-erodible polymer technology from DSM and PRINT® implant manufacturing technology from Envisia. With respect to research collaborations, in connection with entering into the Santen Agreement and the positive topline Mercury 3 results, we have received interest from third parties for a potential collaboration for the clinical development and potential future commercialization of Rhopressa® and Rocklatan® in Europe and potentially elsewhere. We have commenced such discussions with various potential collaborators.

With respect to product candidates, we have commenced a U.S. Phase 2b clinical trial of AR-15512, our dry eye product candidate, we are evaluating the path to a Phase 3 clinical trial for sustained-release retinal implant AR-1105 in both the United States and Europe and our first-in-human clinical trial for sustained-release retinal implant AR-13503 SR is ongoing. With respect to AR-1105, in addition to pursuing next steps regarding clinical advancement, we are also evaluating commercialization prospects in both Europe and the United States. We are in the process of meeting with regulatory agencies in order to harmonize development plans across both Europe and the United States. We believe that the commercial prospects for AR-1105 in Europe are potentially greater than for the Aerie glaucoma franchise in Europe and as a result, we expect to ultimately commercialize this product candidate, if approved, on our own or with a partner. We are also working to advance our preclinical sustained-release retinal implant, AR-14034 SR, for which we anticipate filing an IND with the FDA in the second half of 2022.

- ***Continue to leverage and strengthen our intellectual property portfolio.***

  We believe we have a strong intellectual property position based upon issued patents and pending applications in the United States and internationally, including in Europe and Japan, relating to Rhopressa® and Rocklatan®. Moreover, patents for AR-1105 in the United States provides protection through 2036, and we continue to pursue patent protection for it internationally. If successful, AR-1105 is expected to have international patent protection to 2036. In addition, regarding AR-15512, the Avizorex acquisition has provided us with patent protection in the United States through 2031, and we are pursuing international patent protection that upon issuance is expected to provide patent protection through 2031. We also continue to pursue efforts to strengthen our intellectual property portfolio regarding AR-13503 in the United States and internationally. 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.

Status, Achievements and Regulatory Approvals

The following table summarizes each of our current products and product candidates, their MOA(s) and their status.

Region	Name and Mechanism	Key Dates	Status
	Glaucoma Franchise		
United States	ONCE-DAILY rhopressa (netarsudil ophthalmic solution) 0.02% (ROCK inhibitor)[1]	*April 2018 Commercial Launch*	Marketed Product
United States	ONCE-DAILY rocklatan (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% (ROCK inhibitor and latanoprost, a PGA)[1]	*May 2019 Commercial Launch*	Marketed Product
Europe	Rhokiinsa® (ROCK inhibitor)[1]	*November 2019*	Centralised MA granted by the EC

Region	Name and Mechanism	Key Dates	Status
Europe	Roclanda® (ROCK inhibitor and latanoprost, a PGA)[1]	*January 2021*	Centralised MA granted by the EC
		November 2020	EMA's CHMP adopted positive opinion recommending approval
		September 2020	Reported positive topline data from the Mercury 3 Phase 3 clinical trial, in which Roclanda® achieved non-inferiority to a fixed-dose combination in Europe (Ganfort®)
Japan and Other Asian Countries	Rhopressa® (ROCK inhibitor)[1]	*October 2020*	Executed the Santen Agreement for the development and commercialization of Rhopressa® and Rocklatan® in Japan and eight other Asian countries
Japan and Other Asian Countries	Rocklatan® (ROCK inhibitor and latanoprost, a PGA)[1]		
Japan and Other Asian Countries	Rhopressa® (ROCK inhibitor)[1]	*December 2020*	Initiated the first Phase 3 clinical trial in Japan
		April 2020	Held a meeting with the Japanese PMDA to discuss Phase 3 clinical trial designs in Japan, in which we expect to have three Phase 3 clinical trials, two of which will be 28-day trials and one of which will be a 12-month safety trial
Glaucoma Manufacturing			
Athlone, Ireland Manufacturing Plant	Rhopressa® (ROCK inhibitor)[1]	*Fourth quarter of 2020*	Shipments of commercial supply from the Athlone manufacturing plant to the United States commenced
		Third quarter of 2020	Manufactured clinical supplies of Rhopressa® for the upcoming Phase 3 clinical trials in Japan
		September 2020	Received FDA approval for production for commercial distribution in the United States.
Athlone, Ireland Manufacturing Plant	Rocklatan® (ROCK inhibitor and latanoprost, a PGA)[1]	*Third quarter of 2020*	Shipments of commercial supply from the Athlone manufacturing plant to the United States commenced
		January 2020	Received FDA approval for production for commercial distribution in the United States
Product Candidates and Pipeline			
United States	AR-15512 (TRPM8 agonist)[2]	*Third quarter of 2021*	Expected readout of COMET-1 topline results
		October 2020	Initiated Phase 2b clinical trial, named COMET-1
		September 2020	IND for AR-15512 eye drop for dry eye became effective

Region	Name and Mechanism	Key Dates	Status
United States	AR-1105 implant (dexamethasone steroid)(3)	*July 2020*	Completed and reported topline results for Phase 2 clinical trial in patients with macular edema due to RVO, indicating 6-month efficacy
United States	AR-13503 SR implant (ROCK and Protein kinase C inhibitor)(1)	*Third quarter of 2019*	First-in-human clinical safety study commenced
		April 2019	IND for AR-13503 SR became effective, allowing the initiation of human studies in the treatment of wet AMD and DME
United States	AR-14034 SR implant (pan-VEGF-R inhibitor)(1)	*Second half of 2022*	Anticipate filing of an IND for preclinical AR-14034 SR to potentially allow initiation of human studies in the treatment of wet AMD and DME

(1) Wholly-owned
(2) Wholly-owned; acquired from Avizorex
(3) Wholly-owned; acquired from Envisia

Our Products, Product Candidates and Pipeline

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 MA by the EC in November 2019. Our key target markets outside the United States include Europe and Japan and other countries in Asia.

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, which in aggregate totaled approximately 36 million prescriptions and 55 million units in 2019 according to IQVIA. Healthcare professionals most frequently prescribe 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. Rhopressa® provides eye-care professionals with a valuable alternative therapy to what has been historically available. 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 an adjunctive therapy 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 in April 2018. It 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 MA for Rhokiinsa®.

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 have recently commenced in Japan. Topline results of the Phase 2 clinical trial indicated positive efficacy and tolerability results for the patient population. We held a meeting with the Japanese PMDA in April 2020 to discuss Phase 3 clinical trial designs for Rhopressa®, while continuing to prepare for the trials. We initiated the first Rhopressa® Phase 3 clinical trial in Japan in the fourth quarter of 2020. We expect to have three Phase 3 clinical trials, two of which will be 28-day trials and one of which will be a 12-month safety trial. Further, in October 2020, we entered into the Santen Agreement to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia.

Rocklatan®

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 or ocular hypertension, and was approved by the FDA in March 2019. Based on our clinical data, we believe that Rocklatan® has the potential to provide a greater IOP-reducing effect than any glaucoma medication currently marketed in the United States. We also 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. We have obtained formulary coverage for Rocklatan® for the majority of lives covered under commercial and Medicare Part D plans.

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 Phase 3b clinical 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). In September 2020, we read out interim topline 90-day efficacy data for Mercury 3. The results indicated Roclanda® met the overall trial objective by demonstrating non-inferiority to Ganfort® across nine of nine timepoints over 90 days. Roclanda® also demonstrated consistent IOP reduction throughout the day, with the IOP reductions observed in Mercury 3 exceeding those from both Mercury 1 and Mercury 2. Mercury 3 was not required for regulatory approval; it was designed to gauge the commercialization prospects in Europe. We deemed the Mercury 3 results to be an important determinant as we evaluated the commercialization and profitability potential of Rhokiinsa®, and particularly Roclanda®, in Europe.

In December 2019, the MAA for Roclanda® was accepted for review by the EMA and in November 2020, we received a positive opinion from the CHMP for the MAA for Roclanda®. In January 2021, Roclanda® was granted a Centralised MA by the EC. Since Roclanda® is a fixed-dose combination product that includes Rhokiinsa®, the MAA submission for Roclanda® was predicated on the receipt of a Centralised MA for Rhokiinsa®, which the EC granted in November 2019. In Japan, clinical trials for Rocklatan® have not yet begun.

As a result of the positive Mercury 3 results, third parties have expressed interest in a commercialization partnership in Europe, while we are simultaneously preparing on our own for pricing discussions in Germany. Some third parties have stated potential interest in a commercialization partnership beyond just Europe and discussions are underway. According to IQVIA, it is estimated that the European glaucoma market for the five largest European national markets represented approximately $1 billion in sales with 105 million units in 2019, compared to approximately 55 million units in the United States. We would pursue manufacturing rights with any collaboration and source product from our manufacturing facility in Athlone, Ireland.

Product Candidates and Pipeline Opportunities

To complement our internal research through business development opportunities, we obtained the clinical-stage dry eye product candidate AVX-012 (now named AR-15512) through the acquisition of Avizorex in late 2019. 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 three sustained-release implants focused on retinal diseases, AR-1105, AR-13503 SR and AR-14034 SR, and in the future we believe this technology may be useful as we explore additional sustained-release applications.

AR-15512 (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 (now named AR-15512). The active ingredient in AR-15512 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that regulates tear production and blink rate. In addition, activating the TRPM8 receptor may reduce ocular discomfort by promoting a cooling sensation. 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 AR-15512 to treat signs and symptoms of dry eye. We met with the FDA in June 2020 and are planning to test two concentrations of AR-15512 in a 90-day Phase 2b clinical trial with 360 subjects, which could potentially be considered pivotal. For this upcoming trial, known as COMET-1, we expect the primary endpoints to be ocular discomfort and tear production. The Investigational New Drug Application ("IND") for AR-15512 eye drop for dry eye became effective in September 2020, allowing Aerie to initiate clinical studies in the treatment of dry eye. We initiated COMET-1 in October 2020 and a topline readout is expected in the third quarter of 2021.

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 is comprised of a blend of different polymers and PRINT® technology for the potential treatment of macular edema due to RVO and diabetic retinopathy ("DR"), which we refer to as AR-1105. We submitted the IND for AR-1105 in December 2018 and the IND became effective in January 2019. 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. In July 2020, we reported topline results of the Phase 2 clinical trial for AR-1105 indicating sustained efficacy of up to six months, an important achievement in validating the potential capabilities of Aerie's sustained release platform.

With respect to future plans for AR-1105, we are currently evaluating next steps regarding advancement towards Phase 3 clinical trials along with commercialization prospects in both Europe and the United States. We are in the process of meeting with regulatory agencies in order to harmonize development plans across both Europe and the United States. According to IQVIA, the market for retinal diseases therapeutics totaled nearly $7 billion in the United States and $4 billion in Europe in 2019, yet the injectable steroid market component is in fact currently higher in Europe than in the United States. We believe AR-1105, with the six-month sustained release efficacy profile demonstrated in the Phase 2 data, may be able to further expand the injectable steroid market in both the United States and Europe. The closest competitive product currently generates approximately $100 million in annual net sales in the United States and $300 million in Europe and generally in practice is injected once every two to three months. We believe that the commercial prospects for AR-1105 in Europe are potentially greater than for the Aerie glaucoma franchise in Europe and as a result we expect to ultimately commercialize this product candidate, if approved, on our own or with a partner.

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

Our owned 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 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. 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.

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. The IND for AR-13503 SR became effective in April 2019, allowing us to initiate human studies in the treatment of wet AMD and DME. We initiated a first-in-human clinical safety study for AR-13503 SR in the third quarter of 2019, which is currently ongoing.

AR-14034 SR Implant (pan-VEGF receptor inhibitor)

The active ingredient in our preclinical AR-14034 sustained-release implant is axitinib, a small molecule kinase inhibitor of VEGF receptors. Axitinib is currently approved by the FDA in the United States for the treatment of renal cell carcinoma. AR-14034 SR may have the potential to treat wet AMD, DME and other diseases of the retina. Unlike the anti-VEGF products currently approved for wet AMD and DME that inhibit only one or two of the four known VEGFs, studies have shown axitinib inhibits signaling from all four VEGFs by inhibiting all known VEGF receptors. Based on preclinical data, axitinib has been shown to inhibit choroidal neovascularization and to reduce vessel leakage in preclinical models of wet AMD and DME. Axitinib has been formulated with a proprietary blend of polymers to produce an injectable, bioerodible implant that, based on preclinical data, has the potential to sustain effective retinal drug concentrations for up to 12 months following a single intravitreal injection in patients.

Pending additional studies, AR-14034 SR may have the potential to provide a once per-year injection to treat DME, wet AMD and related diseases of the retina, which has the potential to greatly reduce the treatment burden for patients and their physicians. We anticipate filing the IND for AR-14034 SR with the FDA in the second half of 2022, which if accepted, would allow us to initiate human studies in the treatment of wet AMD and DME.

Other Pipeline Opportunities

We continue to leverage the use of the PRINT® technology platform to evaluate the sustained-release of additional small molecule 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.

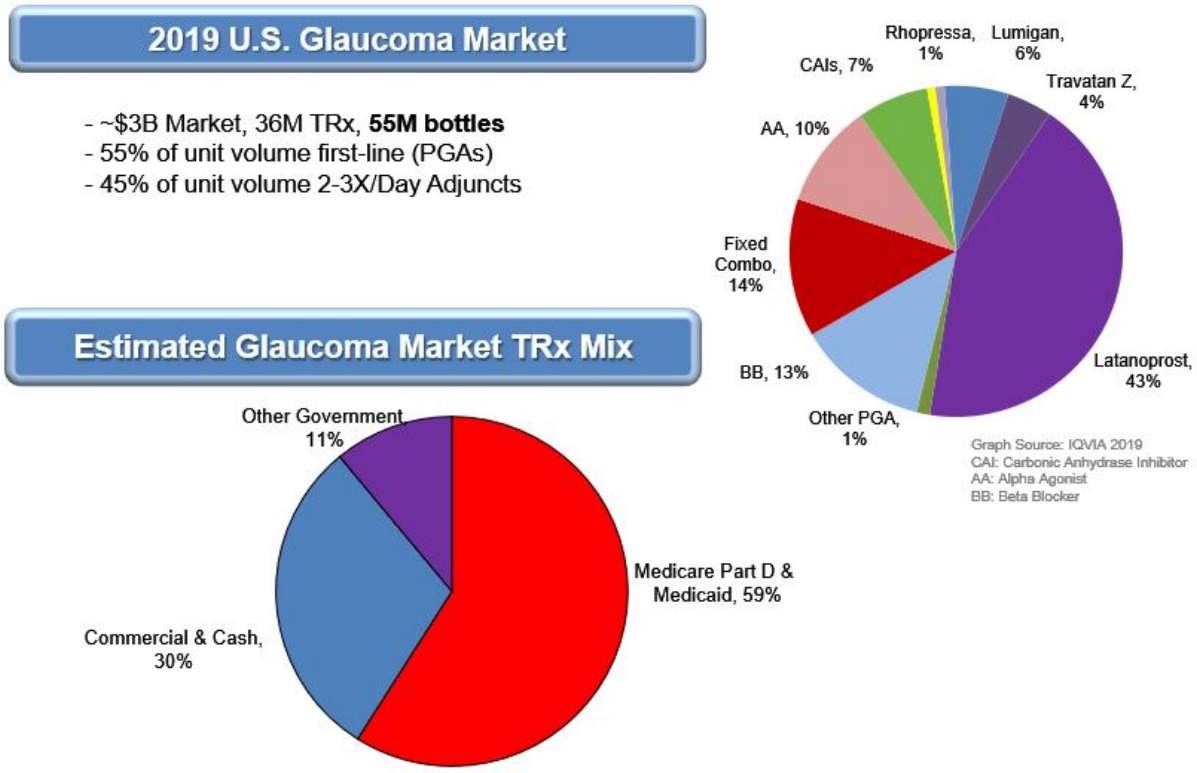
We own over 4,000 ROCK inhibitor molecules, some of which have additional features including the inhibition of other kinases such as Janus kinase and those in the IκB family and we evaluate this library on an ongoing basis for additional development opportunities. Early stage evaluations of these molecules 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 2019, branded and generic glaucoma product sales were approximately $5.0 billion in the United States, the top five national markets in Europe and Japan in aggregate, according to IQVIA. Prescription volume in 2019 for glaucoma products in the United States alone was 36 million, representing 55 million bottles, 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 or 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 launch-to-date volume growth in the United States for both Rhopressa® and Rocklatan®. 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. Based on our clinical data, we believe that Rocklatan®, a fixed-dose combination of Rhopressa® and latanoprost, has the potential to provide a greater IOP-reducing effect than any glaucoma medication currently marketed in the United States. We also 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 millimeters of mercury (“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.

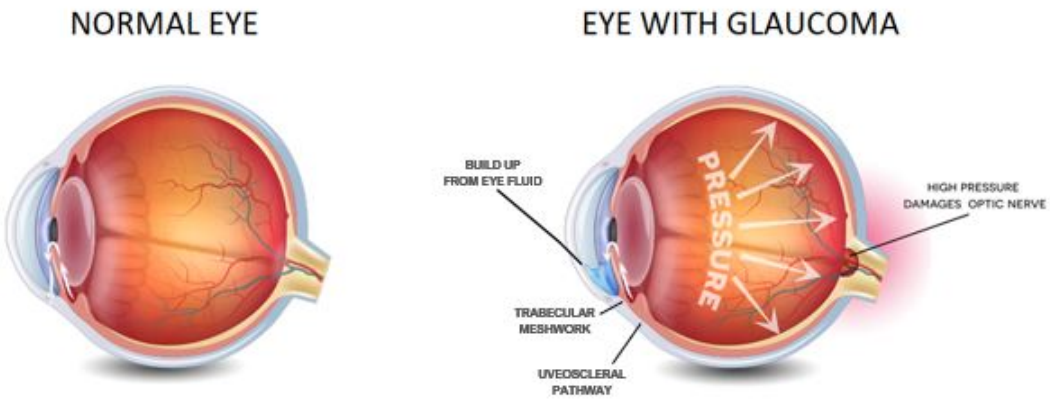
The most common form of glaucoma is open-angle glaucoma, which is characterized by abnormally high IOP as a result of impaired drainage of fluid from the eye’s primary drain, the TM. Open-angle glaucoma is a progressive disease leading to vision loss and blindness for some patients as a result of irreversible 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. Further IOP reduction may be required to prevent additional damage to the optic nerve and further vision loss should the disease progress despite achieving the initial target IOP. 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 a healthy eye.

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 8 mmHg to 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.

Ocular Surface Diseases Overview

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 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 $1.6 billion in 2019, according to third-party sources and internal estimates. 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. AR-15512 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 Overview

The U.S. market for wet AMD, DR and RVO was approximately $6.8 billion in 2019, according to IQVIA. AMD is the leading cause of irreversible vision loss in individuals over 50 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.

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 approximately 520 new cases per million are reported each year.

In wet AMD, DME and RVO, 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 these diseases is intravitreal ("IVT") injection of VEGF inhibitors ("anti-VEGF"). In addition, an alternative therapeutic approach for DME and RVO is 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.

Our drug-eluting implants for retinal disease have the potential to address these unmet needs. AR-1105 has the potential to provide a longer duration therapy for patients with DME or RVO. AR-1105 is designed to be injected once every six months, whereas the currently available dexamethasone implant, OZURDEX®, typically requires injections approximately once every three months. As a longer duration dexamethasone implant, AR-1105 has the potential to 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, since AR-1105 delivers a smaller dose of dexamethasone, there exists the potential for reduced corticosteroid-related adverse events such as cataract formation and increased IOP.

The AR-13503 SR implant potentially addresses the need for new therapies that act differently from the anti-VEGF and corticosteroid products. As an inhibitor of the kinases ROCK and protein kinase c, AR-13503 has 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 in patients who do not respond adequately to anti-VEGF monotherapy. Since the AR-13503 SR implant is designed to

be injected once every six months, it also has the potential to reduce treatment burden on patients, especially those who may require multiple therapies to adequately treat their disease.

The AR-14034 SR implant potentially addresses the need to reduce the injection frequency of anti-VEGF therapies. The AR-14034 SR implant is designed to reduce the treatment burden on patients and physicians by providing a once per-year anti-VEGF injection. The active ingredient, axitinib, has been shown to provide a blockade of all VEGF signaling pathways, which has the potential to provide greater efficacy than current products that block only one or two of the four VEGFs related to retinal disease.

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, AbbVie Inc., Santen Pharmaceutical Co., Ltd. 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. In addition, our segment of the 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. 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, most commonly prescribed as drugs to treat hypertension, are also prescribed for glaucoma. 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 potential systemic exposures from the 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®	ROCK inhibitor (qd)	**United States:** Marketed; launched in April 2018 **Europe:** Centralised MA granted in November 2019 **Japan:** Phase 3
Rocklatan®	ROCK inhibitor + PGA (qd)	**United States:** Marketed; launched in May 2019 **Europe:** Centralised MA granted in January 2021

New PGAs[(1)]

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

(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 open-angle glaucoma, ocular surface diseases and retinal diseases and may prove to be significant competitors. We expect that our competitors will continue to develop new treatments for open-angle glaucoma, ocular surface diseases and retinal diseases, 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.

Sales and Marketing

We have commercialized Rhopressa® and Rocklatan® in the United States with our own focused, specialized sales force. Our commercial team responsible for the sales of Rhopressa® and Rocklatan® includes approximately 100 sales representatives targeting eye-care professionals throughout the United States, and with the addition of a contract sales organization and a separate telesales team, we are able to reach over 16,000 eye-care professionals.

We have obtained formulary coverage for the majority of lives covered for our glaucoma products under commercial plans and Medicare Part D plans. 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.

Outside of the United States we may enter into a collaboration agreement to commercialize Rhokiinsa® and Roclanda® in Europe. We are currently engaged in discussions with potential partners for Europe and potentially other geographies with various potential partners, while we are simultaneously preparing on our own for pricing discussions in Germany. In October 2020, we entered into the Santen Agreement to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia.

Major Customers

For the year ended December 31, 2020, 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 37.4%, 32.4% and 28.8% of total revenues, respectively, for the year then ended.

Manufacturing

We currently rely on our manufacturing plant in Athlone, Ireland, and our current contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® and currently rely on our third-party manufacturers to produce the API. We may rely on a combination of internal manufacturing and third-party manufacturers for our product candidates and future product candidates.

The commercial production of the final drug product is supported by a combination of internal and outsourced manufacturing. In the second quarter of 2019, we completed the build-out of our own manufacturing plant in Athlone, Ireland, for commercial production of Rocklatan® and Rhopressa®. In January 2020, we received FDA approval to produce Rocklatan® at the Athlone manufacturing plant for commercial distribution in the United States. This approval follows a successful pre-approval inspection of the plant and FDA review of the Prior Approval Supplement (“PAS”), which added the Athlone manufacturing plant as a drug product manufacturer for Rocklatan®. The manufacturing plant began production of commercial supplies of Rocklatan® during the first quarter of 2020. Shipments of commercial supply of Rocklatan® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020. We filed a PAS with the FDA in the second quarter of 2020 and received FDA approval to produce Rhopressa® at the Athlone manufacturing plant in September 2020. The Athlone manufacturing plant commenced shipping commercial supply of Rhopressa® to the United States during the fourth quarter of 2020 and has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. We also expect the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® for the United States as well as both the European and Japanese commercial markets. We may continue to use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States, but at reduced levels compared to before the Athlone manufacturing plant was operational.

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 FDA approval of an additional Rocklatan® drug product contract manufacturer in January 2020, which began to supply commercial product in the first quarter of 2020. Latanoprost, used in the manufacture of Rocklatan®, is available in commercial quantities from multiple reputable third-party manufacturers. We expect that in 2021 the Athlone manufacturing plant will manufacture most of our needs for Rhopressa® and Rocklatan® in the United States.

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.

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.

Intellectual Property

We own the worldwide rights to all indications for Rhopressa® and Rocklatan®. 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 commercial success depends on the viability of our existing, future developed or future acquired intellectual property to be useful to provide protection to our products and 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 portfolio consists of patents and pending patent applications related to the compositions of matter, pharmaceutical compositions, methods of use and synthetic methods. We have patent protection for Rhopressa® and Rocklatan® in the United States through early 2034. Additionally, we hold patents for composition of matter, pharmaceutical compositions and method of use in certain foreign jurisdictions for Rhopressa® and Rocklatan® through 2034 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 providing patent protection for pharmaceutical compositions comprising AR-15512 (previously named AVX-012) and methods of its use, including ophthalmic uses. The Avizorex acquisition also enabled Aerie to be the exclusive licensee of pending foreign counterparts to the issued U.S. patents regarding AR-15512. Should these foreign counterparts issue such patents, they will provide patent protection for pharmaceutical compositions in such jurisdictions comprising AR-15512 and methods of its use, including ophthalmic uses, through 2031. Furthermore, we have an issued U.S. patent for AR-1105, which provides patent protection for AR-1105 in the United States through 2036, as well as pending foreign counterparts that upon issuance will provide 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.

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, 2020 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	43	24	2026 - 2039
Australia	13	10	2026 - 2039
Brazil	0	5	2036 - 2038
Canada	4	12	2026 - 2039
China	0	9	2034 - 2038
Europe	61[(1)]	14	2026 - 2039[(1)]
Hong Kong	1	11	2030 - 2039
India	0	5	2035 - 2038
Japan	5	18	2026 - 2039
Mexico	0	5	2026 - 2038
Patent Cooperation Treaty	0	9	2020 - 2022
Singapore	0	4	2036 - 2038
South Korea	0	7	2035 - 2038
Israel	0	1	2039

(1) Includes patent protection in Belgium (3 issued patents), France (10 issued patents), Germany (10 issued patents), Great Britain (10 issued patents), Ireland (1 issued patent), Italy (10 issued patents), Netherlands (3 issued patents), Spain (11 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 New Drug Application ("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, drug developers must submit an initial IND to the FDA, which contains the results of preclinical tests along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol. 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. The sponsor must make a separate submission to the existing IND 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. Each trial subject must also provide informed consent. 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 $2.8 million for fiscal year 2021) 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 and Distribution

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 $330,000 per prescription drug product for fiscal year 2021.

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 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 European Union 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 European Union, 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, beginning in 2019, Medicare Part D beneficiaries pay 25% of brand 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 ranged from $2.5 billion to $4.1 billion, and has remained 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. As the territories were not prepared to implement these changes, the effective date was extended to April 1, 2022. 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.

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 European Union, our products and product candidates will also be subject to extensive regulatory requirements. Regulatory laws for pharmaceuticals are largely harmonized throughout the European Union, so that applicable E.U. law is most significant and national laws have less importance. As in the United States, medicinal products can only be marketed if either a Centralised MA has been obtained from the European Medicines Authority ("EMA") or national authorisations have been obtained from the competent regulatory agencies.

The various phases of preclinical and clinical research in the European Union 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 European Union for these studies follow internationally accepted standards.

Although the E.U. Clinical Trials Directive 2001/20/EC has sought to harmonize the E.U. clinical trial regulatory framework for pharmaceuticals by setting out common rules for the control and authorization of clinical trials in the European Union, the E.U. 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 E.U. 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 competent authorities of the Member State in which they occurred. All clinical trials must conform to current GCP guidelines issued by the European Union 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 E.U. inspectors on regulatory conformance of such clinical trials are likely.

In 2014, the new E.U. 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 European Union, 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, unless a waiver is obtained where justified, 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 where the indication is one found in children. 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 and Approval

In the EEA, which is currently comprised of the 27 Member States of the European Union 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 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 European Union. 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. A third alternative system is mutual recognition in which member states "mutually recognize" an authorization already granted in another member state, which shortens the application process.

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 E.U. 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. Marketing authorisations lapse if the authorized products are not placed on the market for a period of 3 consecutive years.

In November 2019, we received a Centralised MA for Rhokiinsa®, and in January 2021, we received a Centralised MA for Roclanda®. We will complete a further administrative step to have the Roclanda® authorisation accepted in the United Kingdom, subject to the agreement of the Medicines and Healthcare products Regulatory Authority ("MHRA").

Files Required for Obtaining an E.U. Marketing Authorisation

Similar to the United States, applications for MAs in the European Union 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 E.U. 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 E.U. 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 European Union 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 European Union

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 E.U. 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 E.U. 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.

National competent authorities are responsible for coordinating inspections to verify compliance with cGMP, GCP, good laboratory practice and good pharmacovigilance practice within their own territories, and any other aspects of the supervision of authorized medicinal products, subject to laws and guidance provided by the EMA. Where a manufacturing site outside the European Union supplies product in more than one E.U. country, the EMA facilitates cooperation between those concerned competent authorities.

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 European Union

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 ten-year period, 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.

Separately, 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 within the scope of the marketing authorisation, comparable to a PTE in the United States. 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 European Union

As a manufacturer of pharmaceutical products in the European Union, we are subject to extensive E.U. and national legislation that intends to ensure that only safe products will come into circulation. As a manufacturer, we 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 E.U. 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 European Union is based on several E.U. 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 European Union 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 E.U. GMP to obtain a manufacturing authorisation.

In the European Union, 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, E.U. competent authorities issue a GMP certificate or a non-compliance statement, which is entered in a publicly available database (EudraGMDP).

Reimbursement in the European Union

The European Union does not have a centralized healthcare system. Healthcare is provided through very different systems at the national level. Most E.U. 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 E.U. 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 public bodies like the 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 E.U. member states with full reimbursement is achieved, if at all.

E.U. 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 E.U. 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 an administrative law process for 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.

E.U. 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 E.U. data subjects with rights they may exercise in connection with their data such as the "right to be forgotten" and to access to their data.

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 European Union. 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

United Kingdom Drug Review and Approval

In the United Kingdom, the drug approval process is currently very similar to the process in the European Union. The United Kingdom is made up of Great Britain (England, Scotland and Wales) and Northern Ireland. Due to the Northern Ireland Protocol, agreed with the European Union to protect the integrity of trade in the island of Ireland, Northern Ireland is to remain in the E.U. regulatory system for drugs.

The United Kingdom is currently considering how it might develop its regulatory processes since the United Kingdom left the European Union on January 31, 2020 ("Brexit"), with a transition period that ended on December 31, 2020. The MHRA has issued guidance to the effect that products having an E.U. Centralised MA as of the U.K. withdrawal date, i.e. on January 31, 2020, will be grandfathered in the United Kingdom. To this effect and subject to the completion of an administrative process, such E.U. Centralised MAs will be converted by the MHRA into a national U.K. product license. Therefore, we expect Rhokiinsa® will continue to be authorised in the United Kingdom as long as we provide the MHRA with the required additional information.

For products without Centralised MAs as of January 31, 2020, the option in the United Kingdom is to apply for one of three types of National MAs: the United Kingdom as a whole, Great Britain or Northern Ireland. New centralised applications in the European Union are to be notified to the MHRA together with the timetable and a dossier submitted (because the MHRA does not have access to the E.U. regulatory systems). These applications might until December 31, 2022 be used for a procedurally simplified application for a Great Britain MA through what is known as the EC Decision Reliance Procedure. Because the Centralised MA for Roclanda® was received after December 31, 2020, it is subject to this process. The MHRA will review the EMA decision and have the option to reject the application, although the MHRA is not likely to reject many such applications.

The MHRA is obliged under this procedure to make a decision (positive or negative) within 67 days. Alternatively, a separate application might be made to the MHRA for a Great Britain National MA. Similarly, where the mutual recognition or decentralised process is used in the European Union for applications for national marketing authorisations, there is an option in the United Kingdom to apply under a different reliance procedure, which again requires the MHRA to take a decision within 67

days. Alternatively, the application in the United Kingdom (or Great Britain) can be made separately from the one in Europe. There are then two options for Northern Ireland – including it either in a European mutual recognition or decentralised application process or as part of a U.K. national application. The assessment made by the United Kingdom is on the same bases as in the European Union, focusing on quality, safety and efficacy.

Reimbursement in the United Kingdom

Reimbursement in the United Kingdom is determined for new medicinal products by the National Institute for Health and Care Excellence ("NICE"). NICE reviews health economic data and, in particular, efficacy data in the target population and the cost/ benefit in qualified life years ("QUALY"). If the process runs smoothly there is a 245-day timetable to final decision, although the process can take longer, particularly if there are any appeals. NICE determines whether drug products are recommended for use in the National Health Service ("NHS") and for which indications and price that the NHS might pay for the product.

The United Kingdom, although no longer covered by GDPR, has included the same rules within its separate national laws.

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 European Union, Japan, and potentially the United Kingdom, 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.

Environmental, Social and Governance ("ESG") and Human Capital

ESG

We are dedicated to the principles of environmental stewardship, social responsibility, and good corporate governance. We consider these ESG principles to be among our most important values and therefore integrate them in our ongoing and strategic activities. We believe incorporating these values and practices into our operations not only improves our performance but also creates a sustainable and growth-oriented culture that benefits our employees, our customers and our investors. Our Nominating and Governance Committee of the Board of Directors regularly reviews our operations with senior management to assess our progress in realizing these values. With our Board of Directors' leadership, we continue to evaluate our practices and will continue to integrate sustainability into our business.

We recognize our responsibility to be environmentally conscious and to contribute to the global effort of tackling climate change, moving toward a low-carbon economy and expanding our renewable energy production. We employ green processes, materials, practices, equipment and technologies where possible throughout our operations to foster conservation and reduce waste.

Renewable energy is an important part of our commitment to sustainability and we are operating our manufacturing facilities using renewable energy through renewable sources. At our manufacturing facility in Durham, North Carolina, we source our energy from Duke Energy, a leader in renewable energy, including solar and wind, and Duke Energy is adding additional renewable solutions such as microgrids and battery storage. At our Athlone manufacturing plant in Ireland we receive 100% of our electricity from renewable sources and the electric supply is 100% carbon neutral.

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, 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. In 2020, we recycled 63% of the non-hazardous waste produced at our Athlone manufacturing plant. Through these programs and continuous improvement, we strive to reduce our waste while maximizing the proportion that may be recycled. Looking to the future, we plan to continue to further enhance our sustainability posture through detailed monitoring and management.

From a social responsibility perspective, although we have not yet attained profitability as a company, we have donated hundreds of thousands of dollars to causes that we believe are important to society. These donations were directed to support glaucoma research and glaucoma patient education through ongoing collaborations with the Glaucoma Research Foundation, help fund free cataract surgery for 750 indigent patients in the United States over the past three years through a continuing match program with the American Society of Cataract Refractive Surgery Foundation and promote the empowerment of women in ophthalmology as a lead sponsor of Women in Ophthalmology. In addition, these donations were also directed to accelerate treatments and cures for retinal diseases for the next generation through the Foundation Fighting Blindness and expand opportunities for ophthalmology residents from groups that are underrepresented in medicine or who want to work in underserved communities through support of the National Medical Association's Rabb-Venable Excellence in Ophthalmology Research Program. We have also made other donations as well as supported causes of interest to areas beyond our immediate scope in eye care, such as a long-standing relationship with Northside Center for Child Development ("NCCD") and their work with New York City children in need. Our Chief Financial Officer, currently President of the Board of NCCD, has served as a Director since 2009. NCCD has become a pioneer of behavioral health programs for low-income children of color and their families located in Harlem, Brooklyn and the Bronx, New York.

We also strive to be socially conscious in our employment practices. We support diversity in our hiring practices and follow a management philosophy that integrates social responsibility and the highest governance standards. We established an Affirmative Action Plan in 2018 as an Office of Federal Contract Compliance Programs compliance requirement. We are committed to make a good faith effort to improve the incumbency of targeted areas over time when the opportunity is available. All managers are trained in Equal Employment Opportunity compliant recruiting and interviewing practices. See "*Human Capital—Diversity and Inclusion*" below.

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.

Human Capital

In order to successfully attract and retain highly professional and skilled employees, it is crucial that we offer a diverse, inclusive and safe workplace. Our recruitment process begins with hiring individuals that we believe meet our strong culture for respect, commitment, integrity and honesty. We have a philosophy of investing in our employees by providing the necessary resources to grow professionally through our training and development programs, which will ultimately help drive company success. We reward our employees by offering a competitive compensation and benefits package, which includes incentive-based awards, which we believe motivates our employees and drives company performance. We also seek to engage and give back to the community through donations and fundraising for organizations providing help for those with glaucoma, as discussed in "*—ESG*" above.

As of December 31, 2020, we employed approximately 365 full-time employees, of which 299 were employed in the United States and 66 were outside the United States. The majority of our employees outside of the United States primarily support our manufacturing operations in Athlone, Ireland. Of our total employee population, there were 145 sales force and marketing employees, 111 in research and development and medical affairs, 56 in product manufacturing and 53 in general and administrative support roles such as human resources, finance, legal and information technology. We are committed to providing our employees with a positive work environment that helps them realize their full potential and helps them contribute to the success of our company. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Diversity and Inclusion

We have a strong commitment to continue to build a diverse and inclusive work environment that fosters a positive culture. We believe our diverse workforce brings a wide array of skills and experiences that help increase innovation and strategic thinking and ultimately contribute to the success of our company.

Our hiring practices reflect our commitment to increase diversity and inclusion among our employees. We strive to achieve and maintain pay equity for employees of all races and for both female and male employees within our organization. From a governance perspective, our Compensation Committee of the Board of Directors provides oversight of our policies, programs and initiatives focusing on workforce diversity and inclusion. Approximately a third of our employees in the United States identify as a racial or ethnic minority, with the percentage of minority employees in management reflecting the broader employee population in the United States. The female to male ratio for our total employee population is approximately 50:50.

Talent and Development

The success of our company is highly dependent on the performance, skills and industry knowledge of our employees. A significant proportion of our employee base is comprised of professionals who have had prior experience with pharmaceutical and biotechnology companies. In order to attract and retain such highly qualified talent, we invest significant resources to further develop our employees and provide opportunities that help them achieve career goals and lead our organization.

We maintain a robust training curriculum for all our employees and executives based on function. These curricula incorporate training addressing specific regulatory requirements germane to the performance of specific functions. The training for our scientific and quality personnel, for example, includes modules focusing on our good manufacturing and laboratory practices as well as proper documentation and reporting. In addition to specific function-based training, all of our employees are required to regularly train on our Code of Business Conduct and Ethics (the “Code”), receive cyber security training and receive harassment training. We believe a well-trained employee base is the best way to ensure proper business operations and to best ensure the establishment of a collaborative and supportive corporate culture.

For example, in keeping with our commitment to the highest standards of honest and ethical behavior and integrity in carrying out our business activities, all of our employees who interact with health care professionals on behalf of our company are required to be trained in, and knowledgeable of, not only our Code but also our Healthcare Compliance Manual (the “HCM”). The HCM is a compendium of our standards intended to not only help ensure continued compliance with the prevailing laws, regulations and standards of our industry, but also to provide a framework for our expectations for employee behavior, operational excellence and risk mitigation to help us achieve our broader organizational goals of discovering and delivering new technologies and safe and efficacious therapies to those in medical need. The HCM builds on the Code and governs how our employees engage with the healthcare community when conducting promotional activities and scientific exchanges as well as financial interactions. All such employees or those in areas who support those activities are required to follow these policies.

Health and Safety

We are dedicated to creating and maintaining a work environment where are our employees feel safe to carry on their responsibilities. We regularly review health and safety legislation to ensure compliance with current standards, we identify and monitor potential health and safety hazards, we coordinate emergency and fire drills and we train our employees to avoid or minimize any potential risks within the workplace. The health and safety of our employees, patients, prescribers and community are of utmost importance during this time and we are complying with all requirements and mandates from various agencies and governments. We value the patient volunteers who participate in clinical trials and we are committed to protecting their rights and well-being. As such, we have policies and procedures in place to ensure our clinical trial practices comply with laws and regulations in all countries in which we operate clinical trials and meet our high ethical standards. We also have protocols in place to obtain informed consent from patients participating in our clinical trials.

In our research and manufacturing facilities, we maintain a safety culture and seek to eliminate workplace incidents and minimize risks and hazards. We have created and implemented processes to help eliminate safety events by reducing their frequency and severity. These programs include an Illness and Injury Prevention Program and a Safety Committee. We also review and monitor our performance closely. We monitor and constantly seek to reduce safety incidents each year. Through our efforts, we had a recordable incident rate of 1.3 (recordable incidents per 100 employees, as defined by the U.S. Occupational Safety and Health Administration, “OSHA”) at our Athlone manufacturing plant in 2020. This compares to an OSHA incident rate of 1.6 for the U.S. pharmaceutical and medicine manufacturing industry in 2019.

In response to the COVID-19 pandemic, we are taking precautionary measures to protect our employees and our stakeholders by adapting company policy to maintain the continuity of our business. We have adapted our facilities and work practices and implemented all necessary safety controls in line with government health policy guidelines. We have formed interdisciplinary

teams to (i) focus on company-wide communication about the COVID-19 pandemic, including initiatives implemented to address the COVID-19 pandemic and its impact on our business and (ii) discuss, recommend and supervise the implementation of physical measures at our sites to best ensure employee safety. For example, to further support our employees at the Athlone manufacturing plant, we rolled out a Wellbeing Program to boost communication, engagement and wellness initiatives. With precautionary measures implemented company-wide, we continue to operate effectively as most of our manufacturing plant personnel are working on site and the balance of our total workforce is primarily working from home. Especially important in light of the COVID-19 pandemic, we provide all of our employees with excellent healthcare benefits and we make every effort to provide high levels of coverage at the most affordable cost possible.

Compensation and Benefits

To compete in a highly competitive job market and attract, retain and reward outstanding talent, we offer our employees a comprehensive compensation package which includes competitive salaries and benefit programs. Our well-designed compensation package includes salaries, annual bonuses, equity compensation, 401(k) plan with 401(k) plan match, premium health and dental insurance, life insurance, short-term and long-term disability insurance and workers' compensation insurance. In addition, our generous time off policy includes paid time off, paid sick leave, holidays, personal leave of absence, military leave and family medical leave.

Our equity compensation plans, pursuant to which we may grant stock options, restricted stock and equity-based awards, are designed to align employees' interests with our stockholders' interests and motivate effective performance which drives company success. We also adopted an Employee Stock Purchase Plan under which substantially all employees may purchase Aerie common stock through payroll deductions and lump sum contributions at a price equal to 85% of the lower of the fair market value of the stock as of the beginning or end of the offering periods.

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 Factors Summary

The following is a summary of the principal factors that make an investment in our common stock speculative or risky.

Risks Related to Development and Commercialization

- If we or our collaborators are unable to successfully commercialize our products, or experience significant delays in doing so, our business will be materially harmed.
- If we fail to obtain and sustain market acceptance for our products or an adequate level of coverage and reimbursement for our products, potential future sales would be materially adversely affected.
- We face significant competition, and our operating results will suffer if we fail to compete effectively.
- If clinical trials are unsuccessful, we could be required to abandon development.
- We may not be able to identify additional therapeutic opportunities for our products or to expand our portfolio of product candidates.
- Our products may have undesirable or adverse effects, which may result in the delay, denial or withdrawal of regulatory approval or may limit sales of our products after regulatory approval is received.

Risks Related to Regulation

- Regulatory approval may be substantially delayed or may not be obtained for our products if regulatory authorities require additional time or studies to assess the safety and efficacy.
- Our products subject us to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties.
- Legislation may increase the difficulty and cost of commercialization and affect the prices we may obtain.
- If we face allegations of noncompliance with the law or regulations, our reputation, revenues and liquidity may suffer, and our products could be subject to restrictions or withdrawal from the market. If we or our collaborators are unable to successfully commercialize our products, or experience significant delays in doing so, our business will be materially harmed.

Risks Related to Manufacturing

- We anticipate continued reliance on third-party manufacturers. Production at our suppliers' facilities could be disrupted, which could prevent us from producing enough of our products to satisfy demand.

Risks Related to Our Reliance on Third Parties

- Any collaboration arrangement that we may enter into may not be successful, which could adversely affect our ability to develop and commercialize our products or to enter new therapeutic areas.
- We currently depend on third parties for portions of our operations, and we may not be able to control their work as effectively as if we performed these functions ourselves. If the third parties fail to comply with regulations, our financial results and financial condition will be adversely affected.
- 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.

Risks Related to Intellectual Property

- If our pending patent applications fail to issue our business will be adversely affected.

- We may not be able to enforce and protect our intellectual property rights and our proprietary technology.
- We may infringe the intellectual property rights of others, which may prevent or delay product development and disrupt the commercialization of or increase the costs of commercializing our products.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.
- 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.

Risks Related to Our Financial Position and Need for Additional Capital

- We have limited revenue and may never become profitable.
- 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 our products.
- 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.
- We may be unable to raise the funds necessary to repurchase the Convertible Notes if required 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.
- The capped call transactions may affect the value of our common stock and subject us to counterparty risk.
- We may sell additional debt or equity securities at any time, which may result in dilution to our stockholders, cause our stock price to fall and impose restrictions on our business.
- Our ability to use our net operating loss carryforwards may be limited and changes to U.S. tax laws and tax laws in other jurisdictions could materially impact our financial position and results of operations.

Risks Related to Our Business Operations and Industry

- We depend upon our key personnel and our ability to attract and retain employees. 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.
- Our business may be negatively impacted by macroeconomic conditions, including a public health crisis.
- 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.
- Business interruptions could delay the development of our potential products and our manufacturing activities, and could disrupt our potential sales. Our reputation, business and operations may suffer in the event of system failures, cyber-attacks or other security breaches or failure to comply with legal obligations related to information security.
- 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.
- Any litigation could result in substantial damages and may divert management’s time and attention from our business. Any successful litigation may result in the incurrence of substantial liability if our insurance is inadequate.

Risks Related to Ownership of Our Common Stock

- The market price of our common stock has been, and may continue to be, highly volatile.
- 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.
- As we do not intend to declare cash dividends on our common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.
- Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Risks Related to Development 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® and Rocklatan®, and the successful development, regulatory approval and commercialization of any product candidates or future product candidates for the treatment of patients with open-angle glaucoma, ocular surface diseases and retinal diseases. Rhopressa® and Rocklatan® have been approved by the FDA in the United States, and the EC has granted Centralised MAs for the European Union for Rhopressa® (where it will be marketed as Rhokiinsa®) and for Rocklatan® (where it will be marketed as Roclanda®). Roclanda® will undergo an administrative process to obtain authorization to market in the United Kingdom, but a positive decision is not guaranteed. Neither product has received regulatory approval in any other jurisdiction and no sales can be made in any such jurisdiction unless such approval occurs. Centralized marketing authorisations lapse if the authorized products are not placed on the market for a period of three consecutive years. If we are unable to place our products on the market for a period of three consecutive years, which might occur for a variety of reasons, both practical (manufacturing issues) and regulatory (pricing and reimbursement decisions), then we would lose the right and opportunity to do so and would have to reapply for a marketing authorisation. 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 product candidates or future product candidates depends on factors including:

- successfully completing clinical trials;
- receiving and maintaining current regulatory approvals from applicable regulatory authorities;
- developing and maintaining effective sales, marketing and distribution capabilities;
- establishing adequate manufacturing capacity;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- establishing commercial markets;
- obtaining coverage and reimbursement from third-party payers at a commercially reasonable price point; 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 product candidates or future product candidates or to expand into new markets. This 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 product candidates 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.

The commercial success of Rhopressa® and Rocklatan® in the United States will depend on the degree of market acceptance among eye-care professionals, patients, patient advocacy groups, healthcare payers, including pharmacy benefit managers, and the medical community. Similarly, if Rhopressa® and Rocklatan® are approved in jurisdictions outside the United States and the European Union or any product candidates or future product candidates are approved in any jurisdiction in which they may receive approval, those products may not gain such market acceptance in such jurisdictions. There are a number of available therapies marketed for the treatment of open-angle glaucoma, ocular surface diseases and retinal diseases. 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 product candidates 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;
- 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 product candidates 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 product candidates 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 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 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 product candidates 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, ocular surface diseases and retinal diseases includes primarily older drugs, and the leading products for the treatment of open-angle glaucoma, ocular surface diseases and retinal diseases 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 product candidates 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 Rhopressa® and Rocklatan® for the majority of lives covered under commercial plans and Medicare Part D plans. 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 Rocklatan® or if we do not receive approval for reimbursement of any product candidates 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 European Union must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. Reimbursement in the United Kingdom will also need to be negotiated separately. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we or a collaborator 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 or a collaborator may not be able to launch the product uniformly throughout the European Union 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. Our products 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, ocular surface diseases and retinal diseases and may prove to be significant competitors. We expect that our competitors will continue to develop new treatments for open-angle glaucoma, ocular surface diseases and retinal diseases, 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, ocular surface diseases and retinal diseases.

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, 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:

- obtain and maintain patent protection and non-patent exclusivity in all current and potential commercial jurisdictions for our products;
- attract and retain key personnel;
- 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 product candidates or future product candidates, if approved, we may not achieve commercial success.

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® and Rocklatan® in jurisdictions outside the United States or for any product candidates 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 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 product candidates 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 product candidates 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. 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 such products or 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 product candidates or future product candidates after regulatory approval we could face consequences relating to regulations, litigation or reputational harm, including the withdrawal of regulatory approval of the affected product. 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 may not be able to identify additional therapeutic opportunities for Rhopressa®, Rocklatan® or any product candidates 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 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.

Research programs, including through collaboration arrangements, to pursue the development of Rhopressa®, Rocklatan® and any product candidates 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.

We are also focused on furthering the development of our product candidates and future product candidates for treatment of retinal diseases and dry eye disease. We have created a sustained-release ophthalmology platform and are currently developing three sustained-release implants focused on retinal diseases, AR-1105, AR-13503 SR and AR-14034 SR. 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. In July 2020, we reported topline results of the Phase 2 clinical trial for AR-1105 indicating sustained efficacy of up to six months, an important achievement in validating the potential capabilities of Aerie's sustained release platform. With respect to future plans for AR-1105, we are currently evaluating next steps regarding clinical advancement into Phase 3 along with commercialization prospects in both Europe and the United States. We will be meeting with regulatory agencies in order to harmonize development plans across both Europe and the United States. For AR-13503 SR, we initiated a first-in-human clinical safety study in the third quarter of 2019 for the treatment of wet AMD and DME, which is currently ongoing. For preclinical AR-14034 SR, we anticipate filing an IND with the FDA in the second half of 2022 to evaluate its potential utility as a treatment for wet AMD and DME. We acquired Avizorex in 2019 and in October 2020, we initiated a Phase 2b clinical trial, named COMET-1, which is designed to test two concentrations of AR-15512. 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 product candidates 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.

Risks Related to Regulations

Regulatory approval may be substantially delayed or may not be obtained for our products in jurisdictions outside the United States or for any product candidates 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 product candidates 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 product candidates 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.

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.

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 United Kingdom left the European Union on January 31, 2020, with a transitional period that ended on December 31, 2020. The U.K. MHRA has issued guidance to the effect that products having an E.U. Centralised MA as of the U.K. withdrawal date, i.e. on January 31, 2020, will be grandfathered in the United Kingdom. To this effect and subject to the completion of an administrative process, such E.U. Centralised MA will be converted by the MHRA into a national U.K. product license. Therefore, we expect Rhokiinsa® will continue to be authorised in the United Kingdom as long as we provide the MHRA with the required additional information. Because the Centralised MA for Roclanda® was received after December 31, 2020, it is subject to a different, albeit shortened, administrative process. The MHRA will review the EMA decision and have the option to reject the application.

Rhopressa® and Rocklatan® and any product candidates 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 product candidates 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 product candidates 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.

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 results of the presidential and congressional elections in the United States in 2020 may result in changes to 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 had been efforts by former President Trump 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. On December 18, 2019 the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and oral arguments were held on November 10, 2020, although it is unclear when a decision will be made or how the United States Supreme Court will rule. It is uncertain how this decision and other efforts to repeal and replace the PPACA will impact the PPACA and our business.
- In addition, former President Trump and Congress had indicated an intent to address prescription drug pricing and former President Trump signed Executive Orders relating to pharmaceutical pricing and importation. Given the change in administration, it is unclear whether or how the Executive Orders will be implemented by applicable regulatory agencies and it is also unclear if the Biden Administration will continue to enforce the Orders, but these actions show an increased interest by the federal government in pharmaceutical pricing and distribution. In addition, Congressional hearings have brought increased public attention to the costs of prescription drugs. Numerous bills have also 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 and their implementation may impact our strategies for growth in the future.

- Former President Trump and President Biden both issued Executive Orders intended to favor government procurement from domestic manufacturers. In addition, former President Trump issued an Executive Order specifically aimed at the procurement of pharmaceutical products, which instructed the federal government to develop a list of "essential" medicines and then buy those and other medical supplies that are manufactured, including the manufacture of the API, in the United States. It is unclear whether this Executive Order or something similar will be implemented by the Biden Administration.
- 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 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.

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 product candidates 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.

Risks Related to Manufacturing

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 manufacturing of Rhopressa® or Rocklatan® or any product candidates 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 we or our third-party manufacturers do not have a cGMP compliance status or other comparable status acceptable to the FDA or other regulatory authority, as applicable, approval of any NDA or other application that includes those 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 product candidates 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 or other regulatory authority may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

While we expect to rely heavily on our own manufacturing capabilities at our Athlone plant, there will be continued reliance on third-party manufacturers for the commercialization of Rhopressa® and Rocklatan® as back-up suppliers and the development of any product candidates 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 may 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 product candidates 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 product candidates 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 product candidates 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, and we completed the build-out during the second quarter of 2019. In January 2020 and September 2020, we received FDA approval to produce

Rocklatan® and Rhopressa®, respectively, at the Athlone manufacturing plant for commercial distribution in the United States. The Athlone manufacturing plant began manufacturing commercial supplies of Rocklatan® in the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. We expect that the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® for the United States as well as both the European and Japanese commercial markets. 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. If our manufacturing operations fail to achieve regulatory approval or to effectively produce commercial supplies of Rhopressa® or Rocklatan® or any product candidates 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®.

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.

Risks Related to Our Reliance on Third Parties

If we or our collaborators are unable to successfully obtain regulatory approval and commercialize Rhopressa® and Rocklatan® in jurisdictions outside the United States, our business may be harmed.

To obtain regulatory approval and commercial success for our products in jurisdictions outside the United States, we must either conduct clinical trials and develop a sales and marketing organization in such jurisdictions or outsource these functions to third parties through collaboration agreements. While we are currently engaged in discussions with potential partners to commercialize Rhokiinsa® and Roclanda® in Europe, we have announced the Santen Agreement for the development and commercialization of Rhopressa® and Rocklatan® in Japan. We have limited experience conducting clinical trials in jurisdictions outside the United States and no experience selling, marketing or distributing any drug product in any jurisdictions outside the United States. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. See "—Risks Related to Development and Commercialization—*Failure can occur at any stage of clinical development. If the clinical trials are unsuccessful, we could be required to abandon development.*" 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 or our collaborators will successfully launch any product in any jurisdictions outside the United States. If we enter into a collaboration agreement, such as the Santen Agreement, our collaborator may not advance the clinical trials or commercialization milestones as quickly or as successfully as we had expected. See "*—Any collaboration arrangement that we may enter into may not be successful, which could adversely affect our ability to develop and commercialize any product candidates or future product candidates or technologies or to enter new therapeutic areas.*" If we pursue on our own a sales and marketing strategy in an additional jurisdiction, which may occur if a collaboration agreement does not result in a successful product launch, 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 obtain regulatory approval or commercialize our products on our expected timing or at all despite these additional expenditures.

Factors that may inhibit our efforts to successfully obtain regulatory approval and commercialize our products outside the United States include:

- 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 the clinical trials;
- an inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in the clinical trials;
- 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.

Any collaboration arrangement that we may enter into may not be successful, which could adversely affect our ability to develop and commercialize our products, any product candidates 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 product candidates or future product candidates or technologies. In October 2020, we entered into the Santen Agreement to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia, as part of our globalization strategy. We are currently engaged in discussions with potential partners to commercialize Rhokiinsa® and Roclanda® in Europe. 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.

Pursuant to the Santen Agreement, there are various development milestone and sales milestones. If Santen is not able to hit the milestones within the timeframes contemplated by the Santen Agreement, or at all, our development and commercialization efforts in Japan and the other countries will be harmed. Additionally, Santen may terminate the Santen Agreement if, among other events, there are patents issued that may prevent the commercialization of Rhopressa® and Rocklatan® and such termination would require us to repay up to approximately 85% of a $50.0 million upfront payment (the “Upfront Payment”), which Santen paid pursuant to the Santen Agreement, all development milestone payments, and 50% of the development expenses incurred by Santen. Such termination may adversely affect us financially and could harm our reputation.

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.

We have entered into collaboration arrangements and intend to continue exploring 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.

Entering markets outside of the United States is 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, we completed the build-out of our manufacturing plant in Athlone, Ireland, for additional commercial production of Rhopressa® and Rocklatan® in the second quarter of 2019. In January 2020 and September 2020, respectively, we received FDA approval to produce Rocklatan® and Rhopressa®, respectively, at the Athlone manufacturing plant for commercial distribution in the United States. The Athlone manufacturing plant began manufacturing commercial supplies of Rocklatan® in the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. We expect that the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® for the United States as well as both the European and Japanese commercial markets. We have entered into the Santen Agreement to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia, and we are currently engaged in discussions with potential partners to commercialize Rhokiinsa® and Roclanda® in Europe. We also opened offices in Dublin, Tokyo and London 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 or other extra-territorial anti-bribery laws such as the U.K. Bribery Act 2010;
- 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.

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 product candidates 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 product candidates 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 product candidates 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 product candidates or future product candidates, if approved, will be delayed or severely compromised and our results of operations may be harmed.

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, 2020, three distributors represented approximately 37.4%, 32.4% and 28.8% 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.

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, 2020, we owned 51 patents and have 47 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, 2020, 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 pharmaceutical compositions of AVX-012 and its use in treating dry-eye in the United States and pending patent applications internationally. Furthermore, as of December 31, 2020, for AR-1105 we had one issued pending and one pending patent application in the United States and eight pending patent applications internationally. With respect to AR-13503, we owned 41 patent applications in the United States and internationally as of December 31, 2020. 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 product candidates or future product candidates, as well as successfully defending our current and future patents against third-party challenges. As of December 31, 2020, we owned 128 patents and have 132 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 51 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 product candidates 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 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®, Roclanda® or any product candidates 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®, Roclanda® or any product candidates 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®, Roclanda® or any product candidates 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®, Roclanda® or any product candidates 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®, Roclanda® or any product candidates 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. The EC granted Centralised MAs for Rhopressa® (which will be marketed under the trade name Rhokiinsa®) in November 2019 and for Rocklatan® (which will be marketed under the trade name Roclanda®) in January 2021. Any other names we intend to use for our product candidates 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 product candidates or future product candidates, we may be required to adopt an alternative trade name.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our patents for Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any product candidates 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 product candidates 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.

Similarly, Europe provides a mechanism for patent owner to regain a portion of patent grant time lost due to product development and the European regulatory review process. Pursuant to Regulation (EC) No 469/2009 of the European Parliament, the patent owner may file for a Supplementary Protection Certificate (“SPC”) on a country-by-country basis in order to regain such lost patent grant time. Unlike the U.S. PTE, an SPC does not extend the expiration date of a European patent, but is limited to the scope of the marketing authorisation. Rather, it provides to the patent owner all of the rights the European patent provided to the patient holder for up to five (5) years from the expiration of the European patent. Upon approval of Rhokiinsa® in Europe, Aerie has filed for SPCs in a number of E.U. countries for EP Patent 3053913. SPCs have been granted in Italy, Ireland and The Netherlands, and are presently pending in Germany, France, Spain, Belgium, and Great Britain.

Risks Related to Our Financial Position and Need for Additional Capital

We 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 MAs for Rhokiinsa® and Roclanda® from 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 product candidates 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 product candidates or future product candidates, if approved, at acceptable cost levels;
- successfully market and sell Rhopressa® and Rocklatan® and any product candidates or future product candidates, if approved, in the United States and other jurisdictions; and
- successfully complete clinical development, and receive regulatory approval, for our product candidates 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 product candidates 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 funds, 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® generate adequate net revenues to cover operating costs and expenses, if at all.

We have incurred losses in each year since our inception in June 2005. Our net losses were $183.1 million, $199.6 million and $232.6 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $1,079.1 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 product candidates 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 product candidates 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, 2020, 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 increase 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, 2020, 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 product candidates 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 FASB Accounting Standards Codification ("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 will soon no longer be eligible to use the treasury stock method to reflect the shares underlying the Convertible Notes in our diluted earnings per share. Under the treasury stock 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. In August 2020, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40), Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. This would reduce non-cash interest expense, and thereby decrease net loss (or increase net income). Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments whose principal amount may be settled using shares and the if-converted method will be required. ASU 2020-06 will become effective for fiscal years beginning after December 15, 2021 including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. Application of the "if-converted" method may reduce our reported diluted earnings per share.

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 equity or debt securities. The issuance of additional equity would result in dilution to all of our stockholders. 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. In addition, we have been manufacturing our products for a relatively short amount of time. 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.

We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We have relatively 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, 2020, we had U.S. federal and state net operating losses (“NOLs”) of approximately $585.4 million and $561.7 million, respectively. If not utilized, federal NOLs that arose before 2018 and state NOLs begin to expire at various dates beginning in 2031 and 2023, 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, 2020. As of December 31, 2020, we also had foreign NOLs of $98.9 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 Business Operations and Industry

The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, such as COVID-19, could adversely affect our business, results of operations and financial condition.

We could be negatively impacted by the widespread outbreak of an illness or any other communicable disease, or any other public health crisis that results in economic and trade disruptions, including the disruption of global supply chains. In December 2019, there was an outbreak of a new strain of coronavirus ("COVID-19"). On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and workforce participation due to "shelter-in-place" and "stay at home" restrictions by various governments worldwide and created significant volatility and disruption of financial markets.

The COVID-19 pandemic may continue to affect demand for our products because quarantines or other government restrictions on movements have caused and continue to cause changes in demand. Many eye-care professionals' offices are operating with reduced capacity and there is uncertainty if or when they will return to full capacity. Patients may continue to change the quantities in, or the frequency with, which they order our products. Additionally, patients may not visit their eye-care professionals for an extended period of time due to logistical issues or safety concerns, resulting in fewer new diagnoses or prescriptions as the COVID-19 pandemic continues to progress. Our sales force is also limited in its ability to meet with current and potential prescribers, which may negatively affect sales. Our current efforts to utilize virtual tools to remain in contact with eye-care professionals, in addition to face-to-face meetings, may not be adequate to address any negative effect on sales. If the overall economy is negatively affected, including by entering into a recession, current and potential patients may alter their spending patterns and may have less disposable income with which to spend on prescriptions, amongst other changes. The changes in eye-care professional and patient behavior could have a material adverse effect on our results of operations.

The COVID-19 pandemic may also disrupt our third-party partners' ability to meet their obligations to us, which may negatively affect our operations. These third parties include the suppliers of our active pharmaceutical ingredient, suppliers of our finished product and clinical research organizations. While we have not observed disruptions to date with respect to any such third party, as the COVID-19 pandemic progresses as a result of transport restrictions related to quarantines, travel bans or other governmental actions may cause our global supply to become constrained.

The progress of the COVID-19 pandemic may disrupt our clinical operations and regulatory approvals. We are in the process of advancing our products towards approval in jurisdictions outside the United States and advancing our product candidates towards regulatory approval. We also have applications for regulatory approval pending. We do not yet know whether or how the progress of the COVID-19 pandemic will affect our clinical operations, including enrollment of clinical trials, or the timing of regulatory approvals.

The extent of the impact of the COVID-19 pandemic on our operational and financial performance will depend on future developments, including the duration and spread of COVID-19; the effect on eye-care professionals and patients and demand for our products; our ability to sell and provide our products, including as a result of people staying home, the health and safety of our employees and any closures of our offices and our manufacturing plant in Athlone, Ireland, our eye-care professionals' offices and regulatory agencies, all of which are uncertain and cannot be predicted. In addition, the financial markets are currently volatile due to the market conditions discussed above. Conditions in the financial and credit markets may limit the availability of liquidity or increase the cost of such liquidity, which could adversely affect our business, financial position and results of operations. COVID-19, and the volatile economic conditions stemming from the pandemic, as well as reactions to future pandemics or resurgences of COVID-19, could also precipitate or aggravate the other risk factors that we identify in this section, including our ability to achieve market acceptance of our products, our competitiveness, our reliance on third parties,

our dependence on key personnel, our risks related to security breaches and other cybersecurity risks and our manufacturing capabilities. An extended period of global supply chain and economic disruption could materially adversely affect our business, our results of operations, our access to sources of liquidity, our financial condition and the price of our common stock.

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 Chief Human Resources Officer and Vice President, 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.

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 product candidates 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 product candidates or future product candidates, if approved, or develop additional product candidates or technologies.

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 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 product candidates 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 E.U. 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 E.U. 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 European Union, including to the United States and other regions.

The GDPR imposes 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 is a rigorous and time-intensive process that has increased our cost of doing business and required 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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.

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 product candidates 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.

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:

- overall company profitability and ability to generate positive cash flows;
- 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;
- our ability to obtain and maintain successful collaboration arrangements;
- the results of our testing and clinical trials for our product candidates and future product candidates;
- 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 or licensees;
- the results of our efforts to develop, acquire or license additional product candidates or technologies;
- changes in laws or regulations;
- any intellectual property infringement actions in which we may become involved;
- 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 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 historically experienced 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 18.2% of our common stock as of December 31, 2020. 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 January 2022 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. Our Bedminster, New Jersey, location 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

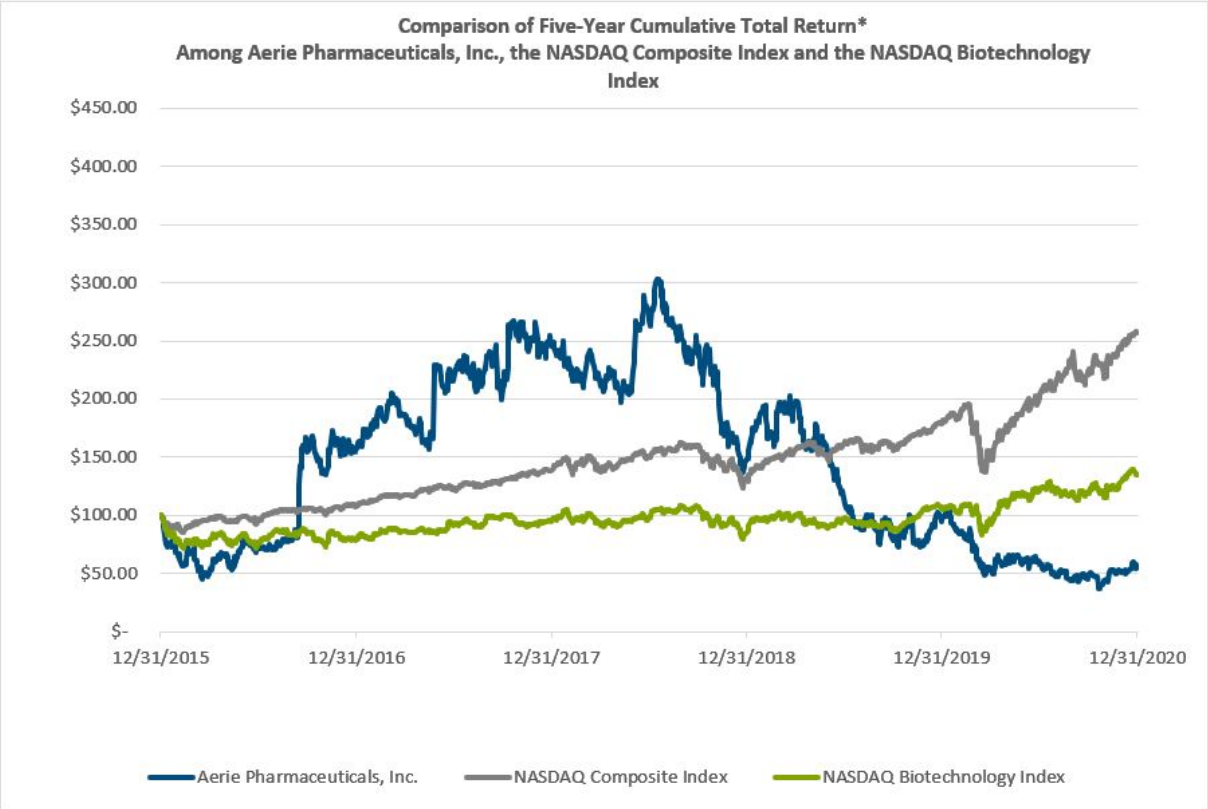
Our common stock is traded on The Nasdaq Global Market under the symbol "AERI."

Stockholders

As of February 19, 2021, we had 46,917,133 shares of common stock outstanding held by approximately 211 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, 2015 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2015, 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, 2020, 2019 and 2018 and the balance sheet data as of December 31, 2020 and 2019 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, 2017 and 2016 and the balance sheet data as of December 31, 2018, 2017 and 2016 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,				
	2020	2019	2018	2017	2016
	(in thousands, except share and per share data)				
Product revenues, net [1]	$ 83,138	$ 69,888	$ 24,181	$ —	$ —
Total revenues, net	83,138	69,888	24,181	—	—
Costs and expenses:					
Cost of goods sold[2]	25,333	4,833	641	—	—
Selling, general and administrative	137,184	138,402	120,614	56,905	34,706
Pre-approval commercial manufacturing[3]	2,304	22,767	26,545	16,710	9,772
Research and development[4]	74,007	91,378	86,123	72,078	52,394
Total costs and expenses	238,828	257,380	233,923	145,693	96,872
Loss from operations	(155,690)	(187,492)	(209,742)	(145,693)	(96,872)
Other income (expense), net[5]	(22,166)	(12,179)	(22,824)	(1,170)	(1,994)
Loss before income taxes	(177,856)	(199,671)	(232,566)	(146,863)	(98,866)
Income tax expense (benefit)[6]	5,245	(90)	3	(1,758)	193
Net loss	$ (183,101)	$ (199,581)	$ (232,569)	$ (145,105)	$ (99,059)
Net loss per common share—basic and diluted	$ (3.99)	$ (4.39)	$ (5.58)	$ (4.11)	$ (3.40)
Weighted average number of common shares outstanding—basic and diluted	45,897,255	45,427,154	41,663,958	35,324,472	29,135,583

(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) Our cost of goods sold for the year ended December 31, 2020 was unfavorably impacted by idle capacity costs due to underutilization at the Athlone manufacturing plant due to the startup of the facility and inventory write-offs, which increased the cost of goods sold by $17.0 million and $2.3 million, respectively.

(3) We received regulatory approval in January 2020 and September 2020 to produce Rocklatan® and Rhopressa®, respectively, at our Athlone manufacturing plant for commercial distribution in the United States. The cost of Rocklatan® and Rhopressa® produced by the Athlone manufacturing plant for commercial distribution following regulatory approval to produce such products for commercial distribution in the United States was capitalized as inventory or expensed to cost of goods sold. Further, we also received regulatory approval for our additional Rocklatan® drug product contract manufacturer to produce such product for commercial distribution in the United States, which began to supply commercial product for commercial distribution in the United States in the first quarter of 2020. The cost of commercial Rocklatan® produced by the additional contract manufacturer following regulatory approval was capitalized as inventory.

(4) We recorded $10.2 million in expenses in the fourth quarter of 2019 associated with the acquisition of Avizorex.

(5) Includes interest expense related to the amortization of issuance costs and fees incurred on the July 2018 and May 2019 tranches of the $200 million senior secured delayed draw term loan facility (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.

(6) Includes $5.0 million in withholding tax incurred in the fourth quarter of 2020 related to the $50.0 million Upfront Payment, which Santen paid pursuant to the Santen Agreement.

	AS OF DECEMBER 31,				
	2020	2019	2018	2017	2016
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 151,570	$ 143,940	$ 202,818	$ 197,569	$ 197,945
Total Investments	88,794	165,250	—	52,086	35,717
Short-term	88,794	165,250	—	52,086	35,717
Total assets	402,045	452,608	285,044	290,276	248,254
Convertible notes, net	210,373	188,651	—	123,845	123,539
Total stockholders' equity	23,968	166,950	227,806	135,599	105,344

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. Refer to Item 7. of our Form 10-K issued on February 24, 2020 for prior year discussion related to fiscal 2018.

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, ocular surface diseases, retinal diseases and potentially other diseases of the eye.

U.S. Commercial Products

Our strategy is to successfully commercialize our FDA-approved products, Rhopressa® and Rocklatan®, which are sold in the United States and comprise our glaucoma franchise. Our commercial team responsible for sales of Rhopressa® and Rocklatan® is targeting eye-care professionals throughout the United States, and with the addition of a contract sales organization and a separate telesales team, we are able to reach over 16,000 eye-care professionals.

Rhopressa® is a once-daily eye drop designed to reduce elevated IOP in patients with open-angle glaucoma or ocular hypertension. Rhopressa® is taken in the evening and has shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

The active ingredient in Rhopressa®, netarsudil, is an Aerie-owned ROCK inhibitor. 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. 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. Rocklatan® is also taken in the evening, and similar to Rhopressa®, has shown in preclinical and clinical trials to be effective in reducing IOP, with a favorable safety profile.

Based on our clinical data, we believe that Rocklatan® has the potential to provide a greater IOP-reducing effect than any glaucoma medication currently marketed in the United States. We also believe that Rocklatan® competes with both 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.

Outside the United States

Our strategy also includes developing business opportunities outside of the United States, including successfully commercializing Rhopressa® and Rocklatan® in Europe and obtaining regulatory approval in Japan and other countries in Asia, and our globalization plan is well underway.

In Europe, Rhokiinsa® was granted a Centralised MA by the EC in November 2019 and Roclanda® was granted a Centralised MA by the EC in January 2021, which followed the EMA's CHMP adopting a positive opinion recommending approval of the MAA for Roclanda® in November 2020.

We reported positive interim topline 90-day efficacy data in September 2020 for our Phase 3b clinical trial for Roclanda®, named Mercury 3, which we believe is important to the execution of our strategy in Europe. As a result of the positive Mercury 3 results and the Roclanda® approval in Europe, third parties expressed interest in a potential commercialization partnership in

and potentially beyond Europe. We are currently engaged in discussions with potential partners, while we are simultaneously preparing on our own for pricing discussions in Germany.

In Japan, we entered into the Santen Agreement in October 2020 to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia. We initiated a Rhopressa® Phase 3 clinical trial in December 2020, the first of three expected Phase 3 clinical trials in Japan. Clinical trials for Rocklatan® have not yet begun.

Glaucoma Product Manufacturing

We have a sterile fill production facility in Athlone, Ireland, for the production of our FDA approved products and clinical supplies with the goal of having the Athlone manufacturing plant supply our ophthalmic products in all markets for which we received regulatory approval and are commercialized. The Athlone manufacturing plant began manufacturing commercial supplies of Rocklatan® in the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. Shipments of commercial supply of Rocklatan® and Rhopressa® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020 and in the fourth quarter of 2020, respectively. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. As the Athlone manufacturing plant commenced operations in 2020, it has not yet reached full capacity. We expect that the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® in the United States as well as for both the European and Japanese commercial markets, if approved for commercial distribution in those markets. We may continue to use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States, but at reduced levels compared to before the Athlone manufacturing plant was operational.

Product Candidates and Pipeline

Our strategy also includes enhancing 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.

AR-15512 is our product candidate for the treatment of dry eye disease, acquired in late 2019, for which we initiated a Phase 2b clinical trial named COMET-1 in October 2020. Furthermore, we are developing three sustained-release implants focused on retinal diseases, AR-1105, AR-13503 SR and AR-14034 SR. For AR-1105, we successfully completed a large Phase 2 clinical trial for patients with macular edema due to RVO in July 2020, which indicates sustained efficacy of up to six months, an important achievement in validating the potential capabilities of Aerie's sustained release platform. With respect to future plans for AR-1105, we are currently evaluating next steps regarding clinical advancement into Phase 3 along with commercialization prospects in both Europe and the United States. For AR-13503 SR, we initiated a first in-human clinical safety study in the third quarter of 2019 for the treatment of wet AMD and DME, which is currently ongoing. In addition, we are also working to advance our preclinical sustained-release retinal implant, AR-14034 SR, for which we anticipate filing an IND with the FDA in the second half of 2022.

We discovered and developed the active ingredient in Rhopressa® and Rocklatan®, netarsudil, and AR-13503 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.

Impact of the COVID-19 Pandemic

In December 2019, there was an outbreak of a new strain of coronavirus ("COVID-19") and on March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and workforce participation due to "shelter-in-place" restrictions by various governments worldwide and created significant volatility and disruption of financial markets.

The health and safety of our employees, patients, prescribers and community are of utmost importance during this time and we are complying with all requirements and mandates from various agencies and governments. We are taking precautionary measures to protect our employees and our stakeholders and adapting company policy to maintain the continuity of our business. We continue to operate effectively as most of our manufacturing plant personnel are working at the manufacturing plant with precautionary measures in place, while the balance of our workforce is primarily working from home.

While many eye-care professionals' offices are operating at reduced capacity, we are using a combination of in-person and virtual tools and resources to remain in contact with eye-care professionals. Aerie territory managers are experiencing

successful engagement with eye-care professionals through either traditional face-to-face office meetings or virtual resources. Our sales force is interactively communicating with physicians via different technological platforms and local peer-to-peer educational meetings are primarily being implemented via webinars. Certain geographic communities have resumed in-person speaker programs, while adhering to strict national guidelines with appropriate social distancing. As part of the support of the eye-care community, our territory managers are either delivering or arranging for delivery of product samples to the eye-care professionals' offices when needed. Further, with the addition of a contract sales organization and a separate telesales team, we are able to reach over 16,000 eye-care professionals.

We have observed no disruptions to date in the supply chain for the production of Rhopressa® and Rocklatan®. We believe we have approximately three years of starting materials and API in inventory, and adequate supply of finished product on hand to support our commercial efforts for at least the next six months. Production of Rhopressa® and Rocklatan® is continuing.

Although there was a decline in total prescription volumes in April 2020, as seen within the entire pharmaceutical market according to IQVIA data, primarily due to the impact of the COVID-19 pandemic, our sales volumes have increased each successive quarter as compared to the first quarter of 2020 for both Rhopressa® and Rocklatan®. We are diligently managing our expenses, including reducing travel and meeting expenses.

Regarding our globalization strategy, in Japan, we entered into the Santen Agreement in October 2020 to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia, held a meeting with the Japanese PMDA in April 2020 to discuss Phase 3 clinical trial designs for Rhopressa®, in which the first of three Rhopressa® Phase 3 clinical trials commenced in the fourth quarter of 2020, as discussed in "*—Outside the United States"* above and Note 13 to our consolidated financial statements included elsewhere in this report for further discussion. In Europe, Roclanda® was granted a Centralised MA by the EC in January 2021, while the six-month efficacy data for the Mercury 3 trial for Roclanda®, which is designed to gauge commercialization prospects in Europe, reported positive interim topline 90-day efficacy data in September 2020, as discussed in "*—Outside the United States"* above.

From a pipeline perspective, the early stage retina implant trials remain on track, and we initiated our Phase 2b clinical trial for dry eye product candidate AR-15512, named COMET-1, in October 2020 and a topline readout is expected in the third quarter of 2021, as discussed in "*—Product Candidates and Pipeline"* above.

Our cash and cash equivalents and investments totaled $240.4 million as of December 31, 2020. We believe that our cash and cash equivalents and investments and projected cash flows from revenues will continue to provide sufficient resources for our current ongoing needs through at least the next twelve months, as discussed in "—Liquidity and Capital Resources" below.

Financial Overview

Our cash and cash equivalents and investments totaled $240.4 million as of December 31, 2020. 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, 2020, we had an accumulated deficit of $1,079.1 million. We recorded net losses of $183.1 million, $199.6 million and $232.6 million for the years ended December 31, 2020, 2019 and 2018, 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 operating 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 product candidates 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 April 2018 and commenced generating product revenues from sales of Rhopressa® during the second quarter of 2018. We launched Rocklatan® in the United States in May 2019 and commenced generating product revenues from sales of Rocklatan® in the second quarter of 2019. Product affordability for the patient drives

consumer acceptance, and this is generally managed through coverage by Third-party Payers and such product may be subject to rebates and discounts payable directly to those Third-party Payers. 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 product candidates 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. In January 2020 and September 2020, we received FDA approval to produce Rocklatan® and Rhopressa® , respectively, at the Athlone manufacturing plant for commercial distribution in the United States. Shipments of commercial supply of Rocklatan® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020. The Athlone manufacturing plant has manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan and has commenced shipping commercial supply of Rhopressa® to the United States in the fourth quarter of 2020. Production costs related to idle or underutilized capacity at the manufacturing plant in Athlone, Ireland, are not included in the cost of inventory but are charged directly to cost of goods sold on the consolidated statements of operations and comprehensive loss in the period incurred. We expect cost of goods sold in 2021 to continue to be unfavorably impacted by idle capacity costs due to the underutilization at the Athlone manufacturing plant as a result of the Athlone manufacturing plant having just recently become operational and not yet reaching full capacity, along with the potential for future inventory obsolescence write-offs, which we do not expect the impact to be material. We expect the underutilization to continue to have an unfavorable impact on cost of goods sold that will decrease over time as the manufacturing plant reaches full capacity.

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 to produce Rocklatan® and Rhopressa® in January 2020 and September 2020, respectively, in our Athlone, Ireland, plant for commercial distribution in the United States as well as approval for our additional API and drug product contract manufacturers during 2019 and early 2020.

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, net 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, including the amortization of debt discounts and issuance costs incurred. Prior to the termination of the credit facility in September 2019, interest expense also included the amortization of issuance costs and commitment fees incurred on the July 2018 and May 2019 tranches of the credit facility. Interest income primarily consists of interest earned on our cash, cash equivalents and investments. See "—Liquidity and Capital Resources" below and Note 10 to our consolidated financial statements included elsewhere in this report for further discussion. Foreign exchange gains and losses are primarily due to the remeasurement of our lease liabilities, which are denominated in a foreign currency and held by a subsidiary with a U.S. dollar functional currency. Also included in other income and expense are changes in fair value related to our equity securities and research and development tax credit refunds.

Income Tax Expense (Benefit)

Income tax expense (benefit) primarily includes withholding tax related to the Upfront Payment paid by Santen pursuant to the Santen Agreement.

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.

Product Revenues

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 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, 2020 were generated through sales of Rhopressa® and Rocklatan® in the United States. 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, 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, 2020, as customer invoicing generally occurs before or at the time of revenue recognition. We did not have any contract liabilities at December 31, 2020, 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 products, which occurs at a point in time, typically upon delivery of products to the distributors. For the year ended December 31, 2020, three distributors accounted for 37.4%, 32.4% and 28.8% 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 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 $202.2 million and $105.9 million in aggregate for the years ended December 31, 2020 and 2019, 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 information regarding returns of Rhopressa® and Rocklatan® as well as 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.

Contract Revenues from License Agreements

In the normal course of business, we conduct research and development activities pursuant to which we may license certain rights of our intellectual property to third parties. The terms of these arrangements typically include payment for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; clinical or commercial supply services and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under such agreements, the five steps outlined in "—*Revenue Recognition*" above are performed. As part of the accounting for these arrangements, judgment is used to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price under step (iv) above; and (d) in some circumstances when control transfers and the appropriate measure of progress in order to recognize revenue under step (v) above. Judgment is used to determine whether milestones or other variable consideration, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

Upfront license fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. At the end of each subsequent reporting period, we will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenues from collaborations during the period of adjustment.

Clinical or commercial supply services: Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as customer options. We assess if these options provide a material right to the licensee and if so, they would be accounted for as separate performance obligations.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, we will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a

significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

See Note 3 to our consolidated financial statements included elsewhere in this report for further discussion.

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. The estimated fair value of stock options is determined using the Black-Scholes option pricing model. 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 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, 2020, 2019 and 2018 appear in the table below.

	YEAR ENDED DECEMBER 31,		
	2020	**2019**	**2018**
Expected term (years)	6.0	6.0	6.0
Expected stock price volatility	74 %	74 %	78 %
Risk-free interest rate	0.9 %	1.9 %	2.7 %
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, 2020 and 2019

The following table summarizes the results of our operations for the years ended December 31, 2020 and 2019:

	YEAR ENDED DECEMBER 31,			
	2020	2019	CHANGE	% CHANGE
	(in thousands, except percentages)			
Product revenues, net	$ 83,138	$ 69,888	$ 13,250	19 %
Total revenues, net	83,138	69,888	13,250	19 %
Costs and expenses:				
Cost of goods sold	25,333	4,833	20,500	*
Selling, general and administrative expenses	137,184	138,402	(1,218)	(1)%
Pre-approval commercial manufacturing	2,304	22,767	(20,463)	(90)%
Research and development expenses	74,007	91,378	(17,371)	(19)%
Total costs and expenses	238,828	257,380	(18,552)	(7)%
Loss from operations	(155,690)	(187,492)	31,802	(17)%
Other (expense) income, net	(22,166)	(12,179)	(9,987)	82 %
Loss before income taxes	$ (177,856)	$ (199,671)	$ 21,815	(11)%
Income tax expense (benefit)	$ 5,245	$ (90)	$ 5,335	*
Net loss	$ (183,101)	$ (199,581)	$ 16,480	(8)%

**Percentage not meaningful*

Product revenues, net

Product revenues, net was $83.1 million and $69.9 million for the years ended December 31, 2020 and 2019, respectively. Revenues recorded during the year ended December 31, 2020 relate to sales of Rhopressa® and Rocklatan®. The year-over-year revenue increase is primarily attributable to volume growth of Rocklatan®, which we launched in the United States in May 2019. This increase is partially offset by the impact of higher rebates largely driven by government sponsored programs, which contributed to a lower net sales per unit. Although there was a decline in total prescription volumes in April 2020, as seen within the entire pharmaceutical market according to IQVIA data primarily due to the impact of the COVID-19 pandemic, our sales volumes have increased each successive quarter in 2020 as compared to the volumes during the first quarter of 2020 for both Rhopressa® and Rocklatan®.

Cost of goods sold

Cost of goods sold was $25.3 million and $4.8 million, and our gross margin percentage was 69.5% and 93.1% for the year ended December 31, 2020 and 2019, respectively. Our cost of goods sold and gross margin percentage for the year ended December 31, 2020 were unfavorably impacted by idle capacity costs due to underutilization at the Athlone manufacturing plant due to the startup of the facility and inventory write-offs, which increased the cost of goods sold by $17.0 million and $2.3 million, respectively, and lowered the gross margin percentage by 20.4% and 2.8%, respectively. We expect the underutilization to continue to have an unfavorable impact on cost of goods sold that will decrease over time as the manufacturing plant reaches full capacity. We received FDA approval to produce Rocklatan® and Rhopressa® in January 2020 and September 2020, respectively, at the Athlone manufacturing plant for commercial distribution in the United States. Prior to this approval, costs incurred for commercial-related manufacturing activities for both products were recorded to pre-approval commercial manufacturing expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased by $1.2 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019, primarily due to lower sales and marketing expenses, lower travel expenses as a result of

COVID-19 related travel restrictions as well as a decrease in stock-based compensation expense during the period. This decrease was partially offset by higher employee related expenses for the year ended December 31, 2020 as compared to the year ended December 31, 2019.

Pre-approval commercial manufacturing expenses

Pre-approval commercial manufacturing expenses decreased by $20.5 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. Expenses were lower primarily due to the receipt of regulatory approval in January 2020 and September 2020 to produce Rocklatan® and Rhopressa®, respectively, at our Athlone manufacturing plant as the cost of Rocklatan® and Rhopressa® produced by the Athlone manufacturing plant for commercial distribution following regulatory approval was capitalized as inventory or expensed to cost of goods sold. Further, expenses were lower due to regulatory approval for our additional Rocklatan® drug product contract manufacturer, which began to supply commercial product in the first quarter of 2020. The cost of commercial Rocklatan® produced by the additional contract manufacturer following regulatory approval was capitalized as inventory.

Research and development expenses

Research and development expenses decreased by $17.4 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. The decrease is primarily due to expenses of $10.2 million recorded in the fourth quarter of 2019 associated with the acquisition of Avizorex, $5.7 million and $2.4 million in lower expenses associated with Rhopressa® and Rocklatan®, respectively, as described below, as well as a $4.0 million decrease in spend related to the development of our retina program. In addition, travel expenses decreased as a result of COVID-19 related travel restrictions. These decreases were partially offset by an increase in spend for the development of AR-15512 primarily due to our Phase 2b clinical trial which commenced in the fourth quarter of 2020. There was also an increase in employee-related expenses.

Research and development expenses for Rhopressa® were $3.2 million for the year ended December 31, 2020 and $8.9 million for the year ended December 31, 2019. Expenses for Rhopressa® decreased $5.7 million primarily due to a decrease in costs associated with the Phase 2 clinical trial conducted in Japan which was completed in January 2020, partially offset by an increase in costs as a result of an ongoing Rhopressa® Phase 3 clinical trial in Japan, which was initiated in Japan in the fourth quarter of 2020. Research and development expenses for Rocklatan® were $6.0 million and $8.4 million for the year ended December 31, 2020 and 2019, respectively. Expenses for Rocklatan® decreased $2.4 million primarily due to lower costs 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			
	2020	2019	CHANGE	% CHANGE
	(in thousands, except percentages)			
Interest income	$ 1,984	$ 2,970	$ (986)	(33)%
Interest expense	(26,476)	(15,255)	(11,221)	74 %
Other income	2,326	106	2,220	*
Other (expense) income, net	$ (22,166)	$ (12,179)	$ (9,987)	82 %

**Percentage not meaningful*

Other (expense) income, net changed by $10.0 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019 and primarily relates to interest expense under the Convertible Notes issued in September 2019, including the amortization of debt discounts and issuance costs incurred.

Interest expense increased by $11.2 million during the year ended December 31, 2020 due to the amortization of debt discounts and issuance costs incurred on the Convertible Notes, which were issued in September 2019. This increase in interest expense was partially offset by costs in the prior year for the amortization of issuance costs and fees incurred on the credit facility.

Other income increased by $2.2 million during the year ended December 31, 2020 and consists of an increase of $1.3 million in unrealized investments gains on equity securities held at the end of the period, as well as an increase due to research and development tax credit refunds.

The increases in interest expense and other income were partially offset by a decrease of $1.0 million in interest income on our cash, cash equivalents and investments.

Income tax expense (benefit)

Income tax expense (benefit) consists of the following:

	YEAR ENDED DECEMBER 31			
	2020	2019	CHANGE	% CHANGE
	(in thousands, except percentages)			
Income tax expense (benefit)	$ 5,245	$ (90)	$ 5,335	*

**Percentage not meaningful*

Income tax expense (benefit) increased by $5.3 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019, primarily due to $5.0 million in withholding tax incurred in the fourth quarter of 2020 related to the $50.0 million Upfront Payment paid by Santen pursuant to the Santen Agreement.

Liquidity and Capital Resources

Since our inception, we have funded operations primarily through the sale of equity securities and the issuance of convertible notes. In addition, we generate cash flow from product revenues related to sales of Rhopressa® and Rocklatan® in the United States. Further, we entered into the Santen Agreement, pursuant to which Santen paid the $50.0 million Upfront Payment.

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 current products and any future products, if commercialized, generate adequate revenues to render us profitable. 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 $83.1 million and $69.9 million for the years ended December 31, 2020 and 2019, respectively. Accounts receivable, net amounted to $56.0 million and $38.4 million as of December 31, 2020 and 2019, respectively;
- issued $316.25 million aggregate principal amount of Convertible Notes in September 2019; and
- entered into the Santen Agreement in October 2020 to advance our clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia. Pursuant to the Santen Agreement, Santen paid the $50.0 million Upfront Payment in the fourth quarter of 2020.

As of December 31, 2020, our principal sources of liquidity were our cash and cash equivalents and investments, which totaled approximately $240.4 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. Further, in October 2020, we entered into the Santen Agreement. See Note 3 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,		
	2020	**2019**	**2018**
Net cash (used in) provided by:	**(in thousands)**		
Operating activities	$ (64,690)	$ (150,430)	$ (152,576)
Investing activities	73,179	(183,247)	20,789
Financing activities	(859)	274,799	137,036
Net increase (decrease) in cash and cash equivalents	$ 7,630	$ (58,878)	$ 5,249

Operating Activities

During the year ended December 31, 2020, net cash used in operating activities of $64.7 million related to a net loss of $183.1 million, adjusted for non-cash items of $73.5 million primarily related to stock-based compensation expense, amortization and accretion and depreciation and net cash outflows of $44.9 million related to changes in operating assets and liabilities. Other changes in operating assets and liabilities included the $50.0 million Upfront Payment paid by Santen.

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, acquisition of Avizorex and amortization and accretion and depreciation, partially offset by a net cash inflow 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 outflow of $13.4 million related to changes in operating assets and liabilities.

Investing Activities

During the year ended December 31, 2020, our investing activities provided net cash of $73.2 million primarily related to sales and maturities of investments of $192.9 million, which were partially offset by purchases of available-for-sale investments of $116.6 million and purchases of property, plant and equipment of $3.1 million, primarily related to the completion of the build-out of our manufacturing plant in Athlone, Ireland.

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 Athlone, 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 and purchases of property, plant and equipment of $31.3 million, primarily related to the build-out of our manufacturing plant in Athlone, Ireland, which were partially offset by sales and maturities of investments of $108.3 million.

Financing Activities

During the year ended December 31, 2020, our financing activities used net cash of $0.9 million primarily related to tax payments made on employees' behalf through withholding of shares on restricted stock.

During the year ended December 31, 2019, our financing activities provided net cash of $274.8 million, which 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.

During the year ended December 31, 2018, our financing activities provided net cash of $137.0 million primarily related to the issuance and sale of common stock under our prior "at-the-market" sales agreement and underwriting agreement related to registered public offerings, from which we received net proceeds of approximately $136.0 million.

Operating Capital Requirements

We expect to incur ongoing operating losses until such a time when Rhopressa®, Rocklatan®, Rhokiinsa® or Roclanda® or any product candidates or future product candidates, if approved, generate sufficient cash flows for Aerie to achieve profitability.

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; 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, which began 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, 2020, we had federal and state NOL carryforwards of approximately $585.4 million and $561.7 million, respectively. Federal NOLs that arose prior to 2018 and state NOLs will begin to expire at various dates beginning in 2031 and

2023, 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, 2020, we had foreign NOL carryforwards of $98.9 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. 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. 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.

On March 27, 2020, the President of the United States signed the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which is aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes several business tax provisions which include, but are not limited to modifications of federal net operating loss carrybacks and deductibility, changes to prior year refundable alternative minimum tax liabilities, increase of limitations on business interest deductions from 30 percent to 50 percent of earnings before interest, taxes, depreciation, and amortization, technical corrections of the classification of qualified improvement property making them eligible for bonus depreciation, increase of the limits on charitable contribution deductions from 10 percent to 25 percent of adjusted taxable income, modifications of the treatment of federal loans, loan guarantees, and other investments, suspension of industry specific excise taxes, deferral of the company portion of OASDI, and implementation of a refundable employee retention tax credit. The CARES Act did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2020. We will continue to monitor additional guidance issued by the U.S. Treasury Department and the Internal Revenue Service.

The CARES Act provides for the delay in the required deposit of the employer portion of the OASDI payroll tax from the date of enactment through the end of 2020. Of the taxes that we can defer, 50 percent of the deferred taxes are required to be deposited by the end of 2021 and the remaining 50 percent are required to be deposited by the end of 2022. As of December 31, 2020, we deferred $1.4 million related to the employer portion of the OASDI tax.

Outstanding 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, which began 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, 2020:

	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	MORE THAN 5 YEARS
			(in thousands)		
Lease obligations[1]	$ 21,521	$ 5,531	$ 3,912	$ 3,233	$ 8,845
Convertible Notes[2]	316,250	—		316,250	—
Purchase obligations[3]	22,944	7,110	14,851	983	—
	$ 360,715	$ 12,641	$ 18,763	$ 320,466	$ 8,845

(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 lease payments related to the manufacturing plant in Athlone, Ireland, under which we are leasing approximately 30,000 square feet of interior floor space. 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, 2020.

(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 14 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, 2020, 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, 2020, 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, 2020 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, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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 “Information About Our Board of Directors,” “Information about Director Nominees,” “Information about Directors Continuing in Office,” “Information About Our Executive Officers,” “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 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on February 24, 2020).
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 (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on February 24, 2020).
10.31	Amendment to Aerie Pharmaceuticals, Inc. Second Amended & Restated Inducement Award Plan (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K (File No. 001-36152) filed on February 24, 2020).
10.32††*	Collaboration and License Agreement by and between Aerie Pharmaceuticals Ireland, Ltd. and Santen Pharmaceutical Co., Ltd., dated as of October 28, 2020.
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.

†† In accordance with Item 601(a)(5) of Regulation S-K, certain schedules (or similar attachments) to this exhibit have been omitted from this filing. The registrant will provide a copy of any omitted schedule to the Securities and Exchange Commission or its staff upon request. In accordance with Item 601(b)(10)(iv) of Regulation S-K, certain provisions or terms of this exhibit have been redacted. The registrant will provide an unredacted copy of the exhibit on a supplemental basis to the Securities and Exchange Commission or its staff upon request.

* 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, 2020 and 2019, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020, 2019 and 2018 (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2020, 2019 and 2018 (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018 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 26, 2021

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 26, 2021
/S/ RICHARD J. RUBINO Richard J. Rubino	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2021
/S/ GERALD D. CAGLE, PH.D. Gerald D. Cagle, Ph.D.	Director	February 26, 2021
/S/ RICHARD CROARKIN Richard Croarkin	Director	February 26, 2021
/S/ MECHIEL M. DU TOIT Mechiel M. du Toit	Director	February 26, 2021
/S/ PETER J. MCDONNELL Peter J. McDonnell	Director	February 26, 2021
/S/ DAVID W. GRYSKA David W. Gryska	Director	February 26, 2021
/S/ BENJAMIN F. MCGRAW III, PHARM. D. Benjamin F. McGraw III, Pharm. D.	Director	February 26, 2021
/S/ JULIE MCHUGH Julie McHugh	Director	February 26, 2021

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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, 2020 and 2019, 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, 2020, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, 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 in 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 matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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. Such provisions include estimated rebates to third-party payers and estimated payments for Medicare Part D prescription drug program. Management estimates the rebates 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 $202.2 million in aggregate for the year ended December 31, 2020, a significant portion of which related to commercial and Medicare Part D rebates. Management estimates the reserves 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 the significant judgment by management due to the significant measurement uncertainty involved in developing these provisions, as the provisions are based on assumptions developed using forecasted customer mix and lagged claims. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing 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, (i) 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; (ii) comparing the independent estimate to the rebates recorded by management; and (iii) testing a sample of actual rebate claims paid and evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 25, 2021

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,	
	2020	**2019**
Assets		
Current assets		
Cash and cash equivalents	$ 151,570	$ 143,940
Short-term investments	88,794	165,250
Accounts receivable, net	56,022	38,354
Inventory	27,059	21,054
Prepaid expenses and other current assets	8,310	7,744
Total current assets	331,755	376,342
Property, plant and equipment, net	54,260	58,147
Operating lease right-of-use assets	14,084	16,523
Other assets	1,946	1,596
Total assets	$ 402,045	$ 452,608
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,826	$ 12,770
Accrued expenses and other current liabilities	90,723	65,376
Operating lease liabilities	4,923	5,502
Total current liabilities	104,472	83,648
Convertible notes, net	210,373	188,651
Deferred revenue, non-current	50,858	—
Long-term operating lease liabilities	10,206	12,102
Other non-current liabilities	2,168	1,257
Total liabilities	378,077	285,658
Commitments and contingencies (Note 14)		
Stockholders' equity		
Preferred stock, $0.001 par value; 15,000,000 shares authorized as of December 31, 2020 and December 31, 2019; None issued and outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 46,821,644 and 46,464,669 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	47	46
Additional paid-in capital	1,103,074	1,062,996
Accumulated other comprehensive loss	(52)	(92)
Accumulated deficit	(1,079,101)	(896,000)
Total stockholders' equity	23,968	166,950
Total liabilities and stockholders' equity	$ 402,045	$ 452,608

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,		
	2020	**2019**	**2018**
Product revenues, net	$ 83,138	$ 69,888	$ 24,181
Total revenues, net	83,138	69,888	24,181
Costs and expenses:			
Cost of goods sold	25,333	4,833	641
Selling, general and administrative	137,184	138,402	120,614
Pre-approval commercial manufacturing	2,304	22,767	26,545
Research and development	74,007	91,378	86,123
Total costs and expenses	238,828	257,380	233,923
Loss from operations	(155,690)	(187,492)	(209,742)
Other (expense) income, net	(22,166)	(12,179)	(22,824)
Loss before income taxes	(177,856)	(199,671)	(232,566)
Income tax expense (benefit)	5,245	(90)	3
Net loss	$ (183,101)	$ (199,581)	$ (232,569)
Net loss per common share—basic and diluted	$ (3.99)	$ (4.39)	$ (5.58)
Weighted average number of common shares outstanding—basic and diluted	45,897,255	45,427,154	41,663,958
Net loss	$ (183,101)	$ (199,581)	$ (232,569)
Unrealized (loss) gain on available-for-sale investments	40	(92)	28
Comprehensive loss	$ (183,061)	$ (199,673)	$ (232,541)

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) INCOME	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT				
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
Issuance of common stock upon exercise of stock options and warrants	51,333	1	171	—	—	172
Issuance of common stock upon exercise of stock purchase rights	60,857	—	724	—	—	724
Issuance of common stock for restricted stock awards, net	244,785	—	(1,754)	—	—	(1,754)
Stock-based compensation	—	—	40,937	—	—	40,937
Other comprehensive income	—	—	—	40	—	40
Net loss	—	—	—	—	(183,101)	(183,101)
Balances at December 31, 2020	46,821,644	$ 47	$ 1,103,074	$ (52)	$ (1,079,101)	$ 23,968

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,		
	2020	**2019**	**2018**
Cash flows from operating activities			
Net loss	$ (183,101)	$ (199,581)	$ (232,569)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	6,366	5,138	2,442
Amortization and accretion	27,792	12,976	1,646
Acquisition of assets expensed to research and development	—	10,171	—
Stock-based compensation	40,095	45,093	38,728
Induced conversion of 2014 Convertible Notes	—	—	24,059
Other non-cash	(732)	(271)	(270)
Changes in operating assets and liabilities			
Accounts receivable, net	(17,668)	(35,639)	(2,715)
Inventory	(5,166)	(10,257)	(9,689)
Prepaid, current and other assets	340	(2,144)	(791)
Accounts payable, accrued expenses and other current liabilities	22,536	28,766	26,583
Operating lease liabilities	(6,010)	(4,682)	—
Deferred revenue	50,858	—	—
Net cash used in operating activities	(64,690)	(150,430)	(152,576)
Cash flows from investing activities			
Acquisition of assets	—	(7,835)	—
Purchase of available-for-sale investments	(116,591)	(165,454)	(56,195)
Proceeds from sales and maturities of investments	192,870	—	108,297
Purchase of property, plant and equipment	(3,100)	(9,958)	(31,313)
Net cash provided (used in) by investing activities	73,179	(183,247)	20,789
Cash flows from financing activities			
Proceeds from loan	8,274	—	—
Repayment of loan	(8,274)	—	—
Proceeds from sale of common stock, net	—	—	135,972
Proceeds related to issuance of stock for stock-based compensation arrangements, net	(859)	684	3,630
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 (used in) provided by financing activities	(859)	274,799	137,036
Net change in cash and cash equivalents	7,630	(58,878)	5,249
Cash and cash equivalents, at beginning of period	143,940	202,818	197,569
Cash and cash equivalents, at end of period	$ 151,570	$ 143,940	$ 202,818
Supplemental disclosures			
Cash paid for interest	$ 5,034	$ 6,496	$ 1,774
Cash paid for income taxes	$ 4,987	$ —	$ —
Non-cash investing and financing activities:			
Conversion of convertible notes to common stock (Note 10)	$ —	$ —	$ 148,078
Liabilities incurred from Avizorex Asset Acquisition	$ —	$ 1,186	$ —
Purchases of property, plant and equipment in accounts payable and accrued expense and other current liabilities	$ 374	$ 771	$ 3,526
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, Aerie Pharmaceuticals Ireland Limited and Avizorex Pharma S.L. ("Aerie Distribution," "Aerie Limited," "Aerie Ireland Limited" and "Avizorex," 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, ocular surface diseases and retinal diseases. The Company has its principal executive offices in Durham, North Carolina, and operates as one business segment.

U.S. Commercial Products

The Company has developed and commercialized 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 in April 2018, and Rocklatan®, which was launched in the United States in May 2019. In addition to actively promoting Rhopressa® and Rocklatan® in the United States, the Company is pursuing its strategy to commercialize Rhopressa® and Rocklatan® in Europe and obtain regulatory approval in Japan. Rhopressa® and Rocklatan® will be marketed under the names Rhokiinsa® and Roclanda®, respectively, if ultimately commercialized in Europe.

Outside the United States

In Europe, Rhokiinsa® was granted a Centralised Marketing Authorisation ("Centralised MA") by the European Commission ("EC") in November 2019 and Roclanda® was granted a Centralised MA by the EC in January 2021.

The Company reported positive interim topline 90-day efficacy data in September 2020 for the Phase 3b clinical trial for Roclanda®, named Mercury 3, a six-month efficacy and safety trial designed to compare Roclanda® to Ganfort®, a fixed-dose combination product marketed in Europe of bimatoprost (a prostaglandin analog), and timolol (a beta blocker).

In Japan, the Company entered into a Collaboration and License Agreement (the "Santen Agreement") with Santen Pharmaceuticals Co., Ltd. ("Santen") in October 2020 to advance its clinical development and ultimately commercialize Rhopressa® and Rocklatan® in Japan and eight other countries in Asia. See Note 3 for additional information. The Company commenced a Rhopressa® Phase 3 clinical trial in Japan in the fourth quarter of 2020. The Company initiated a Rhopressa® Phase 3 clinical trial in December 2020, the first of three expected Phase 3 clinical trials in Japan. Clinical trials for Rocklatan® have not yet begun.

Glaucoma Product Manufacturing

The Company has a sterile fill production facility in Athlone, Ireland, for the production of its FDA approved products and clinical supplies, which was completed in the second quarter of 2019. The Company received FDA approval to produce Rocklatan® and Rhopressa® at the Athlone manufacturing plant for commercial distribution in the United States in January 2020 and September 2020, respectively. The manufacturing plant began manufacturing commercial supplies of Rocklatan® during the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. Shipments of commercial supply of Rocklatan® and Rhopressa® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020 and in the fourth quarter of 2020, respectively. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan.

Product Candidates and Pipeline

The Company is furthering the development of its product candidates focused on dry eye and retinal diseases, particularly AR-15512, AR-1105, AR-13503 SR and AR-14034 SR, described below. The Company acquired Avizorex, a Spanish ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease, in late 2019. The active ingredient in AR-15512 is a potent and selective agonist of the TRPM8 ion channel, a cold sensor and osmolarity sensor that

regulates tear production and blink rate. In addition, activating the TRPM8 receptor may reduce ocular discomfort by promoting a cooling sensation. The Investigational New Drug Application ("IND") for AR-15512 eye drop for dry eye became effective in September 2020, allowing Aerie to initiate clinical studies in the treatment of dry eye. The Company is planning to test two concentrations of AR-15512 in a 90-day Phase 2b clinical trial with 360 subjects, which could potentially be considered pivotal. The Company initiated this clinical trial, named COMET-1, in October 2020 and a topline readout is expected in the third quarter of 2021.

The Company is currently developing three sustained-release implants focused on retinal diseases, AR-1105, AR-13503 SR and AR-14034 SR. In July 2020, the Company completed a Phase 2 clinical trial for AR-1105, a dexamethasone steroid implant, in patients with macular edema due to retinal vein occlusion ("RVO"). Also, in July 2020, the Company reported topline results of the Phase 2 clinical trial for AR-1105 indicating sustained efficacy of up to six months, an important achievement in validating the capabilities of Aerie's sustained release platform.

With respect to future plans for AR-1105, the Company is currently evaluating next steps regarding clinical advancement into Phase 3 along with commercialization prospects in both Europe and the United States. We are in the process of meeting with regulatory agencies in order to harmonize development plans across both Europe and the United States.

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

The preclinical sustained-release implant AR-14034 SR has the potential to deliver the active ingredient axitinib, an inhibitor of VEGF receptors. It has the potential to provide a once per-year injection to treat DME, wet AMD and related diseases of the retina. The Company anticipates filing an Investigational New Drug Application ("IND") for AR-14034 SR with the FDA in the second half of 2022.

Liquidity

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") (Note 10). Further, in October 2020, the Company entered into the Santen Agreement, pursuant to which Santen paid an upfront payment of $50.0 million (Note 3).

The Company expects to incur ongoing operating losses until such a time when Rhopressa® or Rocklatan® or any current or future product candidates, if approved, generate sufficient cash flows for the Company 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.

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 manufacturing plant in Athlone, Ireland, and its current contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® and may rely on its third-party manufacturers to produce the active pharmaceutical ingredient ("API"). The Company may rely on a combination of internal manufacturing and third-party manufacturers for its product candidates and future product candidates.

The commercial production of the final drug product is supported by a combination of internal and outsourced manufacturing. The Company has established its own manufacturing plant in Athlone, Ireland, for the production of our FDA approved products and clinical supplies. The Athlone manufacturing plant began manufacturing commercial supplies of Rocklatan® during the first quarter of 2020 and Rhopressa® in the third quarter of 2020 for distribution to the United States. Shipments of commercial supply of Rocklatan® and Rhopressa® from the Athlone manufacturing plant to the United States commenced in the third quarter of 2020 and in the fourth quarter of 2020, respectively. The Athlone manufacturing plant has also manufactured clinical supplies of Rhopressa® for the Phase 3 clinical trials in Japan. As the Athlone manufacturing plant commenced operations in 2020, it has not yet reached full capacity. The Company expects that the Athlone manufacturing plant will have adequate capacity to produce Rhopressa® and Rocklatan® for the United States as well as the European and Japanese commercial markets. The Company expects that in 2021 the Athlone manufacturing plant will manufacture most of its needs for Rhopressa® and Rocklatan® in the United States. The Company may continue to use contract manufacturers to produce commercial supplies of Rhopressa® and Rocklatan® for distribution in the United States, but at reduced levels compared to before the Athlone manufacturing plant was operational.

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 FDA approval of an additional Rocklatan® drug product contract manufacturer in January 2020, which began to supply commercial product in the first quarter of 2020. Latanoprost, used in the manufacture of Rocklatan®, is available in commercial quantities from multiple reputable third-party manufacturers.

Revenue Recognition

The Company accounts for its revenue transactions 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, 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.

Product Revenues

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, 2020 were generated through sales of Rhopressa® and sales of Rocklatan®. 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.

Contract Revenues from License Agreements

In the normal course of business, the Company conducts research and development activities pursuant to which the Company may license certain rights of the Company's intellectual property to third parties. The terms of these arrangements typically include payment to the Company for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; clinical or commercial supply services and royalties on net sales of licensed products.

The Company would first assess any arrangements under ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether the agreement (or part of the agreement) represents a collaborative arrangement based on the risks and rewards and activities of the parties. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC Topic 606.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"), which was effective for the Company on January 1, 2020. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC Topic 606, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC Topic 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, to align with the guidance in ASC Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC Topic 606; and
- Requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting that transaction together with revenue recognized under ASC Topic 606 is precluded if the collaborative arrangement participant is not a customer.

For arrangements within the scope of ASC Topic 606, in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the five steps outlined in "*—Revenue Recognition*" above. As part of the accounting for these arrangements, the Company must use judgment to determine: (a) the performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price under step (iv) above; and (d) in some circumstances when control transfers and the appropriate measure of progress in order to recognize revenue under step (v) above. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current.

Upfront license fees: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenues from collaborations during the period of adjustment.

Clinical or commercial supply services: Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as customer options. The Company assesses if these options provide a material right to the licensee and if so, they would be accounted for as separate performance obligations.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

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.

Credit Losses

Trade accounts receivable: The allowance for doubtful accounts is based on the Company's assessment of the collectability of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience,

creditworthiness of its customers, the age of the accounts receivable balances and current economic conditions that may affect a customer's ability to pay.

Available-for-sale investments: The Company's investments in debt securities can consist of U.S. federal government and federal agency securities, corporate bonds or commercial paper, money market instruments and certain qualifying money market mutual funds. The investments are short-term in nature and are rated investment grade by at least one bond credit rating service.

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 Company's manufacturing plant in Athlone, 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, 2020, 2019 and 2018, 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 year ended December 31, 2019 include the impact of the acquisition of assets from Avizorex (see Note 14 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 in-process research and development ("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, research and development costs and cost of goods sold 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 comprised of debt securities, including commercial paper and corporate bonds, that 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.

The Company's investments also includes equity securities, which in accordance with the fair value hierarchy described below are recorded at fair value using Level l inputs on the consolidated balance sheets and the subsequent changes in fair values are recorded in other income (expense), net on the consolidated statements of operations and comprehensive loss. As of December 31, 2020, the fair value of the equity securities held at the end of the period was $1.3 million. For the year ended December 31, 2020, the Company had $1.3 million of unrealized investments gains on equity securities held at the end of the period.

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 $2.0 million, $3.0 million and $3.4 million for the years ended December 31, 2020, 2019 and 2018, 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, 2020, 2019 and 2018.

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, 2020, 2019 or 2018.

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, 2020. There were no transfers between the different levels of the fair value hierarchy in 2020 or in 2019.

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 on an effective interest basis 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 debt 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, 2020 and 2019 (Note 11).

As of December 31, 2020 and 2019, 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, 2020, 2019 or 2018.

Adoption of New Accounting Standards

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 became effective for the Company beginning on January 1, 2020 and prescribes different transition methods for the various provisions. The adoption of ASU 2018-13 did not 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 became effective for the Company beginning on January 1, 2020. The new guidance prescribes different transition methods for the various provisions. The Company adoption of ASU 2016-13 or ASU 2018-19 did not have a material impact on its consolidated financial statements and disclosures.

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 became effective for financial statements issued for annual and interim periods beginning on January 1, 2019. The Company had 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 became 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 August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06") to address the complexity associated with applying GAAP to certain financial instruments with characteristics of liabilities and equity. This ASU includes amendments to the guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity. ASU 2020-06 also simplifies the accounting for convertible instruments, which includes eliminating the cash conversion accounting model for convertible instruments. Additionally, ASU 2020-06 will require entities to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. The guidance is effective for the Company beginning on January 1, 2022, with early adoption permitted, and prescribes different transition methods for the various provisions. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements and disclosures.

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 does not expect the adoption of ASU 2019-12 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,		
	2020	**2019**	**2018**
Outstanding stock options	8,588,614	8,425,551	6,935,119
Stock purchase warrants	—	4,500	154,500
Nonvested restricted stock awards	809,527	754,415	572,706
Nonvested restricted stock units	107,182	41,811	—
Total	9,505,323	9,226,277	7,662,325

3. Revenue Recognition

Product Revenues

Net product revenues for the year ended December 31, 2020 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, 2020, three distributors accounted for 37.4%, 32.4% and 28.8% of total revenues, respectively. For the year ended December 31, 2019, three distributors accounted for 36.5%, 33.3% and 28% of total revenues, respectively. 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, 2020 or 2019, 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, 2020 or 2019, 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® 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. Provisions for revenue reserves reduced product revenues by $202.2 million, $105.9 million and $19.6 million in aggregate for the years ended December 31, 2020, 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 information regarding returns of Rhopressa® and Rocklatan® as well as 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.

Santen Collaboration and License Agreement

On October 28, 2020, Aerie Ireland Limited entered into a Collaboration and License Agreement with Santen Pharmaceutical Co., Ltd., a Japanese pharmaceutical company dedicated to ophthalmology that carries out research, development, marketing and sales of pharmaceuticals, over-the-counter products and medical devices. Pursuant to the Santen Agreement, Aerie Ireland Limited granted to Santen the exclusive right to develop, manufacture, market and commercialize Rhopressa® and Rocklatan® (the “Licensed Products”) in Japan, South Korea, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam and Taiwan (such jurisdictions collectively, the “Territories”). The Company is the sole manufacturer of the Licensed Products for Santen. Under the Santen Agreement, Aerie Ireland Limited granted Santen a first right of negotiation for the rights to the Licensed Products in any Asian countries other than the Territories.

Under the Santen Agreement, Santen made an upfront payment of $50.0 million (the “Upfront Payment”) and Aerie Ireland Limited will earn various development milestones of up to $39.0 million and sales milestones of up to $60.0 million upon the achievement of certain events. In addition, Santen will pay Aerie Ireland Limited a royalty in excess of 25% of the Licensed Products’ net sales, such consideration consisting of the cost of products supplied to Santen from Aerie Ireland Limited and a royalty for the Company’s intellectual property. Santen will be responsible for sales, marketing and pricing decisions relating to the Licensed Products. Santen is also responsible for all development and commercialization costs and activities related to the Licensed Products in the Territories, except that Aerie Ireland Limited shares 50% of the costs related to conducting the first Rhopressa® Phase 3 clinical trial in Japan, which commenced in the fourth quarter of 2020.

The term of the Santen Agreement continues on a country-by-country basis in the Territory until the later of (i) the expiration of the last to expire valid patent claim covering the Licensed Product and (ii) 12 years from the date of the first commercial sale of each Licensed Products under a New Drug Application approval, marketing authorization or the equivalent. The Santen Agreement may be terminated by either Aerie Ireland Limited or Santen upon the other party's material breach or bankruptcy or insolvency. Aerie Ireland Limited may also terminate the Santen Agreement upon a patent challenge by Santen, and Santen may terminate the Santen Agreement in its discretion if, following marketing authorization for Rhopressa® in Japan, Santen reasonably determines that the Licensed Products are not commercially viable in the Territory (effective upon 180 days' prior written notice). In addition, in the event that patents are issued that may prevent the commercialization of the Licensed Products, Santen would have the right to terminate the Santen Agreement and require Aerie Ireland Limited's repayment of up to approximately 85% of the Upfront Payment, all development milestone payments and 50% of the development expenses incurred by Santen. In the event of termination, the Licensed Products in the applicable Territories will revert to the Company.

The Company first assessed the Santen Agreement under ASC 808 to determine whether the Santen Agreement (or part of the Santen Agreement) represents a collaborative arrangement based on the risks and rewards and activities of the parties pursuant to the Santen Agreement. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement), which represent a collaborative relationship and not a customer relationship, outside the scope of ASC Topic 606. The Company determined the Santen Agreement meets the definition of a customer for each unit of account and is within the scope of ASC 606.

The Company identified two distinct performance obligations: (i) the exclusive license to Rhopressa® and Rocklatan® and (ii) the Phase 3 clinical trials in Japan. Santen can benefit from the license on its own by developing, manufacturing, marketing and commercializing the Licensed Products using its own resources. In addition, the Company expects to enter into a manufacturing and supply agreement with Santen no later than twenty-four months prior to the first commercial sale of a Licensed Product in the Territory.

For the year ended December 31, 2020, the Company recorded $50.8 million as deferred revenue, non-current, relating to the Upfront Payment as well as for Santen's portion of shared costs related to conducting the first Rhopressa® Phase 3 clinical trial in Japan, which commenced in the fourth quarter of 2020. While the Company determined that the license was a right to use the Company's intellectual property and as of the effective date of the Santen Agreement, the Company had provided all necessary information to Santen to benefit from the license and the license term had begun, revenue was not recognized upon satisfaction of the performance obligation due to the uncertainty around potential termination in the event that patents are issued that may prevent the commercialization of the Licensed Products.

The Company will recognize the Upfront Payment, and any other potential future development milestones and sales milestones, when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

4. Investments

Cash and cash equivalents and investments as of December 31, 2020 included the following:

(in thousands)	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	FAIR VALUE
Cash and cash equivalents:				
Cash and cash equivalents	$ 151,570	$ —	$ —	$ 151,570
Total cash and cash equivalents	$ 151,570	$ —	$ —	$ 151,570
Investments:				
Commercial paper (due within 1 year)	$ 44,122	$ 5	$ (23)	$ 44,104
Corporate bonds (due within 1 year)	44,724	3	(37)	44,690
Total investments	$ 88,846	$ 8	$ (60)	$ 88,794
Total cash, cash equivalents and investments	$ 240,416	$ 8	$ (60)	$ 240,364

Cash, 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

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, 2020			
(in thousands)	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Cash and cash equivalents:				
Cash and cash equivalents	$ 151,570	$ —	$ —	$ 151,570
Total cash and cash equivalents:	$ 151,570	$ —	$ —	$ 151,570
Investments:				
Commercial paper	$ —	$ 44,104	$ —	$ 44,104
Corporate bonds	—	44,690	—	44,690
U.S. government and government agencies	—	—	—	—
Total investments	$ —	$ 88,794	$ —	$ 88,794
Total cash, cash equivalents and investments:	$ 151,570	$ 88,794	$ —	$ 240,364

	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

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 $296.7 million at December 31, 2020.

6. Inventory

Inventory consists of the following:

	DECEMBER 31,	
(in thousands)	**2020**	**2019**
Raw materials	$ 1,875	$ 1,400
Work-in-process	21,648	13,414
Finished goods	3,536	6,240
Total inventory	$ 27,059	$ 21,054

Idle capacity cost associated with the Company's Athlone manufacturing plant was $17.0 million for the year ended December 31, 2020 and was recorded to costs of goods sold. The idle capacity results from the manufacturing plant having commenced operations earlier in 2020 and not reaching full capacity.

7. Property, Plant and Equipment, Net

Property, plant and equipment, net consists of the following:

	DECEMBER 31,	
(in thousands)	**2020**	**2019**
Manufacturing equipment	$ 21,705	$ 18,073
Laboratory equipment	7,948	7,525
Furniture and fixtures	1,681	1,648
Software, computer and other equipment	7,836	7,772
Leasehold improvements	30,178	29,720
Construction-in-progress	1,481	3,892
Property, plant and equipment	70,829	68,630
Less: Accumulated depreciation	(16,569)	(10,483)
Property, plant and equipment, net	$ 54,260	$ 58,147

Depreciation expense was $6.4 million, $5.1 million and $2.4 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Manufacturing Plant

In the second quarter of 2019, the Company completed the build-out on its 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.

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 January 2022 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 Bedminster, New Jersey, location consists of approximately 34,000 square feet of office space under a lease that expires in October 2029. There are also small offices in Ireland, the United Kingdom and Japan.

The Company is leasing approximately 30,000 square feet of interior floor space 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 17 years, some of which include options to extend the leases.

Balance sheet information related to leases was as follows:

	DECEMBER 31,	
(in thousands)	**2020**	**2019**
Operating lease right-of-use assets	$ 14,084	$ 16,523
Operating lease liabilities	$ 4,923	$ 5,502
Long-term operating lease liabilities	10,206	12,102
Total operating lease liabilities	$ 15,129	$ 17,604

The cash paid for amounts included in the measurement of lease liabilities was $6.0 million and $4.7 million during the years ended December 31, 2020 and 2019, respectively. The Company's right-of-use assets obtained in exchange for operating lease obligations were $1.9 million and $3.1 million during the years ended December 31, 2020 and 2019, respectively.

	DECEMBER 31,	
	2020	**2019**
Operating Leases		
Weighted-average remaining lease terms	8 years	8 years
Weighted-average discount rate	9 %	8 %

Maturities of lease liabilities as of December 31, 2020 are as follows:

(in thousands)	**OPERATING LEASES**
Year Ending December 31,	
2021	$ 5,068
2022	2,467
2023	2,139
2024	1,764
Thereafter	10,424
Total undiscounted lease payments	21,862
Less: present value adjustment	(6,733)
Total lease liabilities	$ 15,129

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 $5.6 million, including variable lease payments of $0.7 million, for the year ended December 31, 2020, respectively. 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, rent expense for the Company's operating leases was $3.8 million for the year ended December 31, 2018.

9. Accrued Expenses & Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	DECEMBER 31, 2020	2019
Accrued expenses and other current liabilities:		
Accrued compensation and benefits	$ 15,207	$ 11,169
Accrued consulting and professional fees	2,645	3,810
Accrued research and development [(1)]	2,222	8,734
Accrued revenue reserves[(2)]	66,552	38,450
Accrued other[(3)]	4,097	3,213
Total accrued expenses and other current liabilities	$ 90,723	$ 65,376

(1) Comprised primarily of accruals related to fees for investigative sites, contract research organizations and other service providers that assist in conducting preclinical research studies and clinical trials. As of December 31, 2019, liabilities incurred related to the Avizorex acquisition are also included.

(2) Comprised primarily of accruals related to commercial and government rebates as well as returns. The accrued revenue reserve at December 31, 2020 is higher than prior year primarily due to higher rebates largely driven by government sponsored programs.

(3) Comprised primarily of accruals related to interest payable 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, which began 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 would not expect the conversion to have a dilutive effect on the Company's earnings per share, as applicable. However, the Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements and disclosures, in which the Company will soon no longer be eligible to use the treasury stock method to reflect the shares underlying the Convertible Notes in the Company's dilutive earnings per shares. See Note 2 for additional information.

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, 2020, the conditions allowing holders of the Convertible Notes to elect to convert had not been met. As of December 31, 2020, the if-converted value of the Convertible Notes did not exceed the principal amount of the Convertible Notes.

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 effective interest rate on the liability component was 10.5% for the period from the date of issuance through December 31, 2020. 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.

In connection with the issuance of the Convertible Notes, the Company incurred debt issuance costs of $9.2 million for the three months 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:

	DECEMBER 31,	
(in thousands)	**2020**	**2019**
Gross proceeds	$ 316,250	$ 316,250
Unamortized debt discount	(101,565)	(122,402)
Unamortized issuance costs	(4,312)	(5,197)
Carrying value	$ 210,373	$ 188,651

The following table summarizes the interest expense recognized related to the Convertible Notes:

(in thousands)	DECEMBER 31, 2020	2019
Stated interest	$ 4,751	$ 1,476
Amortized debt discount	20,837	5,989
Amortized issuance costs	885	254
Interest Expense	$ 26,473	$ 7,719

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.

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.

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 (as defined below) 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 2014 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.

Interest Expense

Interest expense was $26.5 million for the year ended December 31, 2020, and included stated interest and amortization of debt discount and issuance costs related to the Convertible Notes. Interest expense was $15.3 million for the year ended December 31, 2019, and included stated interest and 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 $125.0 million aggregate principal amount of senior secured convertible notes (the “2014 Convertible Notes”) 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 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:

	DECEMBER 31,		
(in thousands)	**2020**	**2019**	**2018**
Net loss before income taxes:			
United States	$ (143,349)	$ (153,620)	$ (203,230)
Non-U.S.	(34,507)	(46,051)	(29,336)
Net loss before income taxes	$ (177,856)	$ (199,671)	$ (232,566)

	DECEMBER 31,		
(in thousands, except percentages)	**2020**	**2019**	**2018**
Provision for income taxes:			
Current:			
United States	$ (33)	$ (90)	$ 3
Non-U.S.	5,278	—	—
Total	$ 5,245	$ (90)	$ 3
Deferred:			
United States	$ —	$ —	$ —
Non-U.S.	—	—	—
Total	—	—	—
Provision for income taxes	$ 5,245	$ (90)	$ 3
Effective tax rate	(2.95)%	0.05 %	— %

Significant components of the Company's net deferred income tax assets as of December 31, 2020 and 2019 consist of the following:

	DECEMBER 31,	
(in thousands)	**2020**	**2019**
Net deferred tax assets:		
Net operating loss carryforwards	$ 169,070	$ 142,991
Stock-based compensation	29,884	22,785
U.S. tax credit carryforwards	13,526	10,980
Envisia asset acquisition	5,007	5,476
Basis difference in intangibles	7,625	7,625
Convertible Notes	(19,028)	(22,822)
Other assets	10,697	8,996
Other liabilities	(5,416)	(5,709)
Valuation allowance	(211,365)	(170,322)
Total net deferred income taxes	$ —	$ —

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2020, 2019 and 2018 is as follows:

	DECEMBER 31,		
	2020	2019	2018
U.S. federal tax rate	21.00 %	21.00 %	21.00 %
State income taxes, net of federal benefit	4.02 %	4.97 %	4.56 %
Non-taxable foreign loss	(4.81)%	(4.44)%	0.09 %
Stock-based compensation	(2.29)%	(1.47)%	1.97 %
Other	0.48 %	0.98 %	(1.13)%
Change in valuation allowance	(21.35)%	(20.99)%	(26.49)%
Effective tax rate	(2.95)%	0.05 %	— %

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. In January 2020 the IRS issued new guidance related to sequestration on the AMT tax credits which would restore the portion of the minimum tax credit refunds previously sequestered with respect to MTC refund claims in lieu of bonus depreciation under Section 168(k)(4).

On March 27, 2020, the President of the United States signed the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which is aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes several business tax provisions which include, but are not limited to modifications of federal net operating loss carrybacks and deductibility, changes to prior year refundable alternative minimum tax liabilities to allow the accelerated recovery of refund, increase of limitations on business interest deductions from 30 percent to 50 percent of earnings before interest, taxes, depreciation, and amortization, technical corrections of the classification of qualified improvement property making them eligible for bonus depreciation, increase of the limits on charitable contribution deductions from 10 percent to 25 percent of adjusted taxable income, modifications of the treatment of federal loans, loan guarantees, and other investments, suspension of industry specific excise taxes, deferral of the company portion of OASDI, and implementation of a refundable employee retention tax credit. During 2020, the Company received the remaining accelerated alternative minimum tax refund of $0.8 million. The CARES Act did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2020.

At December 31, 2020, the Company had federal and state NOL carryforwards of approximately $585.4 million and $561.7 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 2023, 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, 2020, the Company also had foreign NOL carryforwards of $98.9 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, 2020. 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, 2020, the Company maintains a valuation allowance on all of its deferred tax assets as of December 31, 2020. 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, 2020, 2019, 2018 and 2017, the Company had a valuation allowance of $211.4 million, $170.3 million, $143.3 million and $83.4 million, respectively. The increase in valuation allowance in 2020, 2019 and 2018 of $41.1 million, $27.0 million and $59.9 million, respectively, was primarily due to the increase in NOL carryforwards.

The Company does not have any unrecognized tax benefits as of December 31, 2020. The Company is subject to taxation in the United States, Ireland, Japan and the United Kingdom. As of December 31, 2020, tax years ended December 31, 2015 through December 31, 2019 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.

13. Stock-based Compensation

Stock-based compensation expense for options granted, RSAs, PSAs, RSUs, SARs and stock purchase rights is reflected in the consolidated statements of operations and comprehensive loss as follows:

	YEAR ENDED DECEMBER 31,		
(in thousands)	**2020**	**2019**	**2018**
Cost of goods sold	$ 2,353	$ —	$ —
Selling, general and administrative	27,176	30,463	26,432
Pre-approval commercial manufacturing	344	3,634	2,622
Research and development	10,222	10,996	9,674
Total	$ 40,095	$ 45,093	$ 38,728

As of December 31, 2020, the Company had $41.8 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 2.1 years as of December 31, 2020. As of December 31, 2020, the Company had $16.1 million of unrecognized compensation expense, related to unvested RSAs, including PSAs. This cost is expected to be recognized over a weighted average period of 2.4 years as of December 31, 2020.

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, 2020, 2019 and 2018 are as follows:

	YEAR ENDED DECEMBER 31,		
	2020	2019	2018
Expected term (years)	6.0	6.0	6.0
Expected stock price volatility	74 %	74 %	78 %
Risk-free interest rate	0.9 %	1.9 %	2.7 %
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, 2019	8,425,551	$ 29.06		
Granted	874,878	16.83		
Exercised	(58,676)	5.28		
Canceled	(653,139)	37.18		
Options outstanding at December 31, 2020	8,588,614	$ 27.36	5.9	$ 15,180
Options exercisable at December 31, 2020	6,405,232	$ 26.44	5.0	$ 14,959

The weighted-average fair values of all stock options granted for the years ended December 31, 2020, 2019 and 2018 was $10.82, $20.70, and $38.38, respectively. The aggregate intrinsic value of options exercised for the years ended December 31, 2020, 2019 and 2018 was $0.6 million, $4.2 million and $32.0 million, respectively. The intrinsic value is calculated as the difference between the fair market value at December 31, 2020 and the exercise price per share of the stock options. The fair market value per share of common stock as of December 31, 2020 was $13.51.

The following table provides additional information about stock options that are outstanding and exercisable at December 31, 2020:

EXERCISE PRICE	OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	OPTIONS EXERCISABLE
$0.20 - $10.00	1,407,002	2.5	1,407,002
$10.01 - $20.00	1,472,021	6.7	962,151
$20.01 - $30.00	2,763,163	6.1	1,841,580
$30.01 - $45.00	1,185,530	6.7	929,942
$45.01 - $55.00	1,061,299	7.2	744,904
$55.01 - $73.10	699,599	7.2	519,653
	8,588,614		6,405,232

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, 2019	754,415	$ 43.07
Granted	424,613	14.37
Vested	(267,872)	42.85
Canceled	(101,629)	35.65
Nonvested RSAs at December 31, 2020	809,527	$ 29.03

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, 2020, 2019 and 2018 was $11.5 million, $9.8 million and $5.1 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. As of December 31, 2020, 98,817 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, 2020, the associated unrecognized compensation expense totaled $2.3 million. This expense is expected to be recognized over the weighted average period of 2.7 years as of December 31, 2020.

	NUMBER OF SHARES	WEIGHTED AVERAGE FAIR VALUE PER SHARE
Nonvested RSUs at December 31, 2019	41,811	$ 19.22
Granted	85,305	12.76
Vested	(12,567)	19.22
Canceled	(7,367)	14.03
Nonvested RSUs at December 31, 2020	107,182	$ 14.43

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, 2019	163,016	$ 41.70		
Granted	73,500	13.95		
Exercised	—	—		
Canceled	(24,472)	40.00		
SARs outstanding at December 31, 2020	212,044	$ 32.28	3.5	$ 46
SARs exercisable at December 31, 2020	50,133	$ 45.24	2.8	$ —

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 November 2019, the Company entered into a Share Purchase Agreement (the "Avizorex Agreement") with Avizorex, under which the Company acquired Avizorex, including its lead product candidate AVX-012 (now known as AR-15512) , 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, 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, plus royalties on net sales of any approved products from Avizorex's development pipeline.

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 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.

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 "DSM 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 DSM Agreement, with an additional $9.0 million payable to DSM through the end of 2020. The DSM Agreement includes contingent payments of up to $75 million that may be due to DSM upon the achievement of certain development and regulatory milestones. In addition, pursuant to the DSM 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 DSM Agreement, if any.

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, 2020, 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, ocular surface diseases and retinal diseases. 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)	**2020**	**2019**
United States	$ 8,391	$ 9,184
Ireland	45,869	48,963
Total long-lived assets	$ 54,260	$ 58,147

16. Selected Quarterly Financial Data (Unaudited)

The following table presents selected unaudited quarterly financial information for the years ended December 31, 2020 and 2019. 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,**
2020				
Total revenues, net	$ 24,683	$ 20,081	$ 18,033	$ 20,341
Total costs and expenses	$ 60,276	$ 53,685	$ 60,586	$ 64,281
Net loss	$ (46,137)	$ (39,648)	$ (48,187)	$ (49,129)
Net loss per common share—basic and diluted	$ (1.00)	$ (0.86)	$ (1.05)	$ (1.07)
	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)

Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934

As of December 31, 2020, 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, 2020, we had issued and outstanding 46,821,644 shares of Common Stock and no shares of preferred stock.

In addition, as of December 31, 2020, we had outstanding 809,527 shares of restricted stock and options to purchase 8,588,614 shares of Common Stock.

As of December 31, 2020 we had 210 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, 2020, options to purchase 8,588,614 shares of Common Stock at a weighted average exercise price of $27.36 per share were outstanding, of which options to purchase 6,405,232 shares of Common Stock were exercisable, at a weighted average exercise price of $26.44 per share.

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.

EXHIBIT 10.32

INFORMATION IN THIS AGREEMENT IDENTIFIED BY "[***]" IS CONFIDENTIAL AND HAS BEEN EXCLUDED PURSUANT TO ITEM 601(b)(10)(iv) OF REGULATION S-K BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

COLLABORATION

AND

LICENSE AGREEMENT

by and between

AERIE PHARMACEUTICALS IRELAND, LTD.

and

SANTEN PHARMACEUTICAL CO., LTD.

Dated as of October 28, 2020

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is entered into as of October 28, 2020 (the "**Effective Date**") by and between Aerie Pharmaceuticals Ireland, Ltd., a company organized and existing under the laws of Ireland with its principal place of business at Athlone Business & Technology Park, Athlone, Co. Westmeath, N37 DW40, Ireland ("**Aerie**"), and Santen Pharmaceutical Co., Ltd., a company organized and existing under the laws of Japan with its principal place of business at 4-20 Ofuka-cho, Kita-ku, Osaka 530-8552, Japan ("**Santen**"). Aerie and Santen are each hereafter referred to individually as a "**Party**" and together as the "**Parties**".

WHEREAS, Aerie has been engaged in the development of certain products containing the compound known as netarsudil as an active pharmaceutical ingredient, and controls patent rights and know-how with respect thereto;

WHEREAS, Santen desires to obtain exclusive rights under the Aerie Patents and Aerie Know-How with respect to such products in the Field and in the Territory;

WHEREAS, the Parties have entered into that certain Non-Binding Term Sheet, dated as of July 17, 2020, and, in connection therewith, the Parties desire to enter into an agreement pursuant to which Aerie will grant an exclusive license to Santen under the Aerie Patents and Aerie Know-How for Santen to develop, manufacture and commercialize the Compounds and Products in the Field and in the Territory, all on the terms set forth below.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1. DEFINITIONS

All references to particular Exhibits, Articles or Sections mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits and Appendices hereto, the following words and phrases have the following meanings:

Section 1.1 "**Abandoned Patent Right**" has the meaning set forth in Section 8.2.3(a).

Section 1.2 "**Aerie**" has the meaning set forth in the Preamble.

Section 1.3 "**Aerie Acquiree**" has the meaning set forth in Section 14.9.

Section 1.4 "**Aerie Acquisition**" has the meaning set forth in Section 14.9.

Section 1.5 "**Aerie Housemarks**" means those trademarks set forth on Exhibit A.

Section 1.6 "**Aerie Improvements**" has the meaning set forth in Section 8.1.3(a).

Section 1.7 "**Aerie Indemnified Parties**" has the meaning set forth in Section 10.1.2.

Section 1.8 "**Aerie IP**" means (a) Aerie Know-How and (b) Aerie Patents.

Section 1.9 "**Aerie Know-How**" means all Know-How (including Know-How within the Aerie Improvements) that (a) is Controlled by Aerie or its Affiliates (subject to Section 14.9), (b) relates to the

Compound or the Products in the Field and (c) is necessary or reasonably useful for (i) the practice of the Aerie Patents or (ii) Regulatory Filings (including with respect to INDs, NDAs, and related pricing and Marketing Approvals) for the Products, in each of clause (i) and (ii) in connection with the Development and Commercialization of the Products by or on behalf of Santen or its Affiliates to the extent provided for in this Agreement. For clarity, Aerie Know-How will include, without limitation, any post-marketing information pertaining to the Products in the United States (e.g., pharmacovigilance and any opinions of key opinion leaders), all clinical data in the United States with respect to the Products (e.g., Phase 2 Clinical Trial data pertaining to Japanese descent in United States), all clinical data in Japan (e.g., Phase 2 Clinical Trial data in Japan), all non-clinical and clinical data pertaining to the Regulatory Filings for the Products filed in the EU (e.g., Marketing Approvals for the Rhopressa Product and applications for the Marketing Approvals (MAAs) for the Rocklatan Product) and other information under clauses (a)-(c) above that Santen reasonably requests during the Term for the purpose of this Agreement.

Section 1.10 "**Aerie Patents**" means (a) the Patent Rights listed on Exhibit B and Controlled by Aerie or its Affiliates in the Territory, (b) any and all other Background Patent Rights Controlled by Aerie or its Affiliates in the Territory (subject to Section 14.9) that Cover the Development or Commercialization of the Compound or the Products by or on behalf of Santen or its Affiliates to the extent provided for in this Agreement, and (c) any and all Patent Rights Controlled by Aerie or its Affiliates in the Territory (subject to Section 14.9) within the Aerie Improvements or that otherwise Cover Know-How within the Aerie Improvements.

Section 1.11 "**Affiliate**" means, with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of this Section, "control" means the direct or indirect ownership of more than fifty percent (50%) of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

Section 1.12 "**Agreement**" has the meaning set forth in the Preamble.

Section 1.13 "**Alliance Manager**" has the meaning set forth in Section 2.1.2.

Section 1.14 "**Anti-Bribery and Anti-Corruption Laws**" has the meaning set forth in Section 9.3(c)(i)(A).

Section 1.15 "**Anti-Corruption Policies**" has the meaning set forth in Section 9.3(c)(i)(A).

Section 1.16 "**Background IP**" means Background Know-How and Background Patent Rights.

Section 1.17 "**Background Know-How**" means Know-How (a) Controlled by a Party prior to the Effective Date or (b) Controlled by such Party during the Term, but not generated in the performance of activities under this Agreement.

Section 1.18 "**Background Patent Rights**" means Patent Rights (a) Controlled by a Party prior to the Effective Date or (b) Controlled by such Party during the Term, but not generated in the performance of activities under this Agreement.

Section 1.19 "**Business Day**" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York, United States or in Tokyo, Japan are authorized or obligated by Law to close.

Section 1.20 "**Calendar Quarter**" means each of the three (3) month periods ending March 31, June 30, September 30 and December 31; *provided, however*, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

Section 1.21 "**Calendar Year**" means each of the twelve (12) month periods ending December 31; *provided, however*, that: (a) the first Calendar Year of the Term shall extend from the Effective Date to December 31 of the year in which the Effective Date occurs; and (b) the last Calendar Year shall extend from the beginning of the Calendar Year in which this Agreement expires or terminates until the effective date of such expiration or termination.

Section 1.22 "**Collaboration IP**" has the meaning set forth in Section 8.1.2.

Section 1.23 "**Collaboration Patents**" means any Patent Rights comprised in Collaboration IP. Notwithstanding anything to the contrary in the foregoing, Collaboration Patents excludes Aerie Patents.

Section 1.24 "**Commercialize**" or "**Commercialization**" means any and all processes and activities conducted to establish and maintain sales for Products, including the conduct of clinical trials conducted after receipt of Marketing Approval for the relevant Indication to the extent such trials are not considered "Development" hereunder, to market, advertise, promote, store, transport, distribute, import, export, offer to sell (including pricing and reimbursement and value and access activities as well as observational research and evidence generation including economic value), detail, and/or sell Products and/or conduct other commercialization activities, including activities conducted in connection with Commercial launch, such as establishing a sales force, including in support of any of the foregoing (including training, materials, public relations and market research), and "**Commercialization**" shall have the correlative meaning with respect to such activities; *provided, however*, that Commercialize shall exclude Medical Affairs Activities and Development and Manufacturing activities (including Manufacturing activities related to Commercialization).

Section 1.25 "**Commercially Reasonable Efforts**" means, with respect to a Party (directly or through Affiliates or Sublicensees) performing activities under this Agreement, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances, but no less than the efforts and resources commensurate with those efforts commonly used in the pharmaceutical industry by a company of comparable size in connection with the Development, Manufacture or Commercialization of pharmaceutical products of similar market potential at a similar stage of Development or Commercialization in its product lifecycle, taking into account market and economic conditions then prevailing, including the competitive environment, profitability, the extent of market exclusivity, the cost to Develop, Manufacture or Commercialize the Products, and other similar factors; provided, however, that, with respect to Santen's obligations under this Agreement, Commercially Reasonable Efforts do not include seeking to optimize or maintain a certain level of profits in favor of any other product researched, developed or commercialized by Santen or in which Santen will share profits or revenues from the sale thereof that competes with the Product in the Field.

Commercially Reasonable Efforts requires, with respect to an obligation under this Agreement, that a Party reasonably and in good faith: (i) set and seek to achieve reasonable objectives for carrying out such obligation and (ii) reasonably make and implement decisions and allocate resources designed to advance progress with respect to such objectives, all taking into account the factors referred to above.

Section 1.26 "**Compound**" means the compound known as netarsudil having a chemical name of (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl)benzyl 2,4-dimethylbenzoate dimesylate.

Section 1.27 "**Confidential Disclosure Agreement**" means the Confidential Disclosure Agreement entered into between the Parties as of November 18, 2019.

Section 1.28 "**Confidential Information**" has the meaning set forth in Section 12.1.1.

Section 1.29 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patent Right, or other intellectual property right, the possession (whether by ownership, license, covenant not to sue or otherwise) by a Party or its Affiliate of the ability to grant to the other Party a license, sublicense, access or other right as provided herein to or under such Know-How, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangement of such Party with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access. For clarity, nothing in this Section 1.29 obligates a Party to obtain rights under the intellectual property rights of any Third Party in order to be able to grant the other Party a license or access as provided herein.

Section 1.30 "**Cover**" means with respect to a Patent Right, that the Exploitation of a given molecule, product, or item would infringe a Valid Claim of such Patent Right (in the absence of ownership of, or a license under, such Patent Right). Cognates of the word "**Cover**" have correlative meanings.

Section 1.31 "**Critical Matter**" means (a) any decision to approve or materially amend any Development Plan, including any decision (i) to increase, decrease or add any activities to be conducted by a Party thereunder, (ii) to approve or amend any Development Budget resulting in an increase in Aerie's obligation thereunder by [***] within a given year as compared to the initial amount budgeted for such year or by [***] for a year as compared to the estimate in the previous year's budget for such year, (iii) to [***], or (iv) that would result in [***]; (b) any decision to have Aerie conduct any Development with respect to any Product in the Territory, beyond conducting the Rhopressa Phase 3 Clinical Trial; (c) [***]; (d) any decision relating to the Manufacture of Products or Compound; (e) utilizing in any Development, Commercialization or other activities under this Agreement any materials, technology or intellectual property that would require any royalty obligation to a Third Party; or (f) dissolving the JDC or JCC once established.

Section 1.32 [***] has the meaning set forth in Section 13.3.4(a).

Section 1.33 "**Develop**" or "**Development**" means those activities required and/or useful to obtain and maintain Marketing Approval of Products for the first and subsequent Indications, including test method development and stability testing, assay development and audit development, pre-clinical/non-clinical studies (including toxicology studies), formulation, pharmacodynamics, quality assurance/quality control development, statistical analysis, clinical studies (for the first and subsequent Indications), packaging development, regulatory affairs, biomarker strategy and development, report

writing and statistical analysis, the preparation, filing and prosecution of Marketing Approval applications, activities to obtain international nonproprietary names and other nonproprietary names for pharmaceutical substances, and research relating to product naming; *provided*, *however*, that Development shall exclude Medical Affairs Activities and Commercialization and Manufacturing activities. Development shall include the conduct of a clinical study after receipt of a Marketing Approval only if such study is required by a Governmental Authority, or agreed in writing with a Governmental Authority, to be conducted as a condition of receiving or maintaining a Marketing Approval. The conduct of all other clinical studies shall be deemed Commercialization.

Section 1.34 "**Development Budget**" means, with respect to a Product, the budget to be established by the JSC in accordance with Section 2.1.3 for activities to be conducted under the Development Plan applicable to such Product. Each such Development Budget will set forth the detailed costs to be incurred for the first (or current) year of such Development Budget and will set forth high-level estimates for each of (a) the one (1) year period immediately following such first (or current) year and (b) the one (1) year period immediately following the year described in subsection (a) to the extent Santen has prepared such an estimate for such year for internal purposes. The Development Budget shall be included as part of the Development Plan for the applicable Product and approved by the JSC on annual basis (or as otherwise agreed by the Parties), in accordance with Section 2.1.3.

Section 1.35 "**Development Costs**" means, with respect to a Product, the Fully Burdened Costs incurred by Santen and its Affiliates during the Term in a manner consistent with the applicable Development Plan and this Agreement that are specifically identifiable and directly allocable to conduct of clinical trials of such Product in support of obtaining Marketing Approval (or thereafter if included in the definition of Development) in the Territory calculated in a manner consistent with Santen's other similar Products and IFRS as the sum of (a) Out-of-Pocket Development Expenses and (b) Development FTE Costs; each only to the extent incurred in accordance with the applicable Development Plan with respect to such Product, and excluding costs of clinical supply of Product or Compound pursuant to Section 3.1, capital expenditures and allocations for overhead.

Section 1.36 "**Development FTE Costs**" means, with respect to a Product, the product of (a) the actual number of FTEs utilized in the Development of such Product in a manner consistent with the applicable Development Plan as documented by Santen and (b) the R&D FTE Rate.

Section 1.37 "**Development Plan**" means, with respect to a Product, the plan and timelines for the Development of such Product, and which shall include (i) a comprehensive plan as determined in accordance with this Agreement and any approved updates or amendments thereto in accordance with this Agreement, for the Development by or on behalf of Santen of such Product, including expected timelines and nonclinical, clinical, manufacturing, regulatory, and product risk assessment activities, (ii) a schedule of Development activities to be conducted and the identification of the Party responsible therefor (including subcontractors and Sublicensees), including a non-binding estimate of the number of FTEs to be allocated to the relevant Development activities, (iii) an overview of the clinical trials anticipated to be conducted to support Marketing Approval of such Product and related timelines, (iv) at an appropriate stage of Development, a publication strategy, (v) at the appropriate stage, plans related to Manufacturing of such Product, (vi) the regulatory plan for such Product, and (vii) the corresponding Development Budget.

Section 1.38 "**Disclosing Party**" has the meaning set forth in Section 12.1.1.

Section 1.39 [***].

Section 1.40 [***].

Section 1.41 [***].

Section 1.42 [***].

Section 1.43 "**Effective Date**" has the meaning set forth in the Preamble.

Section 1.44 "**Enforcing Party**" has the meaning set forth in Section 8.7.5.

Section 1.45 "**Executive Officers**" means (a) with respect to Aerie, the Chief Executive Officer, or any other person that such officer designates from time to time, and (b) with respect to Santen, the Chief Executive Officer, or any other person that such officer designates from time to time.

Section 1.46 "**Existing Patents**" has the meaning set forth in Section 9.2(a).

Section 1.47 "**Exploit**" means to make, have made, import, export, use, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of. Cognates of the word "**Exploit**" shall have correlative meanings.

Section 1.48 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

Section 1.49 "**Field**" means all topically administered uses for the treatment and/or prevention of human ophthalmic diseases, disorders and conditions.

Section 1.50 "**First Commercial Sale**" means, with respect to any Product in any country, the first sale for end use or consumption of such Product in such country after Marketing Approval for such Product has been granted in such country.

Section 1.51 "**Force Majeure**" has the meaning set forth in Section 14.12.

Section 1.52 "**FTE**" means a full-time equivalent person (i.e., one fully-dedicated or multiple partially-dedicated employees aggregating to one full-time employee employed or contracted by Aerie or Santen (or Affiliate thereof), as applicable, based upon [***] undertaken in connection with the conduct of Development or Commercialization in accordance with the applicable Development Plan, Manufacturing, or other activities, including Medical Affairs Activities, consistent with this Agreement. [***].

Section 1.53 "**Fully Burdened Costs**" means: (a) with respect to activities other than Manufacturing activities, all direct costs incurred in performing such activities; and (b) with respect to Manufacturing activities, all direct costs incurred in performing such Manufacturing activities plus [***], as determined in accordance with IFRS or GAAP, as applicable. [***].

Section 1.54 "**GAAP**" means U.S. Generally Accepted Accounting Principles.

Section 1.55 "**Generic Product**" means, with respect to a Product in a particular country in the Territory, any pharmaceutical product that (a) contains the same Compound as such Product, (b) is approved by the applicable Regulatory Authority in such country, in reliance on prior Marketing Approval for such Product, for at least one Indication, and (c) [***].

Section 1.56 "**Governmental Authority**" means any governmental authority of any nature of any multi-national, national, state, county, city or other political subdivision, including any governmental division, subdivision, department, agency, court, tribunal, agency, bureau, branch, office, authority or other instrumentality.

Section 1.57 "**IFRS**" means the then-current International Financial Reporting Standards, in each case consistently applied.

Section 1.58 "**IND**" means, (a) with respect to the United States, an investigational new drug application as defined in applicable regulations promulgated by the FDA and filed with the FDA for human clinical testing or (b) with respect to any other country in the Territory, any equivalent thereof.

Section 1.59 "**Indemnitee**" has the meaning set forth in Section 10.2.1.

Section 1.60 "**Indemnitor**" has the meaning set forth in Section 10.2.1.

Section 1.61 "**Indication**" means the intended use of a product for the treatment, control, mitigation, prevention or cure of a distinct recognized human disease or condition, or of a manifestation of a recognized human disease or condition, or for the relief of symptoms associated with a recognized human disease or condition, in each case in the intended patient population and line of treatment, including any that, if approved in the U.S., would be reflected in the "Indications and Usage" section of labeling pursuant to 21 C.F.R. §201.57(c)(2), or, to the extent applicable, any comparable labeling section outside the U.S. For the avoidance of doubt, the use of a Product in connection with different subsets of patients (e.g., elderly, pediatric, or genetically defined patient subgroups, etc.) or lines of treatment (e.g., moving from second-line therapy to first-line therapy) shall be different Indications.

Section 1.62 "**Indirect Taxes**" has the meaning set forth in Section 7.10.2.

Section 1.63 "Initial Indication" means, with respect to the Rhopressa Product, the Rhopressa Initial Indication and, with respect to the Rocklatan Product, the Rocklatan Initial Indication.

Section 1.64 "**Initiation**" means, with respect to a clinical trial, the first dosing in the first patient in such clinical trial or study. Cognates of the word "**Initiation**" have correlative meanings.

Section 1.65 "**JAMS**" has the meaning set forth in Section 14.5.2(a).

Section 1.66 [***] has the meaning set forth in Section 6.7.1(a).

Section 1.67 [***] has the meaning set forth in Section 13.3.4(a).

Section 1.68 [***] has the meaning set forth in Section 13.3.4(a).

Section 1.69 "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 2.1.3(d).

Section 1.70 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 2.1.3(d).

Section 1.71 "**Joint Manufacturing and Supply Committee**" or "**JMSC**" has the meaning set forth in Section 2.1.3(d).

Section 1.72 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1.1.

Section 1.73 [***].

Section 1.74 [***].

Section 1.75 "**Know-How**" means proprietary techniques, technology, trade secrets, inventions (whether patentable or not), improvements, methods, expertise, knowledge or other know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models, reagents and other physical, biological, or chemical material.

Section 1.76 [***] has the meaning set forth in Section 6.7.2(a).

Section 1.77 [***] has the meaning set forth in Section 13.3.5(a).

Section 1.78 [***] has the meaning set forth in Section 13.4.4(b).

Section 1.79 "**Law**" means, individually and collectively, any and all federal, state, local, and foreign laws, statutes, ordinances, principles of common law, rules, directives, standards, administrative circulars, judgments, orders, writs, injunctions, decrees, arbitration awards, agency requirements, licenses, permits, and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

Section 1.80 "**Losses**" has the meaning set forth in Section 10.1.1.

Section 1.81 "**Manufacturing**" or "**Manufacture**" means any and all processes and activities directed to producing, manufacturing, processing, sourcing of materials, filling, finishing, packaging, labeling, inspecting, quality assurance testing and release, receiving, holding, shipping and/or storage of Products or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, and quality control.

Section 1.82 "**Manufacturing Costs**" means, with respect to a Product, (a) the Fully Burdened Costs incurred by Aerie and its Affiliates during the Term in, and that are specifically identifiable and directly allocable to, the Manufacture of such Product (including the Compound) under this Agreement or the Supply Agreement, consisting of: (i) [***] and in accordance with Aerie's accounting standards and IFRS or GAAP, as applicable; (ii) costs associated with [***] filing requirements, and the like; (iii) costs for any samples of such Product; and (iv) costs directly related to Manufacturing such Product not otherwise described above, including stability testing and other CMC support costs for such Product, write-offs for scrap, and technology transfer for such Product; or (b) such costs and expenses actually incurred by the Parties in accordance with the terms set forth in Exhibit I (Manufacturing & Supply Agreement Terms for Commercial Supply) as mutually agreed by the Parties, including costs incurred to qualify a Back-up Site. In the event that Aerie or any of its Affiliates or designees uses a contract manufacturer to perform any Manufacturing activities under this Agreement with respect to Products, Manufacturing Costs for such activities will be the price Aerie or its Affiliate pays such contract manufacturer (or designee) for such activities, plus the costs to manage and to process materials obtained from such contract manufacturer.

Section 1.83 "**Manufacturing & Supply Agreement**" has the meaning set forth in Section 3.1.1.

Section 1.84 "**Marketing Approval**" means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the customary commercial sale of a Product in such country, including with respect to pricing and reimbursement.

Section 1.85 "**Materials**" has the meaning set forth in Section 3.2.

Section 1.86 "**Medical Affairs Activities**" means design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, a Product, including activities of Medical Liaisons, grants to support continuing independent medical education (including independent symposia and congresses), and development, publication and dissemination of scientific and clinical information in support of an approved indication for such Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing representatives or received by letter, phone call or email or other means of communication. It shall also include such activities conducted in connection with Commercial launch, such as establishing a group of Medical Liaisons.

Section 1.87 "**Medical Liaison**" means those health care professionals employed or engaged by Santen or any of its Affiliates (or their designees) with appropriate health care experience to engage in in-depth dialogues with physicians regarding medical issues associated with a Product, and are not Sales Representatives or otherwise engaged in direct selling or promotion of a Product.

Section 1.88 "**Milestone Events**" has the meaning set forth in Section 7.2.1.

Section 1.89 "**Milestone Payments**" has the meaning set forth in Section 7.2.1.

Section 1.90 "**NDA**" means (a) a New Drug Application, as defined in 21 U.S.C. § 355(b) *et seq*., and the regulations promulgated thereunder, as such Application may be amended or supplemented from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto), or (b) any corresponding foreign application in the Territory.

Section 1.91 "**Net Sales**" means, with respect to a certain time period and Product, the gross invoiced sales prices charged for a Product (after Marketing Approval of such Product) sold by Santen, its Affiliates, and any of their Sublicensees (the "**Selling Party**") in arm's length transactions to Third Parties (other than sales between Santen, its Affiliates, and/or their respective to Sublicensees) during such time period, less the total of the following charges or expenses, as determined in accordance with IFRS (or, if used in lieu of IFRS by the applicable seller, GAAP) and (to the extent consistent with IFRS or GAAP) in accordance with the books and records of Santen or its applicable Affiliate or Sublicensee, consistently applied across all similar products sold by Santen and to the extent actually invoiced, allowed, incurred or applied: (a) [***]; (b) [***]; (c) [***]; and (d) [***]. To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be trued-up in accordance with Santen's (and its Affiliates') accounting policies consistent with IFRS, as consistently applied, and Net Sales and related payments under this Agreement shall be reconciled as appropriate.

Any disposal of Products for, or use of Products in, clinical or pre-clinical trials, given as free samples or at no charge with respect to patient assistance or patient access programs, or distributed at no charge to indigent patients or otherwise for compassionate use shall not be included in Net Sales.

Upon any sale or other transfer for value of a Product that is required to be included within Net Sales for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, then for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable Calendar Quarter for such

Product in the country in which such sale occurred when such Product is sold alone and not with other products. In the event no sales price is available for the Product alone in such country during the applicable Calendar Quarter, then [***].

Section 1.92 "**Non-Publishing Party**" has the meaning set forth in Section 12.3.2.

Section 1.93 [***].

Section 1.94 "**Out-of-Pocket Development Expenses**" means, with respect to a Product, the expenses paid or payable to Third Parties that are incurred by Santen and its Affiliates for, and are specifically identifiable and directly allocable to, the Development of such Product.

Section 1.95 "**Party**" and "**Parties**" has the meaning set forth in the Preamble.

Section 1.96 "**Patent Challenge**" means any action, suit, proceeding or claim by Santen or its Sublicensees or Affiliates challenging the validity, patentability, scope, priority, construction, inventorship, enforceability or Aerie's or its Affiliate's or licensor's ownership of any Aerie Patent or any Patent Rights within the Aerie Improvements or any Collaboration Patent, as applicable, in any forum.

Section 1.97 "**Patent Rights**" means (a) all patents, priority patent filings and patent applications, and (b) any divisional, continuation (in whole or in part), or request for continued examination of any of such patents, and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

Section 1.98 "**Paying Party**" has the meaning set forth in Section 7.10.1.

Section 1.99 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 1.100 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.4.

Section 1.101 "**Phase 3 Clinical Trial**" means a human clinical trial of a Product (whether a standalone trial or a stage of a "Phase 2/3" clinical trial described in the protocol as the "Phase 3 portion"): (a) (1) with a defined dose or a set of defined doses of such Product designed to establish statistically significant efficacy and safety of such Product for the purpose of enabling the preparation and submission of an NDA to the competent Regulatory Authorities in a country of the Territory, or (2) where the results of such clinical trial are intended (if successful) to be used to establish both safety and efficacy of such Product in patients which are the subject of such trial and serve as the basis for initial or supplemental Marketing Approval of such Product, and (b) that satisfies the requirements of 21 CFR § 312.21(c) or its non-U.S. equivalents.

Section 1.102 "**PMDA**" means the Pharmaceuticals and Medical Devices Agency of Japan and any successor agency or authority having substantially the same function.

Section 1.103 "**Post Grant Proceeding**" means any proceedings before any national patent authority involving the review, examination, analysis or any combination thereof, of any issued patent. Examples of Post Grant Proceedings include post grant review proceedings, inter partes review

proceedings, supplemental examination, patent interference proceedings, opposition proceedings initiated on and after issuance of the applicable patent, reissue proceedings, reexamination proceedings, and invalidation.

Section 1.104 "**Product Relevant**" means, with respect to a Product and a [***] in a country in the Territory, the claims of such Patent Right would be infringed by the Commercialization of such Product in such country, absent (a) a finding of invalidity, unpatentability or unenforceability thereof or (b) [***].

Section 1.105 "**Product Trademarks**" has the meaning set forth in Section 8.8.1.

Section 1.106 "**Products**" means the Rhopressa Product and the Rocklatan Product.

Section 1.107 "**Promotional Materials**" has the meaning set forth in Section 6.6.2.

Section 1.108 "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

Section 1.109 "**Publishing Party**" has the meaning set forth in Section 12.3.2.

Section 1.110 "**Quality and Compliance Standards**" means the quality and compliance standards approved by the JSC from time to time, including manufacturing standards, such as Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), quality standards, supply chain standards, such as NMPA, international Good Supply Practice (GSP), distribution standards, such as Good Distribution Practice (GDP), safety and healthcare compliance standards and generally accepted national and international pharmaceutical industry codes of practice (including guidelines under the ICH).

Section 1.111 "**R&D FTE Rate**" means (i) for the period commencing on the Effective Date and ending on December 31, 2020, [***] and (ii) for each Calendar Year thereafter, the R&D FTE Rate in effect for the most recently completed Calendar Year increased by the percentage increase, if any, in CPI as of December 31 of the then most recently completed Calendar Year relative to the level of the CPI as of December 31 of the Calendar Year immediately preceding the then most recently completed Calendar Year (where Consumer Price Index or CPI means the Consumer Price Index - Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index)). For clarity, the same R&D FTE Rate shall apply with respect to each of the Parties.

Section 1.112 "**Receiving Party**" has the meaning set forth in Section 12.1.1.

Section 1.113 "**Regulatory Authority**" means any Governmental Authority or other authority responsible for granting Marketing Approvals for Products, including the FDA, PMDA, and any corresponding national or regional regulatory authorities.

Section 1.114 "**Regulatory Filing**" means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Product.

Section 1.115 "**Reversion Products**" has the meaning set forth in Section 13.5.

Section 1.116 "**Rhopressa Development Costs**" has the meaning set forth in Section 6.5.2.

Section 1.117 "**Rhopressa Product**" means (i) the ophthalmic solution product for topical administration marketed as Rhopressa™, and (ii) any other ophthalmic solution product containing 0.2 mg/mL of netarsudil that is bioequivalent to Rhopressa™ [***].

Section 1.118 "**Rhopressa Initial Indication**" means the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Section 1.119 "**Rhopressa Phase 3 Clinical Trial**" means the Phase 3 Clinical Trial for the Rhopressa Product in Japan, as more fully described in the Development Plan for Rhopressa attached hereto as Exhibit J, and to be conducted by Aerie.

Section 1.120 "**Rocklatan Product**" means (i) the ophthalmic solution product for topical administration marketed as Rocklatan™, and (ii) any other ophthalmic solution product containing 0.2 mg/mL of netarsudil and 0.05 mg/mL of latanoprost that is bioequivalent to Rocklatan™ [***].

Section 1.121 "**Rocklatan Initial Indication**" means the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Section 1.122 "**Royalties**" has the meaning set forth in Section 7.4.1.

Section 1.123 "**Royalty Term**" has the meaning set forth in Section 7.4.2.

Section 1.124 "**Sale Transaction**" has the meaning set forth in Section 14.8.

Section 1.125 "**Sales Representative**" means a pharmaceutical sales representative who is trained with respect to any of the Products, including its labeling and promotional materials, engaged or employed by a Party or its Affiliates to conduct detailing with respect to such Product in accordance with the terms of this Agreement.

Section 1.126 "**Santen**" has the meaning set forth in the Preamble.

Section 1.127 "**Santen Housemarks**" means those trademarks set forth on Exhibit E.

Section 1.128 "**Santen Indemnified Parties**" has the meaning set forth in Section 10.1.1.

Section 1.129 "**Santen Inventions**" has the meaning set forth in Section 8.1.3(b).

Section 1.130 "**Santen IP**" means (a) Santen Know-How and (b) Santen Patents.

Section 1.131 "**Santen Know-How**" means any and all Know-How (including Know-How within the Santen Inventions) that (a) is Controlled by Santen or its Affiliates and (b)(i) is used by Santen or its Affiliates in the research and Development of Products or (ii) is otherwise necessary or reasonably useful for the Exploitation of Products to the extent provided for in this Agreement, including the conduct by Aerie of Development Plan activities. Notwithstanding the foregoing, Santen Know-How shall exclude any Collaboration IP.

Section 1.132 "**Santen Patents**" means any and all Patent Rights (including Patent Rights within the Santen Inventions) Controlled by Santen or its Affiliates that are necessary or reasonably useful for the Exploitation of Products to the extent provided for in this Agreement, including the conduct by Aerie of Development Plan activities. Notwithstanding the foregoing, Santen Patents shall exclude any Collaboration Patents.

Section 1.133 "**Selling Party**" has the meaning set forth in Section 1.91.

Section 1.134 "**Sublicensee(s)**" means a Third Party, other than a Third Party subcontractor or any Distributor, that has been granted a sublicense or other rights under the rights granted to a Party pursuant to Section 4.1 in accordance with Section 4.2, or is deemed to be a Sublicensee under Section 4.5, but shall exclude any wholesaler of a Product that does not market or promote the Product.

Section 1.135 "**Term**" has the meaning set forth in Section 13.1.

Section 1.136 "**Termination Refund**" has the meaning set forth in Section 13.4.4.

Section 1.137 "**Territory**" means Japan, South Korea, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam and Taiwan.

Section 1.138 "**Third Party**" means a Person other than (a) Santen or any of its Affiliates and (b) Aerie or any of its Affiliates.

Section 1.139 "**Third Party Acquirer**" has the meaning set forth in Section 14.8.

Section 1.140 "**Third Party Claim**" has the meaning set forth in Section 10.1.1.

Section 1.141 "**Third Party IP**" has the meaning set forth in Section 7.4.5.

Section 1.142 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

Section 1.143 "**Valid Claim**" means a claim in an issued and unexpired Patent Right or an application for a Patent Right that has not lapsed or been abandoned, canceled, disclaimed, revoked, held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through re-examination, re-issue, disclaimer or otherwise, or lost in an interference proceeding; *provided*, *however*, that if a claim of a pending patent application shall not have issued within [***] after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a Patent Right issues with such claim (from and after which time the same would be deemed a Valid Claim).

ARTICLE 2. RESEARCH COLLABORATION

Section 2.1 Management.

2.1.1 Overview. Within thirty (30) days after the Effective Date, the Parties shall establish a cross-functional, joint steering committee (the "**Joint Steering Committee**" or the "**JSC**"), to serve as a forum for information exchange, discussion and decisions with respect to development and commercialization activities relating to the Products and the Compound in the Field in the Territory.

2.1.2 Alliance Managers. Each of Santen and Aerie shall appoint one representative who possesses a general understanding of Development, regulatory, manufacturing and Commercialization matters to act as its respective alliance manager(s) for this relationship (an "**Alliance Manager**"). Each Party may replace its respective Alliance Manager at any time upon written notice to the other in accordance with this Agreement. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged

with creating and maintaining a collaborative work environment within the JSC. Each Alliance Manager will also be responsible for:

a. providing a primary single point of communication responsible for seeking consensus both within the respective Party's organization and together regarding key strategy and plan issues;

b. ensuring awareness of the governance procedures and rules set forth herein and monitoring compliance therewith; and

c. identifying and raising disputes to the JSC for discussion in a timely manner.

The Alliance Managers shall have the right to attend all JSC and subcommittee meetings. In accordance with Section 2.1.3(c), each Alliance Manager may bring any matter to the attention of the JSC that such Alliance Manager reasonably believes requires the attention of the JSC. Within ten (10) days after the Effective Date, each Party shall appoint and notify the other Party in writing of the identity of such Party's representative to act as its Alliance Manager under this Agreement.

2.1.3 Joint Steering Committee.

a. **Composition**. The JSC shall be comprised of [***] named representatives of each Party (or such other number as the Parties may agree in writing), each of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. The JSC shall appoint a chairperson from among its members, with the first chairperson of the JSC being a representative of Santen. Each chairperson shall serve a term of one (1) Calendar Quarter, with the successor chairperson to be appointed by the JSC from among the representatives of the Party not represented by the outgoing chairperson (e.g., the JSC's second chairperson shall be a representative of Aerie, the JSC's third chairperson shall be a representative of Santen, etc.). The role of the chairperson shall be to convene and preside at the meeting of the JSC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JSC representatives. Within thirty (30) days after the Effective Date, each Party shall designate by written notice to the other Party its initial representatives on the JSC (including its Alliance Manager). The JSC may change its size from time to time by mutual consent of the Parties. Each Party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change. Each Party's representatives on the JSC, and any replacement for any such representative, shall be bound by the obligations of confidentiality set forth in Article 12.

b. **Function and Powers of the JSC**. The JSC shall, consistent with the terms and conditions set forth in this Agreement, and subject to Section 2.1.5:

(i) coordinate the Parties' activities under this Agreement;

(ii) discuss the overall strategy for the development and regulatory approval of the Products in the Field throughout the Territory;

(iii) facilitate communications and discussion between the Parties with respect to the development, manufacture and commercialization of Products;

(iv) discuss and approve each Development Plan and any proposed amendments or revisions thereto, including timeframes for the Development activities to be carried out thereunder, on an annual basis or as otherwise agreed upon by the Parties;

(v) oversee the implementation of each Development Plan for each Product and review and serve as an information-sharing forum for Development and Commercialization for each Product, including discussion of the results of the activities being carried out thereunder;

(vi) define and coordinate regulatory strategy for each Product;

(vii) establish subcommittees, as appropriate, as described more fully in Section 2.1.3(d) below;

(viii) direct and oversee any subcommittee;

(ix) discuss estimated sales forecasts for Products;

(x) establishing a process for reviewing and commenting on Promotional Materials and training materials and programs for each Product for the Territory;

(xi) designate policies for the Parties' reporting and recording of Development Costs and other financial terms set forth in this Agreement;

(xii) resolve disputed matters that may arise at the subcommittees; and

(xiii) perform any and all tasks and responsibilities that are expressly attributed to the JSC under this Agreement or that are otherwise agreed by the Parties in writing.

c. **Meetings**.

(i) The JSC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties, with the location of such meetings alternating between locations designated by Santen and locations designated by Aerie. The chairperson of the JSC shall be responsible for calling meetings on reasonable prior notice. Prior to any meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics which shall be included on such agenda, either prior to or in the course of such meeting. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information

with respect to such proposed items reasonably in advance (at least three (3) Business Days if reasonably practicable) of the applicable meeting. Each Alliance Manager may require topics to be included for the agenda for JSC meetings (to the extent within the scope of the JSC) by forwarding such topics and relevant information to the JSC chairperson. The Parties may mutually agree not to hold a meeting if there is no topic, issue or matter to be included on an agenda for such meeting. The Alliance Managers shall prepare and circulate minutes of each meeting to each member of the JSC for review and approval. The JSC shall agree on the minutes of each meeting as promptly as practicable, but in any event within ten (10) Business Days, following such meeting.

(ii) Representatives of the Parties on the JSC may attend meetings by telephone, videoconference or in person. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party.

(iii) As appropriate (subject to the discretion of the chairperson of the JSC, with approval not to be unreasonably withheld, conditioned or delayed), and *provided* that not less than two (2) Business Days' prior written notice has been given to the other Party, other employees of the Parties may attend JSC meetings as observers, as well as Third Parties; *provided, however,* that a Party shall not bring a Third Party to a meeting without the other Party's prior written consent; and *provided further, however*, that each such Third Party (x) shall not vote or otherwise participate in the decision-making process of the JSC, and (y) shall be bound by obligations of confidentiality and non-disclosure, and obligations to assign inventions, consistent with those set forth in Article 8 and Article 12.

(iv) Each Party may also call for special meetings of the JSC with reasonable prior written notice to the other Party (it being agreed that at least ten (10) Business Days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making authority of the JSC. In the event that there are proposed changes to the Development Plan that require a decision by the JSC prior to the next scheduled JSC meeting, the Parties will promptly schedule a meeting for such purpose.

(v) Each Party shall be responsible for all of its own expenses incurred in connection with participating in all meetings.

d. **Subcommittees**. The JSC may establish and disband such subcommittees as deemed necessary by the JSC, which shall include a joint development committee (the "**Joint Development Committee**" or the "**JDC**"), a joint commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**"), and a joint manufacturing and supply committee (the "**Joint Manufacturing and Supply Committee**" or the "**JMSC**"). Each such subcommittee shall consist of

the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on written notice to the other Party or to send a substitute representative to any subcommittee meeting. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in Article 12. Except as expressly provided in this Agreement or subject to the delegation granted by the JSC of any of its responsibilities, no subcommittee shall have the authority to bind the Parties hereunder and each subcommittee shall report to the JSC. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all meetings. Any matters arising within a subcommittee that are not resolved by members of such subcommittee shall be submitted to the JSC for resolution as set forth in Section 2.1.3(b)(xii).

e. **Specific Responsibilities of the JDC**. Without limiting the generality of Section 2.1.3(d), the JSC (or, if such authority is granted to the JDC by the JSC, the JDC) shall:

(i) review and finalize, for the JSC's approval, any Development Plan (including the then-current Development Budget) or amendments thereto;

(ii) review and monitor the activities being conducted under each Development Plan with respect to each Product and the progress of such activities; and

(iii) perform such other functions as are set forth in this Agreement as the function of the JDC or as the Parties or the JSC (with respect to its designated responsibilities) may otherwise mutually agree in writing.

f. **Specific Responsibilities of the JCC**. Without limiting the generality of Section 2.1.3(d), the JSC (or, if such authority is granted to the JCC by the JSC, the JCC) shall:

(i) review and discuss Commercialization reports provided by Santen pursuant to Section 6.6 (including the commercialization budget);

(ii) discuss pricing of Products;

(iii) monitor the competitive landscape for each Product in the Territory; and

(iv) perform such other functions as are set forth in this Agreement or as the Parties or the JSC (with respect to its designated responsibilities) may otherwise mutually agree in writing.

2.1.4 Cooperation. Each Party shall provide the JSC such information as required under this Agreement or as otherwise reasonably requested by the other Party and reasonably available to such Party to enable the other Party to perform its obligations under this Agreement, in each case relating to the progress against the goals or performance of activities under each Development Plan.

2.1.5 Decisions.

a. The JSC shall serve as (a) a decision-making body as set forth in this Section 2.1 with respect to all matters specified in this Section 2.1, including Development and Commercialization activities under this Agreement, and (b) notwithstanding anything to the contrary herein, solely as an information-sharing forum with no decision-making authority with respect to all other activities of the Parties under this Agreement unless the Parties separately grant further authority to the JSC. Other than as set forth herein, in order to make any decision required of it hereunder, the JSC (or any subcommittee thereof) must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. The JSC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party, and decisions of the JSC (or any subcommittee thereof) shall require unanimous consent of the Parties.

b. The JSC shall strive to seek consensus in its actions and decision making process. If a dispute arises that cannot be resolved by a subcommittee of the JSC, such dispute shall be referred to the JSC for resolution. If the JSC cannot reach a unanimous decision or a dispute arises that cannot be resolved within the JSC (whether the matter originated at the JSC or within a subcommittee) after a period of [***], such dispute shall be referred to the Executive Officers for resolution. Such officers (or their designees) will in good faith seek to resolve the matter within [***] after the matter has been referred to them, or within such longer time periods as the Parties may mutually agree upon. In the event that consensus cannot be reached with respect to a decision after a meeting of the Executive Officers (it being understood and agreed that neither Party shall unreasonably withhold or delay agreement with respect to any such dispute), [***]. Without limiting the foregoing, in no event shall (x) any decision of the JSC knowingly require either Party to take any action that would, or fail to take any action where the failure to take such action would, in the reasonable judgment of such Party, infringe the intellectual property rights of any Third Party, violate applicable Laws or any agreement with any Third Party, or frustrate the purpose of this Agreement, or (y) the JSC have the power to (A) determine, or resolve any dispute as to, what level of efforts constitutes Commercially Reasonable Efforts, (B) allocate to a Party any authority delegated to the JSC other than as set forth in this Agreement (including Santen's right to break deadlocks for non-Critical Matters) or (C) dissolve the JDC, JCC or JFC once established.

2.1.6 Exceptions. Notwithstanding the foregoing, neither Party in exercising its right to finally resolve a dispute pursuant to Section 2.1.5 shall have any power to amend, modify or waive compliance with the terms of this Agreement.

2.1.7 Authority. The JSC and any subcommittee shall have only the powers assigned expressly to it in this Article 2 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC or subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. For the avoidance of doubt, JSC and subcommittee rights to discuss, comment, review or monitor (and other similar activities) shall not require any Party or designee thereof to act or be bound in any respect by such discussion, comment, review, or monitoring.

2.1.8 Discontinuation of JSC. The JSC shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the JSC or (b) expiration or termination of this Agreement.

Section 2.2 Subcontracting. Each Party may engage its Affiliates, or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform its obligations under this Agreement; *provided* that JSC approval shall be required for any subcontractor that Santen may seek to use from time to time unless such subcontractor is set forth on Exhibit G (but only for the services specifically indicated for such listed subcontractor). Any subcontractor to be engaged by a Party to perform such Party's obligations set forth in this Agreement will meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. The activities of any such subcontractors will be considered activities of such subcontracting Party under this Agreement. The subcontracting Party will be responsible for ensuring compliance by any such subcontractors with the terms of this Agreement, as if such subcontractors are such Party hereunder. Each subcontract shall be in writing and shall contain obligations, on the part of the applicable subcontractor, consistent with this Agreement, including Article 8 and Article 12, with respect to confidentiality and non-use and the assignment of, or the grant of equivalent rights under, all Patent Rights, Know-How, inventions and other intellectual property rights that such subcontractor may develop or acquire by reason of work performed under this Agreement. Each subcontracting Party will conduct, and will cause its Affiliates and other subcontractors, if any, to conduct, the relevant activities in accordance with such subcontracting Party's commitments hereunder.

Section 2.3 Information Sharing. Each Party shall promptly provide the other Party with copies of all material non-clinical, analytical, manufacturing and clinical data (including, for clarity, data sets) and information generated by such Party, or on behalf of such Party by any Affiliate or Third Party relating to any and all Products, to the extent necessary for the other Party to provide any support expressly requested by such Party under this Agreement or as otherwise reasonably required for a Party to perform its obligations or exercise its rights under this Agreement. For clarity, information regarding adverse events and serious adverse events shall be provided in accordance with the Pharmacovigilance Agreement. All non-clinical, analytical, manufacturing and clinical data and associated reports disclosed by one Party to the other under this Agreement shall be deemed Confidential Information of the disclosing Party except (a) all data and reports generated under the Development Plan by or on behalf of either Party shall be deemed Confidential Information of both Parties, and (b) as otherwise set forth in this Agreement; *provided* that each Party (or its Affiliates or licensees or Sublicensees) may use such data and reports solely for the purpose of performing its obligations or exercising its rights under this Agreement, including Developing a Product, seeking and obtaining Marketing Approval, or Commercializing the Product. Notwithstanding anything to the contrary in the foregoing, the Aerie Know-How shall be Confidential Information of Aerie, and Aerie shall be deemed the disclosing Party thereof for purposes of Article 12.

Section 2.4 Exclusivity.

2.4.1 General. During the Term, neither Party, itself or through its Affiliates, shall outside of activities conducted under this Agreement directly or indirectly conduct or participate in, or license, authorize, appoint, advise, assist or otherwise enable any Third Party to conduct or participate

in, the Commercialization in the Territory in the Field of any products having the same mode of action as a rho-kinase inhibitor and/or dual inhibition of rho-kinase and norepinephrine transporter.

2.4.2 Reasonable Restrictions. Each Party acknowledges the provisions of this Section 2.4 are reasonable and necessary to protect the legitimate interests of the other Party and to encourage the free sharing of information between the Parties with respect to the Products, and each Party agrees not to contest such limitations in any proceeding. Each Party acknowledges that the other Party would not have entered into this Agreement absent the restrictions set forth in this Section 2.4 and that a breach or threatened breach of this Section 2.4 would be likely to result in irreparable harm to the other Party for which there is no adequate remedy at law. Therefore, each Party shall be entitled to obtain from any court of competent jurisdiction injunctive relief, specific performance, and an equitable accounting of any earnings, profits or benefits arising out of any such breach by the other Party. Nothing in this Section 2.4.2 is intended or will be construed to limit in any way either Party's right to equitable relief or any other remedy for breach of this or any other provision of this Agreement.

ARTICLE 3. MANUFACTURE AND SUPPLY; MATERIAL TRANSFER

Section 3.1 Manufacture and Supply of Compound and Product.

3.1.1 Manufacturing Lead. Aerie will be responsible for the Manufacturing of Products either by itself or through its Affiliates or by Third Party contract manufacturers as provided in the manufacturing and supply agreement to be entered into by the Parties in accordance with Section 3.1.3 (the "**Manufacturing & Supply Agreement**"). Aerie shall consider in good faith any request by Santen to Manufacture Product and/or the final packaging thereof for Santen's use hereunder; provided that any such decision shall be mutually agreed by the Parties. Either Party will have the right to propose alternative Manufacturing sites to Manufacture the Products for the Territory and may transfer the Manufacturing thereof from one site to another from time to time upon prior written agreement between the Parties; provided that such Manufacturing sites shall meet or be capable of meeting the criteria (including the ability of such Manufacturing sites to fulfil the Product specifications required for the designated countries in the Territory) to be proposed by Santen and agreed by both Parties at the JMSC prior to such agreement on any such Manufacturing site. Santen shall reasonably cooperate with Aerie in good faith to obtain such approval for such Manufacturing sites upon Aerie's request.

3.1.2 Manufacturing and Supply. Aerie will use Commercially Reasonable Efforts to supply, at its option, Compound and/or Product in a manner sufficient to Develop and fulfill commercial demand for the Products in the Territory in accordance with Manufacturing & Supply Agreement. With respect to clinical supply of Compound or Products for use by Santen in the Development of Products in the Territory under this Agreement, Santen will reimburse Aerie all its Manufacturing Costs for such Compound or Products within [***] of receipt of the applicable invoice for such Compound or Product, in accordance with the terms set forth in Exhibit H (Supply Agreement Terms for Clinical Supply (Investigational Drugs)). With respect to commercial supply of Compound or Products for use by Santen in the Commercialization of Products in the Territory under this Agreement, the price of such Compound or Products shall be equal [***] and set forth in the Manufacturing & Supply Agreement (such price, the "**Supply Price**"), payable by Santen on delivery thereof in accordance with the Manufacturing & Supply Agreement. Notwithstanding the foregoing, the Supply Price shall reflect the fair market value for commercial supply of such Compound or Product, [***]. All sales of Compound

and Products will be final, subject to returns for failure of any Compound or Product to meet specifications. Compound and Product will be delivered [***] from Aerie's or its Affiliates' or Third Party contract manufacturers' manufacturing site.

3.1.3 Supply and Quality Agreements. No later than [***] prior to the anticipated First Commercial Sale of a Product in the Territory, the Parties shall initiate good faith negotiations to enter into a Manufacturing & Supply Agreement and a Quality Agreement with respect to the supply of such Product by Aerie to Santen for commercial use, substantially on the terms set forth in Exhibit I (Manufacturing & Supply Agreement Terms for Commercial Supply), and the Parties will use Commercially Reasonable Efforts to enter into such Manufacturing & Supply Agreement and Quality Agreement within [***] after the commencement of such negotiations. The Manufacturing & Supply Agreement shall incorporate customary terms and conditions mutually agreed upon by the Parties, including terms regarding technology transfer to Santen, Aerie's Affiliates and Third Parties. The Manufacturing of Products will comply with the Quality and Compliance Standards, Manufacturing & Supply Agreement(s) and Quality Agreement(s).

3.1.4 Distribution. Santen will be solely responsible for the distribution of Products in the Territory. The distribution shall comply with the Quality and Compliance Standards and the requirements set forth in the Quality Agreement. Aerie may perform due diligence and audits of Santen's facilities and those of its Affiliates and Third Parties involved in the distribution of Products with respect to storage and distribution as reasonably necessary to verify compliance with this Agreement.

3.1.5 Brand Security and Anti-Counterfeiting. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto. Practices with respect to brand security will comply with Aerie's then-current standards, where they define Product security features, warehouse/cargo protection requirements, and response and communication process for brand security incidents.

Section 3.2 Material Transfer. To facilitate the Parties' Development or Commercialization activities hereunder, either Party may provide to the other Party certain materials (including chemical compounds), owned by or licensed to such Party for use by the other Party in furtherance of the other Party's Development or Commercialization activities under this Agreement (such materials provided hereunder are referred to, collectively, as "**Materials**"). All Materials are deemed to be the Confidential Information of the Party supplying such Materials, and such Party is deemed to be the Disclosing Party thereof. Except as otherwise expressly provided under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, and the receiving Party shall ensure that such Materials shall be used only in furtherance of the exercise of rights or performance of obligations under this Agreement and in accordance with this Agreement, shall be used solely under the control of the other Party and shall not be used or delivered to or for the benefit of any Third Party, except for permitted subcontractors as set forth in Section 2.2, without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects, in each case unless otherwise specifically contemplated hereunder, and will be used in compliance with all applicable Laws. The provision of Materials to the receiving Party hereunder does not grant such Party any rights other than those specifically granted in this Agreement. Delivery of the Materials shall be [***]. The

receiving Party shall: (a) receive the Materials; (b) notify the supplying Party when the Materials have been received; and (c) forward to the supplying Party any applicable chain of custody forms, in-transport temperature record(s) and receipt verification documentation and such other documentation reasonably requested by the supplying Party. The receiving Party shall be responsible for import clearance (including preparing any necessary documentation with respect thereto) and making entry of shipment. The supplying Party shall provide the relevant shipping documentation, pro forma invoice and airway bill, together with such other documentation necessary for the use, handling, transfer, and/or storage of the Materials. The Materials supplied under this Section 3.2 are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. Except as expressly set forth herein, THE MATERIALS ARE PROVIDED WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY, EXCEPT AS SET FORTH IN ARTICLE 9. For record-keeping purposes, the Parties shall compile a list (that shall include the type of material, quantity, shipping date and any other relevant details) on a Calendar Quarter-by-Calendar Quarter basis setting forth the Materials provided to/from each Party, which document shall be signed by an authorized representative of each Party.

ARTICLE 4. LICENSE GRANT

Section 4.1 License Grants.

4.1.1 License Grant to Santen. Subject to the terms and conditions of this Agreement, Aerie hereby grants to Santen an exclusive (even as to Aerie and its Affiliates, except as expressly set forth in this Agreement and subject to Aerie and its Affiliates retaining the non-exclusive rights reasonably necessary or useful to perform Aerie's obligations under this Agreement and any Development Plan), royalty- and milestone-bearing, sublicenseable (but only in accordance with Section 4.2), license under the Aerie IP and Aerie's interest in Collaboration IP to Develop, Manufacture (subject to Section 3.1.1) and Commercialize Products in the Field in the Territory during the Term.

4.1.2 License Grant to Aerie. Subject to the terms and conditions of this Agreement, Santen hereby grants to Aerie (a) a non-exclusive, royalty-free, sublicenseable (but only in accordance with Section 4.2) license under the Santen IP and Santen's interest in the Collaboration IP, in each case, to perform Aerie's obligations and exercise Aerie's rights in or for the Territory under this Agreement, and (b) a non-exclusive, royalty-free, sublicenseable (but only in accordance with Section 4.2) license under Santen's interest in the Collaboration IP and Santen Inventions, and any other Santen IP necessary for Aerie to practice such Collaboration IP and Santen Inventions in the exercise of Aerie's rights under this Section 4.1.2(b), to Develop, Manufacture and Commercialize the Rhopressa Product and the Rocklatan Product in the Field outside the Territory.

4.1.3 Limitation. Notwithstanding anything to the contrary in this Agreement, in no event shall Santen conduct any Manufacturing activities with respect to the Compound or the Products except as expressly set forth in Section 3.1.1.

Section 4.2 Sublicenses. Each Party shall have the right to grant one or more sublicenses under the licenses granted to such Party under Section 4.1, in full or in part, by means of written agreement to Affiliates or Third Parties (with the right to sublicense through multiple tiers), without the prior written consent of the other Party. As a condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement (including for the avoidance of doubt, that if sales by such Sublicensee are included in Net Sales hereunder, such Sublicensee shall permit audit rights with respect to its reporting of Net Sales that are consistent with those given by Santen hereunder with respect to its sales included in Net Sales); (b) such Party will continue to be responsible for full performance of such Party's obligations under this Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were such Party hereunder; (c) such Party's grant of any sublicense will not relieve such Party or its Affiliates from any of its obligations under this Agreement; (d) any such permitted sublicense shall agree to be bound by all of the applicable terms and conditions of this Agreement, and, where Santen is the sublicensing Party, any such permitted sublicense shall contain terms permitting Santen to (i) terminate such sublicense in the event of a Patent Challenge by such sublicensee and (ii) upon Aerie's request, audit the performance of such sublicensee, including through audit of any applicable books, records, data or other information of such sublicensee; (e) such Party will provide the other Party with a copy of such sublicense promptly, but within five (5) Business Days, after the grant of such sublicense, *provided* that such Party may redact such copy at its discretion to remove financial terms and any other information that is not relevant to this Agreement (provided that financial terms may be provided on a confidential basis to a third party auditor only for purposes of confirming amounts payable hereunder pursuant to any audit in accordance with this Agreement); and (f) the sublicense must be in writing.

Section 4.3 No Other Rights. No right or license under any Patent Rights, Know-How, or other intellectual property rights of a Party is granted or shall be granted by implication to the other Party, and each Party covenants not to practice or use any Patent Rights, Know-How, or other intellectual property rights of the other Party except pursuant to the licenses expressly granted in this Agreement or any other written agreement between the Parties. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement.

Section 4.4 Retained Rights. Notwithstanding anything to the contrary in this Agreement, Aerie shall retain the right to make and use Compound and Products generated under the Development Plan for internal non-clinical research purposes, including as a comparator product in connection with the research and development of other products.

Section 4.5 Distributorships. Santen shall have the right, in its sole discretion, to appoint its Affiliates, and Santen and its Affiliates shall have the right, in their sole discretion, to appoint any other Persons, in the Territory or in any country or other jurisdiction of the Territory, to distribute, market, and sell Products, in circumstances where the Person purchases its requirements of Products from Santen or its Affiliates. If Santen or its Affiliates appoints such a Person as a distributor and such Person is not an Affiliate of Santen nor pays Santen or its applicable Affiliates in connection with such appointment or such Products any consideration other than the arm's length transfer price of such Product, that Person shall be a "**Distributor**" for purposes of this Agreement. If such Person is obligated or has otherwise agreed to pay any royalties, milestones or similar payments (excluding, for the avoidance of doubt, volume rebates and the like) to (or on behalf of) Santen or any of its Affiliates in connection with such

appointment or such Products, such Person shall not be deemed to be a Distributor for purposes of this Agreement, and instead shall be deemed to be a Sublicensee for purposes of this Agreement.

ARTICLE 5. REGULATORY MATTERS

Section 5.1 Santen Responsibilities. Santen will be solely responsible for (and as between the Parties, Santen shall have the sole right with respect to) the preparation, submission and maintenance of all Regulatory Filings and obtaining all Marketing Approvals with respect to Products in the Territory in the Field. Aerie will cooperate with Santen, at Santen's reasonable request and expense (with no cost to Santen for Aerie providing existing documents reasonably required from Aerie to support any Regulatory Filing), with respect to any regulatory matters related to Products for which Santen is responsible hereunder. Santen will own all right, title and interest in and to any and all Regulatory Filings and Marketing Approvals directed to Products, and all such Regulatory Filings and Marketing Approvals will be held in the name of Santen, its Affiliates or its designees. Aerie will execute all documents and take all actions as are reasonably requested by Santen, at Santen's expense, to vest such title in Santen or such Affiliates or designees, as applicable.

Section 5.2 Rights of Reference.

5.2.1 Aerie hereby grants to Santen and its Affiliates and permitted sublicensees the right to use, cross-reference, file or incorporate by reference any relevant Regulatory Filings pertaining to the Products submitted by or on behalf of Aerie outside the Territory or collected in or for the Territory. Santen and its Affiliates and permitted sublicensees may use such rights of reference solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and Commercializing Products in the Territory and otherwise performing its obligations under this Agreement and in interactions with any Regulatory Authority in connection with Development, Manufacturing or Commercialization in the Territory, subject in each case to Santen's obligation to provide written notice reasonably in advance of any submissions made in connection with such right of reference or such interactions or other communications, in each case in order for Aerie to consult with Santen and to propose including, adopting or incorporating any reasonable recommendations or instructions in connection with the rights granted under this Section 5.2. In the event that Santen has a good faith reason to believe that Aerie may be in breach or violation of any representation, warranty or undertaking in Section 9.2(g) (Additional Aerie Representations and Warranties) or if there is any failure on the part of Aerie to comply with the Quality and Compliance Standards or other applicable Laws relating to information or data in the relevant Regulatory Filings pertaining to the Products submitted by or on behalf of Aerie outside the Territory or collected in or for the Territory, upon Santen's request, the Parties shall discuss in good faith any reasonable actions that may be taken in order to address appropriately any such actual breach, violation or failure, including any additional research, trials or any other Development activities necessary for the Regulatory Filings in or for the Territory to be submitted by or on behalf of Santen, in each case as mutually agreed upon in writing by the Parties.

5.2.2 Santen hereby grants to Aerie and its Affiliates and permitted sublicensees the right to use, cross-reference, file or incorporate by reference any relevant Regulatory Filings pertaining to the Products submitted by or on behalf of Santen in the Territory or collected in or for outside the Territory. Aerie and its Affiliates and permitted sublicensees may use such rights of reference solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and Commercializing Products

outside the Territory and in interactions with any Regulatory Authority in connection with Development, Manufacturing or Commercialization outside the Territory, subject in each case to Aerie's obligation to provide written notice reasonably in advance of any submissions made in connection with such right of reference or such interactions or other communications, in each case in order for Santen to consult with Aerie and to propose including, adopting or incorporating any reasonable recommendations or instructions in connection with the rights granted under this Section 5.2.

Section 5.3 Regulatory Updates. Santen shall keep Aerie reasonably informed of all material regulatory developments and filings relating to Products in the Territory, including through the Calendar Quarter development reports under Section 6.4, Santen will use good faith efforts to provide Aerie a meaningful opportunity to (a) review and comment on such filings prior to submission thereof, and Santen will in good faith consider incorporating such comments into, any such filings in the Territory, and (b) unless such Regulatory Authorities object, participate (with Santen in its sole discretion having the right to object to such participation by more than one (1) Aerie representative at any such meeting) in all meetings with Regulatory Authorities relating to any Product in the Territory solely in an observer capacity. For all Products in the Territory, Santen will provide Aerie with a copy of all, in each case to the extent material, of all Regulatory Filings, correspondence with and minutes of meetings with Regulatory Authorities, documents included in such regulatory dossiers and Marketing Approvals.

Section 5.4 Pharmacovigilance. Reasonably prior to any Party's Initiation of any clinical study of any Product under this Agreement, the Parties shall define and allocate each Party's responsibilities with respect to pharmacovigilance activities for each Product and, if the Parties deem necessary, enter into a written agreement with the respect to the same (the "**Pharmacovigilance Agreement**"). These responsibilities shall include adhering to mutually acceptable guidelines and procedures for the receipt, investigation, recording, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety and benefit-risk profile of the Products. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Governmental Authorities. Furthermore, such agreed procedures shall be consistent with relevant International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use) (ICH) guidelines, except where in terms of reporting said guidelines may conflict with existing local regulatory safety reporting requirements, in which case local reporting requirements shall prevail. To the extent the Parties enter into a Pharmacovigilance Agreement, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement (as the Parties may agree to modify it from time to time) and to cause its Affiliates and Sublicensees to comply with such obligations.

ARTICLE 6. DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION MATTERS

Section 6.1 General. Santen shall have the right to Develop (including, for the avoidance of doubt, making Regulatory Filings and obtaining Marketing Approvals), Manufacture (subject to Section 3.1) and Commercialize the Products in the Territory. Subject to the terms of this Agreement, all decisions concerning the Development and Commercialization of Products, including the clinical and regulatory strategy, design, sale, price and promotion of Products shall be within the sole discretion of Santen.

Section 6.2 Development Plans.

6.2.1 Approval. The initial Development Plan for the Development of the Rhopressa Product is attached hereto as Exhibit J, and the initial Development Plan for the Development of the Rocklatan Product is attached hereto as Exhibit J.

6.2.2 Amendments and Updates. The JSC or, as applicable, the JDC, shall review and discuss each Development Plan on a regular basis, and in no event less frequently than once each Calendar Year. Either Party, through its representatives on the JSC or JDC, as applicable, may propose amendments to, and comment upon, each Development Plan (including the corresponding Development Budget) from time to time, and Santen shall consider such proposals and comments in good faith. In any event, an updated Development Plan shall be provided by Santen to the JSC for review and approval no later than [***] of each Calendar Year.

6.2.3 Development Budget. Each Development Budget will set forth the detailed costs to be incurred with respect to Development of the applicable Product and shall include a [***] with respect to the applicable Product, [***] and the remaining [***] of which shall be [***]. Each Development Budget shall be updated least annually with the corresponding Development Plan in accordance with Section 6.2.2.

Section 6.3 Diligence. Santen shall (directly and/or through one or more Affiliates and/or Sublicensees), use Commercially Reasonable Efforts to Develop and obtain Marketing Approval of (subject to Section 6.7.5) and Commercialize (subject to Section 6.7.1 and Section 6.7.2) the Products in each country in the Territory.

Section 6.4 Reports. During the Term, Santen shall provide Aerie and the JSC with detailed reports of the status of Santen's and its Affiliates', subcontractors and Sublicensees' activities related to the Development, Commercialization and other Exploitation of each Product in accordance with the procedures established by the JSC but no less frequently than once per Calendar Quarter. The JSC or, if applicable, the JDC or JCC shall evaluate the work performed in relation to the goals of the applicable Development Plan and/or this Agreement. Santen shall provide such other information pertaining to its Development and Commercialization activities as reasonably requested by the JCC, JDC or JSC, as applicable.

Section 6.5 Costs.

6.5.1 General. Following the Effective Date and at all times during the Term, Santen shall be responsible for, and shall bear all costs incurred by it or on its behalf associated with, the Development, Manufacture (subject to Section 3.1) and Commercialization of Products in or for the Territory, including development, distribution, marketing and sales activities, subject to the obligation of Aerie to pay its share of Development Costs pursuant to Section 6.5.2.

6.5.2 Rhopressa Development Costs. Aerie shall be initially responsible for, and shall initially bear all costs incurred by it or its Affiliates associated with the conduct of the Rhopressa Phase 3 Clinical Trial, including any amounts payable to contract research organizations or other Third Parties in connection therewith (collectively, the "**Rhopressa Development Costs**"); *provided* that Santen shall reimburse Aerie fifty percent (50%) of the Rhopressa Development Costs incurred by Aerie or its

Affiliates; *provided*, *however*, that the Rhopressa Development Costs for the calculation of the reimbursement shall not exceed the amount equal to [***] of the total amount of the Rhopressa Development Costs set forth in the Development Plan. Upon completion of the Rhopressa Phase 3 Clinical Trial, Aerie shall provide Santen with a final report specifying in reasonable detail such Rhopressa Development Costs. Such report will include an allocation of the Rhopressa Development Costs between the Parties in accordance with this Section 6.5.2, and shall include an invoice to Santen for Santen's share of such Rhopressa Development Costs. Santen shall pay such invoices within [***] after receipt of each such invoice.

Section 6.6 Commercialization Activities.

6.6.1 Generally. Santen shall have the sole right to Commercialize Products in the Territory and in the Field under this Agreement.

6.6.2 Promotional Materials. The Parties shall cooperate (with Santen having a lead role unless otherwise agreement) to develop relevant sales, promotion, market access and advertising materials relating to the Products (collectively, "**Promotional Materials**") in each case consistent with applicable Law. Santen shall be responsible for the medical, regulatory and legal review of (and shall have sole approval rights with respect to) Promotional Materials and for the interpretation and adherence to the applicable Law governing the preparation and use of such Promotional Materials, including any advance review of the Promotional Materials required by the applicable Regulatory Authority. Notwithstanding the foregoing, Aerie shall have the right to review and comment on the Promotional Materials to be used in such markets prior to the implementation of such Promotional Materials and Santen shall give good faith consideration to Aerie's comments, including any comments related to the Promotional Materials' compliance with applicable Law. Santen shall not use any Promotional Materials that would reasonably be expected to (i) have a material adverse impact on Aerie's Exploitation of the applicable Product outside the Territory, (ii) potentially infringe a Third Party's intellectual property or other proprietary rights, or (iii) violate applicable Law. Aerie will own all right, title and interest in and to any and all Promotional Materials provided by Aerie hereunder, and all improvements and derivative works thereof. Subject to the foregoing, Santen will own all right, title and interest in and to any and all Promotional Materials developed by Santen for the Products for use in the Territory (except with respect to any corporate names of the other Party included in any Promotional Materials). Upon Santen's reasonable request, Aerie will provide Santen with copies of global marketing and Promotional Materials. To the extent required by applicable Law in a country or other jurisdiction in the Territory, the Promotional Materials, packaging, and product labeling used in connection with the Products in such country or other jurisdiction shall contain the corporate names of both Parties.

6.6.3 Sales Representatives. Santen shall be responsible for all activities conducted by it and its Affiliates and Sublicensees and their respective Sales Representatives, and Santen shall ensure that its Sales Representatives do not make any representation, statement, warranty or guaranty with respect to a Product that is not consistent with the applicable, current package insert of prescribing information or other documentation accompanying or describing such Product, including mutually approved limited warranty and disclaimers, if any. Santen shall each ensure that its Sales Representatives do not make any statements, claims or undertakings to any person with whom they

discuss or promote Products that are not consistent with, nor provide or use any labeling, literature or other materials other than, those Promotional Materials currently approved for use by Santen (or, if applicable, the JSC or its applicable subcommittee). Santen shall handle all medical questions or inquiries from members of the medical profession regarding the Products in the Territory.

6.6.4 Training Materials. Aerie shall have the right to review and comment on the training materials and programs to be used in such markets prior to the implementation of such training materials and programs, in accordance with reasonable processes established by the JSC or its applicable subcommittee, and Santen shall give good faith consideration to Aerie's comments.

6.6.5 Packaging. Santen shall develop and approve packaging and product labeling for each Product, which in all cases shall be in accordance with applicable Law. Aerie shall have the right to review and comment on such packaging and product labeling and Santen shall give good faith consideration to Aerie's comments.

6.6.6 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Product, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, in each case, in any jurisdiction or region, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within twenty-four (24) hours, advise the other Party thereof by orally or in writing, and the Parties shall reasonably and in good faith determine whether a recall or such action is appropriate or required and the manner in which any such recall shall be handled (taking into account the effect of such recall or action in the Territory on other territories in which Aerie Commercializes the Product; *provided, however,* that this Section 6.6.6 shall not limit the obligations of either Party with respect to a recall required by applicable Laws, and shall not limit Santen's right and responsibility to determine whether to conduct a recall and the manner in which any such recall shall be conducted in the Territory in a manner consistent with applicable regulations and its regulatory guidelines and criteria).

6.6.7 Expansion of Territory.

a. In the event Aerie intends to Develop and/or Commercialize the Products with, through or in collaboration with any Third Party in [***] during the Term, Aerie shall notify Santen of such intent, and Santen will have a right of first negotiation, whereby Santen will have the right to [***], the Development and/or Commercialization of any Product in [***] to expand the Territory in accordance with this Section 6.6.7 during the Term (it being acknowledged and agreed by the Parties that neither Party shall be obligated to enter such separate license, only to negotiate in good faith).

b. In the event Aerie intends to Commercialize the Products in [***] during the Term, Aerie shall notify Santen of such intent and, [***] the Parties shall discuss and negotiate in good faith, [***], the terms (including financial terms) of a reasonable expansion of the Territory under this Agreement to include such additional countries. [***].

Section 6.7 [***].

6.7.1 Obligation to Commercialize in Japan. Notwithstanding anything to the contrary herein, Santen shall [***]:

a Aerie enters into a written agreement with [***] pursuant to which [***] in connection with the Development, Manufacture and Commercialization of such Product in the Field [***],

b. [***] or

c. upon receipt of Marketing Approval for such Product in Japan, none of [***] in Japan.

6.7.2 Obligation to Commercialize in Korea. Notwithstanding anything to the contrary herein, Santen shall [***]:

a. Aerie enters into a written agreement with [***] pursuant to which [***] in connection with the Development, Manufacture and Commercialization of such Product in the Field [***],

b. [***]; or

c. upon receipt of Marketing Approval for such Product in Korea, none of [***] in Korea.

6.7.3 [***].

a. Aerie shall be responsible to discuss and negotiate in good faith [***], at Aerie's sole cost and expense.

b. If either Party reasonably believes [***], it shall notify the other Party, and the Parties shall promptly confer regarding an appropriate course of action to take with respect to. Aerie shall have final decision-making authority on whether to [***]; provided, however, that if Aerie is [***], Aerie shall consider Santen's request [***] (such decision not to be unreasonably denied and delayed after Santen's request), then Aerie [***] reasonably practicable after such decision. In the event Aerie decides to file [***], and Santen shall [***]. Santen and Aerie shall equally bear the costs incurred in connection with [***].

c. If [***] either Party reasonably believes [***], it shall promptly notify the other Party, and the Parties shall promptly confer regarding [***]. Aerie shall have final decision-making authority on whether to [***]; provided, however, that if Aerie is [***], Aerie shall [***] and if Aerie decides [***], then Aerie shall [***] as soon as reasonably practicable after such decision. In the event Aerie decides to [***], subject to consultation with Santen (including considering in good faith any reasonable comments provided by Santen in connection therewith), and Santen shall reasonably cooperate with Aerie [***]. Santen and Aerie shall equally bear the costs incurred in connection with [***].

d. If any Product Exploited by or under the authority of either Party, its Affiliates or Sublicensees becomes the subject of [***], [***] shall promptly notify the other Party, and the Parties shall promptly confer to [***]. The Parties shall [***], subject to mutual consultation between the Parties (including considering in good faith any reasonable comments provided by each Party in connection therewith), and each Party shall reasonably cooperate with the other Party [***]. In the case of any disagreement between the Parties, [***].

e. In connection with any [***], Aerie may, in its sole discretion, [***] agrees not to assert [***] in connection with the Commercialization of the Products in the Field in the Territory. Aerie shall bear any payments or other consideration [***].

f. If Aerie grants to [***] any licenses equivalent to those granted to Santen hereunder with respect to the Products in the Field in the Territory after the termination of this Agreement, and if such licenses include any sublicense to the [***], Aerie shall pay to Santen [***] as a royalty for such sublicense until.

6.7.4 Damages Award [***]. In the event of [***] solely or jointly with Aerie, arising from Commercialization by Santen of the Products in the Field in the Territory (a "Damages Award"), Aerie shall be responsible for such damages up to the aggregate amount of (a) [***] pursuant to Section 7.1, (b) [***] pursuant to Section 7.2 and (c) [***] pursuant to Section 7.4, less any amounts refunded as part of [***] or [***]. [***] responsible and liable for the [***], notwithstanding any termination of this Agreement prior to [****]. Notwithstanding anything herein to the contrary, in no event shall [***].

6.7.5 Rocklatan Development.

(a) Rocklatan Development in Japan. [***].

(b) Rocklatan Development in Korea. [***].

ARTICLE 7. FEES, ROYALTIES, & PAYMENTS

Section 7.1 Upfront Payment. As partial consideration for the rights granted by Aerie to Santen pursuant to the terms of this Agreement, for access to the Aerie IP and Aerie undertaking its responsibilities under this Agreement, Santen shall pay to Aerie a non-refundable (subject to Section 13.4.4, Section 13.3.4 and Section 13.3.5), non-creditable payment of Fifty Million Dollars ($50,000,000) within thirty (30) days after the Effective Date.

Section 7.2 Milestone Payments.

7.2.1 As partial consideration for the rights granted by Aerie to Santen pursuant to the terms of this Agreement, for access to the Aerie IP and Aerie undertaking its responsibilities under this Agreement, on a Product-by-Product basis, Santen shall pay to Aerie one-time milestone payments ("**Milestone Payments**") following the first occurrence of the corresponding milestone events ("**Milestone Events**") with respect to any Product for which such Milestone Event is achieved by or on behalf of Santen, as set forth in the following tables:

Development and Regulatory Milestone Events

Milestone Event	Milestone Payment
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
Total potential development and regulatory milestone payments	**$39,000,000**

Commercial Milestone Events

Milestone Event	Milestone Payment
[***]	$[***]
[***]	$[***]
[***]	$[***]
Total potential commercial milestone payments for the Rhopressa Product and Rocklatan Products	**$60,000,000**

7.2.2 If a Milestone Event is achieved prior to the achievement of the preceding Milestone Event for the same Product and country set forth in the relevant chart (i.e., if a lower-listed Milestone Event is achieved before a Milestone Event that is listed higher up in the relevant chart), then upon achievement of the relevant Milestone Event, all preceding Milestone Events for such Product and country set forth in the relevant chart shall become due and payable if not previously paid for that Product. For example, if Marketing Approval for Rhopressa in Japan is obtained without completion of a Phase 3 Clinical Trial for Rhopressa in Japan, the Milestone Payment to be paid upon completion of such Phase 3 Clinical Trial shall be paid at the same time as is the Milestone Payment to be paid upon such Marketing Approval. The maximum amount payable under this Section 7.2 is $99,000,000. Santen shall report to Aerie its achievement of each Milestone Event for which payment to Aerie is due reasonable promptly after Santen determines such achievement has occurred, but in no event later than [***] after such achievement of such Milestone Event, and pay to Aerie such Milestone Payment within [***] after such achievement.

Section 7.3 Supply Price. As consideration for the commercial supply of Product to Santen by Aerie, Santen shall pay to Aerie the Supply Price of such Product as set forth in Section 3.1.2 and the Supply Agreement, payable in accordance with the terms thereof.

Section 7.4 Royalties.

7.4.1 Royalties. As partial consideration for the rights granted by Aerie to Santen pursuant to the terms of this Agreement, for access to the Aerie IP and Aerie undertaking its responsibilities under this Agreement, subject to the provisions of this Section 7.4, Santen shall pay to Aerie royalties on quarterly Net Sales of Products during the applicable Royalty Term, calculated as set forth in Section 7.4.3 (the "**Royalties**"). Royalties will be payable on a Calendar Quarter-by-Calendar Quarter basis and any such payments shall be made within [***] after the end of the Calendar Quarter during which the applicable Net Sales of Products occurred.

7.4.2 Royalty Term. Santen's obligation to pay Royalties with respect to a Product in a particular country shall commence upon the First Commercial Sale of such Product in such country and shall expire on a [***] on the latest of (a) [***] and (b) the twelfth (12^{th}) anniversary of the First Commercial Sale of such Product in such country (the "**Royalty Term**").

7.4.3 Royalty Payments. The royalty payments payable under Section 7.4.1 shall be an amount equal to (i) the aggregate amount of Net Sales of Products in an applicable Quarter multiplied by the tiered percentage applicable to such Net Sales set forth below, less (ii) [***] Exhibit I (Manufacturing & Supply Agreement Terms for Commercial Supply), the [***] sold in such Quarter (including any Compounds):

Aggregate Annual (Calendar Year) Net Sales of the Rhopressa Product and Rocklatan Product	Tiered Percentage
Portion of [***]	[***]%
Portion of [***]	[***]%
Portion of [***]	[***]%

For the avoidance of doubt, for all royalty payments pursuant to this Section 7.4.3, if the sale of a Product is Covered by more than one Valid Claim, the above Royalties shall be paid only once.

7.4.4 Royalty Reduction; Expiration of Valid Claims.

a. On a [***] basis, in the event that the Exploitation of a Product is not Covered by a Valid Claim of an Aerie Patent in such country, the payments of the Royalties with respect to Net Sales for such Product in such country for such Calendar Quarter shall be reduced by [***] of such Royalties as set forth in, and in accordance with, Section 7.4.3. That is, and for example purposes only, to the extent that [***], then such royalty rate, after [***], would be reduced for [***], such that the royalty rate would be equal to [***] would be reduced for [***], such that the royalty rate would be equal to [***]; and the [***], such that the royalty rate would be equal to [***].

b. **Generic Product Reduction.** On a [***] basis, during any period in a country in which sales of a Generic Product are equal to or greater than [***] of the volume of its corresponding branded Product in such country in the Territory (the volume as measured by prescriptions or other similar information available in such country), the royalty rates set forth in Section 7.4.3 (that is, the percentage calculated pursuant to clause (i) of Section 7.4.3) with respect to

Net Sales for such Product in such country for such Calendar Quarter shall be reduced by [***] of the portion of such royalty rates that is not allocated to the consideration for Aerie's commercial supply of such Product to Santen payable pursuant to Section 3.1.2 after the application of any deduction pursuant to Section 7.4.4(a), if any. For example purposes only, if such royalty rate [***], and after [***] such royalty rate would be [***], then such rate [***] under this Section 7.4.4(b).

7.4.5 Third Party Intellectual Property. In the event that the Parties reasonably determine that a Third Party owns or otherwise controls intellectual property that is necessary for the Exploitation of a Product in the Territory and in the Field (collectively, "**Third Party IP**"), Santen shall have the right (but not the obligation) to obtain a license to such Third Party IP; *provided* that Aerie shall have the first right (but not the obligation) to obtain such license if such Third Party IP primarily relates to the Aerie IP, and, if Aerie elects not to obtain such license, Santen shall have the right to do so, provided that [***]. In the event Santen (or, at Santen's direction, its applicable Affiliate, subcontractor or Sublicensee) obtains any license described in this Section 7.4.5, [***].

7.4.6 Maximum Reduction. The maximum aggregate reduction with respect to any Product in any country during any Calendar Quarter pursuant to Section 7.4.4(a) and Section 7.4.5 (alone or in combination) shall be capped at [***] of the amount of the Royalties that would be payable in respect of Net Sales in such country under Section 7.4.3, prior to any such reductions.

7.4.7 Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying Royalties and other amounts required hereunder.

Section 7.5 Invoicing. To the extent an invoice is required to be submitted hereunder, such invoice shall be addressed to:

If Santen is the paying Party:

Santen Pharmaceutical Co., Ltd.
4-20, Ofukacho, Kita-ku, Osaka 530-8552
Japan
Attention: [***]

If Aerie is the paying Party:

Aerie Pharmaceuticals Ireland, Ltd.
Athlone Business & Technology Park
Athlone, Co. Westmeath, N37 DW40, Ireland
Attn: [***]
Fax: [***]

Section 7.6 Method of Payment. Unless otherwise agreed by the Parties, all payments due from the paying Party under this Agreement shall be paid in U.S. Dollars by wire transfer or electronic funds transfer of immediately available funds to an account designated by the non-paying Party.

Section 7.7 Currency Conversion. All royalties shall be payable in U.S. Dollars. Any sales of Products incurred in a currency other than U.S. Dollars shall be converted to the U.S. Dollar equivalent using Santen's then-current standard exchange rate methodology as applied to its external reporting for the conversion of foreign currency sales into U.S. Dollars consistent with IFRS.

Section 7.8 Reports; Records and Audits.

7.8.1 After the First Commercial Sale of the first Product by Santen and until expiration or termination of this Agreement, Santen shall prepare and deliver to Aerie reports of the sale of Products by Santen or its Affiliates, and their respective Sublicensees for each Calendar Quarter together with the corresponding royalty payment or other consideration to be paid to Aerie, specifying on a [***] basis, a detailed and itemized calculation of Net Sales. The first of such reports will be delivered to Aerie within fourteen (14) days after the end of each Calendar Quarter and include actual Net Sales data for the first two (2) months of such Calendar Quarter and an estimate Net Sales data for the remaining third month of Calendar Quarter. A second report will be delivered to Aerie within [***] after such Calendar Quarter has ended which will include actual Net Sales data for the entirety of such Calendar Quarter.

7.8.2 Santen will keep complete and accurate records of Development Costs with respect to each Product and all royalty, milestone and other payments required under this Agreement, for a period of [***] after the end of the Calendar Year in which such Development Costs were incurred or such payment was due. Santen shall require its Affiliates, and its and their respective Sublicensees to retain and provide to Santen all records of payments that Santen would be required to keep as if sales of Product by such Affiliates or Sublicensees were sales of Product by Santen, to enable Aerie to audit such records pursuant to this Section 7.8. Aerie will have the right, not more than once in any Calendar Year at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to Santen's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), review any such records of Santen and its Affiliates upon reasonable written notice (which shall be no less than thirty (30) days prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement within the [***] preceding the date of the request for review. Upon Aerie's written request, Santen shall use good faith efforts to conduct audits of its subcontractors and Sublicensees, and Aerie shall have the right to receive and retain a copy of the applicable audit report. No Calendar Year will be subject to audit under this Section 7.8 more than once without the consent of Santen. Santen will receive a copy of each such report within ten (10) Business Days following receipt by Aerie, and such accounting firm shall report to the Parties only whether or not such calculations are correct and the amount of any discrepancy. No other information shall be shared. Aerie shall treat the results of any such review of Santen's records under this Section 7.8 as Confidential Information of Santen and subject to the terms of Article 12. Should such inspection lead to the discovery of a discrepancy to Aerie's detriment, Santen will, within [***] after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy together with interest at the rate set forth in Section 7.9. Aerie will pay the full cost of the review unless the underpayment of

amounts due to Aerie is more than [***] of the amount due for the entire period being examined, in which case Santen will pay the cost charged by such accounting firm for such review. Should the audit lead to the discovery of a discrepancy to Santen's detriment, Santen may credit the amount of the discrepancy, without interest, against future payments payable to Aerie under this Agreement or, if there are no such payments payable, then Aerie shall pay to Santen the amount of the discrepancy, without interest, within [***] of Aerie's receipt of the report.

Section 7.9 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of the sum of (a) [***] plus (b) the prime interest rate quoted by *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com on the date such payment is due, the interest being compounded on the last day of each Calendar Quarter; *provided*, *however*, that in no event shall such annual interest rate exceed the maximum rate permitted by Law. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any Party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment, including termination of this Agreement as set forth in Article 13. With respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Section 7.10 Taxes.

7.10.1 Withholding. In the event that any Law requires a Party making any payment pursuant to this Agreement (the "**Paying Party**") to withhold taxes with respect to any such payment, the Paying Party (a) will notify the non-Paying Party of such withholding requirement prior to making the payment to the non-Paying Party (such notice, which shall include the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for the non-Paying Party to obtain reduction of or relief from such deduction or withholding), and (b) provide such assistance to the non-Paying Party, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in the non-Paying Party's efforts to claim an exemption from or reduction of such taxes. The Paying Party will, in accordance with such Law, withhold taxes from such payment, remit such taxes to the appropriate tax authority, and furnish the non-Paying Party with proof of payment of such taxes within [***] following the payment. In the event that the non-Paying Party refunds to the Paying Party any payment made by the Paying Party pursuant to this Agreement that is subject to withholding taxes and the Paying Party paid such taxes to the applicable tax authority, (a) the Paying Party shall (i) apply for a withholding tax refund to the relevant Governmental Authority as may be permitted under applicable Laws and (ii) provide reasonable assistance to the non-Paying Party to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid and (b) the non-Paying Party shall provide reasonable assistance to the Paying Party to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. The non-Paying Party shall provide the Paying Party any tax forms (including Internal Revenue Service Forms W-9 or applicable W-8) that may be reasonably necessary in order for the Paying Party to determine whether to withhold tax on any such payments or to withhold tax on such payments at a reduced rate under applicable Law, including any applicable

bilateral income tax treaty. For the avoidance of doubt, each Party shall be responsible for its own income taxes.

7.10.2 Indirect Taxes. All payments due to the non-Paying Party from the Paying Party pursuant to this Agreement shall be paid exclusive of any value-added tax, sales tax, consumption taxes and other similar taxes excluding customs and other duties ("**Indirect Taxes**") (which, if applicable and chargeable by the non-Paying Party, shall be payable by the Paying Party upon receipt of a valid Indirect Tax invoice); *provided, however*, that where the Paying Party provides written notice to the non-Paying Party that, despite reasonable efforts, it is unable to claim a credit or deduction for the invoiced Indirect Taxes, the Parties agree that the Paying Party's obligation to pay the Indirect Tax invoice shall be fulfilled by payment of the total invoiced amount less [***] of the amount of the notified Indirect Taxes that are not recoverable. Where Indirect Taxes are required to be withheld by the Paying Party on payments made to the non-Paying Party, the amount payable to the non-Paying Party shall be grossed up so that the non-Paying Party receives the same amount as if such Indirect Tax withholding had not applied. Should non-recoverable Indirect Taxes be identified after issuance and settlement of an invoice, or where Indirect Taxes are accounted for via a reverse charge or self-assessment and the Paying Party provides written notice to the non-Paying Party that, despite reasonable efforts, it is unable to claim a credit or deduction for the applicable Indirect Taxes, then the Parties shall share the cost of those non-recoverable Indirect Taxes equally. The Parties shall reasonably cooperate to issue valid invoices for all amounts due under this Agreement consistent with applicable Law and to lawfully eliminate or minimize the amount of any Indirect Taxes imposed on or in connection with the transactions contemplated by this Agreement. If the non-Paying Party determines that it is required to report any such tax, the Paying Party shall promptly provide the non-Paying Party with applicable receipts and other documentation necessary or appropriate for such report. For the avoidance of doubt Indirect Taxes shall not include customs duties and other similar taxes, duties and fees.

ARTICLE 8. INTELLECTUAL PROPERTY

Section 8.1 Intellectual Property Ownership.

8.1.1 Background IP. Each Party owns all right, title and interest in its Background IP.

8.1.2 Collaboration IP. As between the Parties, any and all inventions, Know-How and other subject matter, and all Patent Rights and other intellectual property rights therein, that (i) are discovered, invented, conceived, reduced to practice, developed or otherwise created jointly by or on behalf of Aerie and Santen or their respective Affiliates [***]; or (ii) [***] ("**Collaboration IP**"), shall be owned jointly by the Parties. Inventorship for the purpose of this Section 8.1.2 will be determined according to U.S. Patent Law (without reference to any conflict of law principles). Except as expressly provided in this Agreement, neither Party shall have any obligation to account to the other for profits, or to obtain any approval of the other Party to license or exploit Collaboration IP, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. For the avoidance of doubt, Collaboration IP

shall be deemed to be Confidential Information of both Parties, and both Parties shall be bound by the obligations of confidentiality set forth in Article 12.

8.1.3 Improvements.

a. Aerie Improvements. As between the Parties, Aerie solely owns all right, title and interest in and to any and all inventions, Know-How and other subject matter, and all Patent Rights and other intellectual property rights therein (i) that are discovered, invented, conceived, reduced to practice, developed or otherwise created (x) [***] ("**Sole Aerie Improvements**") or (y) [***] ("**Collaborative Aerie Improvements**"), (ii) that are unique to or exclusively cover the Products or any methods of use or manufacture solely thereof, or any improvements, modifications or enhancements thereto, and (iii) [***] (collectively, "**Aerie Improvements**"). Santen hereby assigns, and agrees to assign, to Aerie all right, title and interest in and to any and all Collaborative Aerie Improvements. Santen will cooperate with Aerie to execute any agreements, instruments and documents and take such other action as may be reasonably required to perfect Aerie's right, title and interest in and to the Collaborative Aerie Improvements to the extent permitted by applicable Law. Inventorship for the purpose of this Section 8.1.3 will be determined according to U.S. Patent Law (without reference to any conflict of law principles). For the avoidance of doubt, Aerie Improvements shall be included in [***].

b. Santen Inventions. As between the Parties, Santen solely owns all right, title and interest in and to any and all inventions, Know-How and other subject matter, and all Patent Rights and other intellectual property rights therein, that are discovered, invented, conceived, reduced to practice, developed or otherwise created [***] ("**Santen Inventions**"). For the avoidance of doubt, Santen Inventions shall be included in the Santen IP licensed to Aerie pursuant to Section 4.1.2 to the extent such Santen Inventions are necessary to perform Aerie's obligations and exercise Aerie's rights under this Agreement or Develop, Manufacture and Commercialize the Rhopressa Product and the Rocklatan Product outside the Territory.

8.1.4 Disclosure; Further Assurances. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, and Sublicensees to so disclose, the conception of any Collaboration IP, and, in the case of Santen or its Affiliates, licensees and Sublicensees, Aerie Improvements. Each Party shall cause its Sublicensees and Affiliates, and their respective employees, consultants, agents, or independent contractors to so assign to such Party, such person's or entity's right, title and interest in and to the foregoing, and all intellectual property rights therein, as is necessary to enable such Party to fully effect the ownership of the foregoing, and intellectual property rights therein, as provided in this Agreement. Each Party shall also include provisions in its relevant agreements with Third Parties performing activities on its behalf pursuant to this Agreement, that effect the intent of this Article 8. Each Party hereby appoints the other Party as attorney-in-fact of such Party to execute and deliver all documents reasonably required to evidence or record any assignment pursuant to this Agreement if such Party is unable, after making reasonable inquiry, to obtain assistance of such other Party with respect to any such document. Each Party shall, and shall cause its Sublicensees and Affiliates, and their respective employees, consultants, agents, or independent contractors to, cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments

and documents as may be reasonably required to perfect such other Party's right, title and interest in and to intellectual property as set forth in this Section 8.1.

Section 8.2 Patent Prosecution and Maintenance.

8.2.1 Aerie Patents. Aerie will be solely responsible, at its own cost, for preparing, filing, prosecuting (including provisional, reissue, reexamination, continuing, divisional, continuation, continuation-in-part, and substitute applications and any foreign counterparts thereof) and maintaining all Aerie Patents and conducting any Post Grant Proceedings relating to such Patent Rights. Aerie will use Commercially Reasonable Efforts to (a) prepare, file, prosecute and maintain all Aerie Patents owned solely by Aerie that Cover any Product, (b) conduct any interferences and oppositions or similar proceedings relating to such Patent Rights, if reasonably necessary for the prosecution and maintenance of such Patent Rights, and (c) keep Santen reasonably informed with regard to the preparation, filing, prosecution and maintenance of such Patent Rights.

8.2.2 Santen Patents. Santen will be solely responsible, at its own cost, for preparing, filing, prosecuting (including provisional, reissue, reexamination, continuing, divisional, continuation, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Santen Patents owned solely by Santen, and conducting any Post Grant Proceedings relating to such Patent Rights. Santen will use Commercially Reasonable Efforts to (a) prepare, file, prosecute and maintain all Santen Patents owned solely by Santen that Cover any Product, (b) conduct any interferences and oppositions or similar proceedings relating to such Patent Rights, if reasonably necessary for the prosecution and maintenance of such Patent Rights, and (c) keep Aerie reasonably informed with regard to the preparation, filing, prosecution and maintenance of such Patent Rights.

8.2.3 Collaboration Patents.

a. With respect to Collaboration Patents, the Parties shall confer and cooperate with the preparation, filing, prosecution and maintenance of such patent applications, and conducting any Post Grant Proceedings relating to such Collaboration Patents. Each Party will review and comment upon the text and content of such applications at least [***] before filing. Each Party shall consider prosecution strategy and suggestions from the other Party for such patent applications. In the event of disagreement between the Parties, subject to Section 8.2.3(b), [***]. In the event either Party declines to prosecute or maintain any Collaboration Patent before all appeals within the respective patent office have been exhausted (each, an "**Abandoned Patent Right**"), then: (i) such Party shall provide the other Party with reasonable notice of such decision so as to permit the non-abandoning Party to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office); (ii) the non-abandoning Party, at the non-abandoning Party's expense, may assume control of the filing, prosecution or maintenance of such Abandoned Patent Rights; (iii) the non-abandoning Party shall have the right, at its expense, to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel (outside or internal) selected by the non-abandoning Party; (iv) the abandoning Party shall, at the non-abandoning Party's reasonable request and at the non-abandoning Party's expense, assist and cooperate in the filing, prosecution and maintenance of such Abandoned Patent Rights; and (v) the abandoning

Party hereby assigns all of its right, title and interest in the Abandoned Patent Rights to the non-abandoning Party, and shall execute any agreements, instruments and documents and take such other action as may be reasonably required to perfect the non-abandoning Party's sole right, title and interest in and to the Abandoned Patent Rights.

b. Notwithstanding the foregoing, neither Party shall take any action in connection with the conduct of its activities under this Section 8.2.3 over the objection of the other Party that such action would be materially in opposition to any positions taken by the other Party in any related patent application of the other Party or would be materially prejudicial to any element, including the validity, patentability, scope, priority, construction, inventorship, enforceability, or the other Party's or its Affiliate's ownership, of any Collaboration Patent in any forum.

8.2.4 Inventor's Remuneration. Each Party shall be solely responsible for any remuneration that may be due to such Party's inventors under any applicable inventor remuneration Laws.

Section 8.3 Patent Term Extensions. The Parties will cooperate with each other in gaining any available Patent Right term extension for the appropriate Aerie Patents and Collaboration Patents, including supplementary protection certificates, to the extent applicable to Products; *provided* that, [***].

Section 8.4 Defense and Settlement of Third Party Claims. If any Product Exploited by or under authority of either Party, its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right in the Territory (except for [***]), the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, Santen shall have the right to control the defense of such claim, [***]. Santen shall not [***] without Aerie's written consent, after good faith discussions between the Parties. In any event, Aerie shall reasonably assist Santen and cooperate in any such litigation [***].

Section 8.5 Third Party Defense or Counterclaim.

8.5.1 If a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 8.7, that any Aerie Patent, Santen Patent or Collaboration Patent is invalid or unenforceable, then the Party defending such infringement action shall promptly give written notice to the other Party. Each Party shall reasonably cooperate with the other Party in any such action.

8.5.2 With respect to the Collaboration Patents outside the Territory or the Aerie Patents in the Territory, Aerie shall respond to such defense and use Commercially Reasonable Efforts to defend against such counterclaim (as applicable) and, if Santen is pursuing the applicable infringement action under Section 8.7, Aerie shall allow Santen to control such response or defense (as applicable). Any costs and expenses of Aerie with respect to such response or defense against such counterclaim [***]. Aerie agrees to consult with and take into account Santen's reasonable comments on such response or defense.

8.5.3 With respect to the Collaboration Patents in the Territory, Santen shall respond to such defense and use Commercially Reasonable Efforts to defend against such counterclaim (as

applicable) and, if Aerie is pursuing the applicable infringement action under Section 8.7, Santen shall allow Aerie to control such response or defense (as applicable). Any costs and expenses of Santen with respect to such response or defense against such counterclaim [***]. Santen agrees to consult with and take into account Aerie's reasonable comments on such response or defense.

8.5.4 With respect to the Santen Patents outside the Territory, Santen shall have the first right to respond to such defense and to defend against such counterclaim (as applicable) and, if Santen does not elect to exercise the first right or Aerie is pursuing the applicable infringement action under Section 8.7, Santen shall allow Aerie to control such response or defense (as applicable). Any costs and expenses of Santen with respect to such response or defense against such counterclaim [***]. Santen agrees to consult with and take into account Aerie's reasonable comments on such response or defense.

8.5.5 Notwithstanding the foregoing, if one Party fails to assume such defense and use Commercially Reasonable Efforts in respect to any Collaboration Patent, the other Party or its Affiliates or Sublicensees shall have the right to defend against such action or claim [***]. The defending Party agrees to consult with and take into account the other Part's reasonable comments on such response or defense.

Section 8.6 Third Party Declaratory Judgment or Similar Action.

8.6.1 If a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party, that any Santen Patent, Collaboration Patent or Aerie Patent is invalid or unenforceable, then the Party first becoming aware of such action or claim shall promptly give written notice to the other Party. Each Party shall reasonably cooperate with the other Party in any such action.

8.6.2 Santen shall use Commercially Reasonable Efforts to defend against such action or claim against any Collaboration Patent in the Territory [***]. Aerie shall use Commercially Reasonable Efforts to defend against such action or claim against any Collaboration Patent outside the Territory or any Aerie Patent at its own cost and expense. If one Party fails to assume such defense and use Commercially Reasonable Efforts in respect to any such Collaboration Patent, the other Party or its Affiliates or Sublicensees shall have the right to defend against such action or claim.

8.6.3 Santen shall have the first right to defend against such action or claim against any Santen Patent outside the Territory [***]. If Santen does not elect to exercise its right to defend against such action or claim in respect to any such Santen Patent, Aerie will have the right to defend against such action its own cost expense.

Section 8.7 Enforcement.

8.7.1 Notice of Infringement. The Parties shall inform each other promptly of any infringement or colorable cause of action for infringement of any Patent Right within the Collaboration Patents, Aerie Patents or Santen Patents that claim the Compound, the composition of matter of,

methods of making, or methods of using any Product, and the Parties shall promptly confer to consider the best appropriate course of action.

8.7.2 Enforcement of Aerie Patents. Aerie shall have the sole right, but no obligation, to enforce the Aerie Patents outside the Territory, and to retain any damages, settlements or other monetary awards recovered in connection therewith. Aerie shall have the first right to enforce the Aerie Patents in the Territory, and Aerie will consider in good faith the interests of Santen in such enforcement of such Aerie Patents in the Territory. Aerie shall at all times keep Santen informed as to the status of such enforcement in the Territory pursuant to this Section 8.7.2. Aerie may, at its own expense, institute suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.7.6. Santen shall reasonably cooperate in any such litigation [***]. Santen will have the right to participate, [***] and with counsel of its choice, in such suit brought by Aerie against any infringer or alleged infringer to enforce its licenses granted hereunder. Aerie shall not enter into any settlement of any claim described in this Section 8.7.2 that admits to the invalidity or unenforceability of any Santen Patents or Collaboration Patents in the Territory (or otherwise affects the scope, validity or enforceability of such Santen Patents or Collaboration Patents in the Territory), incurs any financial liability on the part of Santen or requires an admission of liability, wrongdoing or fault on the part of Santen without Santen's prior written consent, not to be unreasonably withheld, conditioned or delayed. In the event Aerie does not elect to enforce any Aerie Patents in the Territory, Santen shall be entitled to do so in the Territory [***] with Aerie's prior written consent, not to be unreasonably withheld, conditioned or delayed.

8.7.3 Enforcement of Collaboration Patents.

a. **By Santen**. Santen shall have the first right to enforce the Collaboration Patents in the Territory, and Santen will consider in good faith the interests of Aerie in such enforcement of such Collaboration Patents. Santen shall at all times keep Aerie informed as to the status of any enforcement pursuant to this Section 8.7.3(a). Santen may institute, [***], suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.7.6. Aerie shall reasonably cooperate in any such litigation, at Santen's expense. Santen shall not enter into any settlement of any claim described in this Section 8.7.3(a) that admits to the invalidity or unenforceability of any Aerie Patents or Collaboration Patents (or otherwise affects the scope, validity or enforceability of such Aerie Patents or Collaboration Patents), incurs any financial liability on the part of Aerie or requires an admission of liability, wrongdoing or fault on the part of Aerie without Aerie's prior written consent, not to be unreasonably withheld, conditioned or delayed. In the event that Santen does not elect to enforce any Collaboration Patent in the Territory, then Aerie shall be entitled to do so [***], unless Santen has a good faith belief that Aerie's enforcement of such Patent Rights would be reasonably likely to unreasonably jeopardize the Exploitation of a Product in the Territory. Aerie shall not enter into any settlement of any claim described in this Section 8.7.3(a) that admits to the invalidity or unenforceability of any Collaboration Patents (or otherwise effects the scope, validity or enforceability of such Collaboration Patents), incurs any financial liability on the part of Santen or requires an admission of liability, wrongdoing or fault

on the part of Santen without Santen's prior written consent, not to be unreasonably withheld, conditioned or delayed.

b. **By Aerie**. Aerie shall have the first right to enforce the Collaboration Patents outside the Territory, and Aerie will consider in good faith the interests of Santen in such enforcement of such Collaboration Patents. Aerie shall at all times keep Santen informed as to the status of any enforcement pursuant to this Section 8.7.3(b). Aerie may institute, at its own expense, suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.7.6. Santen shall reasonably cooperate in any such litigation, [***]. Aerie shall not enter into any settlement of any claim described in this Section 8.7.3(b) that admits to the invalidity or unenforceability of any Santen Patents or Collaboration Patents (or otherwise affects the scope, validity or enforceability of such Santen Patents or Collaboration Patents), incurs any financial liability on the part of Santen or requires an admission of liability, wrongdoing or fault on the part of Santen without Santen's prior written consent, not to be unreasonably withheld, conditioned or delayed. In the event that Aerie does not elect to enforce any Collaboration Patent outside the Territory, then Santen shall be entitled to do so [***], unless Aerie has a good faith belief that Santen's enforcement of such Patent Rights would be reasonably likely to unreasonably jeopardize the Exploitation of a Product outside the Territory. Santen shall not enter into any settlement of any claim described in this Section 8.7.3(b) that admits to the invalidity or unenforceability of any Collaboration Patents (or otherwise effects the scope, validity or enforceability of such Collaboration Patents), incurs any financial liability on the part of Aerie or requires an admission of liability, wrongdoing or fault on the part of Aerie without Aerie's prior written consent, not to be unreasonably withheld, conditioned or delayed.

8.7.4 Enforcement of Santen Patents. Santen shall have the sole right, but no obligation, to enforce the Santen Patents in the Territory, and to retain any damages, settlements or other monetary awards recovered in connection therewith. Santen shall have the first right to enforce the Santen Patents outside the Territory, and Santen will consider in good faith the interests of Aerie in such enforcement of such Santen Patents outside the Territory. Santen shall at all times keep Aerie informed as to the status of such enforcement in the Territory pursuant to this Section 8.7.4. Santen may, [***] institute suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.7.6. Aerie shall reasonably cooperate in any such litigation [***]. Aerie will have the right to participate, [***] and with counsel of its choice, in such suit brought by Santen against any infringer or alleged infringer to enforce its licenses granted hereunder. Santen shall not enter into any settlement of any claim described in this Section 8.7.4 that admits to the invalidity or unenforceability of any Aerie Patents or Collaboration Patents outside the Territory (or otherwise affects the scope, validity or enforceability of such Aerie Patents or Collaboration Patents outside the Territory), incurs any financial liability on the part of Aerie or requires an admission of liability, wrongdoing or fault on the part of Aerie without Aerie's prior written consent, not to be unreasonably withheld, conditioned or delayed. In the event Santen does not elect to enforce any Santen

Patents outside the Territory, Aerie shall be entitled to do so outside the Territory [***] with Santen's prior written consent, not to be unreasonably withheld, conditioned or delayed.

8.7.5 Progress Reporting. The Party initiating or defending any enforcement action under this Section 8.7 (the "**Enforcing Party**") shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice at its own expense.

8.7.6 Allocation of Recoveries. Except as otherwise expressly provided herein, the costs and expenses of the Party bringing suit under this Section 8.7 shall be borne by such Party, and any damages, settlements or other monetary awards recovered shall be shared as follows: (1) [***]; and then (2) [***]:

1. [***]; and

2. in all other cases, [***];

with such recovery, if any, [***].

[***].

Section 8.8 Product Trademarks.

8.8.1 Ownership and Prosecution of Product Trademarks. Aerie shall own all right, title, and interest to trademarks (including the trademarks listed in Exhibit F), branding and logos associated specifically with each Product and all goodwill associated therewith (collectively, "**Product Trademarks**") in the Territory, and shall be responsible for the registration, prosecution, and maintenance thereof. Aerie shall prepare, file, prosecute and use Commercially Reasonable Efforts to maintain all Product Trademarks that are necessary for Santen to Exploit the Product in the Territory. All costs and expenses of registering, prosecuting, and maintaining the Product Trademarks in the Territory shall [***]. Santen shall provide, [***], assistance and documents reasonably requested by Aerie in support of its prosecution, registration and maintenance of the Product Trademarks. Santen shall not, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country; (ii) file, register or maintain any registrations for any trademarks or trade names that are identical or confusingly similar to any Product Trademark in any country without the express prior written consent of Aerie; or (iii) authorize or assist any Third Party to do the foregoing.

8.8.2 License to Product Trademarks.

a. Aerie hereby grants to Santen an [***] to use the Aerie Housemarks and Product Trademarks pre-approved by Aerie solely as set forth in the Promotional Materials and other materials provided to it by Aerie, solely to Commercialize Products in the Territory in accordance with this Agreement.

b. Upon Aerie's reasonable request, the Parties shall discuss in good faith the use of the Santen Housemarks in Aerie's Promotional Materials for the Products [***] in accordance with Sections 12.1.5, 12.2 and 12.3 of this Agreement.

8.8.3 Quality Control.

a. Promotional Materials and all packaging, labeling and package inserts for Products in the Territory will display the Aerie Housemarks and the Santen Housemarks in equal prominence to the extent allowed by applicable Law and in accordance with the Commercialization Plan. Once approved by the applicable Regulatory Authority, Aerie will as soon as practicable label Product for the Territory with Aerie and Santen logos displayed of equal size.

b. Each Party agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and the other Party's Housemarks by such Party is accompanied by an acknowledgement that such Product Trademarks are owned by Aerie and such Housemarks are owned by the other Party; (ii) not use such Product Trademarks or the other Party's Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of the other Party therein; and (iii) not use any trademarks or trade names so resembling any of such Product Trademarks or the other Party's Housemarks as to be likely to cause confusion or deception. All use of the other Party's Housemarks shall be subject to the prior written approval of such other Party. Each Party shall comply with the other Party's trademark policies and guidelines when using such other Party's Housemarks and shall upon written request provide samples and specimens of any intended or prior use of such other Party's Housemarks.

c. Santen will not have, assert or acquire any right, title or interest in or to any Aerie Housemarks or Product Trademarks or the goodwill pertaining thereto, and Aerie will not have, assert or acquire any right, title or interest in or to any Santen Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement. Santen shall not use or register any mark or domain name or social media account which is confusingly similar to the Aerie Housemarks or Product Trademarks, without the prior written consent of Aerie, and Aerie shall not use or register any mark or domain name or social media account which is confusingly similar to the Santen Housemarks, without the prior written consent of Santen. Santen shall not market any Products under any trademarks other than the Product Trademarks approved by Aerie. Santen shall not use the Product Trademarks in connection with any products or services other than the applicable Product under this Agreement.

d. To the extent required by applicable Law in a country or other jurisdiction in the Territory, the Promotional Materials, packaging, and product labeling used in connection with the Products in such country or other jurisdiction shall contain the Housemarks of both Parties.

8.8.4 Enforcement of Product Trademarks. Aerie shall have the sole right and responsibility for taking such action as Aerie deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, misappropriation, or other violation of, or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory. [***] relating to any enforcement action commenced pursuant to this Section 8.8.4 and any

settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith. In the event Aerie does not elect to enforce any Product Trademarks in the Territory, Santen shall be entitled to do so in the Territory, [***] with Aerie's prior written consent, not to be unreasonably withheld, conditioned or delayed.

8.8.5 Third Party Claims. [***] shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates, or otherwise violates any trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Product in the Territory. [***] shall bear the costs and expenses relating to any defense commenced pursuant to this Section 8.8.5 and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

8.8.6 Notice and Cooperation. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, promptly after becoming aware of the foregoing. [***] agrees to cooperate fully with [***], at [***] sole cost and expense, with respect to any enforcement action or defense commenced pursuant to this Section 8.8. [***] shall consult with [***] and consider any input from [***] in good faith with respect to the registration, prosecution, maintenance, enforcement or defense of any Product Trademarks used in connection with any Products.

ARTICLE 9. REPRESENTATIONS, WARRANTIES AND COVENANTS

Section 9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party, as of the Effective Date, that:

a. it is duly incorporated and validly existing, in the case of Aerie, under the Law of Ireland, and in the case of Santen, Japan, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

b. it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

c. this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (x) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any material applicable Law or (y) require any consent or approval of its stockholders or similar action; and

d. it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement.

Section 9.2 Additional Aerie Representations and Warranties. Aerie represents and warrants to Santen that, as of the Effective Date:

a. Aerie has full legal or beneficial title and ownership of, or an exclusive license to, the Aerie Patents listed on Exhibit B as of the Effective Date (the "**Existing Patents**") as is necessary to grant the licenses (or sublicenses) to Santen to such Aerie Patents that Aerie purports to grant pursuant to this Agreement;

b. Aerie has the rights necessary to grant the licenses to Santen under Aerie Know-How that Aerie purports to grant pursuant to this Agreement;

c. the Aerie Patents owned by Aerie, and to Aerie's knowledge the Aerie Patents licensed to Aerie, are not subject to any liens or encumbrances, and Aerie has not, and will not during the Term, grant any right to any Third Party under or with respect to the Aerie IP that would conflict with the rights granted to Santen hereunder or terminate any rights granted by a Third Party to Aerie or its Affiliates that are further granted to Santen hereunder;

d. no claim or action has been brought or, to Aerie's knowledge, threatened any Third Party alleging that (i) the Existing Patents are invalid or unenforceable or (ii) use of the Aerie IP existing as of the Effective Date infringes or misappropriates or would infringe or misappropriate Patent Rights or any right of any Third Party (other than [***]), and no Aerie Patent is the subject of any interference, opposition, cancellation or other protest proceeding. Aerie has not received any written notice from any Third Party asserting or alleging that the development, manufacture, use or sale of any Product infringes the rights of such Third Party in the Territory;

e. to Aerie's knowledge, there are no pending actions, claims, investigations, suits or proceedings against Aerie or its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither Aerie nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against Aerie or such Affiliate, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the Aerie IP existing as of the Effective Date;

f. to Aerie's knowledge, no Third Party, including any current or former employee or consultant of Aerie, is infringing or misappropriating or has infringed or misappropriated the Aerie IP existing as of the Effective Date; and

g. to Aerie's knowledge, no material safety, efficacy, or regulatory claims or allegations have been alleged in writing by any Governmental Authority that would preclude Santen from Developing, Commercializing and otherwise Exploiting the Products in the Field in the Territory in compliance with applicable Laws.

Section 9.3 Covenants.

a. Employees, Consultants and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, contractors, agents and Sublicensees who perform Development activities pursuant to this Agreement or otherwise participate in the Exploitation of Products pursuant to this Agreement, which agreements will obligate

such persons to obligations of confidentiality and non-use and to assign inventions in a manner consistent with the provisions of this Agreement.

b. Debarment. Each Party represents, warrants and covenants to the other Party that it is not debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings under the U.S. Food, Drug and Cosmetic Act or comparable Laws in any country or jurisdiction other than the U.S. and, to its knowledge, does not, and will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates or Sublicensees, the services of any person who is debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment, exclusion or disqualification or threatened debarment, exclusion or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

c. Compliance. Each Party shall comply with applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement. Neither Party (nor any of their Affiliates) shall be required under this Agreement to take any action or to omit to take any action otherwise required to be taken or omitted by it under this Agreement if the taking or omitting of such action, as the case may be, could in its reasonable opinion violate any settlement, consent order, corporate integrity agreement, or judgment to which it may be subject from time to time during the Term. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of its Affiliates shall be required to take, or shall be penalized for not taking, any action that such Party reasonably believes is not in compliance with applicable Law.

i. Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates and agents, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder: (A) it will comply with the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable Law relating to or concerning public or commercial bribery or corruption (collectively, "**Anti-Bribery and Anti-Corruption Laws**") and its applicable anti-corruption policies ("**Anti-Corruption Policies**"), and will not take any action that will cause the other Party or its Affiliates to be in violation of any such laws or policies; (B) it will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to any Public Official or Entity for the purpose of influencing the acts of such Public Official or Entity to induce them to use their influence with any Governmental Authority, or obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Anti-Bribery and Anti-Corruption Laws or Anti-Corruption Policies; and (C) it will not directly or indirectly solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Bribery and Anti-Corruption Laws or the Anti-Corruption Policies.

ii. Each Party, on behalf of itself and its officers, directors, employees, Affiliates, agents and representatives, represents and warrants to the other Party that, in connection

with the matters that are the subject of this Agreement, and the performance by each Party of its obligations hereunder: (A) to its knowledge, as of the Effective Date, it and its Affiliates have not committed any Material Anti-Corruption Law Violation; and (B) to its knowledge, none of its contracts, licenses or other assets that are the subject of this Agreement were procured in violation of the Anti-Bribery and Anti-Corruption Laws.

iii. Each Party will keep and maintain accurate books, accounts, invoices and reasonably detailed records in connection with the performance of its obligations under, and payments made in connection with, this Agreement, including all records required to establish compliance with the provisions of this Section 9.3(c), until the later of (A) [***] after the end of the period to which such books and records pertain or (B) the expiration of the applicable statute of limitations (or any extension thereof).

iv. If a Party becomes aware that any of its officers, directors or employees becomes during the Term a Public Official or Entity in a position to take or influence official action for or against a Party in connection with the performance of its obligations under this Agreement, that Party will promptly notify the other Party. A Party shall notify the other Party upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its representatives that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation in connection, in either case in connection with this Agreement.

v. If either Party requests that any other Party complete a compliance certification certifying compliance with this Section 9.3(c), which request shall occur no more than twice in the first Calendar Year that a Party makes such request and once per Calendar Year thereafter, such other Party shall promptly complete and deliver such compliance certification truthfully and accurately. If either Party requests, in connection with a corporate integrity agreement or similar arrangement with a Governmental Authority, that any other Party complete a compliance certification certifying adherence to and compliance with such other Party's code of conduct and compliance program with respect to such other Party's activities under this Agreement, which request shall occur no more than once per Calendar Year, such other Party shall cooperate with the first Party to promptly complete and deliver such compliance certification truthfully and accurately, and should there be reasonable additional requests of such other Party as a result of a corporate integrity agreement or similar arrangement with a Governmental Authority of the requesting Party, such other Party shall comply with such requests.

vi. In the event that a Party has a good faith reason to believe that the other Party may be in breach or violation of any representation, warranty or undertaking in this Section 9.3(c), such Party shall have the right to conduct an examination and audit of relevant books and records of the other Party and, during the pendency of such examination, to suspend any obligations on the part of such Party to the other Party, other than the obligation to pay any payments payable to the other Party pursuant to this Agreement. In the event that a Party becomes aware, whether or not through audit, that the other Party is in breach of or in violation of any representation, warranty or undertaking in this Section 9.3(c), then that Party shall have the right to take such steps as are reasonably necessary in order to avoid a violation or continuing violation of the Anti-Bribery and

Anti-Corruption Laws, including by requesting such additional representations, warranties, undertakings and other provisions including a further audit as it believes in good faith are reasonably necessary.

d. No Grant of Conflicting Rights. Neither Party nor any of its respective Affiliates will, during the Term, enter into any agreements or grant any right, title or interest to any Person that is inconsistent with the rights and licenses granted to the other Party hereunder, and each Party will maintain and keep in full force and effect all agreements necessary to perform its obligations, and grant the rights granted to the other Party, hereunder.

Section 9.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENT RIGHTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

ARTICLE 10. INDEMNIFICATION

Section 10.1 Indemnity.

10.1.1 By Aerie. Aerie agrees to defend Santen, its Affiliates, and each of their respective directors, officers, employees and agents (the "**Santen Indemnified Parties**"), at Aerie's cost and expense, and will indemnify and hold Santen and the other Santen Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including reasonable legal fees and expenses) (collectively, "**Losses**") in connection with any claims, actions, demands, suits or proceedings brought by a Third Party (including product liability claims) (a "**Third Party Claim**") to the extent arising out of or resulting from (a) the gross negligence or willful misconduct of Aerie, its Affiliates or their respective Sublicensees or subcontractors in connection with this Agreement; (b) the breach of this Agreement or any of the representations, warranties or covenants made hereunder by Aerie; or (c) the research, Development, Manufacture, Commercialization or other Exploitation of any Product by or on behalf of Aerie or its Affiliates or their respective sublicensees (including from product liability claims) outside the Territory; except, in each case, to the extent such Losses result from clause (a), (b), (c), or (d) of Section 10.1.2.

10.1.2 By Santen. Santen agrees to defend Aerie, its Affiliates and their respective directors, officers, employees and agents (the "**Aerie Indemnified Parties**"), at Santen's cost and expense, and will indemnify and hold Aerie and the other Aerie Indemnified Parties harmless from and against any Losses in connection with any Third Party Claims to the extent arising out of or resulting from (a) the gross negligence or willful misconduct of Santen, its Affiliates, or their respective Sublicensees, Distributors or subcontractors in connection with its activities under this Agreement;

(b) the breach of this Agreement or any of the representations, warranties or covenants made hereunder by Santen; (c) the research, Development, Manufacture, Commercialization or other Exploitation of any Product by or on behalf of Santen or its Affiliates or their respective Sublicensees, Distributors or subcontractors (including from product liability claims) in or for the Territory; or (d) the exercise of the licenses or sublicenses granted under this Agreement; except, in each case, to the extent such Losses result from clause (a), (b) or (c) of Section 10.1.1.

Section 10.2 Procedure.

10.2.1 Notice. The indemnified Party ("**Indemnitee**") will promptly notify the indemnifying Party ("**Indemnitor**") in writing of the assertion or the commencement of the relevant Third Party Claim; *provided, however*, that any failure or delay to notify shall not excuse any obligation of the Indemnitor, except to the extent the Indemnitor is actually prejudiced thereby. Such notice must contain a description of the claim and the nature and amount of any Losses (to the extent that the nature and the amount of such Losses is known at such time). The Indemnitee shall furnish promptly to the Indemnitor copies of all papers and official documents received in respect of any Losses and Third Party Claims.

10.2.2 Control of Defense. The Indemnitee hereby grants the Indemnitor the right to assert sole management and control, at the Indemnitor's sole expense, of the defense of such Third Party Claim and its settlement; *provided, however*, that the Indemnitor shall not settle any such Third Party Claim without the prior written consent of the Indemnitee if such settlement does not include a complete release from liability or if such settlement would involve the Indemnitee undertaking an obligation (including the payment of money by the Indemnitee), would bind or impair the Indemnitee, or includes any admission of wrongdoing by the Indemnitee or that any intellectual property or proprietary right of Indemnitee or this Agreement is invalid, narrowed in scope or unenforceable. The assertion of the defense of a Third Party Claim by the Indemnitor shall not be construed as an acknowledgment that the Indemnitor is liable to indemnify the Indemnitee in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnitor of any defenses it may assert against the Indemnitee's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnitor may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnitor, which shall be reasonably acceptable to the Indemnitee. In the event the Indemnitor assumes the defense of a Third Party Claim, except as provided in this Section 10.2.2, the Indemnitor shall not be liable to the Indemnitee for any legal expenses subsequently incurred by such Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the Indemnitor. In the event that it is ultimately determined that the Indemnitor is not obligated to indemnify, defend or hold harmless the Indemnitee from and against the Third Party Claim, the Indemnitee shall reimburse the Indemnitor for any Losses incurred by the Indemnitor in defense of the Third Party Claim. The Indemnitee shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. Notwithstanding the foregoing, the Indemnitee will have the right to employ separate counsel at the Indemnitor's expense and to control its own defense of the applicable Third Party Claim if: (a) the employment thereof, and the assumption by the Indemnitor of such expense, has been specifically authorized by the Indemnitor in writing, (b) the Indemnitor has failed to assume the defense and employ counsel in accordance with this Section 10.2.2 (in which case, the Indemnitee shall control the defense), (c) there are or may be legal defenses available to the Indemnitee that are different from or additional to those available to the

Indemnitor, or (d) in the reasonable opinion of counsel to the Indemnitee, a conflict or potential conflict exists between the Indemnitee and the Indemnitor that would make such separate representation advisable; *provided* that in no event will the Indemnitor be required to pay fees and expenses under this sentence for more than one firm of attorneys in any jurisdiction in any one legal action or group of related legal actions. In such event, the Indemnitee shall not settle or compromise such Third Party claim without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld, conditioned or delayed. The Indemnitor shall not be liable for any settlement, compromise or other voluntary disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnitor.

10.2.3 Cooperation. Regardless of whether the Indemnitor chooses to defend or prosecute any Third Party Claim, Indemnitee shall, and shall cause each other indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnitor to, and reasonable retention by the Indemnitee of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnitor shall reimburse the Indemnitee for all of its reasonable out-of-pocket expenses in connection therewith as set forth in Section 10.2.4.

10.2.4 Expenses. The reasonable and verifiable costs and expenses, including costs, expenses, fees and disbursements of counsel, incurred by the Indemnitee pursuant to Section 10.2.3 shall be reimbursed on a monthly basis in arrears by the Indemnitor, without prejudice to the Indemnitor's right to contest the Indemnitee's right to indemnification and subject to refund in the event the Indemnitor is ultimately held not to be obligated to indemnify the Indemnitee.

ARTICLE 11. LIMITATIONS OF LIABILITY

Section 11.1 LIMITATION OF DAMAGES. EXCEPT FOR WILLFUL MISCONDUCT, IN NO EVENT SHALL A PARTY BE LIABLE TO THE OTHER PARTY WITH RESPECT TO THIS AGREEMENT FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 11.1 SHALL NOT APPLY WITH RESPECT TO ANY BREACH OF ARTICLE 12. NOTHING IN THIS SECTION 11.1 WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER ARTICLE 10 WITH RESPECT TO ANY DAMAGES PAID OR REQUIRED TO BE PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

Section 11.2 Insurance. Each of the Parties will, at their own respective expense, procure and maintain during the Term, insurance policies consistent with the normal business practices of prudent biopharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to

provide materially the same level and type of protection). Such insurance will not create a limit to either Party's liability hereunder.

ARTICLE 12. CONFIDENTIALITY

Section 12.1 Confidential Information.

12.1.1 Confidential Information. Each Party (the "**Receiving Party**") may receive during the course and conduct of activities under this Agreement, certain proprietary or confidential information of the other Party (the "**Disclosing Party**") as furnished to the Receiving Party by or on behalf of the Disclosing Party. The term "**Confidential Information**" means all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing of Affiliates or Third Parties. Notwithstanding anything to the contrary in the foregoing, (a) any information that includes Aerie Know-How or Aerie Improvements shall be Confidential Information of Aerie, and Aerie shall be deemed the Disclosing Party thereof for purposes of this Article 12, (b) Collaboration IP shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the Disclosing Party and the Receiving Party with respect thereto for purposes of this Article 12, and (c) any other information disclosed by or on behalf of Aerie hereunder to Santen that is necessary for the Exploitation of any Product shall, for the avoidance of doubt, be the Confidential Information of both Parties for purposes of this Article 12.

12.1.2 Restrictions. During the Term and for [***] thereafter (or, for any trade secret, for so long as the Disclosing Party maintains such trade secret as a trade secret), Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are bound by restrictions on use and disclosure consistent with this Section 12.1.2. Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 12.1.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

12.1.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate with documentary evidence that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure without any obligation of confidentiality with respect to such information (*provided* that subsection (a) shall not apply to Santen's obligation of nondisclosure and the limitations upon the right to use any information that includes Aerie IP or Aerie Improvements that is first disclosed by Santen to Aerie); (b) is or becomes public knowledge through no wrongful act, fault or omission of Receiving Party or any of

its Affiliates; (c) is subsequently obtained by Receiving Party or any of its Affiliates from a Third Party not known by the Receiving Party after due inquiry to be under an obligation of confidentiality; (d) has been independently discovered or developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records; or (e) was released from the restrictions set forth in this Agreement by express prior written consent of the Disclosing Party.

12.1.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

a. in order to comply with applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like) or with a legal or administrative proceeding, or in connection with prosecuting or defending litigation;

b. in connection with prosecuting and defending litigation, Marketing Approvals and other Regulatory Filings and communications, and filing, prosecuting and enforcing Patent Rights in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

c. in connection with exercising its rights hereunder, to its Affiliates, potential and future collaborators (including Sublicensees), advisors, or independent contractors; and, to the extent necessary in connection with their evaluation of potential or actual investment, financing, acquisition or other transaction, investment bankers, legal or other advisors, investors, lenders, financial partners and their attorneys and agents, acquirers or permitted assignees who have a need to know and are under written confidentiality and non-use agreements at least as restrictive as hereunder, but may be of shorter duration (except for trade secrets which shall be maintained as confidential as long as they are trade secrets) to the extent such shorter duration is reasonable and customary in the case of investment bankers, legal or other advisors, investors, lenders, or financial partners and their attorneys and agents;

provided, *however*, that (1) with respect to Sections 12.1.4(a) or 12.1.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed and, in the event that no protective order or other remedy is obtained, or the Disclosing Party waives compliance with the terms of this Agreement, the Receiving Party shall furnish only that portion of Confidential Information that the Receiving Party is advised by counsel is legally required to be disclosed; and (2) with respect to Section 12.1.4(c), (A) each of those named people and entities are bound by restrictions on use and disclosure consistent with Section 12.1.2 (other than advisors, investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality) and (B) financial terms shall not be disclosed to any such potential acquirer or investor if it has a competing product to any Product.

12.1.5 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions

imposed by this Section 12.1.5 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the Disclosing Party's counsel, is required by applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like) or with a legal or administrative proceeding, or in connection with prosecuting or defending litigation; *provided* that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

Section 12.2 Terms of this Agreement; Public Announcements.

12.2.1 The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by this Agreement. Except as required by Law or as permitted under Section 12.1.4, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed. Without limiting Section 12.1.4, the Parties agrees to seek reasonable and customary redactions in any filing of this Agreement with the SEC.

12.2.2 The Parties agree that each Party may issue future announcements concerning the advancement of a Product; *provided* that, except as permitted under Section 12.1.4, any such announcement by Aerie has been mutually agreed upon by the Parties (such agreement not to be unreasonably withheld, conditioned, or delayed) or contains only information that has been previously publicly announced. The foregoing notwithstanding, Aerie may publicly announce the achievement and amount of any milestone entitling Aerie to receive a payment; *provided* that, except as permitted under Section 12.1.4, Aerie shall submit to Santen for prior review a draft of the proposed announcement and reasonably consider comments made by Santen and, to the extent practicable if so desired by Santen, the Parties shall coordinate the timing of any such release.

Section 12.3 Publication.

12.3.1 Subject to the requirements of this Article 12, each Party who conducted the relevant research or study in the performance of its obligation under this Agreement will have the sole right to publish and make scientific presentations, issue press releases (except with respect to the terms of this Agreement, which is governed by Section 12.2) or make other public disclosures with respect to such research or study consistent with such Party's publication policy. The other Party will not issue any such publications without such Party's prior written consent, except as required by applicable Law or as otherwise permitted under this Agreement. Notwithstanding the foregoing, any such publication or presentation to be made by each Party that names the other Party will require the prior written consent of the other Party.

12.3.2 The Party that is entitled under this Section 12.3 to make a publication or presentation (the "**Publishing Party**") will deliver to the other Party (the "**Non-Publishing Party**") a copy of the proposed written publication or outline of presentation to be made by the Publishing Party at least thirty (30) days in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and the Non-Publishing Party will have the right to: (a) require a delay of submission of not more than

sixty (60) days to enable the filing of patent applications and information from such proposed publication or presentation in accordance with this Agreement; and (b) prohibit disclosure of any of the Non-Publishing Party's Confidential Information in any such proposed publication or presentation. If the Non-Publishing Party has not provided any comments or otherwise exercised its rights as described in this Section 12.3.2 within thirty (30) days of receiving a copy of such proposed written publication or outline of presentation, the Publishing Party shall be free to submit such publication or to orally disclose or publish the disclosed information in a manner consistent with this Article 12.

Section 12.4 Relationship to the Confidentiality Agreement. This Agreement supersedes the Confidential Disclosure Agreements; *provided, however*, that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement.

Section 12.5 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

Section 12.6 Survival. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 12.1.2.

ARTICLE 13. TERM & TERMINATION

Section 13.1 Term. The term of this Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13, shall continue in full force and effect, on a [***] basis, until expiration of the obligation to make payments under this Agreement with respect to each Product in each country (the "**Term**").

Section 13.2 Termination by Aerie.

13.2.1 Santen Breach. Aerie will have the right to terminate this Agreement in the event of any material breach by Santen of any terms and conditions of this Agreement (which shall be deemed to include any breach by Santen of its obligations under Section 6.3); *provided, however*, that such termination will not be effective if such breach has been cured within [***] after written notice thereof is given by Aerie to Santen specifying the nature of the alleged breach and Santen has not exercised a right to cure under this Section 13.2.1 with respect to any other material breach (including earlier related breaches) more than once in the [***]; *provided further, however*, if such breach (except for payment breaches or breaches not subject to cure pursuant to the foregoing) is not reasonably subject to cure within [***] after receipt of written notice thereof, then Santen shall have an additional [***] to effect such cure provided that Santen is undertaking Commercially Reasonable Efforts to cure such breach

during such additional [***] and shall have provided to Aerie a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.2.1, in the event of a good faith dispute as to whether a material breach by Santen allowing for termination hereunder has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided, however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

13.2.2 Santen Bankruptcy or Insolvency. Aerie will have the right to terminate this Agreement if, at any time, Santen: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Santen or of its assets, in each case that is not dismissed within [***] after the filing thereof; (b) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within [***] after the filing thereof; (c) passes a resolution for its winding up or proposes to be or is a party to any dissolution or liquidation; or (d) makes or will make an assignment of substantially all of its assets for the benefit of its creditors.

13.2.3 Termination for Patent Challenge. Aerie will have the right to terminate this Agreement immediately upon written notice to Santen if Santen or any of its Sublicensees or Affiliates initiates or asserts any Patent Challenge and fails to initiate rescission of such Patent Challenge within [***] after such written notice and thereafter fails to rescind such Patent Challenge within [***] after such written notice. In the event any Sublicensee (or any Person acting on its behalf) of Santen initiates or asserts any Patent Challenge in any forum, Santen shall, upon written request by Aerie, immediately terminate the applicable sublicense agreement with such Sublicensee.

Section 13.3 Termination by Santen.

13.3.1 Aerie Breach. Santen will have the right to terminate this Agreement in the event of any material breach by Aerie of any terms and conditions of this Agreement; *provided, however*, that such termination will not be effective if such breach has been cured within [***] after written notice thereof is given by Santen to Aerie specifying the nature of the alleged breach; *provided further, however*, if such breach (except for payment breaches) is not reasonably subject to cure within [***] after receipt of written notice thereof, then Aerie shall have an additional [***] to effect such cure provided that Aerie is undertaking Commercially Reasonable Efforts to cure such breach during such additional [***] and shall have provided to Santen a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.3.1, in the event of a good faith dispute as to whether a material breach by Aerie allowing for termination hereunder has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided, however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

13.3.2 Aerie Bankruptcy or Insolvency. Santen will have the right to terminate this Agreement if, at any time, Aerie: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Aerie or of its assets, in each case that is not dismissed

within [***] after the filing thereof; (b) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within [***] after the filing thereof; (c) passes a resolution for its winding up or proposes to be or is a party to any dissolution or liquidation; or (d) makes or will make an assignment of substantially all of its assets for the benefit of its creditors.

13.3.3 Discretionary Termination. Santen, in its sole discretion, may terminate this Agreement in its entirety upon delivery of at least [***] prior written notice to Aerie if Santen [***] (including, without limitation, due to [***]).

13.3.4 Termination due to [***].

a. Santen, in its sole discretion, may terminate this Agreement, in whole or with respect to Japan, during the period of [***] after Marketing Approval of the Rhopressa Product in Japan (such [***] period, the [***]), if (i) [***] and (ii) either of the following occurred: (A) [***], or (B) [***] that (1) any of the Products [***] or (2) [***] (clause (A) or (B), a "**[***]**"); *provided*, *however*, that, notwithstanding the foregoing, in the event that Santen is a party to a pending court proceeding that may reasonably be expected to result in the outcome described in [***], Santen shall not [***] unless and until [***], in which case (x) Santen shall be entitled to [***] (a "**[***]**"), and (y) Aerie shall be obligated to [***]; and *provided further* that if such [***], Santen shall not have the right to [***]. Santen may terminate this Agreement, in whole or with respect to Japan, pursuant to this Section 13.3.4(a) by providing written notice delivered to Aerie within [***] after a [***] (without a [***]) or a [***] (without a [***]), as applicable.

b. In the event that neither clause (A) nor clause (B) of Section 13.3.4(a) occurs within the [***], both Parties will discuss in good faith to evaluate any issues arising from the [***]; *provided*, *however*, that Santen shall have the right to terminate this Agreement, [***], which claim or allegation would reasonably be expected to result in a Damages Award against Santen; *provided further*, *however*, that in the event of such termination [***], (i) Santen shall not be entitled to any portion of the Termination Refund and (ii) in the event of any subsequent Damages Award, (x) Aerie's aggregate liability for such Damages Award shall be [***] and (y) [***], which obligation and liability shall survive termination of this Agreement.

13.3.5 Termination due to [***].

a. Santen, in its sole discretion, may terminate this Agreement, in whole or with respect to Korea, during the period of [***] after Marketing Approval of the Rhopressa Product in Korea (such [***] period, the [***]) if (i) [***] and (ii) either of the following occurred: (A) [***], or (B) [***] (clause (A) or (B), a "**[***]**"); *provided*, *however*, [***], unless and until [***], in which case (x) [***] (a "**[***]**"), and (y) [***]; and *provided further* that if such [***]. Santen may terminate this Agreement, in whole or with respect to Korea, pursuant to this Section 13.3.5(a) by providing written notice delivered to Aerie within [***] after a [***] (without a [***]) or a [***] (without a [***]), as applicable.

b. In the event that neither clause (A) nor clause (B) of Section 13.3.5(a) occurs within the [***], both Parties will discuss in good faith to evaluate any issues arising from the [***]; *provided*, *however*, that Santen shall have the right to terminate this Agreement, [***]; *provided*

further, *however*, that in the event of such termination [***], (i) Santen shall not be entitled to any portion of the [***] and (ii) in the event of any subsequent Damages Award, (x) Aerie's aggregate liability for such Damages Award shall be [***] and (y) [***], which obligation and liability shall survive termination of this Agreement.

Section 13.4 Effects of Expiration and Termination. Following the expiration of the Term, the licenses granted to Santen pursuant to Section 4.1.1 shall become perpetual, irrevocable, royalty-free and fully paid up. Upon termination by a Party, as applicable, under Section 13.2 or Section 13.3 (or, to the extent this Agreement is terminated solely with respect to a particular Product, then the remainder of this Section 13.4 shall only apply to the terminated Product), the following shall apply:

13.4.1 Ongoing Clinical Studies. If Santen is conducting (or having conducted on its behalf) any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced, Santen shall, subject to Aerie's rights under Section 13.5, either (a) transfer responsibility for such clinical studies to Aerie, or (b) responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, and in the case of (a) and (b) Santen will be responsible for any costs associated therewith.

13.4.2 Termination of Licenses and Sublicense; Payments. Except as set forth herein, all relevant licenses and sublicenses granted under Article 4, as of the effective date of such termination, shall terminate automatically unless otherwise agreed by the Parties. All undisputed amounts due or payable to a Party hereunder that were accrued prior to the date of termination shall remain due and payable.

13.4.3 Destruction of Confidential Information. Each Party shall destroy or cause to be destroyed (or, at the other Party's written request, return or cause to be returned) all Confidential Information of the other Party in the possession of such Party or its Affiliates or Sublicensees as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the nonuse and nondisclosure provisions of this Agreement), and any Confidential Information of the other Party contained in its laboratory notebooks or databases; *provided* that each Party may retain and continue to use such Confidential Information of the other Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received Confidential Information under this Agreement. Santen shall destroy or cause to be destroyed, or at Aerie's option, return or cause to be returned to Aerie, all Materials of Aerie in the possession of Santen or its Affiliates or Sublicensees as of the effective date of expiration or termination.

13.4.4 Termination Refund.

a. **Termination Refund in Japan**. In the event that Santen terminates this Agreement pursuant to Section 13.3.4, in whole or with respect to Japan, within the Japan Post-Approval Period [***], Aerie shall make a refund to Santen (the "**Termination Refund**") to Santen as follows, in the aggregate: (i) (x) [***] of the upfront payment paid by Santen to Aerie pursuant to

Section 7.1, if Santen terminates this Agreement in whole; or (y) [***] of the upfront payment paid by Santen to Aerie pursuant to Section 7.1 if Santen terminates this Agreement only with respect to Japan; (ii) (x) thirty-nine million USD ($39,000,000) of the Development Milestones paid by Santen to Aerie pursuant to Section 7.2 if Santen terminates this Agreement in whole; or (y) fifty percent (50%) of the Development Milestones for Japan paid by Santen to Aerie pursuant to Section 7.2 if Santen terminates only with respect to Japan; and (iii) [***] of the Development Costs in Japan incurred by Santen for the Rhopressa Products and Rocklatan Products (which include the Rhopressa Development Costs reimbursed by Santen to Aerie in accordance with Section 6.5.2); *provided*, *however*, that [***].

b. **Termination Refund in Korea.** In the event that Santen terminates this Agreement pursuant to Section 13.3.5, in whole or in part with respect to Korea, within the [***], Aerie shall make a refund (the [***]) to Santen as follows, in the aggregate: (i) [***] of the upfront payment paid by Santen to Aerie pursuant to Section 7.1; (ii) [***] of the Development Milestones for Korea paid by Santen to Aerie pursuant to Section 7.2; and (iii) fifty percent (50%) of the Development Costs in Korea incurred by Santen for the Rhopressa Products and Rocklatan Products (which include the Rhopressa Development Costs reimbursed by Santen to Aerie in accordance with Section 6.5.2); *provided*, *however*, that [***].

Section 13.5 Product Reversion. Upon termination by Aerie pursuant to Section 13.2 or by Santen pursuant to Section 13.3.3 or Sections 13.3.4 or 13.3.5 (in whole or with respect to Japan or Korea, as applicable), with respect to each Product in the Territory or, as applicable, in Japan or Korea (a "**Reversion Product**"), within thirty (30) days after the earlier of delivery of notice of such termination or the effective date of such termination, Aerie may request to Santen in writing that the Parties work in good faith to agree upon a transition plan to coordinate their obligations under this Section 13.5 in an efficient manner, in which case the following shall apply to the extent applicable:

a. To the extent that Santen or its Affiliates holds any Regulatory Filings and/or Marketing Approvals applicable to the Reversion Products, at Aerie's request Santen shall (and shall cause its Affiliates to) transfer any of their respective rights, title and interests therein (to the extent permitted) to Aerie or its designee at Aerie's sole cost and expense. At Aerie's request, a copy of all material documents necessary to further Exploit the Reversion Products and that otherwise relate to the Reversion Products, to the extent Controlled by Santen or its Affiliates, and all of Santen's and its Affiliates' right, title and interest therein and thereto, shall be provided to Aerie or its designee as promptly as reasonably practicable thereafter (to the extent permitted), at Aerie's sole cost and expense. At Aerie's request, any existing agreements between Santen or its Affiliates and any Third Party that are solely related to the Exploitation of any Reversion Product, and all of Santen's and its Affiliates' right, title and interest therein and thereto, shall at Aerie's option be terminated or assigned and transferred to Aerie or its designee, to the extent permissible pursuant to the terms thereof (and for any such agreement that by its terms cannot be so assigned, Santen shall reasonably cooperate with Aerie to provide to Aerie the benefits of such agreement). At Aerie's election, Santen shall transition to Aerie (or its designee) the conduct of any ongoing clinical studies for which Santen has responsibility hereunder and in which patient dosing has commenced, to the extent permitted by applicable Law and not reasonably expected by Santen to have a serious adverse effect on patient safety, at Aerie's sole cost and expense.

b. At Aerie's request within such [***], should Santen or its Affiliates own or control any inventory of any Reversion Product suitable for use or sale in the terminated portion of the Territory, Santen shall notify Aerie in writing and Aerie shall (i) if Aerie manufactured such Reversion Product, arrange for delivery of such Reversion Product to Aerie or its designee at Aerie's cost, or (ii) if Santen manufactured such inventory, purchase such Reversion Product from Santen at a price equal to Santen's or its Affiliate's actual cost of procuring such Reversion Product. Furthermore, if upon such termination of this Agreement, Santen or its Affiliate or Third Party contractor is then making the Reversion Product, Santen or its Affiliate or Third Party contractor, at Aerie's option, shall continue to make and supply to Aerie or its Affiliates or their sublicensees the Reversion Product upon commercially reasonable terms for a reasonable period of time until Aerie has secured an alternative supply of such Reversion Product.

c. At Aerie's request within such [***], Santen shall assign (or, if applicable, cause its Affiliate to assign) to Aerie all of Santen's (and such Affiliates') right, title and interest in and to any trademark or internet domain name that relates solely to the Reversion Products in the applicable terminated Territory and used by Santen or any of its Affiliates solely in the Exploitation of the Reversion Products prior to such termination of this Agreement, at Aerie's sole cost and expense.

d. At Aerie's request, upon the effectiveness of such termination, Santen shall and hereby does grant to Aerie an exclusive, royalty-free, worldwide license, with the right to grant sublicenses through multiple tiers of sublicensees, under the Santen Inventions and Santen's interest in the Collaboration IP, and any other Santen IP necessary for Aerie to practice such Collaboration IP and Santen Inventions in the exercise of Aerie's rights under this Section 13.5(d), that are Controlled by Santen or any of its Affiliates as of the date of such termination and that are reasonably useful or necessary to Exploit such Reversion Products in the Territory.

e. Without limiting the foregoing, at Aerie's request and to the extent permissible pursuant to applicable Laws, Santen shall transition all ongoing material Exploitation activities and contracts, including with respect to manufacturing, undertaken by Santen and its Affiliates in the applicable terminated Territory hereunder to Aerie or Aerie's designee, at Aerie's sole cost and expense, and shall use Commercially Reasonable Efforts to cause to be transitioned any such activities undertaken by any of Santen's Sublicensees.

f. At Aerie's request, Santen shall destroy all Reversion Product literature, Promotional Materials, samples and other sales or sales training materials in the possession of Santen and its Affiliates as promptly as practical after the date of such termination (to the extent then existing).

g. The Parties will use Commercially Reasonable Efforts to complete all transfer and transition activities required in this Section 13.5 as promptly as practicable following the effective date of such termination and each Party shall be responsible for its own costs in connection therewith.

Section 13.6 Remedies. Except as otherwise expressly provided herein, any termination in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

Section 13.7 Survival. In addition to the expiration or termination consequences set forth in Section 13.4, Section 13.5, Section 13.6 and this Section 13.7, the following provisions will survive termination or expiration of this Agreement: Article 1, Section 7.2 (with respect to a milestone reached

prior to such the effective date of such expiration or termination), Section 7.4 (with respect to sales made before the effective date of such expiration or termination), Section 7.5 through Section 7.10 inclusive (with respect to periods with sales of Products made before the effective date of such expiration or termination), Section 8.1, Section 8.4 through Section 8.7 (with respect to any action initiated prior to the effective date of such expiration or termination), Section 8.8.1, Sections 8.8.4-8.8.6 (with respect to any action initiated prior to the effective date of such expiration or termination), Section 9.4, Article 10, Article 11, Article 12 and Article 14. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon termination or expiration of this Agreement.

ARTICLE 14. MISCELLANEOUS

Section 14.1 Entire Agreement; Amendment. This Agreement and all Exhibits attached hereto or thereto, constitute the entire agreement between the Parties as to the subject matter hereof (and all references to this Agreement shall be deemed to include the Exhibits hereto). All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement, including the Confidential Disclosure Agreements, are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. Neither of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by Santen and Aerie.

Section 14.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement. All rights granted to either Party under this Agreement shall be deemed to exist immediately before the occurrence of any bankruptcy case in which the other Party is the debtor.

Section 14.3 Independent Contractors. The relationship between Santen and Aerie created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties, including for all tax purposes. No such Party is a legal representative of the other Party, and no such Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each such Party shall use its own

discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 14.4 Governing Law; Jurisdiction. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Patent Right, which issue shall be determined in accordance with the laws of the country in which such patent was issued. Except to the extent otherwise set forth in Section 14.5, each of the Parties hereby irrevocably and unconditionally (a) consents to submit to the exclusive jurisdiction of the courts of the State of New York located in the City of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts, (b) waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the courts of the State of New York located in the City of New York, and (c) waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The Parties agree that a final judgment in any such matter shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement shall be exclusively conducted in the English language.

Section 14.5 Dispute Resolution.

14.5.1 Disputes; Resolution by Executive Officers. The Parties recognize that disputes as to certain matters may from time to time arise during the Term that relate to decisions to be made by the Parties herein or to the Parties' respective rights and/or obligations hereunder. It is the desire of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 14.5 if and when a dispute arises under this Agreement, subject to Section 2.1.5 and Section 14.5.3. Accordingly, any disputes, controversies or claims that may arise between the Parties out of or in relation to or in connection with this Agreement shall be promptly presented to the Alliance Managers for resolution. If the Alliance Managers are unable to resolve such dispute within [***] after a matter has been presented to them, then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party within [***] after receipt by the other Party of such written notice. If any such matter, other than a matter within the final decision-making authority of [***], is not resolved within [***] following presentation to the Executive Officers, then either Party may invoke the provisions of Section 14.5.2.

14.5.2 Arbitration. Any dispute that is not resolved pursuant to Section 14.5.1, shall be settled by binding arbitration to be conducted as set forth in this Section 14.5.2.

a. Either Party, following the end of the [***] period referenced in Section 14.5.1, may refer such issue to arbitration by submitting a written notice of such request to the other Party. In any proceeding under this Section 14.5.2, there shall be one (1) arbitrator chosen upon mutual agreement of the Parties. If the Parties do not agree upon a single arbitrator within [***] after delivery of such notice, each Party will nominate one arbitrator in accordance with the then current rules of the

Judicial Arbitration and Mediation Services ("**JAMS**"). The two (2) arbitrators so nominated will nominate a third arbitrator to serve as the single arbitrator of the dispute, such nomination to be made within [***] after the selection of the second arbitrator. The arbitrator shall be neutral and independent of both Parties and all of their respective Affiliates, shall have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries, shall have appropriate experience with respect to the matter(s) to be arbitrated, and shall have some experience in mediating or arbitrating issues relating to such agreements. In the case of any dispute involving Section 6.3 (Diligence), including an alleged failure to use Commercially Reasonable Efforts, the arbitrator shall in addition be an individual with experience and expertise in the worldwide development and commercialization of pharmaceuticals and the business, legal and scientific considerations related thereto. In the case of a dispute involving a scientific or accounting matter or determination, an expert having applicable expertise and experience will be selected by the Parties to assist the arbitrator in such scientific or accounting matter or determination (and the arbitrator will select such expert if the Parties cannot agree on such expert within [***] following the selection of the arbitrator). The governing law in Section 14.4 shall govern such proceedings. No individual will be appointed to arbitrate a dispute pursuant to this Agreement unless he or she agrees in writing to be bound by the provisions of this Section 14.5.2. The place of arbitration will be New York, New York, United States unless otherwise agreed to by the Parties, and the arbitration shall be conducted in English.

b. The arbitrator shall set a date for a hearing that shall be held no later than [***] following his or her appointment as the arbitrator. The Parties shall have the right to be represented by counsel. Except as provided herein, the arbitration shall be governed by the Comprehensive Arbitration Rules of JAMS applicable at the time of the notice of arbitration pursuant to Section 14.5.2(a), including the right of each Party to undertake document requests and up to five (5) depositions.

c. The arbitrator shall use his or her best efforts to rule on each disputed issue within [***] after completion of the hearing described in Section 14.5.2(b). The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon the Parties. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties as soon as is reasonably possible. Nothing contained herein shall be construed to permit the arbitrator to award punitive, exemplary or any similar damages. The arbitrator shall render a "reasoned decision" within the meaning of the Commercial Arbitration Rules, which shall include findings of fact and conclusions of law. Any arbitration award may be entered in and enforced by a court in accordance with Section 14.5.2(d).

d. Any award to be paid by one Party to the other Party as determined by the arbitrator as set forth above under Section 14.5.2 shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 14.5, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in a court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. With respect to money damages, nothing contained herein shall be construed

to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages. The only damages recoverable under this Agreement are compensatory damages.

e. Each Party shall bear its own legal fees in connection with any arbitration procedure. The arbitrator may in his or her discretion assess the arbitrator's cost, fees and expenses (and those of any expert hired by the arbitrator) against the Party losing the arbitration.

14.5.3 Injunctive Relief. Nothing in this Section 14.5 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Each Party further acknowledges and agrees that the restrictions set forth in Section 2.4, Article 4, Article 8 and Article 12 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Section or Article may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. For the avoidance of doubt, nothing in this Section 14.5.3 shall otherwise limit either Party's opportunity to cure a material breach as permitted in accordance with Article 13.

14.5.4 Confidentiality. The arbitration proceedings shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by applicable Law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and any award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable Law. Notwithstanding the foregoing, each Party shall have the right to disclose information regarding the arbitration proceedings to the same extent as it may disclose Confidential Information of the other Party under Article 12.

14.5.5 Survival. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

14.5.6 Patent and Trademark Disputes. Notwithstanding Section 14.5.2, and without prejudice to Aerie's rights pursuant to Section 13.2.3, any dispute, controversy or claim relating to the inventorship, scope, validity, enforceability or infringement of any Patent Rights Covering, or the scope, validity, enforceability or infringement of any trademark used in connection with, the manufacture, use,

importation, offer for sale or sale of Products shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

14.5.7 Waiver of Jury Trial. THE PARTIES EXPRESSLY WAIVE AND FOREGO ANY RIGHT TO TRIAL BY JURY.

Section 14.6 Notice. Any notice required or permitted to be given by this Agreement shall be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective if (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by facsimile followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 14.6, in each case, addressed as set forth below unless changed by notice so given:

If to Aerie: Aerie Pharmaceuticals Ireland, Ltd.
c/o Aerie Pharmaceuticals, Inc.
Athlone Business & Technology Park
Athlone, Co. Westmeath, N37 DW40, Ireland
Attn: [***]
Fax: [***]

with copies (which shall not constitute notice) to:

Aerie Pharmaceuticals Inc.
2030 Main St, #1500
Irvine, CA 92614
Attn: [***]
Fax: [***]

and

Aerie Pharmaceuticals Inc.
550 Hills Dr.
Bedminster, NJ 07921
Attn: [***]
[***]

If to Santen: Santen Pharmaceutical Co., Ltd.
4-20, Ofuka-cho, Kita-ku Osaka 533-8651 Japan
Attn: General Manager of Global Business Development
Fax: [***]

Any such notice shall be deemed given on the date received, except any notice received after 5:00 p.m. (in the time zone of the receiving Party) on a Business Day or received on a non-Business Day shall be

deemed to have been received on the next Business Day. A Party may add, delete, or change the Person or address to which notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 14.6.

Section 14.7 Compliance With Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 14.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed, except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate); *provided* that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any sale of all or substantially all of the assets of the Party that relate to this Agreement to a Third Party, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise (a "**Sale Transaction**"; such Third Party, a "**Third Party Acquirer**"); *provided* that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement, and *provided*, *further*, that if any such assignment by a Paying Party would result in withholding or other similar taxes becoming due on payments to a non-Paying Party under this Agreement (which withholding or other similar taxes would not have been due if the assignment did not occur), then any such assignment will require the non-Paying Party's prior written consent and the paying Party or the assignee shall pay or reimburse the non-Paying Party for any increase in such taxes resulting from such assignment that are not deductible or creditable by the non-Paying Party under applicable Law. A copy of such written agreement by such assignee shall be provided to the non-assigning Party within [***] of execution of such written agreement.

Section 14.9 Sale Transaction or Aerie Acquisition. In the event of (a) a Sale Transaction involving Aerie, or (b) the acquisition by Aerie of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, a **"Aerie Acquiree**"), whether by merger, sale of stock, sale of assets or otherwise (a "**Aerie Acquisition**"), the intellectual property rights of the Third Party Acquirer in a Sale Transaction, or the Aerie Acquiree, as applicable, that existed prior to the effective date of such Sale Transaction or Aerie Acquisition (or that is developed thereafter without any use of intellectual property rights of Aerie or any of its Affiliates existing prior to the Sale Transaction or Aerie Acquisition or acquired or developed thereafter) shall not be included in the Patent Rights, Know-How, or other intellectual property rights licensed hereunder by Aerie to Santen, or otherwise subject to this Agreement.

Section 14.10 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not

constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 14.11 Performance by Affiliates. Each Party may use one (1) or more of its Affiliates to perform its obligations and duties hereunder and such Affiliates are expressly granted certain rights herein; *provided* that each such Affiliate shall be bound by the corresponding obligations of such Party and such Party shall remain liable hereunder for the prompt payment and performance of all of their respective obligations hereunder.

Section 14.12 Force Majeure. Each Party shall be excused from the performance of its obligations (except payment obligations) under this Agreement to the extent that such performance is prevented by Force Majeure (defined below) and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues. The Party affected by such Force Majeure also shall notify the other Party of the anticipated duration of such Force Majeure, any actions being taken to avoid or minimize its effect after such occurrence, and shall take reasonable efforts to remove the condition constituting such Force Majeure. For purposes of this Agreement, "**Force Majeure**" shall mean conditions beyond the control of the Parties, including acts of God, acts of terrorism, voluntary or involuntary compliance with any Law of any Governmental Authority, embargoes, insurrections, war, acts of war (whether war be declared or not), shortages, epidemics, quarantines, labor strikes, lock-outs or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), civil commotion, riots, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, hurricane, storm, flood, or like catastrophe, or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the nonperforming Party or any of its Affiliates of any term or condition of this Agreement). The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its ability to perform. The Party not subject to such Force Majeure may terminate this Agreement if such Force Majeure exists for [***] in any 365-day period pursuant to Section 13.2.1 or Section 13.3.1, as applicable, unless the Party affected by such Force Majeure continues to use Commercially Reasonable Efforts to remove such Force Majeure if it is reasonably expected that such efforts would be capable of removing such Force Majeure.

Section 14.13 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof, except for the provisions of Article 10 (with respect to which the persons to which Article 10 applies shall be Third Party beneficiaries for Article 10 only in accordance with the terms and conditions of Article 10).

Section 14.14 Headings; Exhibits; Appendices. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement, and in no way define, describe,

extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. All Exhibits are incorporated herein by this reference.

Section 14.15 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The term "including," "include," or "includes" as used herein means including, without limiting the generality of any description preceding such term. The word "will" shall be construed to have the same meaning and effect as the word "shall". The words "herein", "hereof" and "hereunder" and words of similar import will be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 14.16 Counterparts Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

AERIE PHARMACEUTICALS IRELAND, LTD.

By: /s/ Christopher Staten
Name: Christopher Staten
Title: Director

SANTEN PHARMACEUTICAL CO., LTD.

By: /s/ Shigeo Taniuchi
Name: Shigeo Taniuchi
Title: President and Chief Executive Officer

Exhibit A
Aerie Housemarks

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit B
Aerie Patents

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit C

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit D

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit E
Santen Housemarks

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit F
Product Trademarks

This exhibit regarding certain intellectual property has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit G
Permitted Subcontractors

This exhibit regarding certain permitted subcontractors has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit H
Supply Agreement Terms for Clinical Supply (Investigational Drugs)

This exhibit regarding certain supply agreement terms has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit I
Manufacturing & Supply Agreement Terms for Commercial Supply

This exhibit regarding certain supply agreement terms has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

Exhibit J
Development Plan

This exhibit regarding certain development plans has been omitted pursuant to Item 601(a)(5) of Regulation S-K because the information contained therein is not material and is not otherwise publicly disclosed. Aerie will furnish supplementally a copy of the exhibit to the Securities and Exchange Commission or its staff upon request.

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 25, 2021 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 25, 2021

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 26, 2021

/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 26, 2021

/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, 2020 (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 26, 2021

/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, 2020 (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 26, 2021

/s/ RICHARD J. RUBINO
Richard J. Rubino
Chief Financial Officer
(Principal Financial and Accounting Officer)