

[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-K**

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

For the fiscal year ended December 31, 2020

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 001-38709

Osmotica Pharmaceuticals plc

(Exact name of registrant as specified in its charter)

Ireland

(State or other jurisdiction of
incorporation or organization)

Not Applicable

(I.R.S. Employer
Identification No.)

**400 Crossing Boulevard
Bridgewater, NJ 08807**

(Address of principal executive offices)
(Zip Code)

(908) 809-1300

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, \$0.01 nominal value per share	OSMT	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange 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 (\$232.405 of this chapter) 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 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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
			Emerging growth company <input checked="" type="checkbox"/>

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 Exchange Act). Yes No

The aggregate market value of the voting and non-voting shares held by non-affiliates of the registrant on June 30, 2020, based upon the closing price of \$6.73 of the registrant's ordinary shares as reported on the Nasdaq Global Select Market, was approximately \$78.9 million.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding at March 29, 2021
Ordinary shares, \$0.01 nominal value per share	62,719,131 shares

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2021 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III items 10-14 of this Annual Report on Form 10-K.

[Table of Contents](#)

TABLE OF CONTENTS

	<u>Page</u>
PART I	
<u>Item 1. Business</u>	5
<u>Item 1A. Risk Factors</u>	31
<u>Item 1B. Unresolved Staff Comments</u>	86
<u>Item 2. Properties</u>	86
<u>Item 3. Legal Proceedings</u>	86
<u>Item 4. Mine Safety Disclosures</u>	87
PART II	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	88
<u>Item 6. Selected Financial Data</u>	88
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	89
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	110
<u>Item 8. Financial Statements and Supplementary Data</u>	111
<u>INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</u>	111
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	149
<u>Item 9A. Controls and Procedures</u>	149
<u>Item 9B. Other Information</u>	150
PART III	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	150
<u>Item 11. Executive Compensation</u>	150
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	150
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	150
<u>Item 14. Principal Accountant Fees and Services</u>	150
PART IV	
<u>Item 15. Exhibits and Financial Statement Schedules</u>	150
<u>Item 16. Form 10-K Summary</u>	151
<u>SIGNATURES</u>	157



Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "should," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives and financial needs. Examples of forward-looking statements include, among others, statements we make regarding: our intentions, beliefs or current expectations concerning, among other things, our review of strategic alternatives to maximize shareholder value, future operations; future financial performance, trends and events, particularly relating to sales of current products and the development, approval and introduction of new products; U.S. Food and Drug Administration, or the FDA and other regulatory applications, approvals and actions; the continuation of historical trends; our ability to manage costs and service our debt; and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs.

We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following:

- if we are unable to successfully develop or commercialize new products, or do so on a timely or cost effective basis, our operating results will suffer;
- due to our dependence on a limited number of products, our business could be materially adversely affected if one or more of our key products do not perform as well as expected;
- failures of or delays in clinical trials could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales for new products;
- we are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes;
- as of December 31, 2020, we had total outstanding indebtedness of approximately \$219.5 million (net of deferred financing costs), and we had unused commitments of \$50.0 million under our senior secured credit facilities. Our substantial debt could adversely affect our liquidity and our ability to raise additional capital to fund operations and could limit our ability to pursue our growth strategy or react to changes in the economy or our industry;
- we face intense competition from both brand and generic companies, which could materially adversely affect our financial results and significantly limit our growth;
- a business interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on could have a material adverse effect on our business;
- our profitability depends on our major customers, and if our relationships with them do not continue as expected, our business, prospects and results of operations could materially suffer;
- if we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell our products;

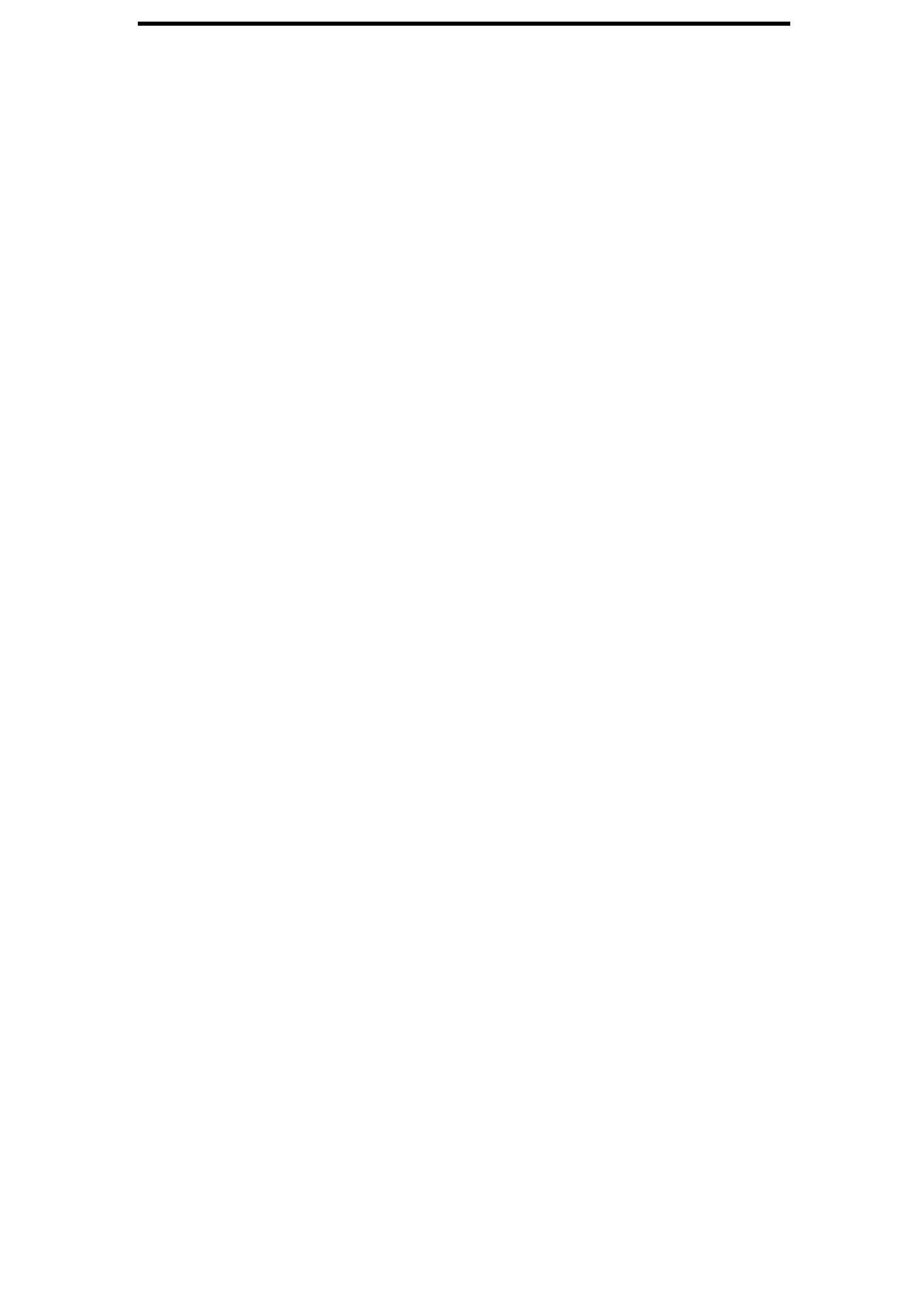


Table of Contents

- our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business;
- our profitability depends on coverage and reimbursement by governmental authorities and other third-party payors and healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels;
- we are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations;
- our products or product candidates may cause adverse side effects that could delay or prevent their regulatory approval, or result in significant negative consequences following regulatory approval;
- manufacturing or quality control problems may damage our reputation, require costly remedial activities or otherwise negatively impact our business; and
- other factors that are described in “Risk Factors,” beginning on page 31 of this Annual Report on Form 10-K.

The forward-looking statements included in this Annual Report on Form 10-K are made only as of the date hereof. You should not rely upon forward-looking statements as predictions of future events. We cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by applicable law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date hereof to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our ordinary shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary and other risks that we face can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC, before making an investment decision regarding our ordinary shares.

- Due to our dependence on a limited number of products, our business could be materially adversely affected if one or more of our key products do not perform as well as expected.
- Our business may be adversely affected by the ongoing coronavirus outbreak.
- If we are unable to successfully develop or commercialize new products, or to do so on a timely or cost effective basis, or to extend life cycles of existing products, our operating results will suffer.
- Our profitability depends on our major customers. If these relationships do not continue as expected, including as a result of the continuing trend of consolidation of certain customer groups, our business, financial condition, prospects and results of operations could materially suffer.
- We face intense competition from both brand and generic companies, including companies that sell branded generics or authorized generics, which could significantly limit our growth and materially adversely affect our financial results.
- Our branded pharmaceutical expenditures may not result in commercially successful products.



[Table of Contents](#)

- There is no certainty that we will be able to execute on any strategic alternatives to maximize shareholder value. If we are unable to execute such strategic alternatives, we may be forced to significantly cut costs.
- We expend a significant amount of resources on research and development, including milestones on in licensed products, which may not lead to successful product introductions.
- Upneeq® may fail to achieve market acceptance by clinicians and patients, or others in the medical community, and the market opportunity for Upneeq may be smaller than we estimate.
- If we are unable to maintain our sales, marketing and distribution capabilities, or establish additional capabilities if and when necessary, we may not be successful in commercializing Upneeq.
- If our products or product candidates do not produce the intended effects, our business may suffer.
- Failures of or delays in clinical trials are common and have many causes, and such failures or delays could result in increased costs to us and could prevent or delay our ability to obtain regulatory approval and commence product sales for new products.
- Our profitability depends on coverage and reimbursement by governmental authorities, private health plans, MCOs and other third party payors; healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels.
- The drug regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes.

PART I

ITEM 1.BUSINESS

Overview

We are a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. In 2020, we continued to transition our business to a specialty pharmaceutical company focused on proprietary products primarily in the eye care and neuroscience areas. The primary drivers of our strategy are highlighted by the recent FDA approval of and commercial launch of RVL-1201, or Upneeq, and the resubmission of our new drug application, or NDA, for arbaclofen extended-release (ER) tablets. Although we received a complete response letter, or CRL, from the FDA with respect to the arbaclofen ER NDA, we continue to support the filing and are evaluating a path forward for FDA approval.

In 2020, we generated total revenues of \$177.9 million across our portfolio of promoted specialty eye care, women's health and neurology products, and other non-promoted products, many of which are complex formulations of generic drugs. Our women's health products include Divigel® (estradiol gel, 0.1%) for the treatment of moderate to severe vasomotor symptoms due to menopause. Our neurology products include M-72 (methylphenidate hydrochloride extended-release tablets, 72 mg) for the treatment of attention deficit hyperactivity disorder, or ADHD, in patients aged 13 to 65 and Osmolex ER (amantadine extended-release tablets) for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions, which are involuntary muscle movements caused by certain medications, in adults. Some of our products use our proprietary osmotic-release drug delivery system, Osmodex®, which we believe may offer advantages over alternative ER technologies.

In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution, 0.1%), the first approved non-surgical treatment for acquired blepharoptosis, or droopy eyelid, in

Table of Contents

adults. We launched Upneeq in September 2020. Our in-person sales efforts are currently focused on ophthalmologists and optometrists while we explore broadening reach to other healthcare professionals. We process prescriptions and dispense Upneeq directly to patients from our own pharmacy, RVL Pharmacy. Also in July 2020, we announced that we entered into an exclusive license agreement with Santen Pharmaceutical Co., Ltd, or Santen, covering the development, registration, and commercialization rights in Japan, China, and other Asian countries as well as EMEA countries to RVL-1201. Santen is responsible for further development of RVL-1201 as well as regulatory approvals and commercialization of RVL-1201 in the licensed territories. Under the terms of the license agreement with Santen, we received an upfront cash payment of \$25 million and may receive up to an additional \$64 million in cash payments based on the achievement of regulatory and sales milestones in Santen's territories. We are also entitled to royalty payments on net sales of RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries.

Our sales representatives are fully engaged in the launch and in-person promotion of Upneeq, while we continue to maintain non-personal promotional efforts for certain other products in our portfolio, including M-72 in specialty neurology, Divigel in women's health and OB Complete, our family of prescription prenatal dietary supplements. As of December 31, 2020, our commercial portfolio consisted of approximately 35 promoted and non-promoted products. The cash flow from these products has contributed to our investments in research and development and business development activities. Some of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, and U.S. Drug Enforcement Administration, or DEA, regulation and quotas for API.

Many of our generic products compete in markets where barriers to entry are lower than markets in which certain of our promoted products compete. Generic products generally contribute most significantly to revenues and gross margins at the time of launch or in periods where no or a limited number of competing products have been approved and launched. In the United States, the consolidation of buyers in recent years has increased competitive pressures on the industry as a whole. As such, the timing of our new product launches can have a significant impact on our financial results. The entrance into the market of additional competition can have a negative impact on the pricing and volume of the affected products which are outside of our control. In particular, methylphenidate ER tablets, venlafaxine ER tablets, or VERT, and Lorzone have experienced, and are expected to continue to experience, significant pricing and market erosion due to additional competition from other generic pharmaceutical companies. This generic pricing erosion has resulted in lower net sales, revenue and profitability from methylphenidate ER tablets, VERT and Lorzone in 2020, and this erosion is expected to continue.

In June 2020, we resubmitted to the FDA our NDA for arbaclofen ER tablets for the alleviation of spasticity in Multiple Sclerosis ("MS") patients. In December 2020, we received a CRL from the FDA with respect to the arbaclofen ER NDA. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in the Total Numeric-transformed Ashworth Scale in the most affected limb, or TNmAS-MAL, scores comparing arbaclofen ER 40 mg to placebo, one of the co-primary endpoints. The FDA made a number of recommendations in its CRL, including that we conduct a new study in order to provide substantial evidence of efficacy of arbaclofen ER. We continue to believe that arbaclofen ER tablets can provide a meaningful benefit to patients. On March 4, 2021, we participated in a meeting with the FDA to discuss their recommendations in the CRL, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study.

In November 2020, we and our board of directors announced that we were undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include divestitures of non-strategic assets, re-financings, commercialization or collaboration agreements.

Our Strategy

Our goal is to become a leading specialty biopharmaceutical company by developing and commercializing drugs that provide meaningful benefit to patients with significant market opportunities, potential barriers to entry and long product life cycles. Our strategy to achieve this goal is focused on the following:

[Table of Contents](#)

Establish Upneeq as the First-line Treatment Option for Acquired Ptosis and Continue to Grow Sales.

Upneeq is the first and only FDA-approved treatment option for acquired ptosis (droopy eyelid). We believe that there is a significant commercial opportunity for Upneeq given the meaningful unmet need for a non-invasive treatment across millions of acquired ptosis patients in the United States. Our near-term focus is to gain acceptance for Upneeq among eye care providers as the first-line treatment for this common condition. While promotion of the product will rely heavily on our sales force engaging eye care practices during the first several months of launch, we have also started to raise patient awareness of acquired ptosis and Upneeq through social media (e.g., Facebook and Instagram) and are planning to increase direct-to-consumer advertising in 2021. We believe that healthcare provider interest in Upneeq may ultimately transcend eye care, and we are exploring introducing Upneeq to other therapeutic specialties in the future.

Support Sales of Other Marketed Products. In addition to Upneeq, we continue to market over 35 other products, which continue to generate sales and cash flow for our business. As of December 31, 2020, M-72, Divigel, and OB Complete were products that did not face generic competition and continue to be supported by non-personal promotional efforts such as telesales and providing product samples to physicians. Further, we continue to market a portfolio of non-promoted products highlighted by complex osmotic extended-release formulations methylphenidate ER and VERT. Our non-promoted products are supported by a national account team that manages relationships with major drug-buying consortia, pharmaceutical wholesalers and retailers in the United States.

Successfully Develop Our Osmodex Product Pipeline. We are focused on advancing the development of our clinical programs to further diversify our revenue base. Arbaclofen ER is a late-stage development program that leverages our proprietary Osmodex drug delivery technology. Following the re-submission of the NDA upon completion of Phase III studies, we received a CRL from the FDA. We continue to believe the totality of clinical efficacy and safety data from our clinical studies support a path to FDA approval and that Arbaclofen ER represents an attractive potential product candidate with a significant addressable multiple sclerosis spasticity market in the United States. A study published in 2019 found that up to 913,900 people suffer from multiple sclerosis in the United States. Another study conducted from 1996 to 2003 found that approximately 84% of multiple sclerosis patients suffered from some degree of spasticity. With clinicians indicating that approximately 65% of multiple sclerosis patients with spasticity have received pharmacological treatment, we estimate arbaclofen ER's primary addressable patient population to be approximately 498,980 patients in the United States. We continue to develop other NDA and abbreviated new drug application, or ANDA, product candidates that leverage our proprietary Osmodex drug delivery technology. More specifically, OS870 is an NDA pipeline product intended to treat neurodegenerate disease. The program entered Phase I studies in December 2020 following a pre-IND meeting with the FDA in November 2020. We also continue to advance two additional generic neuroscience ANDA product candidates in various stages of development.

Opportunistically Acquire or In-License Rights to Clinically Differentiated Products, Pipeline Candidates or Technologies. We seek to selectively acquire or in-license approved products and late-stage product candidates that complement our existing product portfolio, pipeline, technology or commercial infrastructure. Our management team has a history of successfully executing and integrating product and company acquisitions, which we believe positions us to capitalize on these opportunities.

Upneeq (RVL-1201) for Acquired Blepharoptosis

We are focused on growing Upneeq with eye care professionals and providing a convenient prescription experience for patients through our pharmacy, RVL Pharmacy. RVL Pharmacy was established as a wholly-owned subsidiary of RVL Pharmaceuticals, Inc. (formerly Revitalid, Inc. and the NDA holder of Upneeq), which is our wholly-owned subsidiary commercializing Upneeq. RVL Pharmacy dispenses Upneeq only and operates only on a cash basis (i.e., it does not submit any claims to third party payors for prescriptions filled). As the first pharmacological treatment for acquired blepharoptosis approved by the FDA in the United States, we believe Upneeq represents an important therapy in the continuum of care for patients with acquired blepharoptosis.

Blepharoptosis, or ptosis, may be present at birth, called congenital blepharoptosis, or acquired over time due to age or illness, called acquired blepharoptosis. Ptosis manifests itself as mild, moderate or severe and can look like the following:

[Table of Contents](#)

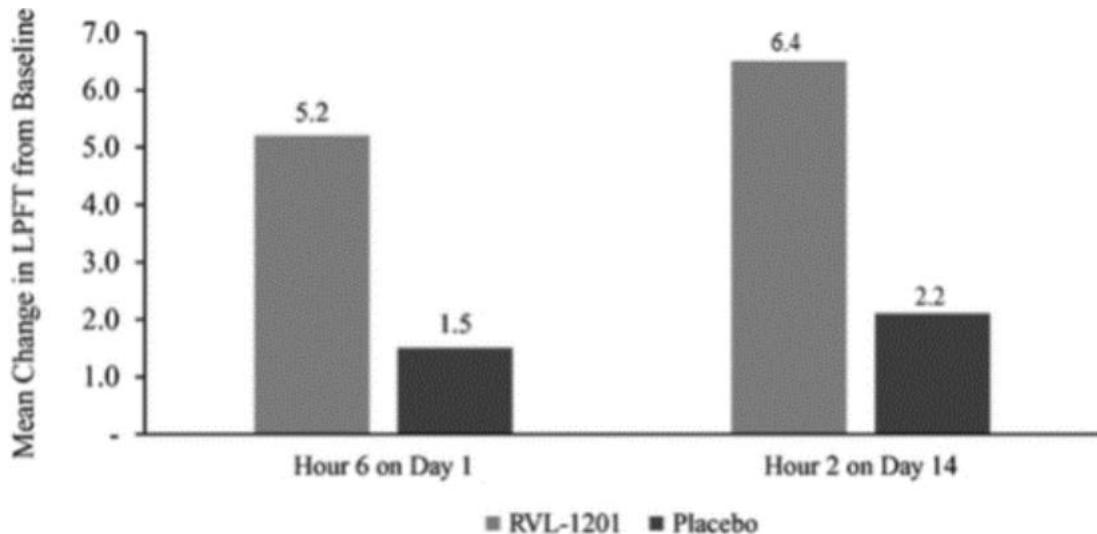


According to a 2018 survey of U.S. optometrists, ophthalmologists and surgeons, approximately 38% of blepharoptosis cases were mild and 48% were moderate. While no robust epidemiological studies exploring the prevalence of blepharoptosis exist, we believe it is a condition affecting millions of Americans. A study conducted in 1995 in the United Kingdom found some level of blepharoptosis in 12% of a sample set of adults age 50 years and older and that 90% of the sample had acquired blepharoptosis after birth.

We acquired the worldwide rights to RVL-1201 in 2017 in exchange for an upfront cash payment plus the obligation to make additional payments based on our net sales of the product. RVL-1201 is manufactured and supplied to us by Nephron Pharmaceuticals Corporation under an exclusive supply agreement that has a term of five years from the production of the initial commercial batches, and automatically renews for additional one-year periods unless either party provides at least 90 days' advance written notice of non-renewal. Milestone payments in an aggregate amount of up to \$2.1 million could become payable by us upon the achievement of certain regulatory and sales milestones.

Results from RVL-1201's initial Phase III clinical trial showed that the formulation met its primary efficacy endpoint and was well-tolerated. The 2:1 randomized, double-masked, placebo-controlled study comprised 140 patients with blepharoptosis in two treatment groups for 42 days. Patients treated with RVL-1201 received one full drop in each eye each morning while patients treated with the placebo also received one full drop in each eye each morning. The primary efficacy endpoints were change in baseline visual field using the Leicester Peripheral Field Test or LPFT, on Hour 6 Day 1 ($p=0.0003$) and Hour 2 on Day 14 ($p<0.0001$). As shown below, patients who received RVL-1201 once-daily experienced a statistically significant improvement in visual field when compared to the placebo group.

RVL-1201 Phase III Clinical Trial Efficacy: Leicester Peripheral Field Test (LPFT) (Intent-to-Treat Population)



RVL-1201 was generally well tolerated by patients in this clinical trial when administered once daily over a 6-week period. There were no serious adverse events identified from treatment with RVL-1201 in this Phase III clinical trial.

[Table of Contents](#)

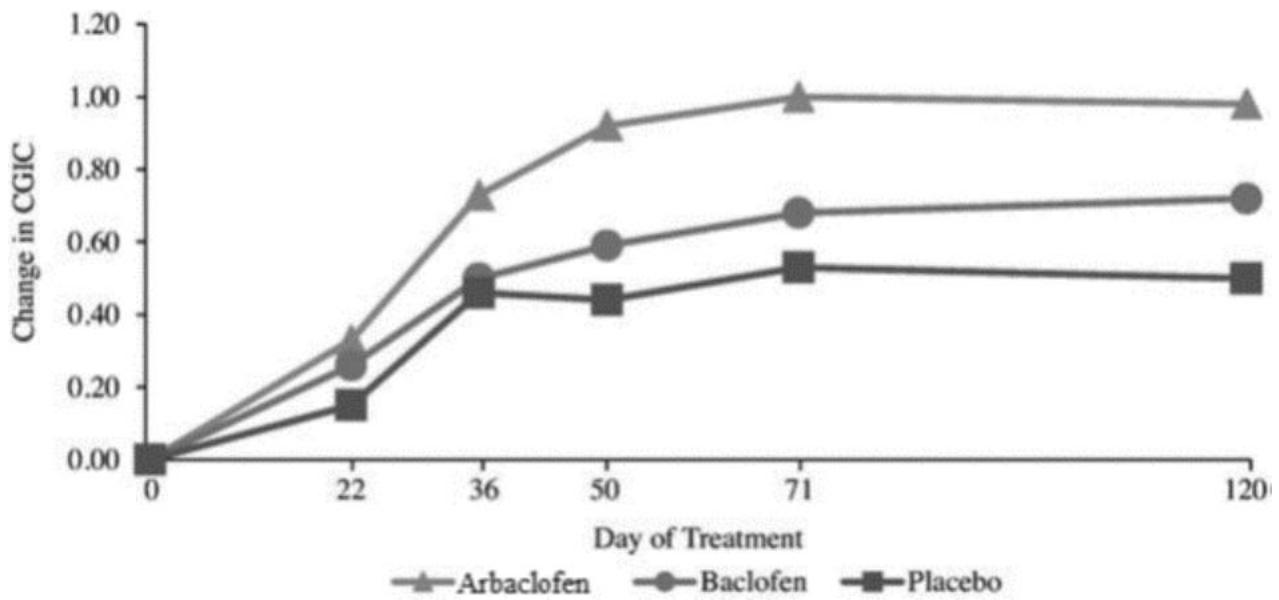
The second Phase III trial was a six-week randomized, multicenter, double-masked, placebo-controlled study to evaluate the safety and efficacy of once-daily treatment of RVL-1201 compared with placebo for the treatment of acquired blepharoptosis. The primary endpoint was a measurement of the mean change from baseline of the number of points seen out of a total of 35 in the top four rows of the LPFT as measured in two time points: hour 6 on day 1 and hour two on day 14. The secondary endpoint was a measurement of the distance between the center of the pupillary light reflex and the upper eyelid margin, or MRD-1. Topline results from the second Phase III trial showed that the trial met both the primary and secondary endpoints. The mean change from baseline on the LPFT on hour 6, day 1 was 6.3 for RVL-1201 versus 2.1 for vehicle ($p < 0.0001$) and on hour two, day 14 was 7.7 for RVL-1201 versus 2.4 for vehicle ($p < 0.0001$). The results also showed a statistically significant improvement in MRD-1 at 5 and 15 minutes, and 2 and 6 hours post dose on days 1 and 14. We also completed a 12-week randomized, multicenter, double-masked, placebo controlled safety study to evaluate the safety of RVL-1201 compared with vehicle for the treatment of acquired blepharoptosis. Results of the safety study showed RVL-1201 was well tolerated when administered once daily over a 12-week period where the majority of adverse events were mild and did not require treatment. On July 8, 2020, the FDA approved Upneeq for the treatment of acquired blepharoptosis, or droopy eyelid, in adults.

Arbaclofen ER for the Alleviation of Spasticity in Multiple Sclerosis (“MS”) Patients

We are also developing arbaclofen ER tablets. Baclofen is the only FDA-approved product that targets the GABA b receptor to treat spasticity. Baclofen is a racemic mixture comprised of an R and an S-isomer. The R-isomer of baclofen, or arbaclofen, has been shown in vivo to be up to 100 times more effective at targeting the GABA b receptor than the S-isomer. We developed our product candidate arbaclofen ER, or arbaclofen, using our proprietary Osmodex drug delivery system for the treatment of spasticity in multiple sclerosis patients. Arbaclofen has received orphan drug designation by the FDA in this indication, and we have patent coverage for arbaclofen extending to 2036.

In 2014, we completed our initial Phase III clinical trial exploring the efficacy, safety and tolerability of arbaclofen in the treatment of spasticity associated with multiple sclerosis. The multicenter, randomized (1:1:1), double-blind, active and placebo-controlled, 16-week study included 341 patients across three groups: Arbaclofen tablets 40 mg/day, baclofen 80 mg/day and placebo. This study compared the efficacy and safety of arbaclofen doses (20 mg/day for 14 days, 30 mg/day for 14 days, and 40 mg/day for 12 weeks) with baclofen tablets (40 mg/day for 14 days, 60 mg/day for 14 days, and 80 mg/day for 12 weeks) against a placebo. The trial’s co-primary efficacy endpoints were Clinician Global Impression of Change, or CGIC, and Total Numeric-transformed Ashworth Scale in the most affected limb, or TNmAS-MAL. As shown below, in this Phase III clinical trial, arbaclofen demonstrated a statistically significant improvement in CGIC when compared to the placebo while baclofen failed to demonstrate a statistically significant improvement in CGIC when compared to the placebo.

Summary of Change in CGIC Score by Treatment Day



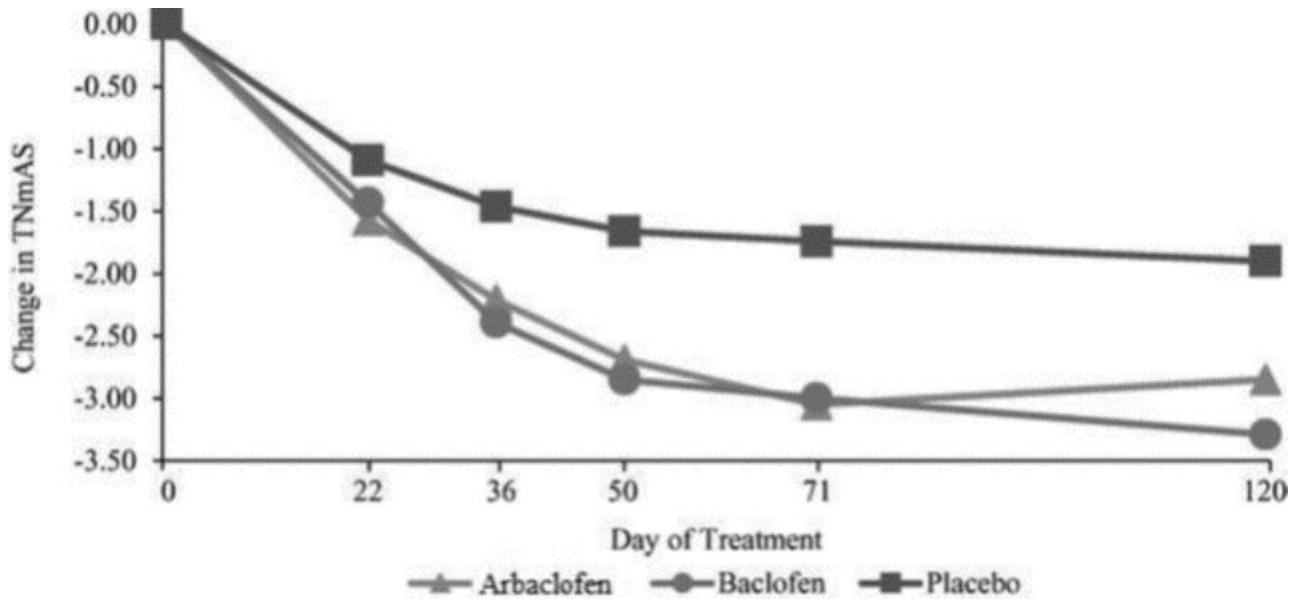
CGIC Day 120	Summary of CGIC Score Results, Intent-to-Treat Population(1)		
	Statistic	Arbaclofen	Placebo
LS Mean (standard error)	1.00 (0.12)	0.68 (0.12)	0.52 (0.11)
p-value vs placebo	0.0004	0.2434	

(1) Least squares means (LS Means) and p-values from analysis of covariance model including factors for site and treatment group

[Table of Contents](#)

As shown below, arbaclofen also demonstrated a statistically significant improvement in the TNmAS-MAL in most affected limb when compared to the placebo.

Summary of Change in TNmAS Score by Treatment Day



TNmAS Day 120	Summary of TNmAS Results, Intent-to-Treat Population(1)		
	Statistic	Arbaclofen	Baclofen
	LS Mean (standard error)	-2.9 (0.24)	-3.32 (0.25)
	p-value vs placebo	0.0006	<0.0001

(1) LS Means and p-values from analysis of covariance model including factors for site and treatment group

This clinical trial supported our conclusion that daily treatment with arbaclofen was safe and well tolerated by subjects with muscle spasticity related to multiple sclerosis. Adverse events reported in this study were consistent with the expected adverse events for baclofen, and there did not appear to be any new or unexpected safety issues relative to treatment with arbaclofen extended-release tablets. The overall incidence of treatment emergent adverse events, or TEAEs, and the number of TEAEs leading to discontinuation from the study were lower in the arbaclofen group compared to the baclofen group.

[Table of Contents](#)

Preferred Term	Summary of Treatment Emergency Adverse Events >2%, Safety Population			
	Arbaclofen (N=110) n (%)	Baclofen (N=113) n (%)	Placebo (N=118) n (%)	All Subjects (N=341) n (%)
Somnolence	17 (15.5)	27 (23.9)	6 (5.1)	50 (14.7)
Dizziness	8 (7.3)	12 (10.6)	4 (3.4)	24 (7.0)
Headache	8 (7.3)	7 (6.2)	1 (0.8)	16 (4.7)
Multiple sclerosis relapse	3 (2.7)	0 (0.0)	4 (3.4)	7 (2.1)
Muscle spasticity	3 (2.7)	2 (1.8)	2 (1.7)	7 (2.1)
Urinary tract infection	9 (8.2)	12 (10.6)	6 (5.1)	27 (7.9)
Nasopharyngitis	3 (2.7)	2 (1.8)	4 (3.4)	9 (2.6)
Influenza	4 (3.6)	0 (0.0)	1 (0.8)	5 (1.5)
Asthenia	13 (11.8)	21 (18.6)	5 (4.2)	39 (11.4)
Fatigue	4 (3.6)	4 (3.5)	2 (1.7)	10 (2.9)
Irritability	3 (2.7)	2 (1.8)	1 (0.8)	6 (1.8)
Muscular weakness	12 (10.9)	13 (11.5)	3 (2.5)	28 (8.2)
Pollakiuria	6 (5.5)	11 (9.7)	3 (2.5)	20 (5.9)
Urinary incontinence	3 (2.7)	4 (3.5)	2 (1.7)	9 (2.6)
Micturition urgency	0 (0.0)	6 (5.3)	0 (0.0)	6 (1.8)
Nocturia	0 (0.0)	4 (3.5)	1 (0.8)	5 (1.5)
Nausea	4 (3.6)	4 (3.5)	2 (1.7)	10 (2.9)
Dry mouth	1 (0.9)	7 (6.2)	0 (0.0)	8 (2.3)
Fall	1 (0.9)	3 (2.7)	2 (1.7)	6 (1.8)
Ear and labyrinth disorders	5 (4.5)	7 (6.2)	1 (0.8)	13 (3.8)
Vertigo	3 (2.7)	6 (5.3)	0 (0.0)	9 (2.6)
Cough	0 (0.0)	3 (2.7)	0 (0.0)	3 (0.9)

The results are reported as n (%) for the safety population.

The results summarized in the table and charts above are from the corrected dataset from the initial Phase III clinical trial. On June 10, 2015, Osmotica Holdings Corp Limited submitted an NDA containing data from this initial Phase III clinical trial, which was conducted and completed prior to the Business Combination. During the NDA review process, the FDA requested an independent audit of five of the 35 study sites, which were located in Russia and Ukraine. The audit found numerous irregularities and deviations from good clinical practices, which led to a complete response letter on July 9, 2016. The audit observations were thoroughly investigated, and data were corrected where appropriate. In December 2016, we met with the FDA to discuss the path forward for the application. The FDA indicated that, based on the initial audit findings, it considered the data from the Phase III clinical trial to be insufficient to support a marketing application. Following the meeting, we decided to complete a single additional Phase III clinical trial.

In the first quarter of 2019, we received topline data from our second Phase III clinical trial of arbaclofen in multiple sclerosis patients with spasticity, or the 3004 study. The 3004 study was a multicenter, randomized, double-blind placebo controlled study in which treatment groups received either placebo, 40 mg arbaclofen per day or 80 mg arbaclofen per day. The co-primary endpoints were change from baseline in TNmAS-MAL on day 84, and CGIC scores on day 84. Arbaclofen did not meet the co-primary endpoint of showing greater improvement than placebo as measured by CGIC scores; however, the study did meet the co-primary endpoint of showing a statistically significant improvement in spasticity relative to placebo as measured by the TNmAS-MAL for both doses of arbaclofen ($p=0.0482$ and $p=0.0118$ for 40 mg and 80 mg per day, respectively).

However, positive mean CGIC values indicated all three treatment groups improved from baseline. Further, it appears that there was a dose-response relationship between the two strengths as the 80 mg per day dose exhibited a greater improvement in spasticity as assessed by the TNmAS-MAL values than the 40 mg per day dose. Though arbaclofen 80 mg per day had a higher discontinuation rate in the study, the safety and tolerability data were in line with previously



[Table of Contents](#)

reported results, most notably a somnolence incidence of 10.1% and 14.5% for the 40-mg and 80-mg treatment arms, respectively, compared to 10.1% for the placebo treatment arm. Somnolence is one of the most frequently reported dose-limiting adverse events associated with baclofen treatment today. Our analysis of the integrated 40 mg data from both the 3002 and 3004 studies exhibited a statistically significant benefit for subjects in both TNmAS-MAL and CGIC endpoints. Based on these results, we requested a Type C meeting with the FDA to address questions regarding our plans for resubmission of our NDA and in lieu of a face-to-face meeting we received written responses from the FDA in the fourth quarter of 2019.

In June 2020, we resubmitted to the FDA our NDA for arbaclofen ER tablets, and on December 28, 2020, the FDA issued a CRL. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, one of the co-primary endpoints. The FDA made recommendations in its CRL, including that we conduct a new study in order to provide substantial evidence of efficacy of arbaclofen ER. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL's recommendations and obtain advice on a path forward for the NDA. The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. If we are required to conduct any additional clinical trials for arbaclofen, our development costs will increase, our regulatory approval process could be delayed or denied and we may not be able to commercialize and commence sales of arbaclofen ER in the timeframe currently contemplated, if at all.

Our Technology

Osmodex: Our Proprietary Drug Delivery System

Certain of our products incorporate our Osmodex drug delivery technology. Our technology allows us to manufacture tablets with one or more active drugs, and in combinations of immediate-release, controlled-release, delayed-release and extended-release, or ER. We believe that our proprietary Osmodex drug delivery system is well-suited to address certain limitations of existing therapies that have less than optimal efficacy or unfavorable side effect profiles as a result of formulation, pharmacokinetic profiles or other complexities. However, whether our proprietary Osmodex drug delivery system will suitably be paired with a given API is not certain or predictable. Each successful pairing that we have achieved in the past was the result of rigorous research, development and innovation. With that approach, our research and development team has led the successful clinical development of approved NDAs incorporating our proprietary Osmodex drug delivery system, including Allegra D® (pseudoephedrine and H1 antagonist), venlafaxine extended-release tablets (VERT), Khedezla® (desvenlafaxine extended-release tablets) and Osmolex ER.

Our Portfolio

As of December 31, 2020, we marketed a diverse portfolio consisting of approximately 35 promoted and non-promoted products, several of which incorporate our proprietary Osmodex drug delivery system. Many of our existing products benefit from potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, and DEA regulation and quotas for API. The following table shows our promoted and non-promoted product portfolio at December 31, 2020.

[Table of Contents](#)

Promoted Products (in-person)	Indication	Osmodex Technology	U.S. Regulatory Status
<i>Eye Care</i>			
Upneeq	Acquired blepharoptosis (droopy eyelid)	No	Approved
<i>Promoted Products (telesales)</i>			
<i>Specialty Neurology</i>			
M-72	ADHD in patients aged 13 to 65	Yes	Approved
Arbaclofen ER	Multiple sclerosis spasticity	Yes	Phase III
OS870	Neurodegenerative disorder	Yes	Phase I
<i>Women's Health</i>			
Divigel	Menopause	No	Approved
OB Complete	Various dietary needs during prenatal, pregnancy and postnatal periods	No	Dietary Supplement
<i>Non-Promoted Products</i>			
Methylphenidate ER	ADHD	Yes	Approved
Venlafaxine ER tablets (VERT)	Major Depressive Disorder and Social Anxiety Disorder	Yes	Approved
Hydromorphone ER	Pain	Yes	Approved
Nifedipine ER*	Hypertension	Yes	Approved
Sodium Benzoate / Sodium Phenylacetate	Hyperammonemia	No	Approved
Oxybutynin ER*	Overactive bladder	Yes	Approved
Prescription Prenatal Vitamins	Nutritional requirements during pregnancy	No	Dietary Supplement
Chlorzoxazone (Lorzone AG)	Muscle spasms	No	Approved
Tramadol ER (ConZip AG)	Pain	No	Approved
Nitrofurantoin	Urinary tract infections	No	Approved
Osmodex ANDAs	Various	Yes	In Development (2)

- Out-licensed ANDAs with a commercial partner

Our promoted products are led by Upneeq, the first and only FDA-approved treatment for acquired blepharoptosis, or droopy eyelid, in adult patients, which was approved by FDA in July 2020 and was launched in September 2020. As the first pharmacological treatment for acquired blepharoptosis in the United States, Upneeq represents an important daily therapy in the continuum of care for patients with acquired blepharoptosis.

While our sales representatives are fully engaged in the launch and in-person promotion of Upneeq, we continue to maintain non-personal promotional efforts for certain other products in our portfolio, including M-72 in specialty neurology, Divigel in women's health, and OB Complete, our family of prescription prenatal dietary supplements. M-72, a novel once-daily dosage of a single 72-mg tablet of extended-release methylphenidate, was approved by the FDA in July 2017 to treat ADHD in patients aged 13 to 65. We launched M-72 in the United States in April 2018. We are the only provider to date of the 72-mg single-dose tablet. Accordingly, we believe there is a market opportunity for the convenience of the single daily dose offered by M-72, which studies have shown to be bioequivalent to two 36-mg methylphenidate ER tablets. As the only approved 72-mg single-dose tablet of methylphenidate in the United States, the FDA has designated M-72 as the reference standard. A reference standard is the drug product selected by the FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval. We have obtained patent protection through February 2037 covering certain aspects of the formulation of M-72 that prevent the accelerated release of methylphenidate when exposed to alcohol.

Divigel contains plant-based estradiol and is used as a hormone replacement therapy to treat moderate to severe vasomotor symptoms, which include hot flashes, sweating and flushing caused by menopause. The product was

[Table of Contents](#)

approved by the FDA in June 2007. Menopause typically occurs between the ages of 49 and 52 when a woman's menstrual cycle stops. As a result, a woman's ovaries cease producing hormones (estrogen and progesterone), which can lead to vasomotor symptoms. Accordingly, for patients experiencing moderate to severe symptoms, treatment focuses on hormonal replacement. Divigel is available to patients in fixed dose packets of five strengths, 0.25 mg, 0.50 mg, 0.75 mg, 1.0 mg and 1.25 mg. The gel is applied once daily to the upper thigh. The Divigel 1.0 mg dosage has been shown to reduce moderate to severe hot flashes by nearly half at two weeks of use and eliminate hot flashes by almost 80% at 12 weeks of use. Divigel is manufactured by Orion Corporation pursuant to a supply agreement that will expire in January 2026 and, unless terminated by either Orion Corporation or us upon at least two years' notice, will automatically renew for successive five-year terms.

VERT (venlafaxine extended release tablets) was approved in May 2008 and is indicated for the treatment of major depressive disorder, or MDD, and social anxiety disorder, or SAD. VERT is approved for four dosage strengths: 37.5 mg, 75 mg, 150 mg and 225 mg, and is available as a brand and authorized generic version. As of December 31, 2020, the FDA had approved two AB rated generic equivalents of the 37.5 mg strength, four AB rated generic equivalents of the 75 mg strength, five AB rated generic equivalents of the 150 mg strength, and five AB rated generic equivalents of the 225 mg strength. Lorzone is an immediate-release form of chlorzoxazone indicated for the treatment of acute musculoskeletal pain in conjunction with rest and physical therapy that was approved by the FDA in June 2010. It is available in two dosage strengths, 375 mg and 750 mg. We launched an authorized generic form of chlorzoxazone in April 2019. As of December 31, 2020, the FDA had approved five AB rated generic equivalents of the 375 mg strength and six AB rated generic equivalents of the 750 mg strength. ConZip, tramadol hydrochloride (a Schedule IV opioid), is indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. ConZip was approved by the FDA in May 2010, and is available in three strengths: 100 mg (25 mg immediate release/75 mg extended release), 200 mg (50 mg immediate release/150 mg extended release) and 300 mg (50 mg immediate release/250 mg extended release). We launched an authorized generic version of tramadol in 2015. There are currently no AB rated generic equivalents approved by the FDA.

Our NDA development pipeline is highlighted by arbaclofen ER. OS870, another product candidate that leverages our Osmodeix drug delivery system, is currently in Phase 1 clinical trials. Our non-promoted product portfolio includes methylphenidate ER and VERT as well as smaller volume ANDAs and prescription dietary supplements. As of December 31, 2020, our non-promoted pipeline included two generic neuroscience ANDA products in various stages of development.

Research and Development

Our research and development team leverages its expertise across a variety of scientific disciplines to formulate product candidates and advance programs through the drug development and approval process and post marketing studies. We have capabilities in regulatory affairs, pharmaceutical science, analytical chemistry, preclinical studies, clinical trial design and operations, quality assurance and compliance, medical affairs and pharmacovigilance. We deploy these competencies to advance a product candidate through the drug development process, and develop data and intellectual property to improve our products, support commercialization and extend product life cycles. Scientific staff in Buenos Aires, Argentina, Bridgewater, New Jersey and Marietta, Georgia use their expertise in formulation development (including in our proprietary Osmodeix drug delivery system), chemistry and material science to focus on identifying drug compounds for re-formulation to achieve either new therapeutic attributes (e.g., extended release) or indications. Our clinical development team utilizes its experience to design and implement clinical trials to support submission of NDAs for organically developed and in-licensed product candidates. Additionally, we perform early-stage manufacturing and technology transfer engineering and evaluate any unique intellectual property arising from these activities. For development candidates that we have elected to progress forward, scale-up process engineering has been performed at our manufacturing plant in Marietta, Georgia.

As of December 31, 2020, we had 84 employees in our research and development department worldwide. Our staff of research scientists has expertise in the drug development process, from pre-formulation studies and formulation development, to scale-up and manufacturing. The clinical development and medical affairs team assumes product stewardship from pre-clinical testing and first-in-human studies, Phase I, Phase II and Phase III clinical trials through to

[Table of Contents](#)

post-marketing studies, risk management and pharmacovigilance activities. Our research and development team has extensive experience developing and coordinating clinical trial programs and communicating with the FDA throughout the process to ensure proper trial design and an efficient clinical and drug development process. Our team has a successful track record of developing products and receiving FDA approval for NDAs and ANDAs.

Intellectual Property

We have built and continue to develop our intellectual property portfolio for our products and product candidates. We rely on our substantial know-how, technological innovation, patents, trademarks, trade secrets, other intellectual property and in-licensing opportunities to maintain and develop our competitive position. We pursue patent protection in the United States and selected international markets. As of December 31, 2020, we had 45 U.S. patents, 34 patents outside the United States and 25 pending patent applications, the last of which expires in 2039.

Competition

The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We will continue to face competition from various global pharmaceutical, biotechnology, specialty pharmaceutical and generic drug companies that engage in drug development activities. Many of our competitors have similar products that focus on the same diseases and conditions that our current and future pipeline products address. Many of our competitors have greater financial flexibility to deploy capital in certain areas as well as more commercial and other resources, marketing and manufacturing organizations, and larger research and development staff. As a result, these companies may be able to pursue strategies or approvals that we are not able to finance or otherwise pursue and may receive FDA, European Medicines Agency or other applicable regulatory approvals more efficiently or rapidly than us. Also, our competitors may have more experience in marketing and selling their products post-approval, and gaining market acceptance more quickly. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our products could become less competitive if our competitors are able to license or acquire technology that is more effective or less costly and thereby offer an improved or a cheaper alternative to our products. We expect any products that we develop and commercialize will compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product portfolio in our target commercial markets.

Government Regulation and Approval Process

Government authorities in the United States at the federal, state and local level, including the FDA, the Federal Trade Commission, or FTC, and the DEA, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of products such as those we market. For both currently marketed and future products, failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of operations.

Additionally, future healthcare legislation or other legislative proposals at the federal and state levels could bring about major changes in the affected health care systems, including statutory restrictions on the means that can be employed by brand and generic pharmaceutical companies to settle Paragraph IV patent litigations. We cannot predict the outcome of such initiatives, but such initiatives, if passed, could result in significant costs to us in terms of costs of compliance and penalties associated with failure to comply.

[Table of Contents](#)

Pharmaceutical Regulation in the United States

In the United States, the FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, Warning Letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug or a generic version of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- approval by an institutional review board, or IRB, before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's Current Good Manufacturing Practice, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- submission to the FDA of an NDA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

When developing a branded product and bringing it to market, the first step in proceeding to clinical studies is preclinical testing. Preclinical tests are intended to provide a laboratory or animal study evaluation of the product to determine its chemistry, formulation and stability. Toxicology studies are also performed to assess the potential safety of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of these studies are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials, including concerns that human research subjects are or would be exposed to an unreasonable and significant risk of illness or injury, and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB must review and approve

[Table of Contents](#)

the plan for any clinical trial and informed consent information for subjects before the trial commences and it must monitor the study until completed.

The FDA, the IRB or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. GCP requirements include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, unless a narrow regulatory exemption applies. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase I: In Phase I, through the initial introduction of the drug into healthy human volunteers or patients, the drug is tested to assess absorption, distribution, metabolism, elimination, pharmacokinetics and safety.
- Phase II: Phase II usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks.
- Phase III: Phase III clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase III clinical trials to demonstrate the efficacy of the drug. A single Phase III clinical trial with other confirmatory evidence may be sufficient in rare instances, for example, where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer or sponsor under an approved NDA is also subject to annual program fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, as amended, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that are intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapies. The FDA endeavors to review most applications subject to Standard Review within ten to twelve months whereas the FDA's goal is to review most Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the NDA unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective for the labeled indication.

[Table of Contents](#)

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter, which authorizes commercial marketing of the drug with specific prescribing information for specific indications, or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or certain problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on www.ClinicalTrials.gov. Information related to the product, subject 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 discuss certain results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label

[Table of Contents](#)

uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. There also are extensive DEA regulations applicable to controlled substances.

Adverse event reporting and submission of periodic reports is also required following FDA approval of an ANDA or NDA. Additionally, the FDA may require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to comply with cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments and list their marketed products with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, Warning Letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The Hatch-Waxman Amendments

505(b)(2) NDAs

The FDA is also authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) 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 from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications

The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs, for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where rate or extent of absorption are difficult or impossible to measure. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the reference listed drug. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the reference listed drug if it is intended for a different use or if it is not subject to, and requires, an approved Suitability Petition.



[Table of Contents](#)

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (i) that there is no patent listed with the FDA as covering the relevant branded product, (ii) that any patent listed as covering the branded product has expired, (iii) that the patent listed as covering the branded product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent or (iv) that any patent listed as covering the branded drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label 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 reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the Paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

For example, for listed drugs that were considered new chemical entities at the time of approval, an ANDA or 505(b)(2) application referencing that drug may not be filed with the FDA until the expiration of five years after approval of that drug, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. In addition, drugs approved for diseases for which the patient population is sufficiently small, or orphan indications, are entitled to a seven year data exclusivity period.

Orphan Drugs

Arbaclofen has received Orphan Drug Designation for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which means a disease or condition that affects fewer than 200,000 individuals in the United States, or affects more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from domestic sales of the product. Orphan drug designation must be requested before submitting an NDA, and both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act and FDA's implementing regulations at 21 C.F.R. Part 316. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

[Table of Contents](#)

Orphan drug designation entitles the applicant to incentives such as grant funding towards clinical study costs, tax advantages, and waivers of FDA user fees. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is also entitled to seven years of orphan drug exclusivity. During the seven-year marketing exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process and a subsequent grant of orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

DEA Regulation

Several of our products, including ConZip, methylphenidate ER (including M-72) and hydromorphone ER are regulated as “controlled substances” as defined in the Controlled Substances Act of 1970, as amended, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with, among other things, the control of handlers of controlled substances and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Methylphenidate (including methylphenidate ER and M-72) and hydromorphone (including hydromorphone ER) are listed as Schedule II drugs and tramadol hydrochloride (including ConZip) is listed as a Schedule IV drug by the DEA under the Controlled Substances Act. The manufacture, shipment, storage, sale and use of Schedule II drugs are subject to a high degree of regulation. For example, Schedule II drug prescriptions generally must be signed by a physician and may not be refilled without a new prescription. Substances in Schedule IV are considered to have a lower potential for abuse relative to substances in Schedule II. A prescription for controlled substances in Schedule IV may be issued by a practitioner through oral communication, in writing or by facsimile to the pharmacist and may be refilled if so authorized on the prescription or by call-in. In the future, our other potential products may also be listed by the DEA as controlled substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports must be made to the DEA, including, for example, distribution reports for Schedule II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and authorization must be obtained to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule II. Distributions of any Schedule II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA establishes annually an aggregate quota for how much of a Schedule II substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of any particular Schedule II substance that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule II substance for use in

[Table of Contents](#)

manufacturing. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our and our contract manufacturers' quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our and our contract manufacturers' quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products.

Regulation of Dietary Supplements

The formulation, manufacturing, packaging, labeling, advertising, distribution and sale of dietary supplements, such as our OB Complete family of prescription prenatal dietary supplements, are subject to regulation by multiple federal agencies, including the FDA, the FTC and the Consumer Product Safety Commission.

The Dietary Supplement Health and Education Act of 1994, or DSHEA, amended the FDCA to establish a new framework governing the composition, safety, labeling, manufacturing and marketing of dietary supplements. Generally, under the FDCA, dietary ingredients that were marketed in the United States prior to October 15, 1994 may be used in dietary supplements without first notifying the FDA. "New" dietary ingredients (i.e., dietary ingredients that were not marketed in the United States before October 15, 1994) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without being "chemically altered." A new dietary ingredient notification must provide the FDA evidence of a history of use or other evidence of safety establishing that use of the dietary ingredient will reasonably be expected to be safe. A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing of the new dietary ingredient. The FDA may determine that a new dietary ingredient notification does not provide an adequate basis to conclude that a dietary ingredient is reasonably expected to be safe. Such a determination could prevent the marketing of such dietary ingredient or a dietary supplement including such dietary ingredient.

All facilities that manufacture, process, package, or store food for human consumption, including dietary supplements, must register with the FDA as a food facility under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Facility registrations must be updated biennially. The FDA schedules periodic inspections at registered facilities to determine whether the inspected facilities are in compliance with applicable FDA regulations. The FDA's cGMP regulations for dietary supplements apply to manufacturers and holders of finished dietary supplement products, including dietary supplements manufactured outside the United States that are imported for sale into the United States. Among other things, the FDA's cGMP regulations: (i) require identity testing on all incoming dietary ingredients; (ii) call for a scientifically valid system for ensuring finished products meet all specifications; (iii) include requirements related to process controls, including statistical sampling of finished batches for testing and requirements for written procedures; and (iv) require extensive recordkeeping. The failure of a manufacturing facility to comply with the cGMP regulations renders products manufactured in such facility "adulterated" under the FDCA, and subjects such products and the manufacturer to a variety of potential FDA enforcement actions.

Dietary supplements are also regulated by various state and local governmental agencies. The FTC regulates the advertising of dietary supplements and the National Advertising Division, or NAD, of the Council of Better Business Bureaus oversees an industry sponsored, self-regulatory system that permits competitors to resolve disputes over advertising claims. The NAD has no enforcement authority of its own, but may refer matters to the FTC or the FDA for further action.

[Table of Contents](#)

Federal agencies, including the FDA and the FTC, have a variety of procedures and enforcement remedies available to them, including initiating investigations, issuing Warning Letters and cease and desist orders, requiring corrective labeling or advertising, requiring consumer redress, seeking injunctive relief or product seizures, imposing civil penalties or commencing criminal prosecution.

Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, the FDA requires, among other things, that companies that manufacture or distribute dietary supplements report serious adverse events associated with their products to the FDA and fulfill certain recordkeeping requirements for adverse events. Based on serious adverse event (or other) information, the FDA may take actions against dietary supplements or dietary ingredients that in its determination present a significant or unreasonable risk of illness or injury. In addition, the FDA could issue consumer warnings with respect to the products or ingredients in such products.

The FDA Food Safety Modernization Act, or FSMA, enacted on January 4, 2011, amended the FDCA to enhance the FDA's authority over various aspects of food regulation, including dietary supplements. Under the FSMA, the FDA is authorized to issue a mandatory recall when the FDA determines that there is a reasonable probability that a food, including a dietary supplement, is adulterated or misbranded and that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals. Also under the FSMA, the FDA has (i) expanded access to records; (ii) the authority to suspend food facility registrations and require high-risk imported food to be accompanied by a certification; (iii) stronger authority to administratively detain food; (iv) the authority to refuse admission of an imported food if it is from a foreign establishment to which a U.S. inspector is refused entry for an inspection; and (v) the authority to require that importers verify that the foods they import meet domestic standards.

The FSMA requirements may result in the detention and refusal of admission of imported products, the injunction of manufacturing of any dietary ingredients or dietary supplements until the FDA determines that such ingredients or products are in compliance, and the potential imposition of fees for re-inspection of noncompliant facilities.

The FDCA, as amended by the DSHEA, permits statements of nutritional support often referred to as "structure/function claims" to be included in labeling for dietary supplements without FDA premarket approval. FDA regulations require that dietary supplement manufacturers notify the FDA of those statements within 30 days of marketing. Among other things, the statements may describe the role of a dietary ingredient intended to affect the structure or function of the body or characterize the documented mechanism of action by which a dietary ingredient maintains such structure or function, but may not expressly or implicitly represent that a dietary supplement will diagnose, cure, mitigate, treat, or prevent a disease. A company that uses a statement of nutritional support in labeling must possess information substantiating that the statement is truthful and not misleading. If the FDA determines that a particular statement of nutritional support is an unacceptable drug claim or an unauthorized version of a health claim, or if the FDA determines that a particular claim is not adequately supported by available information or is otherwise false or misleading, the claim could not be used and any product bearing the claim could be subject to regulatory action.

The FTC and the FDA have pursued a coordinated effort to investigate the scientific substantiation for dietary supplement claims. Their efforts to date have resulted in a significant number of investigations and enforcement actions. Dietary supplement claims could also be the subject of inquiries from the NAD and states' Attorneys General.

The FDA has broad authority to enforce the FDCA provisions applicable to dietary supplements, including powers to issue a public warning or notice of violation letter to a company, publicize information about illegal products, request a voluntary recall, order a mandatory recall, administratively detain domestic products, detain products offered for import, request the U.S. Department of Justice, or DOJ, to initiate a seizure action, initiate an injunction action or a criminal prosecution in the U.S. courts and administratively revoke manufacturing facility registrations, thereby effectively enjoining manufacturing of dietary ingredients and dietary supplements without judicial process.

States also regulate foods and drugs under laws that generally parallel federal statutes. These products are also subject to state consumer health and safety regulations, such as the California Safe Drinking Water and Toxic Enforcement Act of 1986, or Proposition 65. Violation of Proposition 65 may result in substantial monetary penalties.

[Table of Contents](#)

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of our products. Government authorities and third-party payors increasingly are challenging the price of medical products and services. On the government side, there is a heightened focus, at both the federal and state levels, on cost containment under Medicaid, Medicare and other government benefit programs. For example, we are obligated under the Medicaid drug program to pay rebates on certain utilization of our products, under state Medicaid programs. Many state Medicaid programs have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our current products or future drug candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products. The focus on cost containment has also led to an increase in federal and state legislative initiatives related to drug prices, which could significantly influence the purchase of pharmaceutical products, resulting in lower prices and changes in product demand. If enacted, these changes could lead to reduced payments to pharmaceutical manufacturers.

In addition, third-party payors have been imposing additional requirements and restrictions on coverage and limiting reimbursement levels for pharmaceutical products. Third-party payors may require manufacturers to provide them with predetermined discounts from list prices and limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not include all of the FDA-approved pharmaceutical products for particular indications. Third-party payors may challenge the price and examine the medical necessity and cost-effectiveness of pharmaceutical products in addition to their safety and efficacy. Manufacturers may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of pharmaceutical products in addition to the costs required to obtain the FDA approvals. Adequate third-party reimbursement may not be available to enable manufacturers to maintain price levels sufficient to realize an appropriate return on their investment in drug development.

Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the United States. It is uncertain what other legislative proposals may be adopted or what actions federal, state, or private payors may take in response to any healthcare reform proposals or legislation. We cannot predict the effect such reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. The law includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates, (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts, (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees, (iv) require manufacturers to provide discounts on Medicaid Part D spending in the coverage gap for branded and authorized generic prescription drugs (which discount subsequent legislation increased beginning in 2019), and (v) levy a significant excise tax on the industry to fund the healthcare reform.

Over the past few years, there were ongoing efforts to modify or repeal all or certain provisions of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under the ACA for individuals who do not maintain mandated health insurance coverage beginning in 2019. The ACA has also been subject to judicial challenge. The case Texas v. Azar, which challenges the constitutionality of the ACA, including provisions that are unrelated to healthcare reform but were enacted as part of the ACA, was argued before the Supreme Court in November 2020. Pending resolution of the litigation, all of the ACA but the individual mandate to buy health insurance remains in effect.

Beyond the ACA, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the

COVID-19 pandemic, including an

[Table of Contents](#)

expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70%. A number of regulations were issued in late 2020 and early 2021. For example, revisions to the federal anti-kickback statute, now effective 2023, would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to PBMs and health plans. Some of these changes have been and may continue to be subject to legal challenge. For example, courts temporarily enjoined a new “most favored nation” payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would limit payment based on international drug price.

The nature and scope of health care reform in the wake of the transition from the previous administration to the current administration remains uncertain. The Department of Justice under the Biden administration informed the Supreme Court that the government no longer takes the position that the individual mandate is unconstitutional and cannot be severed from the rest of the ACA. President Biden has temporarily halted implementation of new rules issued immediately prior to the transition that had not yet taken effect (which include a number of health care reforms) to allow for review by the new administration. The revisions to the federal anti-kickback statute initially scheduled to take effect in 2022 now take effect in 2023. More generally, President Biden supported reforms to lower drug prices during his campaign for the presidency.

More generally, there has been considerable recent public and government scrutiny in the United States of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale.

We cannot predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Healthcare Regulations

Pharmaceutical companies are subject to various federal and state laws that are intended to combat health care fraud and abuse and that govern certain of our business practices, especially our interactions with third-party payors, healthcare providers, patients, customers and potential customers through sales and marketing or research and development activities. These include anti-kickback laws, false claims laws, sunshine laws, privacy laws and FDA regulation of advertising and promotion of pharmaceutical products.

Anti-kickback laws, including the federal Anti-Kickback Statute, make it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referral of an individual for, or the purchase, order or recommendation of, any good or service reimbursable by, a federal health care program (including our products). The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and patients, prescribers, purchasers and third party payors on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal fines and penalties of up to \$104,330 per violation and three times the amount of the unlawful remuneration. A new federal anti-kickback statute enacted in 2018 prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities and laboratories) and applies to services

[Table of Contents](#)

reimbursed by private health plans as well as government health care programs. Criminal sanctions (up to \$200,000 fine and ten years imprisonment) can be imposed for violations.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit knowingly presenting, or causing to be presented, claims for payment to the federal government (including Medicare and Medicaid) that are false or fraudulent (and, under the Federal False Claims Act, a claim is deemed false or fraudulent if it is made pursuant to an illegal kickback). 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. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in significant monetary penalties, including fines ranging from \$11,665 to \$23,331 for each false claim, and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other improper sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers’ and manufacturers’ compliance with applicable fraud and abuse laws.

The Federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, supplier or practitioner providing Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to \$20,866 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Federal criminal statutes prohibit, among other actions, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and 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. As with the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, may apply to products and services reimbursed by non-governmental third-party payors, including commercial payors. Additionally, there are state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or that otherwise restrict payments that may be made by pharmaceutical companies to healthcare providers. There are also state and foreign laws that require drug manufacturers to report marketing expenditures or pricing information.

Sunshine laws, including the federal Open Payments law enacted as part of the ACA, require pharmaceutical manufacturers to disclose payments and other transfers of value made to physicians and certain other health care providers or professionals. Under the federal Open Payments law pharmaceutical manufacturers are required to submit reports annually to the government. Failure to submit the required information may result in civil monetary penalties of up to an aggregate of \$176,495 per year (or up to an aggregate of \$1,176,638 per year for “knowing failures”) for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations. Certain states and foreign governments require the tracking and reporting of gifts, compensation and other remuneration to certain healthcare providers.

Privacy laws, including HIPAA, restrict how entities may use or disclose health information. Under HIPAA, covered entities are defined to include health care providers, such as physicians, hospitals,

pharmacies and laboratories, as well as

[Table of Contents](#)

health insurers. Although pharmaceutical manufacturers are not covered entities under HIPAA, our ability to acquire or use protected health information from covered entities to aid in our research, development, sales and marketing activities may be affected by HIPAA and other privacy laws. HIPAA, was amended by HITECH. Those changes were adopted in regulation through a final omnibus rule published on January 25, 2013. Among other things, HITECH and the omnibus rule made HIPAA's privacy and security standards directly applicable to "business associates," which are defined as contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

The FDA regulates the sale and marketing of prescription drug products and, among other things, prohibits pharmaceutical manufacturers from making false or misleading statements and from promoting products for unapproved uses. There has been an increase in government enforcement efforts at both the federal and state level. Numerous cases have been brought against pharmaceutical manufacturers under the Federal False Claims Act, alleging, among other things, that certain sales or marketing-related practices violate the Anti-Kickback Statute or the FDA's regulations, and many of these cases have resulted in settlement agreements under which the companies were required to change certain practices, pay substantial fines and operate under the supervision of a federally appointed monitor for a period of years. Due to the breadth of these laws and their implementing regulations and the absence of guidance in some cases, it is possible that our practices might be challenged by government authorities. Violations of fraud and abuse laws may be punishable by civil and criminal sanctions including fines, civil monetary penalties, as well as the possibility of exclusion of our products from payment by federal health care programs.

Government Price Reporting

We must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid drug rebate program, the "federal ceiling price" drug pricing program, the 340B drug pricing program and the Medicare Part D Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid drug rebate program and Medicare Part B. The calculations necessary to determine the prices reported are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities, and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to such agency or the amounts themselves. Because the process for making these calculations, and our judgments supporting these calculations, involve subjective decisions, these calculations are subject to audit. In the event that a government authority challenges our report of payments, such authority may impose civil and criminal sanctions, which could have a material adverse effect on our business. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Many government and third-party payors reimburse the purchase of certain prescription drugs based on a drug's AWP. In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, which they have suggested have led to excessive payments by state and federal government agencies for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various state and federal court actions alleging improper or fraudulent practices related to the reporting of AWP.

Drug Pedigree Laws

State and federal governments have proposed or passed various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the

[Table of Contents](#)

purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, companies are required to file with the FTC and DOJ certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC also enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Information about our Executive Officers

Brian Markison, 61, became a director and our Chief Executive Officer in 2016. Mr. Markison has been a healthcare industry advisor to Avista since September 2012 and has more than 30 years of operational, marketing, commercial development and sales experience with international pharmaceutical companies. From July 2011 to July 2012, he served as the President and Chief Executive Officer and member of the board of directors of Fougera Pharmaceuticals Inc., a specialty pharmaceutical company in dermatology that was sold to Sandoz Ltd., the generics division of Novartis AG. Before leading Fougera, Mr. Markison was Chairman and Chief Executive Officer of King Pharmaceuticals, Inc., which he joined as Chief Operating Officer in March 2004. He was promoted to President and Chief Executive Officer later that year and elected Chairman in 2007. Prior to joining King Pharmaceuticals, Inc., Mr. Markison held various senior leadership positions at Bristol-Myers Squibb Company, including President of Oncology, Virology and Oncology Therapeutics Network; President of Neuroscience, Infectious Disease and Dermatology; and Senior Vice President, Operational Excellence and Productivity. He serves as Chairman of the board of Lantheus Holdings, Inc. and is on the board of directors of Avista Healthcare Public Acquisition Corp., National Spine and Pain Centers, LLC and Braeburn

[Table of Contents](#)

Pharmaceuticals, Inc. He is also a Director of the College of New Jersey. Mr. Markison received a B.S. degree from Iona College.

Tina DeVries, Ph.D., 60, became our Executive Vice President, Research & Development in May 2016. Dr. deVries most recently served as the Principal of TM deVries Consulting, LLC from October 2014 to April 2016. From October 2013 to September 2014, she held the position of Vice President of Nonclinical and Clinical Pharmacology at Actavis plc. Dr. deVries previously served as the Vice President of Clinical Pharmacology at Warner Chilcott plc, a specialty pharmaceutical company, from April 1996 until the company was acquired by Actavis in October 2013. Dr. deVries holds a B.S. in Pharmacy and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Andrew Einhorn, 61, became our Chief Financial Officer in September 2017. Mr. Einhorn has more than 15 years of experience in the pharmaceutical industry. From March 2014 to March 2017, Mr. Einhorn served as the Chief Financial Officer of Edge Therapeutics, Inc., a clinical-stage biotechnology company that he joined as Executive Vice President of Corporate Development in May 2013. Prior to that, he was a co-founder, Executive Vice President and Chief Financial Officer at Oceana Therapeutics, Inc. from May 2008 to January 2012. Previously, Mr. Einhorn was a co-founder and Chief Financial Officer of both Esprit Pharma, Inc., from June 2005 to October 2007, and ESP Pharma, Inc., from April 2003 to March 2005. From 1983 to 2003, Mr. Einhorn was an investment banker with Credit Lyonnais Securities, PNC Capital Markets, Chase Securities, Inc., Bankers Trust Company and the Chase Manhattan Bank. Mr. Einhorn is licensed as a Certified Public Accountant in the State of New Jersey and holds a B.S. in Finance and Accounting from The American University.

James Schaub, 39, has served as our Executive Vice President and Chief Operating Officer since 2016. Prior to that he served as Chief Operating Officer, Trigen Laboratories beginning in December 2013. Mr. Schaub previously served as Vice President, M&A of Fougera Pharmaceuticals, Inc. from August 2011 to September 2012. Prior to that, Mr. Schaub spent five years with King Pharmaceuticals, Inc., where he held several commercial roles of increasing responsibility. He joined our company in December 2013. Mr. Schaub holds a B.A. in Economics from Middlebury College and an M.B.A. from Rutgers Business School.

Christopher Klein, 57, became our General Counsel and Secretary in December 2013. Mr. Klein previously served as the General Counsel of Fougera Pharmaceuticals Inc. from August 2011 to September 2012. Prior to his time at Fougera Pharmaceuticals Inc., Mr. Klein spent six years with King Pharmaceuticals, Inc. where he held the position of Deputy General Counsel prior to King Pharmaceuticals, Inc.'s acquisition by Pfizer, Inc. Prior to that, Mr. Klein spent six years in senior legal roles with Bristol-Myers Squibb Company. Mr. Klein holds a B.A. in Biology from Adelphi University, an M.A. in Education from Columbia University and a J.D. from Fordham University.

Employees

As of December 31, 2020, we had a total of 302 full time employees (including 39 employees in Argentina and two employees in Hungary). We have one union employee in Argentina who is subject to a collective bargaining agreement. Otherwise, we have no collective bargaining agreements with our employees and none are represented by labor unions. We consider our current relations with our employees to be good.

Corporate Information

Our principal executive offices are located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807, and our registered office in Ireland is 25-28 North Wall Quay, Dublin 1, Ireland and our telephone number is (908) 809-1300. Our website address is www.osmotica.com.

[Table of Contents](#)

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, or the Exchange Act. We file periodic reports, current reports, proxy statements, and other information with the Securities and Exchange Commission, or SEC. The SEC maintains a website at <http://www.sec.gov> that contains all of our information that has been filed or furnished electronically with the SEC. We make available free of charge on our website a link to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and 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 such material is electronically filed with, or furnished to, the SEC.

ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. We have presented the below risks as “Risks related to our business,” “Risks related to the development and commercialization of products,” “Risks related to our intellectual property rights,” “Risks related to our industry,” “Risks related to our indebtedness,” “Risks related to our ordinary shares,” “Risks related to being an Irish corporation listing ordinary shares,” “Risks related to taxation” and “General risks.” If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially and adversely affect our business, prospects, operating results or financial condition.

Risks related to our business

Due to our dependence on a limited number of products, our business could be materially adversely affected if one or more of our key products do not perform as well as expected.

We generate a significant portion of our total revenues and gross profit from the sale of a limited number of products. For the years ended December 31, 2020 and 2019, our top ten products by product sales accounted for approximately 95% and approximately 97%, respectively, of our total revenues and a significant portion of our gross profit. Any material adverse developments, including increased competition, pricing pressures or supply shortages, with respect to the sale or use of one or more of these products or our failure to successfully introduce new key products, could have a material adverse effect on our revenues and gross profit. For example, we have experienced significant increased pricing and market share pressure on methylphenidate ER, VERT and Lorzone due to additional market entrants, which we expect to continue.

Upneeq may fail to achieve market acceptance by clinicians and patients, or others in the medical community, and the market opportunity for Upneeq may be smaller than we estimate.

Upneeq may fail to gain market acceptance by clinicians, patients, and others in the medical community. While there are no drugs other than Upneeq currently approved in the United States for the treatment of acquired blepharoptosis in adults, some clinicians may treat blepharoptosis with off-label use of other products or with surgery, or they may not treat the condition at all. Additionally, as the first drug approved for blepharoptosis, we spend significant resources on educating clinicians about the disorder and the impact on patients' lives. Our education efforts may not be sufficient to convince clinicians to prescribe Upneeq for their patients suffering from blepharoptosis.

If Upneeq does not achieve adequate levels of acceptance by clinicians or patients, we will not generate significant product revenues. The degree of market acceptance of Upneeq will depend on a number of factors, including:

- the efficacy and potential advantages of Upneeq compared to alternative treatments, including surgery;
- the price at which we offer Upneeq;

Table of Contents

- the clinical indication for which Upneeq is approved;
- the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies;
- the effectiveness of our marketing and distribution support, and our available resources to support adequate marketing efforts; and
- the timing of market introduction of competitive products.

Our assessment of the potential market opportunity for Upneeq is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of acquired blepharoptosis, or droopy eye lid, is difficult to precisely estimate. The results from our physician and patient surveys may be less reflective of the acquired blepharoptosis population as a whole than a survey conducted with a larger sample size. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size or otherwise fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for Upneeq may be smaller than we expect, and as a result our product revenue may be less than expected. The uncertainty with respect to the future progression of the COVID-19 pandemic and its long-term effects may also adversely impact the accuracy of such estimates and our potential market opportunity for Upneeq.

Upneeq is only available through our pharmacy, RVL Pharmacy, and is a cash only product not covered by any private or government insurance. We control the price for Upneeq which is consistent for all patients. Although we believe this cash only model with consistent pricing is a benefit to patients, the price or distribution model may not be accepted by clinicians or patients and may negatively impact filled prescriptions and sales of Upneeq.

Our decision to establish and dispense Upneeq exclusively through a wholly-owned mail order pharmacy represents a new distribution model for us and has expanded the scope of applicable government regulation and may provoke government scrutiny.

We have made the decision to dispense Upneeq solely through a mail order pharmacy operated by RVL Pharmacy LLC. RVL Pharmacy was established as a wholly-owned subsidiary of RVL Pharmaceuticals, Inc. (formerly RevitaLid, Inc. and the NDA holder of Upneeq), which is our wholly-owned subsidiary commercializing Upneeq. The pharmacy dispenses only Upneeq and operates only on a cash basis (i.e., it does not submit any claims to third party payors for prescriptions filled). We cannot be certain that this business model will be successful. As a pharmacy, RVL Pharmacy is subject to certain regulations that have not historically applied to our operations, including state pharmacy licensure requirements and privacy and data security laws applicable only to health care providers. For example, none of our companies have historically been a covered entity under HIPAA. Going forward, we may make the determination that one or more of our companies, such as RVL Pharmaceuticals, Inc. or RVL Pharmacy, may be a HIPAA covered entity. HIPAA covered entities are subject to comprehensive data privacy, security and breach notification obligations and non-compliance may result in civil money penalties as well as criminal fines and imprisonment. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our pharmacy operations. For example, pharmacies licensed under California law are subject to California's Confidentiality of Medical Information Act, CMIA, which places restrictions on the use and disclosure of medical information by providers of health care, including pharmacies, and can impose a significant compliance

[Table of Contents](#)

obligation on such providers. Violations of the CMIA can result in criminal, civil and administrative sanctions, and the CMIA also provides individuals a private right of action with respect to disclosures of their health information that violate CMIA.

Compliance with data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, and restrict our ability to collect, use and disclose data. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Also, certain pharmacies owned by or closely affiliated with pharmaceutical manufacturers have been subject to government scrutiny in the past. Although we do not expect the pharmacy to submit claims to third party payors and anticipate that patients will be responsible for the costs associated with the product, there can be no assurance that RVL Pharmacy and its relationship to RVL Pharmaceuticals, Inc. will not be subject to government scrutiny. Such scrutiny could result in increased regulatory costs to us or cause us to be the subject of a regulatory investigation or sanctions, which could adversely affect our business, results of operations or financial condition, which would materially harm our business.

Our business may be adversely affected by the ongoing coronavirus outbreak.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. COVID-19 has since spread to other regions in China and other countries, including the United States, where we have our executive offices and principal operations. Infections and deaths related to COVID-19 have disrupted the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay the FDA approval with respect to, our clinical trials and product candidates. It is unknown how long these disruptions could continue. Other known and unknown factors caused by COVID-19 could also materially delay our clinical trials that may be required for these or other product candidates, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and/or approval of our product candidates.

The economic impact of COVID-19's spread, which has caused a broad impact globally, such as restrictions on travel and quarantine policies put into place by businesses and governments, may adversely affect us. In particular, we expect that the COVID-19 outbreak will negatively affect demand for our products by limiting the ability of our sales representatives to meet with physicians and patients to visit their doctors and pharmacists to receive prescriptions for our products. Specifically, we expect that our in-person sales and marketing efforts for Upneeq may be negatively impacted by the COVID-19 outbreak as patients de-prioritize or delay non-critical physician visits and procedures, such as those related to eye care.

We have experienced increased demand for certain of our products as customers increase stock as a precautionary measure during the pandemic. We expect that this stockpiling of our product will result in decreased demand for our products in the future as customers use their higher inventory as opposed to placing new customer orders or filing new prescriptions. We have increased inventory of one of our products to avoid supply issues if our contract manufacturer is unable to operate due to the pandemic. If demand for the product does not increase or maintain at a certain level we may be forced to write off product that becomes outdated.

Additionally, while the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the pandemic has resulted in and could continue to result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and our ability to execute on our strategic plans.



[Table of Contents](#)

The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted. We cannot reasonably estimate the length or severity of the COVID-19 pandemic or the related mitigation efforts, including the length of time it may take for normal economic and operating conditions to resume or the extent to which the disruption may materially impact our business, financial position, results of operations or cash flows.

If we determine that our goodwill and other intangible assets have become impaired, we may record significant impairment charges, which would adversely affect our results of operations.

Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. In the future, goodwill and intangible assets may increase as a result of future acquisitions. We review our goodwill, indefinite lived intangible assets and definite lived intangible assets at least annually for impairment. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business. Any impairment of goodwill or other intangible assets would result in a non-cash charge against earnings, which would adversely affect our results of operations. For example, we incurred charges for impairments of intangible assets of \$49.0 million during the fourth quarter of 2020, primarily related to the write-off to fair value of venlafaxine due to lower revenue due to generic competition and a write down to fair value of arbaclofen ER due to a delay in the anticipated commercialization date, if approved. For the year ended December 31, 2020, we recorded non-cash impairment charges of \$72.2 million related to adjustments to the forecasted operating results for certain of our acquired generic, developed technology, product and distribution rights compared to their originally forecasted operating results at the date of acquisition.

In certain circumstances, we issue price adjustments and other sales allowances to our customers, including providing lower pricing to underinsured or non-insured patients. If our estimates for these price adjustments are incorrect, any reserves which we establish for these programs may be inadequate, and may result in adjustments to these reserves or otherwise have a material adverse effect on our financial position and results of operations.

For some of our products, we enjoy a period of time during which we may be the only party, or one of a small number of parties, marketing and selling a certain product. This might be seen more often with one of our brand products, but may also occur in instances where we are one of a small number of parties selling a generic product. At some point other parties, selling either a competitive brand or generic product, may enter the market and compete for customers and market share resulting in a significant price decline for our drug. When we experience price declines following a period of marketing exclusivity or semi-exclusivity, or at any time when a competitor enters the market or offers a lower price with respect to a product we are selling, we may decide to lower the price of our product to retain market share. As a result of lowering prices, we may provide price adjustments to our customers for the difference between our new (lower) price and the price at which we previously sold the product which is still held in inventory by our customers, which is known as a shelf stock adjustment. While we do establish reserves for shelf stock adjustments, if actual shelf stock adjustments differ from our estimates, our operating results could be negatively affected. There are also circumstances under which we may decide not to provide price adjustments to certain customers, and consequently, as a matter of business strategy, we may risk a greater level of sale returns of products in the customer's existing inventory and lose future sales volume to competitors rather than reduce our pricing.

We establish reserves for chargebacks, rebates and incentives, other sales allowances and product returns at the time of sale, based on estimates. Separately, these same reserves may be used to support a patient assistance program. A patient assistance program is a program designed to improve patient access to products by reducing barriers to access caused by potentially high out-of-pocket expenses for patients. The program assists under-insured or non-insured patients by helping to defray their out-of-pocket costs, in some cases entirely. Our estimates on the number of participants for the patient assistance program or other similar programs, currently or in the future, may affect the adequacy of our reserves. Although we believe our processes for estimating reserves are adequate, we cannot provide assurances that our reserves will ultimately prove to be adequate. Increases in sales allowances may exceed our estimates for a number of reasons, including unanticipated competition or an unexpected change in one or more of our contractual relationships. We will continue to evaluate the effects of competition and will record a price adjustment reserve if and when we deem it

[Table of Contents](#)

necessary. Any failure to establish adequate reserves with respect to sales allowances may result in a material adverse effect on our financial position and results of operations.

Rebates include mandated discounts under the Medicaid Drug Rebate Program, Medicare Part D Prescription Drug Benefit Program and TRICARE Retail Pharmacy Refunds Program (TRICARE). Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements with benefit providers. We estimate the allowance for rebates based on statutory discount rates and expected utilization at the time of sale. We adjust the allowance for rebates quarterly to reflect actual experience. If we change the way rebates are applied or calculated, it may impair our ability to accurately accrue for rebates and have a material adverse effect on our financial position and results of operations. See “Risks Related to Our Industry — Our profitability depends on coverage and reimbursement by governmental authorities, managed care organizations, or MCOs, and other third-party payors; healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels.”

We may incur operating losses in the future.

Our net loss was \$79.6 million for the year ended December 31, 2020. Our operating results may fluctuate significantly from quarter to quarter and year to year.

We devote significant amounts of financial resources to the manufacture, marketing and commercialization of our approved products, and support of our research and development of our clinical and preclinical programs. We may incur significant expenses in the future. Some of these expenses will be made in connection with our ongoing activities, as we:

- launch new products into the marketplace;
- conduct clinical trials and seek regulatory approval for arbaclofen ER and additional indications for Upneeq;
- continue development of our pipeline product candidates;
- conduct preclinical studies for product candidates;
- add personnel to support our marketing, commercialization and sales of approved products, including Upneeq, and continue clinical and preclinical product development efforts;
- continue our research and development efforts for new product opportunities, including business development and acquisitions; and
- operate as a public company.

To become profitable, we must succeed in developing or acquiring products, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. Even if we achieve profitability for any period in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other products or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

Our profitability depends on our major customers. If these relationships do not continue as expected, including as a result of the continuing trend of consolidation of certain customer groups, our business, financial condition, prospects and results of operations could materially suffer.

As of December 31, 2020, we had approximately 55 customers, some of which are part of larger buying groups. Our three largest customers accounted for approximately 94% of our total revenues for the year ended December 31, 2020, as follows: Cardinal Health, Inc. 20%; McKesson Corporation 43%; and AmerisourceBergen Corporation 31%. The loss of



[Table of Contents](#)

any one or more of these or any other major customer or the substantial reduction in orders from any one or more of our major customers could have a material adverse effect upon our business, prospects, future operating results and financial condition.

Our ability to successfully commercialize any generic or branded product depends in large part upon the acceptance of the product by third parties, including pharmacies, government formularies, other retailers, physicians and patients. Therefore, our success will depend in large part on market acceptance of our products. We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of MCOs and similar institutions, potentially enable those groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers and retailer customers forming partnerships, such as the alliance between Walgreens and AmerisourceBergen Corporation, the alliance between Rite Aid and McKesson Drug Company and the alliance between CVS and Cardinal Health. The result of these developments may have a material adverse effect on our business, financial condition and results of operations.

Our branded pharmaceutical expenditures may not result in commercially successful products.

Commercializing branded products is more costly than generic products. We have made significant investments in the development, launch and commercialization of branded products. This has led to increased infrastructure costs. We cannot be certain that these business expenditures will result in the successful development or launch of branded products or will improve the long-term profitability of our business. Just as our generic products take market share from the corresponding branded products, we will confront the same competitive pressures from other generic pharmaceutical companies that may seek to introduce generic versions of our branded products. Generic products generally are sold at a significantly lower cost than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs, or may be required by law to be substituted for branded versions by pharmacies. Competition from generic equivalents, accordingly, could have an adverse effect on our branded products. While we have endeavored (with our relevant development and manufacturing partners, as applicable) to protect our branded assets by incorporating specialized manufacturing processes and by securing regulatory exclusivities and intellectual property protections, such exclusivities and protections are subject to expiry and to legal challenges.

We continue to consider product or business acquisitions or licensing arrangements to expand our product line. The success of our branded products will be based largely on the successful commercialization of our existing products, the identification of products for acquisition or future development and the acquisition or in-licensing of new product opportunities. Our current and future investments in acquisition or license arrangements may not lead to expected, adequate or any returns on investment. We also may not be able to execute future license or acquisition agreements on reasonable or favorable terms in order to continue to grow or sustain our branded products. In addition, we cannot be certain that our branded product expenditures will result in commercially successful launches of these products or will improve the long-term profitability of our branded products. Any future commercialization efforts that do not meet expectations could result in a write-down of assets related to the relevant products.

We may discontinue the manufacture and distribution of certain existing products, which may adversely impact our business, results of operations and financial condition.

We continually evaluate the performance of our products, and may determine that it is in our best interest to discontinue the manufacture and distribution of certain of our products for various reasons, including commercial, regulatory, strategic or other reasons. We cannot guarantee that we have correctly forecasted, or will correctly forecast in the future, the appropriate products to discontinue or that our decision to discontinue various products is prudent if conditions, including market conditions, change. In addition, we cannot assure you that discontinuing one or more products will reduce our operating expenses or will not cause us to incur material charges associated with such a decision. Furthermore,

discontinuing one or more existing products entails various risks, including, in the event that we decide to sell the discontinued product, the risk that we will not be able to find a purchaser for such products or that the purchase

[Table of Contents](#)

price obtained will not be equal to at least the book value of the net assets for such products. Other risks include managing the expectations of, and maintaining good relations with, our customers who previously purchased products that we subsequently discontinued, which could prevent us from selling other products to them in the future. Moreover, we may incur other significant liabilities and costs associated with discontinuing one or more of our products, which could have a material adverse effect on our business, results of operations and financial condition.

We face intense competition from both brand and generic companies, including companies that sell branded generics or authorized generics, which could significantly limit our growth and materially adversely affect our financial results.

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical industry include:

- introduction of other brand or generic drug manufacturers' products in direct competition with our products;
- introduction of authorized generic products in direct competition with our products, particularly during exclusivity periods;
- ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- the willingness of our customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- pricing pressures by competitors and customers;
- a company's reputation as a manufacturer and distributor of quality products;
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- product appearance and labeling; and
- a company's breadth of product offerings.

We face, and will continue to face, competition from pharmaceutical, biopharmaceutical, biotechnology and dietary supplement companies developing similar products and technologies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products or processes competitive with, or superior to, our own. Furthermore, we may not be able to differentiate our products from those of our competitors, to successfully develop or introduce new products, on a timely basis or at all, that are less costly than those of our competitors, or to offer payment and other commercial terms to customers as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technological advances and consolidations continue. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

We also face price competition generally as other manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower than our production costs (sometimes significantly), especially lower-cost non-U.S. jurisdictions. Any of these factors, in turn, could result in reductions in our sales prices and gross profit. This price competition has led to an increase in customer demands for downward price adjustments by pharmaceutical distributors. There can be no

[Table of Contents](#)

assurance that we will be able to compete successfully in the industry or that we will be able to develop and implement any new or additional strategies successfully.

Some of our products, including VERT and Divigel, are reference listed drugs. Manufacturers may seek approval of generic versions of our reference listed drugs through the submission of ANDAs. In order to obtain approval of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use and labeling as the reference listed drug, and that the generic version is bioequivalent to the reference listed drug, meaning that it is chemically identical and is absorbed in the body at the same rate and to the same extent. An ANDA applicant need not conduct its own clinical trials to demonstrate the safety or effectiveness of its generic product, but instead may rely on the prior findings of safety and effectiveness for the reference listed drug. As a result, generic products may be significantly less costly to bring to market than reference listed drugs, and companies that produce generic products are generally able to offer them at lower prices. Moreover, many states allow or require substitution of a therapeutically equivalent generic drug at the pharmacy level even if a reference listed drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the market share of a reference listed drug may be lost to the generic product. Competition from generic versions of our products could negatively impact our future total revenues, profitability and cash flows. For example, methylphenidate ER tablets, VERT and Lorzone have experienced, and are expected to continue to experience, significant pricing erosion due to additional competition from other generic pharmaceutical companies.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generics are generic pharmaceutical products that are introduced by brand companies, either directly or through third parties, under the brand's NDA approval for its own branded drug. Authorized generics, which have already been approved for marketing under the brand's NDA, are not prohibited from sale during the 180-day marketing exclusivity period granted to the first-to-file ANDA applicant. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for companies that have been granted 180 days of marketing exclusivity, because an authorized generic can materially decrease the profits that such a company could receive as an otherwise exclusive marketer of a product. Branded drug product companies may also reduce the price of their branded drug products to compete directly with generic drug products entering the market, which would similarly have the effect of reducing gross profit. Such actions have the effect of reducing the potential market share and profitability of generic products and may inhibit the development and introduction of generic pharmaceutical products corresponding to certain branded drugs.

Approximately 70% and 77% of our net product sales for the years ended December 31, 2020 and 2019, respectively, were generated by our generic products. Our future profitability depends, in part, upon our ability to introduce, on a timely basis, new generic products. The timeliness of our product introductions is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of competing products. As additional suppliers introduce comparable generic pharmaceutical products, price competition intensifies, market access narrows and product sales prices and gross profit decline, often significantly and rapidly.

As our competitors introduce their own generic equivalents of our generic pharmaceutical products, our revenues and gross profit from such products generally decline, often rapidly.

Revenues and gross profit derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product often is able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share and the price of that product will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. For example, our revenues from methylphenidate ER declined 57% for the year ended December 31, 2020 compared to the year ended December 31, 2019 due to price erosion as result of generic competition from other pharmaceutical companies. Additionally, we are experiencing, and expect to continue to experience, significant price and market pressure on VERT and Lorzone, which experienced 66% and 74% revenue declines over the same period, respectively. We cannot provide assurance that the number of

[Table of Contents](#)

competitors with such products will not increase to such an extent that we may stop marketing a product for which we previously obtained approval, which may have a material adverse impact on our total revenues and gross profit.

A business interruption at our manufacturing facility in Marietta, Georgia, our warehouses in Sayreville, New Jersey and Tampa, Florida, our pharmacy in Sayreville, New Jersey or at facilities operated by third parties that we rely on, could have a material adverse effect on our business, financial condition and results of operations.

All of the products that we manufacture are produced at our manufacturing facility in Marietta, Georgia, and our inventory passes through our warehouses in Sayreville, New Jersey and Tampa, Florida. Upneeq is distributed to patients through our pharmacy, RVL Pharmacy, in Sayreville, New Jersey. These facilities, or the facilities of third parties that we rely on for the development, supply, marketing or distribution of raw materials or finished products, including Nephron Pharmaceuticals' facility in South Carolina, which we rely upon for the manufacture of Upneeq, could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. For example, the ongoing COVID-19 outbreak has resulted in increased travel restrictions and may result in extended shutdown of our facilities or certain of our suppliers' businesses, which may negatively affect our suppliers' operations. These or any further political or governmental developments or health concerns in countries in which we or our suppliers operate could result in social, economic and labor instability, which could have a material adverse effect on the continuity of our business, including with respect to the availability of raw materials for production. A significant disruption at any of these facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial condition and results of operations.

We depend to a large extent on third-party suppliers and distributors for the raw materials for our products, particularly the chemical compounds comprising the API used in our products, as well as suppliers and distributors for certain finished goods. A prolonged interruption in the supply of such products could have a material adverse effect on our business, financial position and results of operations.

We purchase raw materials, including API, and finished goods from both U.S. and non-U.S. companies. If we experience supply interruptions or delays, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. We may source raw materials or API from a single source, which increases the risk to our business if supply from that source is interrupted. For example, Orion Corporation is our only supplier of Divigel and Nephron Pharmaceuticals Corporation is our only supplier of Upneeq. We also contract with third parties to distribute finished products, including Lannett Company, Inc. for oxybutynin ER and nifedipine ER.

Further, third parties with whom we have agreements may allege that we have failed to perform our obligations under such agreements and we may become involved in lawsuits or other proceedings related to such agreements. If any dispute with a third-party supplier or distributor were determined adversely to us, it could have a material adverse effect on our business, financial position and results of operations.

In addition, changes in our raw material suppliers, including suppliers of API, could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption could have a material adverse effect on our business, research and development programs, financial condition, prospects and results of operations. Because the federal drug approval application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier may be required. A delay in the manufacture and marketing of the drug involved while a new supplier becomes approved by the FDA and its manufacturing process is determined to meet FDA standards could, depending on the particular product, have a material adverse effect on our results of operations and financial condition. Generally, we attempt to mitigate the potential effects of any such situation by providing for, where economically and otherwise feasible, two or more suppliers of raw materials for

the drugs that we manufacture. In addition, we may attempt to enter into a contract with a raw material supplier in an effort to ensure adequate supply for certain of our products.

[Table of Contents](#)

We depend on third-party agreements for a portion of our product offerings and product candidates, including certain key products, and any failure to maintain these arrangements or enter into similar arrangements with new partners could result in a material adverse effect.

A component of our business model involves entering into a variety of third-party agreements covering a combination of joint development, supply, marketing and distribution of products. For example, we rely on a variety of third parties for the development and supply of API for products that we manufacture at our manufacturing facility in Marietta, Georgia. For the year ended December 31, 2020, 32% of our total revenues were generated from products manufactured under contract or under license. We cannot provide assurance that the development, manufacturing or supply efforts of our contractual partners will continue to be successful, that we will be able to maintain or renew such agreements or that we will be able to enter into new agreements for additional products. These third parties may also exercise their rights to terminate these agreements or may fail to perform their obligations as required under these agreements. Alternatives for some of these agreements may not be easily available.

Any alteration to or termination of our current distribution and marketing agreements, any failure to enter into new and similar agreements, any disputes regarding our manufacturing agreements with third parties, whether or not such disputes result in litigation, any failure to fulfill obligations by a third party, or any other interruption of our product supply under the distribution and marketing agreements, could materially adversely affect our business, financial condition, prospects and results of operations.

If we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell our products, including Upneeq.

For the years ended December 31, 2020 and 2019, we spent \$36.3 million and \$50.0 million, respectively, on sales and marketing. We face a number of additional risks in developing or maintaining internal sales and marketing capabilities, including:

- not being able to attract talented and qualified personnel to build an effective marketing or sales force capability, or not be able to attract personnel with sufficient experience in marketing to the physicians and pharmacies in the eye care space;
- the cost of establishing a marketing and sales force capability may not be justified in light of the total revenues generated from our products;
- our direct sales and marketing efforts for Upneeq may not be successful; and
- our virtual sales and marketing efforts for our other products may not be successful.

If we are unable to establish or maintain adequate sales and marketing capabilities or are unable to do so in a timely manner, our ability to generate revenues and profits from our products will be limited and this could have a material adverse effect on our business, financial position and results of operations.

As we gain approval and launch new products, including Upneeq, we will invest in expanding our sales and marketing organization into new areas such as eye care. In 2020, we established our sales and marketing infrastructure for the commercial launch of Upneeq and the distribution of Upneeq directly to patients through RVL Pharmacy. As a company we have limited experience in the sales, marketing and distribution of ophthalmic products. We are currently expanding our sales force and increasing the number of managers and sales people with eye care experience.

There are risks involved with establishing, maintaining and expanding our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any future product launch. Further, we may underestimate the size of the sales force required for successful commercialization of Upneeq and may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial success of Upneeq is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.



[Table of Contents](#)

Factors that may inhibit our efforts to commercialize Upneeq on our own include:

- our inability to recruit, train and retain adequate numbers of effective eye care sales and marketing personnel;
- the inability of sales personnel to obtain access to clinicians, including as a result of limitation on office visits as a result of COVID-19 or other health concerns, or persuade adequate numbers of clinicians to prescribe Upneeq; and
- unforeseen costs and expenses associated with maintaining and expanding an independent sales, marketing and pharmacy organization.

Our future success depends on our ability to attract and retain key employees and consultants.

Our future success depends, to a substantial degree, upon the continued service of the key members of our management team. The loss of the services of key members of our management team, including Brian Markison, Tina DeVries, Andrew Einhorn and James Schaub, or their inability to perform services on our behalf could have a material adverse effect on our business, financial condition, prospects and results of operations. Our success also depends, to a large extent, upon the contributions of our sales, marketing, scientific and quality assurance staff. We compete for qualified personnel against other brand and generic pharmaceutical manufacturers that may offer more favorable employment opportunities. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we could experience constraints that would adversely affect our ability to sell and market our products effectively and to support our research and development programs. In particular, sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales, marketing and quality assurance representatives. Although we believe that we have been successful in attracting and retaining skilled personnel in all areas of our business, we cannot provide assurance that we can continue to attract, train and retain such personnel. Any failure in this regard could limit our ability to generate sales and develop or acquire new products.

Any acquisitions we may undertake in the future involve numerous risks, including the risks that we may be unable to integrate the acquired products or businesses successfully and that we may assume liabilities that could adversely affect us.

We may acquire products or businesses. For example, in October 2017, we acquired the rights to RVL-1201, which has since been approved by the FDA as Upneeq, the first approved non-surgical treatment for acquired blepharoptosis in adults. Acquisitions involve numerous risks, including operational risks associated with the integration of acquired businesses or products. These risks include, but are not limited to:

- difficulties in achieving identified revenue synergies, growth opportunities, operating synergies and cost savings;
- difficulties in assimilating the personnel, operations and products of an acquired company, and the potential loss of key employees;
- difficulties in consolidating information technology platforms, business applications and corporate infrastructure;
- difficulties in integrating our corporate culture with local customs and cultures;
- possible overlap between our products or customers and those of an acquired entity that may create conflicts in relationships or other commitments detrimental to the integrated businesses;
- difficulties in obtaining approval from governmental authorities such as the Federal Trade Commission, or FTC;



Table of Contents

- our inability to achieve expected total revenues and gross profit for any products we may acquire;
- possible contingent liability that includes, among others, known or unknown environmental, patent or product liability claims;
- the diversion of management's attention from other business concerns; and
- risks and challenges of entering or operating in markets in which we have limited or no prior experience, including the unanticipated effects of export controls, exchange rate fluctuations, foreign legal and regulatory requirements, and political and economic conditions.

In addition, non-U.S. acquisitions involve numerous additional risks, including those related to the potential absence or inadequacy of policies and procedures sufficient to assure compliance by a non-U.S. entity with U.S. regulatory and legal requirements. There can be no assurance that we will not be subject to liability arising from conduct which occurred prior to our acquisition of any entity.

We incur significant transaction costs associated with our acquisitions, including substantial fees for investment bankers, attorneys, and accountants. Any acquisition could result in our assumption of unknown or unexpected, and potentially material, liabilities. Additionally, in any acquisition agreement, the negotiated representations, warranties and agreements of the selling parties may not entirely protect us, and liabilities resulting from any breaches may not be subject to indemnification by the suing parties and could exceed negotiated indemnity limitations. These factors could impair our growth and ability to compete, divert resources from other potentially more profitable endeavors, or otherwise cause a material adverse effect on our business, financial condition and results of operations.

The financial statements of the companies we have acquired or may acquire in the future are prepared by management of such companies and are not independently verified by our management. In addition, any pro forma financial statements prepared by us to give effect to such acquisitions may not accurately reflect the results of operations of such companies that would have been achieved had the acquisition of such entities been completed at the beginning of the applicable financial reporting periods. Finally, we cannot guarantee that we will continue to acquire businesses at valuations consistent with our prior acquisitions or that we will complete acquisitions at all.

We may make acquisitions of, or investments in, complementary businesses or products, which may be on terms that may not turn out to be commercially advantageous, may require additional debt or equity financing, and may involve numerous risks, including those set forth above. We may also divest assets, which may not be commercially advantageous.

We regularly review the potential acquisition of technologies, products, product rights and complementary businesses and are currently evaluating, and intend to continue to evaluate, potential product and company acquisitions and other business development opportunities. We may choose to enter into such transactions at any time. Nonetheless, we cannot provide assurance that we will be able to identify suitable acquisition or investment candidates. To the extent that we do identify candidates that we believe to be suitable, we cannot provide assurance that we will be able to reach an agreement with the selling party or parties, that the terms we may agree to will be commercially advantageous to us, or that we will be able to successfully consummate such investments or acquisitions even after definitive documents have been signed. If we make any acquisitions or investments, we may finance such acquisitions or investments through our cash reserves, debt financing (such as borrowings available to us under our senior secured credit facilities, including our revolving credit facility), which may increase our leverage, or by issuing additional equity securities, which could dilute the holdings of our then-existing shareholders. If we require financing, we cannot provide assurance that we will be able to obtain any required financing when needed on acceptable terms or at all. In addition, we may divest certain of our assets. Such divestitures may not be on favorable terms and the proceeds from such divestitures may not outweigh the benefits such divested assets could have provided to our business.

[Table of Contents](#)

There is no certainty that we will be able to execute on any strategic alternatives to maximize shareholder value.

On November 10, 2020, we and our board of directors announced that we were undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include divestitures of non-strategic assets, re-financings, commercialization or collaboration agreements. There can be no assurance that this comprehensive review process will result in a transaction, or that if a transaction does occur, that it will successfully enhance shareholder value. Our cash position, net of all liabilities, limits our attractiveness to potential merger candidates and the value that we may receive in such merger, joint venture, partnership, or other business combination scenarios may be less than our current market value.

The process of exploring strategic options could adversely impact our business, financial condition and results of operations. We could incur substantial expenses associated with identifying, evaluating, and executing on potential strategic alternatives, including those related to equity compensation, severance pay and insurance, legal, accounting and financial advisory fees. In addition, the process may be time consuming and disruptive to our business operations, could divert the attention of management and the board of directors from our business, could negatively impact our ability to attract, retain and motivate key employees, and could expose us to potential litigation in connection with this process or any resulting transaction. Further, speculation regarding any developments related to the review and execution of strategic alternatives and perceived uncertainties related to our future could cause our share price to fluctuate significantly.

Risks related to the development and commercialization of products

If we are unable to successfully develop or commercialize new products, or to do so on a timely or cost-effective basis, or to extend life cycles of existing products, our operating results will suffer.

Developing and commercializing a new product is time consuming and costly and is subject to numerous factors that may delay or prevent development and commercialization. Our future results of operations will depend to a significant extent upon our ability to successfully gain FDA approval of and commercialize new products in a timely and cost-effective manner, especially new branded products as we shift from focusing on generic to branded products. There are numerous difficulties in developing and commercializing new products, including:

- the ability to develop products in a timely and cost-effective manner and in compliance with regulatory requirements;
- the success of the pre-clinical and clinical testing processes to assure that new products are safe and effective or chemically identical and bioequivalent to the branded reference listed drug;
- the risk that any of our products presently under development, if and when fully developed and tested, will not perform as expected;
- delays or unanticipated costs, including delays associated with the completion of clinical trials for our branded products;
- delays associated with FDA registration, listing and approval processes and the ability to obtain in a timely manner, and maintain, required regulatory approvals;
- legal actions against our generic products brought by brand competitors, and legal challenges to our branded products or branded product intellectual property;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;
- our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of products in compliance with regulatory requirements; and



[Table of Contents](#)

- acceptance of our products by physicians, patients, payors and the healthcare community.

As a result of these and other difficulties, products currently in development may or may not receive necessary regulatory approvals on a timely basis or at all and we may not succeed in effectively managing our development costs. Further, if we are required by the FDA or any equivalent foreign regulatory authority to complete clinical trials in addition to those we currently expect to conduct, or to repeat a clinical trial that has already been completed, or if there are any delays in completing preclinical studies, filing an IND or completing clinical trials, our expenses could increase.

This risk exists particularly with respect to the introduction of new branded products as we continue our shift away from focusing on generic markets. NDAs for branded products are subject to uncertainties, higher costs and lengthy time frames associated with research and development of such products and the inherent unproven market acceptance of such products. For example, in December 2020 we received a complete response letter, or CRL, from the FDA in connection with our NDA for arbaclofen ER for the treatment of multiple sclerosis patients with spasticity. In the CRL, FDA recommended that we conduct a new study in order to provide substantial evidence of efficacy of arbaclofen. On March 4, 2021, we participated in a meeting with the FDA during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. The FDA's review, as well as any subsequent clinical testing, could delay or prevent the commercial launch of arbaclofen ER and increase our operating expenses, including the expenses associated with any additional clinical trials for arbaclofen ER, which could have a material adverse effect on our business, financial position and results of operations. If we are unable or delayed in our attempts to develop and commercialize branded products successfully, we may have to rely primarily on revenue from existing and future generic products to support research and development efforts.

If any of our products, when acquired or developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products.

We expend a significant amount of resources on research and development, including milestones on in-licensed products, which may not lead to successful product introductions.

Much of our development effort is focused on technically difficult-to-formulate products or products that require advanced manufacturing technology. We expend resources on research and development primarily to enable us to manufacture and market FDA-approved products in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. We spent \$19.7 million and \$32.3 million on research and development expenses in the years ended December 31, 2020 and 2019, respectively. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various research and development events and regulatory approvals. As we continue to develop and in-license new products, we will likely incur increased research, development and licensing expenses. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of new FDA-approved products. Also, after we or our development partners submit an ANDA or NDA, the FDA may request that we conduct additional bioequivalence studies for an ANDA or additional clinical trials for an NDA. For example, in December 2020 we received a CRL from the FDA in connection with our NDA for arbaclofen ER. In the CRL FDA indicated we would need to conduct a new study in order to provide substantial evidence of efficacy of arbaclofen given that the primary endpoint for Study OS440-3004, change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, was not met and the co-primary endpoint, results from the clinical global impression of change on Day 84, did not support a treatment benefit.. Any additional clinical studies required for arbaclofen ER as a result of our discussions with the FDA regarding the CRL may result in substantial additional research and development costs.

We may be unable to reasonably determine the total research and development costs required to develop a particular product. As a result, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercializing the product. To the extent that we expend significant resources on research and development efforts and are not ultimately able to introduce successful new products as a result of those efforts or

[Table of Contents](#)

cost-effectively commercialize new products, our business, financial position and results of operations may be materially adversely affected.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing proprietary product candidates for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

[Table of Contents](#)

The testing required for the regulatory approval of our products is conducted primarily by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications for the regulatory approval of our products, including both internally developed and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, CROs or independent research facilities). Our ability to obtain and maintain regulatory approval of the products being tested is dependent, in part, upon the quality of the work performed by these third parties, the quality of the third parties' facilities and the accuracy of the information provided by third parties. Our control over any of these factors may be limited. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of all of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites.

We have in the past been subject to audits by the FDA that have identified irregularities and deviations from GCP. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if at all.

We also rely on contract laboratories and other third parties, such as CROs, to conduct or otherwise support our preclinical studies properly and on time, which are subject to GLP requirements. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies comply with applicable GCP and GLP regulations. In addition, our clinical trials must be conducted with products produced under the FDA's cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates may be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP and GLP requirements.

If testing of our product candidates is not performed properly, or if the FDA or any equivalent foreign regulatory authority finds that the clinical trials are deficient, we may be required to repeat the clinical trials or to conduct additional clinical trials, which would result in additional expenses and may adversely affect our ability to obtain or maintain regulatory approvals. As a result, our ability to launch or continue selling products could be denied, restricted or delayed.

Although we have received orphan drug designation for arbaclofen, we may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity for arbaclofen.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs intended for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA to market the same product for the same indication for seven years, except in limited circumstances, such as a

[Table of Contents](#)

showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Although we have received orphan drug designation for arbaclofen for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, we may not receive the full set of benefits potentially associated with orphan drug designation. The FDA has previously approved baclofen, a racemic mixture comprised of an R- and an S-isomer, for the treatment of intractable muscle spasticity in multiple sclerosis patients. If the FDA determines that our product, arbaclofen, which is the R-isomer of baclofen, contains the same active ingredient and is indicated for the same use as the approved product, we could be precluded from obtaining orphan drug exclusivity for our product unless we are able to demonstrate that our product is clinically superior to the approved product, which could potentially require a head-to-head study. Moreover, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Additionally, orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Our products or product candidates may cause undesirable side effect or have other adverse properties that could delay or prevent their regulatory approval or limit the scope of any approved package insert or market acceptance, or result in significant negative consequences following marketing approval.

Treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although many of our products or product candidates contain active ingredients that have already been approved, meaning that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable or unknown side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

If any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result. If side effects are identified with our marketed products, or if manufacturing problems occur, changes in labeling of our products may be required, which could have a material adverse effect on our sales. Label changes may be necessary for a number of reasons, including the identification of actual or potential safety or efficacy concerns by regulatory agencies or the discovery of significant problems with a similar product that implicates an entire class of products. Any significant concerns raised about the safety or efficacy of the products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to the manufacturing processes, or to seek re-approval of the relevant manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. Our products, including ConZip, Divigel and VERT, have in the past been subject to safety labeling changes, which we have addressed and incorporated into relevant product labeling. Our products and product candidates may become subject to additional safety labeling changes in the future. New safety issues may require us to, among other things, provide additional warnings or restrictions on product package inserts, even including boxed warnings in the United States or similar warnings outside of the United States, directly alert healthcare providers of new safety information, narrow our approved indications, conduct additional clinical studies, alter or terminate current or planned trials for additional uses of products, impose restrictions on distribution, require implementation of REMS, or even remove a product from the market, any of which could have a significant adverse impact on potential sales of the products or require us to expend significant

additional funds. The revision of product labeling or the regulatory actions described above could have a material adverse effect on our sales of the affected products and on our business and

[Table of Contents](#)

results of operations. Additionally, we could be sued and held liable for harm caused to patients, and our reputation may suffer.

If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived lack of effect or harmful effects, our business, financial condition, results of operations and prospects could be harmed significantly.

If our products or product candidates do not produce the intended effects, our business may suffer.

If our products or product candidates do not produce the effects intended our business may suffer. For example, in July 2020, we received regulatory approval from the FDA for Upneeq, the first approved non-surgical treatment for acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 with an in-person sales effort focused on ophthalmologists and optometrists. Despite these efforts, Upneeq may not produce sufficient treatment such that patients or eye care specialists deem it an effective treatment for acquired blepharoptosis. Our products and product candidates, including Upneeq, may not have the effect intended if they are not taken in accordance with applicable instructions. For example, if a patient switches from using another company's product to one of our products, there may be an actual or perceived lack of efficacy or increase in side effects. This is not uncommon and has been observed, for example, in patients switching between products containing methylphenidate. In this instance, the FDA has the ability to change the designation from AB to BX, or alternatively, to discontinue the product's approval. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended.

Failures of or delays in clinical trials are common and have many causes, and such failures or delays could result in increased costs to us and could prevent or delay our ability to obtain regulatory approval and commence product sales for new products.

We may experience failures of or delays in clinical trials of our product candidates. Our clinical trials may fail or be delayed for a variety of reasons, including, among others: delays in obtaining regulatory approval to commence a trial; imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities; delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them; delays in obtaining required IRB approval at each site; difficulties or delays enrolling a sufficient number of patients or in having patients complete participation in a trial or return for post-treatment follow-up, or clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment; time required to add new clinical sites; or delays or failure by us or our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials, in a timely manner. Patient enrollment and completion of the trials is affected by factors including: the severity of the disease under investigation; the design of the trial protocol; the size of the patient population; the eligibility criteria for the trial in question; the perceived risks and benefits of the product candidate under trial; the proximity and availability of clinical trial sites for prospective patients; the availability of competing therapies and clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; and the ability to monitor patients adequately during and after treatment.

If we are unable to initiate or complete our planned clinical trials or any such clinical trial is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could fail or be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

Moreover, clinical data are often susceptible to varying interpretations, and many companies that have believed their drug candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their

[Table of Contents](#)

drug candidate. Furthermore, results from our clinical trials may not meet the level of statistical significance or otherwise provide the level of evidence or safety and efficacy required by the FDA or other regulatory authorities for approval of a drug candidate. Finally, clinical trials are expensive and require significant operational resources to implement and maintain.

Many companies in the pharmaceutical and biotechnology industries, including our company, have suffered significant setbacks in later-stage clinical trials even after achieving promising results in earlier-stage clinical trials. For example, the results from completed preclinical studies and clinical trials may not be replicated in later clinical trials, and ongoing clinical trials for our drug candidates may not be predictive of the results we may obtain in later-stage clinical trials or of the likelihood of approval of a drug candidate for commercial sale. In addition, from time to time, we report interim data from our clinical trials. Interim data from a clinical trial may not be predictive of final results from the clinical trial. Failure to advance drug candidates through clinical development could impair our ability to ultimately commercialize products, which could materially harm our business and long-term prospects.

The use of legal, regulatory and legislative strategies by brand competitors, including authorized generics and citizen's petitions, as well as the potential impact of proposed legislation, may increase our costs associated with the introduction or marketing of our generic products, delay or prevent such introduction or significantly reduce the profit potential of our products.

Brand drug companies often pursue strategies that may serve to prevent or delay competition from generic alternatives to their branded products. These strategies include, but are not limited to:

- marketing an authorized generic version of a branded product at the same time that we introduce a generic equivalent of that product, directly or through agreement with a generic competitor;
- filing citizen petitions with the FDA that may limit generic competition and result in delays of our product approvals;
- using REMS-related distribution restrictions or other means of limiting access to their branded products to prevent us from obtaining product samples needed to conduct bioequivalence testing required for ANDA approval, thereby delaying or preventing us from obtaining FDA approval of a generic version of such branded products;
- seeking to secure patent protection of certain “Elements to Assure Safe Use” of a REMS program, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient, in an attempt to prevent the generic company’s ability to avoid infringement of the patents in question or secure approval;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a generic product’s bioequivalence or “sameness” to the related branded product;
- initiating legislative and administrative efforts in various states to limit the substitution of generic versions of branded products for the corresponding branded products;
- filing suits for patent infringement that automatically delay FDA approval of generic products;
- introducing “next-generation” products prior to the expiration of market exclusivity for their branded product, which often materially reduces the demand for the generic product for which we may be seeking FDA approval;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other methods;

[Table of Contents](#)

- persuading the FDA to withdraw the approval of branded drugs for which the patents are about to expire, thus allowing the brand company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- seeking temporary restraining orders and injunctions against selling a generic equivalent of their branded product based on alleged misappropriation of trade secrets or breach of confidentiality obligations;
- seeking temporary restraining orders and injunctions against a generic company that has received final FDA approval for a product and is attempting to launch an at risk product prior to resolution of related patent litigation;
- reducing the marketing of the branded product to healthcare providers, thereby reducing the branded drug's commercial exposure and market size, which in turn adversely affects the market potential of the equivalent generic product; and
- converting branded prescription drugs that are facing potential generic competition to over-the-counter products, thereby potentially blocking the sale of generic prescription drugs under the operation of the Durham-Humphrey amendments to the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, or significantly impeding the growth of the generic prescription market for the drugs.

The FDCA provides for an additional six months of marketing exclusivity attached to another period of exclusivity, such as a five-year period of exclusivity granted to the first applicant to obtain approval of an NDA for a new chemical entity or if a sponsor conducts pediatric clinical trials in response to a written request from the FDA. Some companies have lobbied Congress for amendments to the Hatch-Waxman legislation that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials, rather than the one-half year that is currently permitted. If proposals like these were to become effective, our entry into the market and our ability to generate revenues associated with new generic products may be delayed, reduced or eliminated, which could have a material adverse effect on our business, prospects and financial position.

Risks related to our intellectual property rights

We depend on our ability to protect our intellectual property and proprietary rights. We may not be able to keep our intellectual property and proprietary rights confidential and protect such rights.

Our success depends on our ability to protect and defend the intellectual property rights associated with our current and future products. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that may be confused with, our products, and our generic competitors may obtain regulatory approval to make and distribute generic versions of our branded products. We cannot be certain that patents will be issued with respect to any of our patent applications or that any existing or future patents issued to or licensed by us will provide competitive advantages for our products or will not be challenged, invalidated, circumvented or held unenforceable in proceedings commenced by our competitors or other third parties. Furthermore, our patent rights may not prevent or limit our present and future competitors from developing, making, importing, using or commercializing products that are functionally similar to our products. Some of our products, including some of our promoted products, are not protected by patents at all.

The patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been and remains the subject of significant litigation in recent years. Legal standards relating to scope and



[Table of Contents](#)

validity of patent claims are evolving and may differ in various countries. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Any patents we have obtained, or may obtain in the future, may be challenged, invalidated or circumvented. For example, Upneeq is protected by three years of new product data exclusivity that expires July 8, 2023, and six patents listed in the FDA Orange Book, three of which expire August 26, 2031 and three of which expire December 16, 2039. A competitor that develops a generic version of Upneeq can submit an ANDA at any time, and that ANDA may include a Paragraph IV certification alleging that our Orange Book-listed patents are invalid, unenforceable or not infringed. If that were to occur, we would need to assert one or more of our patents. Litigation in which generic companies challenge Orange Book listed patents tends to be lengthy and expensive, and may result in one or more of our patents being held invalid, unenforceable or not infringed and, may expose us to generic competition sooner than we otherwise expect. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

In addition to the above limitations, our patent protection outside the United States may be further limited. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. We generally select to pursue patent protection in only a limited number of jurisdictions outside of the United States. Even where we wish to pursue protection, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. The laws of certain non-U.S. countries do not protect proprietary rights to the same extent or in the same manner as the U.S., and therefore we may encounter additional problems in protecting and defending our intellectual property in certain non-U.S. jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions.

Proceedings to enforce patent rights, whether in the United States or in non-U.S. jurisdictions, could: result in substantial costs and divert our efforts and attention from other aspects of our business; put our patents at risk of being invalidated or interpreted narrowly; put our patent applications at risk of not issuing; and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage.

We also rely particularly on trade secrets, unpatented know-how and proprietary expertise and continuing innovation to develop and maintain our competitive position. We generally enter into confidentiality agreements with licensees, suppliers, employees, consultants and other parties. This is done in part because not all of our products are protected by patents. We cannot provide assurance that these agreements will not be breached. We also cannot be certain that we will have recourse to adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not be independently developed or otherwise become known by our competitors or, if patents are not issued with respect to internally developed products, that we will be able to maintain the confidentiality of information relating to these products. Efforts to enforce our intellectual property rights can be costly, time-consuming and ultimately unsuccessful. Any failure to adequately prevent disclosure of our know-how, trade secrets and other propriety information could have a material adverse impact on our business and our prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trademark office, or the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent

application process. While an inadvertent lapse may, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which

[Table of Contents](#)

noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly prepare and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business, prospects and financial position.

Our competitors or other third parties may allege that we, our suppliers or partners are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to “at-risk” product launches, could have a material adverse effect on our business, financial position and results of operations.

Companies that produce branded products routinely bring litigation against entities selling or seeking regulatory approval to manufacture and market generic or other copies of their branded products, or products related to their branded products or technologies. These companies or other patent holders, including patent holders who do not have related products, may allege patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling an approved product, including an approved generic product. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic or other products. For example, a certain period of delay may be statutorily prescribed, or a court could grant a patent holder injunctive relief for the period of the litigation. If third party patents are held valid, enforceable and infringed by our products, we may, unless we could obtain a license from the patent holder, need to delay selling our corresponding product, pay damages, and, if we are already selling our product, cease selling and potentially destroy existing product stock. These risks apply to our branded products as well as our generic products. Third parties, including our competitors, may allege that one of our branded products violates their patent rights, which would expose us to the same risks. A license may not be available from the patent holder on commercially reasonable terms, or at all. If available, we may choose to take a license under a third party’s patent rights to resolve a dispute, even in the absence of a finding by a court that a patent is valid, enforceable and infringed.

There may be situations in which we may make business and legal judgments to manufacture, market or sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon our belief that such patents are invalid, unenforceable, or are not infringed by our manufacturing, marketing and sale of such products. This is referred to in the pharmaceutical industry as an “at-risk” launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, permanent injunctive relief preventing the sale of the product and damages measured as a reasonable royalty or by the profits lost by the patent holder, which can be significantly higher than the profits we make from selling our product. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such inventory that we are unable to market or sell.

Litigation concerning intellectual property rights in the pharmaceutical industry is commonplace and can be protracted and expensive. Pharmaceutical companies with patented branded products regularly sue companies that file applications to produce generic equivalents of their patented branded products for alleged patent infringement or other violations of intellectual property rights, which are expensive to defend and may delay or prevent the entry of such generic products into the market. Generally, a generic drug may not be marketed until the applicable patent(s) on the brand name drug expire or are held to be invalid, unenforceable or not infringed by the generic product at issue. When we or our development partners submit an ANDA to the FDA for approval of a generic drug, we or our development partners must certify either (i) that there is no patent listed with the FDA as covering the relevant branded product, (ii) that any patent listed as covering the branded product has expired, (iii) that the patent listed as covering the branded product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent or (iv) that any patent listed as covering the branded drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted, which we refer to as a “Paragraph IV” certification. Whenever we file an ANDA with a Paragraph IV certification, there is a high likelihood that a brand pharmaceutical company will sue us for alleged patent infringement or other violations of intellectual property rights. Also, competing pharmaceutical companies may file lawsuits against us

alleging patent infringement or other violations of intellectual property rights or may file declaratory judgment actions against us alleging non-infringement, invalidity,

[Table of Contents](#)

or unenforceability of our own patents. Because substantially all of our current business involves the development and marketing of products that are subject to potential claims of patent infringement by third parties or, with respect to our own branded products, are subject to third-party challenges, the threat of litigation, the outcome of which is inherently uncertain, is always present. Such litigation is often costly and time consuming and could result in a substantial delay in, or prevent, the introduction or marketing of our products, which could have a material adverse effect on our business, financial condition, prospects and results of operations. For more information on our material pending litigation, see “Legal Proceedings.”

If we fail to comply with our obligations in the agreements under which we license rights from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us various development, regulatory and commercial diligence obligations, payment of milestones or royalties and other obligations. Additionally, existing or future license agreements may include a sublicense from a third party that is not the original licensor of the intellectual property at issue. Under such an agreement, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost, on reasonable terms or at all, and this may impact our ability to continue to develop or commercialize our products incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our existing or future important licenses were to be terminated by the licensor, we would likely need to cease further development and commercialization of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license. In the case of marketed products that depend upon a license agreement, we could be required to cease our commercialization activities, including sale of the affected product.

Disputes may arise between us and any of our licensors regarding intellectual property subject to such agreements, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed intellectual property, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us, should any such joint creation occur;
- our right to transfer or assign the license; and
- the effects of termination.

These or other disputes over intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such



[Table of Contents](#)

dispute, or termination of a necessary license, could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

We may be subject to claims that our employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to our management team. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

We may be subject to claims challenging the inventorship or ownership of our owned or in-licensed patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees and consultants. However, these agreements may be breached and may not effectively assign intellectual property rights to us. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of inventions. The owners of intellectual property in-licensed to us could also face such claims. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish our products and product candidates from the products of our competitors. Our trademark applications may not result in registered trademarks. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in substantial cost, loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. Even if we are successful in defending the use of our trademarks or preventing third parties from infringing our trademarks, resolution of such disputes may result in substantial costs.

[Table of Contents](#)

Risks related to our industry

Our profitability depends on coverage and reimbursement by governmental authorities, private health plans, MCOs and other third-party payors; healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels.

We have obtained coverage and reimbursement at varying levels for our products from governmental payors, private health insurers and other third-party payors such as MCOs. There is no assurance; however, that any drug that we market will be covered by any third-party payor, or that, once a coverage determination has been made, the third-party payor will offer an adequate reimbursement level for our product. Third-party payors may limit coverage to specific products on an approved formulary, which might not include all of the approved products for a particular indication. In determining whether to approve reimbursement for our products and at what level, we expect that third-party payors will consider factors that include the efficacy, cost effectiveness and safety of our products, as well as the availability of other treatments including other generic prescription drugs and over-the-counter alternatives. Further, in order to obtain and maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we may face mounting pressure to offer discounts or rebates from list prices to increase existing discounts and rebates, to offer discounts and rebates to a greater number of third-party payors or to implement other unfavorable pricing modifications. Obtaining and maintaining favorable reimbursement can be a time consuming and expensive process, and there is no guarantee that we will be able to negotiate or continue to negotiate pricing terms with third-party payors at levels that are profitable to us, or at all. Additionally, any reimbursement granted may not be maintained and any limits on reimbursement available from third-party payors may reduce the demand for, or negatively affect the price of those products, and could significantly harm our business, results of operations, financial condition and cash flows.

In particular, there is no assurance that drug plans participating under the Medicare Part D program will cover our products or that any covered drugs will be reimbursed at amounts that reflect current or historical levels. Medicare Part D is a voluntary program that offers prescription drug coverage through private plans to Medicare beneficiaries (primarily the elderly over 65 and the disabled) enrolled with the plan. Medicare Part D coverage may vary from plan to plan and the plans may implement formularies and certain utilization management activities (such as tiered co-pay structures and prior authorization requirements) as well as negotiate rebates with pharmaceutical manufacturers to manage access and costs. Manufacturers must also provide discounts on Medicare Part D brand name prescription drugs sold to Medicare beneficiaries in the Medicare Part D coverage gap (i.e., the so called “donut hole”), which discount increased from 50% to 70% in 2019.

There is no assurance that Medicaid programs will continue to offer coverage, and adequate reimbursement levels, for our pharmaceutical products. Most state Medicaid programs have established preferred drug lists, and the process, criteria and timeframe for obtaining placement on the preferred drug list varies from state to state. For drugs not on the preferred drug list, the prescriber may have to request and obtain prior authorization in order for the drug to be covered. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate for single source products (including authorized generics) is based on the greater of (i) a specified percentage of the product’s average manufacturer price or (ii) the difference between the product’s average manufacturer price and the best price offered by the manufacturer. The rebate for multiple source products is a specified percentage of the product’s average manufacturer price. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a preferred drug list. The profitability of our products may depend on the extent to which they appear on the preferred drug lists of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. In addition, there is significant fiscal pressure on the Medicaid program, and legislative and regulatory action to lower the pharmaceutical costs of the program is possible. For example, legislation enacted in 2019 revises how certain prices are calculated under the Medicaid Drug Rebate Program, a revision that the Congressional Budget Office estimated will save the federal government approximately \$3 billion in the next ten years. Any such legislative action could materially adversely affect our anticipated total revenues and results of operations.

In addition, third-party payors are increasingly challenging pricing of pharmaceutical products, and imposing controls to manage costs. For example, we were subject to an audit by the Office of Inspector General related to purported overcharges with respect to the prices of VERT that were purchased by the

U.S. Department of Veterans Affairs. Although we believe that the prices we charged in these transactions were appropriate and have settled this matter,

[Table of Contents](#)

adverse determination of other audits could result in the imposition of significant financial penalties, which could have a material adverse impact on our results of operations and financial condition.

The trend toward managed healthcare in the United States and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. The ACA was signed into law in March 2010. A number of provisions of the ACA continue to have a negative impact on the price of our products sold to U.S. government entities. As examples, the legislation includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the Medicaid rebate to utilization under Managed Medicaid; (iv) require manufacturers to provide point of sale discounts on Medicare Part D beneficiary spending in the coverage gap for branded and authorized generic prescription drugs (which discount was recently increased effective in 2019); and (v) levy a significant excise tax on the industry to fund the healthcare reform. Such cost containment measures and healthcare reform may affect our ability to sell our products and could have a material adverse effect on our business, results of operations and financial condition.

Executive, legislative and judicial action subsequent to the enactment of the ACA has sought to repeal, modify or delay implementation of the ACA. Tax reform legislation enacted in 2017 removed the tax penalty applicable to the “individual mandate,” which requires Americans to carry a minimal level of health insurance. Starting in 2019, the tax penalty for not carrying such insurance is zero. Effective January 1, 2019, the point-of-sale discount that pharmaceutical manufacturers who participate in Medicare Part D must provide to Medicare Part D beneficiaries in the coverage gap was increased from 50% to 70%. There have also been judicial challenges to the ACA. The case *Texas v. Azar*, which challenges the constitutionality of the ACA, including provisions that are unrelated to healthcare reform but were enacted as part of the ACA, was argued before the Supreme Court in November 2020. Pending resolution of the litigation, all of the ACA but the individual mandate to buy health insurance remains in effect.

Beyond the ACA, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes. A number of regulations were issued in late 2020 and early 2021. For example, revisions to the federal anti-kickback statute, now effective 2023, would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to PBMs and health plans. Some of these changes have been and may continue to be subject to legal challenge. For example, courts temporarily enjoined a new “most favored nation” payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would limit payment based on international drug price.

The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain. The Department of Justice under the Biden administration informed the Supreme Court that the government no longer takes the position that the individual mandate is unconstitutional and cannot be severed from the rest of the ACA. President Biden has temporarily halted implementation of new rules issued immediately prior to the transition that had not yet taken effect (which include a number of health care reforms) to allow for review by the new administration. The revisions to the federal anti-kickback statute initially scheduled to take effect in 2022 now take effect in 2023. More generally, President Biden supported reforms to lower drug prices during his campaign for the presidency.

Future healthcare legislation could also have a significant impact on our business. There is uncertainty with respect to the impact these changes, if any, may have, and any changes likely will take time to unfold. Any additional federal healthcare reform measures adopted in the future could limit the amounts that federal and state governments will pay for healthcare products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability. Due to the uncertainties regarding the outcome of future healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the future reform proposals will be adopted or the effect such adoption may have on us.

[Table of Contents](#)

In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' commercial success. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2030 (except May 1, 2020 to March 31, 2021) unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

There has been heightened public pressure and government scrutiny over pharmaceutical pricing practices, which may negatively impact our ability to generate revenues from our products, which could result in material adverse effects to our business, financial position and results of operations.

There has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several Congressional inquiries in recent years and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing; review the relationship between pricing and manufacturer patient assistance programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have become increasingly active in passing, or seeking to pass, legislation and regulations designed to control pharmaceutical and biological product pricing, including laws establishing maximum drug reimbursement rates for governmental or other payors within a state, laws limiting consumer copayment obligations, transparency and disclosure measures related to drug price increases and laws seeking to encourage drug importation from other countries and bulk purchasing. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Any downward pricing pressure on the price of certain of our products arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition.

There has also been increasing U.S. federal and state enforcement interest with respect to drug pricing. For instance, the DOJ has brought actions against pharmaceutical companies, seeking information about the sales, marketing and pricing of certain generic drugs, some of which have been resolved through settlements. In addition to the effects of any investigations or claims brought against us, our business, results of operations and financial condition could also be adversely affected if any such inquiries, of us or of other pharmaceutical companies or the industry more generally, were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products.

Certain prescription product coding databases may choose to reclassify prescription dietary supplements as non-prescription, or over-the-counter, which may result in limited or no insurance coverage for these products and a decrease in utilization of such products

Many private and government insurance plans refer to product listing databases to determine whether or not a product is a prescription product, a non-prescription, or over-the-counter product or a medical food product. How a product is listed in these databases impacts whether or not a product is covered by insurance, or whether it receives limited coverage, as many payors may choose not to cover over-the-counter products. For example, on May 15, 2017, First Databank, a prescription coding database, announced that starting in June 2017 it would classify all dietary supplements as non-prescription. Several companies have sued First Databank, in an effort to prevent or delay the implementation of the reclassification. Subsequently, First Databank proceeded with reclassifying prenatal and non-prenatal dietary supplements to non-prescription which affected some of our products. Payors, however, are not bound by the listing databases and may still decide to cover prenatal supplements. If other listing databases were to re-classify all dietary supplements, including prenatal dietary supplements, as non-prescription or over-the-counter, this could prevent insurance coverage for our prescription prenatal dietary supplements and negatively impact our future total revenues, profitability and cash flows.

[Table of Contents](#)

We are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations. Any non-compliance may result in fines or other sanctions, including debarment, product seizures, product recalls, injunctive actions and criminal prosecutions, which could result in material adverse effects to our business, financial position and results of operations.

The pharmaceutical industry operates in a highly regulated environment subject to the actions of courts and governmental agencies that influence the ability of a company to successfully operate its business and is subject to regulation by various governmental authorities at the federal, state and local levels with respect to the development, manufacture, labeling, sale, distribution, marketing, advertising and promotion of pharmaceutical products. As a pharmaceutical manufacturer and distributor, we are subject to extensive regulation by the federal government, principally the FDA and the Drug Enforcement Administration, or DEA, as well as by state governments.

The FDCA, the Controlled Substances Act, the Generic Drug Enforcement Act of 1992, or the Generic Drug Act, and other federal, state and local statutes and regulations govern the testing, manufacture, safety, labeling, storage, disposal, tracking, recordkeeping, approval, advertising and promotion (including to the healthcare community) of our products. If we, our products, the manufacturing facilities for our products, our CROs, or other persons or entities working on our behalf fail to comply with applicable regulatory requirements either before or after marketing approval, a regulatory agency, such as the FDA, may, depending on the stage of product development and approval, revoke, withdraw, or suspend approvals of previously approved products for cause, debar companies and individuals from participating in the drug-approval process, request or in certain circumstances mandate recalls of allegedly violative products, seize allegedly violative products, issue Warning Letters or Untitled Letters, mandate modifications to promotional materials or require the provision of corrective information to healthcare practitioners, amend and update labels or package inserts, suspend or terminate any ongoing clinical trials, refuse to approve pending applications or supplements to applications filed, refuse to allow entry into government contracts, obtain injunctions to close manufacturing plants allegedly not operating in conformity with FDA's cGMP requirements, stop shipments of allegedly violative products, impose fines perhaps significant in amount, require entry into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance and other sanctions imposed by courts or regulatory bodies, including criminal prosecutions. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. From time to time, we have voluntarily recalled our products and may do so in the future.

Because of the chemical ingredients of pharmaceutical products and the nature of the manufacturing process, the pharmaceutical industry is subject to extensive environmental laws and regulation and the risk of incurring liability for damages and the costs of remedying environmental problems. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of hazardous materials and pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment, which could cause environmental or property damage or personal injuries, and which could result in (i) our noncompliance with such environmental and occupational health and safety laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an unapproved or illegal environmental discharge or accident occurred or if we were to discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, then we could be liable for cleanup, damages or fines, which could have a material adverse effect on our business, financial position, results of operations and cash flow. In the future, we may be required to increase expenditures in order to remedy environmental problems or comply with changes in applicable environmental laws and regulations. We could also become a party to environmental remediation investigations and activities. These obligations may relate to sites that we currently or in the future may own or lease, sites that we formerly owned or operated, or sites where waste from our operations was disposed. Additionally, if we fail to comply with environmental regulations to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the provisions of our operating licenses, the licenses could be revoked, and we could be subject to criminal sanctions or substantial civil liability or be required to suspend or modify our manufacturing operations. We currently operate in Florida, Georgia, and New Jersey, and in overseas

jurisdictions including Argentina and Hungary, and we are required to comply with the laws and regulations of those states or

[Table of Contents](#)

overseas jurisdictions in addition to any federal laws and regulations. We may in the future establish or acquire operations in other jurisdictions subject to equally or more stringent laws and regulations.

Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to us, and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures, as well as other costs and liabilities, which could materially adversely affect us.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are now required to file with the FTC, and the DOJ certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The potential for FTC investigations and litigation and private-party lawsuits associated with arrangements between brand and generic drug manufacturers could adversely affect our business. In recent years, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged payment from the brand company to the generic company (so-called “pay for delay” patent litigation settlements) and to call on legislators to pass stronger laws prohibiting such settlements. In 2013, the U.S. Supreme Court held that certain of such settlements could violate anti-trust laws and must be evaluated under a “rule of reason” standard of review.

We are subject to the effects of changes in statutes, regulations and interpretative guidance that may adversely affect our business and that could require us to devote increased time and resources to our compliance efforts, which may not be successful. Any changes in statutes, regulations or interpretative guidance could have a material adverse effect on our business, financial condition, prospects and results of operations.

We also cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If any legislative or administrative actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted, and if we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products or product candidates, which would adversely affect our ability to generate revenues and achieve or maintain profitability.

These risks, along with others, have the potential to materially and adversely affect our business, financial position, results of operations and prospects. Although we have developed compliance programs to address the regulatory environment, there is no guarantee that these programs will meet regulatory agency standards now or in the future. Additionally, despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we are deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected.

The manufacture, packaging, labeling, advertising, promotion, distribution and sale of our dietary supplements are also subject to regulation by numerous national and local governmental agencies, including the FDA and FTC. Failure to comply with regulatory requirements pertaining to any of our products, including prescription drugs and dietary supplements, may result in various types of penalties or fines. These include injunctions, product withdrawals, recalls, product seizures, fines and criminal prosecutions. Individual U.S. states also regulate dietary supplements. A state may seek to interpret claims or products presumptively valid under federal law as illegal under that state's regulations. Any or all of these requirements could have a material adverse effect on us. In addition, the FDA's policies may change and additional government regulations could impose more stringent product labeling and post-marketing testing and other requirements. For example, the FDA has stated that there is no specific upper limit on the amount of folic acid permitted in dietary supplements. If the FDA were to regulate products with higher amounts of folic acid as drugs, it may require us to stop marketing and selling certain dietary supplement products. There can be no assurance that the regulatory environment in which we operate will not change or that such regulatory environment, or any specific action taken against us, will not result in a material adverse effect on us.

[Table of Contents](#)

The drug regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable and typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons. For example:

- the FDA or comparable foreign regulatory authorities may disagree that our product candidates meet the criteria for the NDA or ANDA regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or chemically identical and bioequivalent to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market certain of our product candidates, which would harm our business, results of operations and prospects significantly. In addition, even if we obtain approval for our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

If we are found to have improperly promoted our products, we may be subject to restrictions on the sale or marketing of our products and significant fines, penalties and sanctions, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies, including regulatory authorities outside the United States, strictly regulate the marketing and promotional claims that are made about drug products. In particular, promotion for a product must be balanced, truthful, non-misleading and consistent with its labeling approved by the FDA or by regulatory agencies in other countries. We cannot prevent physicians from prescribing our products for indications or uses that are inconsistent with the approved package insert. If, however, we are found to have promoted such unapproved uses prior to the FDA's approval for an additional indication, we may, among other consequences, receive Untitled or Warning Letters and become subject to significant liability, which would materially harm our business. Both the U.S. federal government and foreign regulatory authorities have levied significant civil and criminal fines against companies and individuals for

[Table of Contents](#)

alleged improper promotion and have entered into settlement agreements with pharmaceutical companies to limit inappropriate promotional activities. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our reputation could be damaged.

Our business operations and current and future relationships with investigators, healthcare professionals, third-party payors, patient organizations and customers are subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, third-party payors, patient organizations and customers subject us and our customers to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products and product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or arrangement for, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act or EKRA, enacted in 2018, which prohibits certain payments related to referrals of patients to certain providers (such as recovery homes, clinical treatment facilities and laboratories) and applies to services reimbursed by private health plans as well as government health care programs;
- the U.S. federal civil and criminal false claims, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal law HIPAA, which created additional federal criminal statutes which prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and its implementing regulations, which imposes certain privacy, security and breach reporting obligations, with respect to individually identifiable health information upon covered entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers as well as the covered entities' business associates, which are independent contractors of a covered entity that perform certain services that involve creating, using, maintaining or transmitting individually identifiable health information;

- the U.S. federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence

[Table of Contents](#)

the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the U.S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;
- the U.S. "Federal Sunshine Law," or Open Payments, and its implementing regulations, which require certain manufacturers of drugs and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians, non-physician practitioners and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing sales, shipping and marketing information, which includes tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives and reporting to certain states the shipment of opioid products into those states; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the European Union, or the EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties.

Our operations in non-U.S. jurisdictions subject us to increased regulatory oversight and regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position and results of operations.

We are subject to certain risks associated with our operations in non-U.S. jurisdictions, including Argentina and Hungary, and with having assets and operations located in non-U.S. jurisdictions. Our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in

Table of Contents

exchange rates and controls, interest rates and taxation policies and increased government regulation. Certain jurisdictions have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations there to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, we operate in countries, including Argentina and Hungary, where there have been reported instances of government corruption and there are circumstances in which anti-bribery laws may conflict with some local customs and practices.

Our international operations may subject us to heightened scrutiny under the U.S. Foreign Corrupt Practices Act, or FCPA, other federal statutes and regulations, including those established by the Office of Foreign Assets Control, the Irish Criminal Justice (Money Laundering and Terrorist Financing) Acts 2010-2018, or the Irish Money Laundering Acts, the Irish Criminal Justice (Corruption Offences) Act 2018, the U.K. Bribery Act, anti-corruption provisions in the Hungarian Criminal Code, Argentina's recently enacted Law 27.401 and other similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws and regulations. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The Irish Criminal Justice (Corruption Offences) Act 2018 renders a company liable for prosecution where any of its officers, managers, employees, agents or subsidiaries are found to be involved in corruption. The only defense is for the company to show that it took all reasonable steps and exercised all due diligence to prevent such corruption from taking place. The legislation also applies to certain international activities. The Irish Money Laundering Acts provide for criminal sanctions for engaging in "money laundering offences," which are offenses committed where a person knows or believes that (or is reckless as to whether or not) the property represents the proceeds of criminal conduct and the party is involved in concealing or disguising the true nature, source, location, disposition, movement or ownership of property, or in converting, transferring, handling, acquiring possession or using the property, or removing the property from, or bringing the property into, Ireland. In addition, the U.K. Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the U.K. Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to our business practices, including the cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase our compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition. As a result of our policy to comply with the FCPA, the Irish Money Laundering Acts, the Irish Criminal Justice (Corruption Offences) Act 2018, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws and regulations.

We are subject to various laws protecting the confidentiality of certain patient health information, and other personal information, and our failure to comply could result in penalties and reputational damage.

Numerous U.S. states and countries in which we operate, manufacture and sell our products have, or are developing, laws protecting data privacy and the confidentiality of certain personal data, including not only patient health information but also data on employees, customers, contractors and other types of individuals with whom we interact. The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations, and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. One example of such a law is the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including

the right to receive certain details regarding the processing of their data by covered companies, the right to request deletion of their data, and the right to opt out of sales of their data. The CCPA

[Table of Contents](#)

additionally imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities. The CCPA provides for imposition of substantial fines on companies that violate the law and also confers a private right of action on data subjects to seek statutory or actual damages for breaches of their personal information. In Europe, the EU General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Economic Area (EEA) and substantial fines for breaches of the data protection rules. The GDPR expanded the territorial scope of European data privacy legislation to include not only entities that are established in the EEA, but also entities that are not established in the EEA but that offer goods or services to individuals located in the EEA or monitor the behavior of individuals located in the EEA. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition. The GDPR also provides for the assessment of fines on entities that violate the regulation of up to 20 million Euros or four percent of annual turnover and provides data subjects a private right of action to seek compensation for damages suffered as a result of violations of the regulation.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the EEA, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data and the processing of personal data for research purposes), meaning that inconsistencies between different member states will still arise. EEA member states have their own regimes on medical confidentiality and national and EU-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the EEA.

European data protection law generally prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, unless there are specific frameworks or mechanisms in place, such as the European Commission approved standard contractual clauses, or if very narrow legal exceptions (such as data subject consent) apply. Our ability to receive data from the EEA could be affected by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as challenges to these mechanisms in the European courts.

In recent years, U.S. and European regulators have expressed concern over electronic marketing and the use of third-party cookies, web beacons and similar technology for online behavioral advertising. In the EEA, informed consent is required for the placement of many types of cookies on a user's device, such as cookies used for online behavioral advertising, as well as for the sending of many types of electronic marketing communications. The current EU laws that cover the use of cookies and similar technology and marketing online or by electronic means are under reform. A draft of the new ePrivacy Regulation is currently going through the European legislative process. Unlike the current ePrivacy Directive, the draft ePrivacy Regulation will be directly implemented into the laws of each of the EU member states, without the need for further enactment. When implemented, it is expected to alter rules on third-party cookies, web beacons and similar technology for online behavioral advertising and to impose stricter requirements on companies using these tools. The current provisions of the draft ePrivacy Regulation also significantly increase penalties.

Failure to comply with data protection laws and regulations could result in government enforcement actions, which may involve civil and criminal penalties, private litigation and/or adverse publicity and could negatively affect our business, financial condition and results of operations. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business, financial condition and results of operations.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by

HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or

[Table of Contents](#)

conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information that we receive throughout the clinical trial process or in the course of our research collaborations. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws and consumer protection laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. If we or third-party CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Our reporting and payment obligations under the Medicaid drug rebate program and other governmental purchasing and discount or rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, which could have a material adverse effect.

The requirements regarding price reporting and discount or rebate obligations applicable to the various government pricing and reimbursement programs, such as the Medicaid Drug Rebate Program, are complex.

Our calculations and methodologies related to government pricing reporting are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. For example, we were subject to an audit by the Office of Inspector General related to purported overcharges with respect to the prices of VERT that were purchased by the U.S. Department of Veterans Affairs. Although we believe that the prices we charged in these transactions were appropriate and have settled this matter, an adverse determination of other audits could result in the imposition of significant financial penalties, which could have a material adverse impact on our results of operations and financial condition.

Any governmental agencies that have commenced (or that may commence) an investigation of our company could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, there may be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority could take a position contrary to a position that we have taken and may impose civil or

criminal sanctions on us. Any such penalties, sanctions, or exclusion from federal health care programs could have a

[Table of Contents](#)

material adverse effect on our business, financial position and results of operations. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Many government and third-party payors, including Medicare, Medicaid, MCOs and others, reimburse doctors and others for the purchase of certain prescription drugs based on a drug's average wholesale price, or AWP. In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, in which the agencies have suggested that reporting of inflated AWPs by manufacturers have led to excessive payments for prescription drugs. We can give no assurance that we will be able to resolve any future actions that may be brought against us on terms that we deem reasonable, or that such settlements or adverse judgments, if entered, will not exceed the amount of any reserve. Accordingly, such actions could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

Increased scrutiny around the abuse of opioids, including law enforcement concerns over diversion and legislative and regulatory efforts to combat abuse, could impact some of our pharmaceutical products, and could reduce the demand and increase the cost, burden and liability associated with the commercialization of opioids.

Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may affect our opioid products, such as tramadol extended-release capsules and hydromorphone ER (hydromorphone hydrochloride extended-release tablets). For the year ended December 31, 2020, our opioid products represented 17% of our total revenues. Aggressive enforcement by the DEA or other regulators, unfavorable publicity regarding, for example, the use or misuse of opioid drugs or the limitations of abuse-deterrent formulations, litigation, public inquiries or investigations related to the abuse, sales, marketing, distribution or storage of our products could harm our reputation, result in financial consequences in the form of litigation costs, fines, penalties, damages, and other costs, or suspension or revocation of licenses necessary to manufacture and distribute controlled substances. Such negative publicity could also reduce the potential size of the market for our drugs and decrease the total revenues we are able to generate from sales. In addition, efforts by the FDA and other regulatory bodies to combat the abuse of opioids may negatively impact the market for our products. The FDA continues to evaluate extended-release and abuse-deterrent opioids in the post-market setting. We expect that the FDA will continue to scrutinize the impact of abuse-deterrent opioids and in the future could impose further restrictions to products currently on the market, which may include changing labeling, imposing additional prescribing restrictions, or seeking a product's removal from the market, which could have an adverse effect on our financial performance.

In addition, some states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have recently enacted, intend to enact, or have considered legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate-release forms of opiates, mandate the use by prescribers of prescription drug databases and mandate prescriber education. The attorneys general from nearly every state have also either opened an investigation into or filed a lawsuit against pharmaceutical manufacturers and distributors of opioid products.

At the state and local level, a number of states, cities, counties, Native American tribes, third party payors, hospitals and other health service providers, schools, individuals and guardians of children diagnosed with neonatal abstinence syndrome have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. Over 2,400 of these lawsuits have been consolidated in multi-district litigation in the Northern District of Ohio in *In re: National Prescription Opiate Litigation*, 1:17-md-2804, or Federal Opioid MDL. The outcome of those bellwether cases will be used to evaluate the settlement and litigation value of the remaining coordinated cases. We are not named in any of the cases pending in the multi-district litigation, but cases continue to be filed in federal courts across the country and continue to be consolidated into the Federal Opioid MDL. Cases against pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioids drugs, also continue to be separately litigated in state courts across the country. For example, on August 26, 2019, an Oklahoma court

ordered Johnson & Johnson to pay \$572 million, which was later reduced to \$465 million, for its role in the state's opioid crisis,

[Table of Contents](#)

including for violating Oklahoma's public nuisance law. On March 15, 2018, a coalition of local governments in Arkansas, comprised of 75 counties and 15 cities, jointly filed a lawsuit in the Circuit Court of Crittenden County, Arkansas against more than 60 defendants, including us. The summons and complaint that we received on April 30, 2018 claimed that we and the other defendants, including prescription opioid manufacturers, distributors and retailers, and several physicians, were negligent and violated public nuisance law as well as various Arkansas controlled substance laws as a result of alleged opioid sales and marketing practices. The lawsuit sought damages and restitution for past and prospective spending related to opioid use, as well as punitive and treble damages. On July 17, 2018, the court entered an order in the Arkansas litigation voluntarily dismissing us from the lawsuit without prejudice. If similar federal or state lawsuits are filed against us in the future, we may be subject to excessive litigation or settlement costs, negative publicity, diversion of management time and attention, decreased sales or removal of one or more of our opioid products from the market, which could have a material adverse effect on our business, results of operations and financial condition. The risk of inclusion in the Federal Opioid MDL may intensify the impact of negative publicity and could lead to a proliferation of lawsuits naming us.

Additionally, in March 2017, President Trump announced the creation of a commission, through the Office of National Drug Control Policy, to make recommendations to the President on how to best combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. On October 26, 2017, President Trump declared the opioid crisis a "national public health emergency." The commission's final report was released in early November 2017. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the Centers for Disease Control and Prevention, or CDC, guidelines and a seven-day limit on the supply of opioids for acute pain. In September 2017, CVS Pharmacy announced that it would only fill first time opioid prescriptions for acute pain for a seven day supply. State legislative initiatives may take various forms, including attempts to tax opioid products. For instance, in 2018, New York enacted a state law (The Opioid Stewardship Act) which intended to raise \$600 million from opioid manufacturers and distributors by taxing morphine milligram equivalents. A federal district court subsequently determined that the law was unconstitutional because the law violated the commerce clause. That ruling is currently on appeal. These and other similar initiatives and actions, whether taken by governmental authorities or other industry stakeholders, may result in the reduced prescribing and use of opioids, including our opioid products, which could adversely affect our ability to commercialize our opioid products, and in turn adversely affect our business, financial condition and results of operations.

Some of our products, including methylphenidate ER, are stimulant products and face intense competition from existing or future stimulant products and also have the potential for misuse, which could reduce the demand and increase the cost, burden and liability associated with the commercialization of such products.

Some of our products and product candidates are stimulants, including methylphenidate ER. The markets for methylphenidate ER and other stimulants to treat ADHD are well developed and populated with established drugs marketed by large pharmaceutical, biotechnology and generic drug companies. There have also been efforts to develop stimulant products that are less prone to abuse, and such products may compete with our products. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis or otherwise, drug products or drug delivery technologies that are more effective, less costly or less prone to abuse than our stimulant products, or any product candidate that we may develop. In addition, because of the potential for abuse of stimulant products, regulatory agencies may develop and apply policies that seek to limit the abuse of such stimulant products. If our competitors develop and market stimulant products that are more effective, safer or less expensive than our product or future product candidates, if any, or if abuse of our stimulant products result in increased liability or reduced demand for such products, this could impact our ability to generate revenues from such stimulant products and will adversely affect our business and financial condition.

[Table of Contents](#)

The DEA limits production of some of our products and limits the availability of certain of our products' active ingredients. Procurement and production quotas set by the DEA may not be sufficient to allow us to complete clinical trials or to meet commercial demand, and may result in clinical delays.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Methylphenidate included in our methylphenidate ER and M-72 products and hydromorphone included in our hydromorphone ER product are listed as Schedule II drugs and tramadol hydrochloride included in our ConZip product is listed as a Schedule IV drug by the DEA under the Controlled Substances Act. The manufacture, shipment, storage, sale and use of Schedule II drugs are subject to a high degree of regulation. For example, Schedule II drug prescriptions generally must be signed by a physician and may not be refilled without a new prescription. Substances in Schedule IV are considered to have a lower potential for abuse relative to substances in Schedule II. A prescription for controlled substances in Schedule IV may be issued by a practitioner through oral communication, in writing, or by facsimile to the pharmacist, and may be refilled if so authorized on the prescription or by call-in. In the future, our other potential products may also be listed by the DEA as controlled substances.

Furthermore, the DEA limits the availability of the active ingredients in certain of our current drug products and sets a quota on the production of these products. We, or our contract manufacturing organizations, must annually apply to the DEA for procurement and production quotas in order to obtain these substances and produce our products. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials, which may result in delays in clinical trials or inability to meet commercial demand. Moreover, the DEA may adjust these quotas from time to time during the year. Any delay or refusal by the DEA to establish or modify our quotas for controlled substances could delay or stop clinical trials or product launches, or could cause trade inventory disruptions, which could have a material adverse effect on our business, financial position, results of operations and cash flows.

We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums.

Like all pharmaceutical companies, we face the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We likely cannot avoid such claims. Unanticipated side effects or unfavorable publicity concerning any of our products would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies and other retailers, customers, patients and clinical trial participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management's time, damage our reputation and impair the marketability of our products. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. In addition, insurance coverage for product liability may become prohibitively expensive in the future or, with respect to certain high-risk products, may not be available at all. For example, some product liability insurance carriers exclude from coverage claims related to abuse or misuse of our opioid products, such as hydromorphone ER. As a result we may not be able to maintain adequate product liability insurance coverage to mitigate the risk of large claims, or we may be required to maintain a larger self-insured retention than we would otherwise choose.

Manufacturing or quality control problems may damage our reputation for quality production, require costly remedial activities and negatively impact our business, results of operations and financial condition.

As a pharmaceutical company, we are subject to substantial regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and other healthcare regulators with respect to the manufacture of pharmaceutical products. We must register our facilities, whether located in the United States or elsewhere, with the FDA as well as regulators outside the United States. Also, our products, including our investigational products, must be made in a manner consistent with

applicable cGMP regulations, or similar standards in each territory in which we manufacture. The failure of one of our facilities, or a facility of one of our third-party suppliers, to comply with

[Table of Contents](#)

applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility.

In addition, the FDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or a Warning Letter for violations of “regulatory significance” that may result in enforcement action if not promptly and adequately corrected. We have in the past received Warning Letters from the FDA regarding certain operations. For example, in May 2017, the FDA issued a Warning Letter to us for violation of post-marketing adverse drug experience reporting requirements, specifically for (i) failing to develop written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences, and (ii) failing to submit periodic adverse drug experience reports annually. This Warning Letter was based on an October-November 2016 FDA inspection. We have been providing periodic updates to FDA outlining our corrective steps taken in response to this Warning Letter. In July 2018, the FDA conducted an inspection of our pharmacovigilance function as follow up to the May 10, 2017 Warning Letter. On October 25, 2018, the FDA sent us a letter stating that it completed an evaluation of our corrective actions and confirming that we had addressed the violations contained in the Warning Letter but we cannot be assured that the FDA will continue to be satisfied with our quality control and manufacturing systems and standards with respect to this or other matters. Failure to comply strictly with these regulations and requirements may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production or distribution, withdrawal or suspension of the applicable regulator’s review of our submissions, enforcement actions, injunctions and criminal prosecution. Further, other federal agencies, our customers and partners in our development, manufacturing, collaboration and other partnership agreements with respect to our products and services may take any such FDA observations or Warning Letters into account when considering the award of contracts or the continuation or extension of such partnership agreements. The delay and cost of remedial actions, or obtaining approval to manufacture at a different facility, could negatively impact our business. Any failure by us to comply with applicable laws and regulations or any actions by the FDA and other agencies as described above could have a material adverse effect on our business, financial position and results of operations.

The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition.

Third parties could illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation and our business.

Public loss of confidence in the integrity of our pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our reputation, business, results of operations and financial condition.

Our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business.

Misconduct by our employees and independent contractors, including consultants, vendors and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities;

[Table of Contents](#)

(ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, 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. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and results of operations.

Risks related to our indebtedness

Our substantial indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting obligations on our indebtedness.

We currently have a substantial amount of indebtedness. As of December 31, 2020, our total indebtedness was \$219.5 million (net of deferred financing costs), with unused commitments of \$50.0 million under the senior secured credit facilities.

Subject to the limits contained in our senior secured credit facilities, we may incur substantial additional indebtedness from time to time to finance working capital, capital expenditures, investments or acquisitions, or for other purposes. If we do so, the risks related to this high level of debt could intensify. Specifically, the high level of debt could have important consequences, including, but not limited to:

- making it more difficult for us to satisfy our obligations with respect to our debt;
- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- limiting our ability to obtain additional financing to fund future working capital, capital expenditures, acquisitions or other general corporate requirements;
- increasing our vulnerability to general adverse economic and industry conditions;
- exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under the senior secured credit facilities, which are at variable rates of interest;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete;
- placing us at a disadvantage compared to other, less leveraged competitors; and
- increasing our cost of borrowing.

[Table of Contents](#)

The terms of the credit agreement governing our senior secured credit facilities, or the Credit Agreement, restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.

The Credit Agreement contains a number of restrictive covenants that impose significant operating and financial restrictions on our operating subsidiaries and may limit our ability to engage in acts that may be in our long-term best interest, including restrictions on our ability to:

- incur additional indebtedness;
- pay dividends or make other distributions or repurchase or redeem our share capital;
- prepay, redeem or repurchase certain debt;
- make loans and investments;
- sell assets or enter into sale and lease-back transactions;
- incur liens;
- enter into transactions with affiliates;
- alter the businesses we conduct;
- enter into agreements restricting our subsidiaries' ability to pay dividends;
- consolidate, merge or sell all or substantially all of our assets;
- amend or modify the organizational documents of our operating subsidiaries;
- amend or modify certain indebtedness of our operating subsidiaries;
- change our fiscal year; and
- enter into certain derivative transactions.

In addition, the restrictive covenants in the Credit Agreement require us to comply with certain financial covenants. As of the end of each fiscal quarter, our operating subsidiaries must (i) maintain a Total Leverage Ratio (as defined in the Credit Agreement) no greater than 4.50:1.00 and each subsequent fiscal quarter and (ii) maintain a Consolidated Fixed Charge Coverage Ratio not less than 1.25:1.00. Our ability to meet these financial ratios can be affected by events beyond our control.

A breach of the covenants under the Credit Agreement could result in an event of default under the Credit Agreement. Such an event of default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies which could have a material adverse effect on our business, operations and financial results. In addition, an event of default under the Credit Agreement would permit the lenders under the senior secured credit facilities to terminate all commitments to extend further credit under that facility. Furthermore, if we were unable to repay the amounts due and payable under the senior secured credit facilities, those lenders could proceed against the collateral granted to them to secure that indebtedness which could force us into bankruptcy or liquidation. In the event our lenders accelerate the repayment of the borrowings, we and our subsidiaries may not have sufficient assets to repay that indebtedness. Any acceleration of amounts due under the Credit Agreement

[Table of Contents](#)

or the exercise by the applicable lenders of their rights under the related security documents would likely have a material adverse effect on us. As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively or to take advantage of new business opportunities. These restrictions may affect our ability to grow in accordance with our strategy.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness.

We expect our near term levels of cash flow to be negatively affected by price competition on methylphenidate ER, VERT and Lorzone, and increased expenses associated with new product launches. As a result, we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations. This could, among other things, force us to raise additional funds or force us to reduce our expenses through cost cutting measures either of which could have a material adverse effect on our business. If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. The Credit Agreement restricts our ability to dispose of assets and use the proceeds from those dispositions and also restricts our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. We may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations when due.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, would materially and adversely affect our financial position and results of operations and our ability to satisfy our obligations, including our indebtedness.

If we cannot make scheduled payments on our debt, we will be in default and, as a result:

- our debt holders could declare all outstanding principal and interest to be due and payable;
- the lenders under the senior secured credit facilities could terminate their commitments to loan us money and foreclose against the assets securing the borrowings; and
- we could be forced into bankruptcy or liquidation.

We will require a significant amount of cash to service our indebtedness. The ability to generate cash or refinance our indebtedness as it becomes due depends on many factors, some of which are beyond our control.

Our ability to make scheduled payments on, or to refinance our respective obligations under, our indebtedness and to fund planned capital expenditures and other corporate expenses will depend on the ability of our subsidiaries to make distributions, dividends or advances to us, which in turn will depend on our subsidiaries' future operating performance and on economic, financial, competitive, legislative, regulatory and other factors and any legal and regulatory

[Table of Contents](#)

restrictions on the payment of distributions and dividends to which they may be subject. Many of these factors are beyond our control. We cannot be certain that our business will generate sufficient cash flow from operations or that future borrowings will be available to us in an amount sufficient to enable us to satisfy our respective obligations under our indebtedness or to fund our other needs. In order for us to satisfy our obligations under our indebtedness and fund planned capital expenditures, we must continue to execute our business strategy. If we are unable to do so, we may need to reduce or delay our planned capital expenditures, implement certain cost-saving initiatives, divest assets or refinance all or a portion of our indebtedness on or before maturity. Significant delays in our planned capital expenditures, implementing cost savings measures or divestiture of assets may materially and adversely affect our future revenue prospects. In addition, we cannot assure our creditors that we will be able to refinance any of our indebtedness on commercially reasonable terms or at all.

We are a holding company with nominal net worth and will depend on dividends and distributions from our subsidiaries, which are restricted from paying dividends and distributions to us pursuant to the terms of our existing indebtedness and may be restricted pursuant to the terms of future indebtedness, which as a result may restrict us from paying dividends to you.

We are a holding company with nominal net worth. We do not have any material assets or conduct any business operations other than our investments in our subsidiaries. Our business operations are conducted primarily out of our indirect operating subsidiaries, Vertical Pharmaceuticals, LLC, Trigen Laboratories, LLC, RVL Pharmaceuticals, Inc. and Osmotica Pharmaceutical US LLC. As a result, notwithstanding any restrictions on payment of dividends under our existing indebtedness or under Irish law, our ability to pay dividends, if any, will be dependent upon cash dividends and distributions or other transfers from our subsidiaries. Payments to us by our subsidiaries will be contingent upon their respective earnings and subject to any limitations on the ability of such entities to make payments or other distributions to us. The Credit Agreement restricts our subsidiaries from paying dividends and making distributions to its direct or indirect equity holders unless there are available exceptions thereunder. If we are not able to meet such available exceptions that would allow our subsidiaries to pay a dividend or make a distribution to us, and which would then allow us to pay a dividend to you, then we will need to obtain a waiver from the lenders under the senior secured credit facilities.

Despite our current level of indebtedness, we and our subsidiaries may still be able to incur substantially more debt. This could further exacerbate the risks to our financial condition described above.

We and our subsidiaries may be able to incur significant additional indebtedness in the future. Although the Credit Agreement contains restrictions on the incurrence of additional indebtedness, these restrictions are subject to a number of qualifications and exceptions, and the additional indebtedness incurred in compliance with these restrictions could be substantial. These restrictions also will not prevent us from incurring obligations that do not constitute indebtedness. If new debt is added to our current debt levels, the related risks that we and the guarantors now face could intensify.

Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase significantly.

Borrowings under the senior secured credit facilities are at variable rates of interest and expose us to interest rate risk. Historically, we have elected that Borrowings under the senior secured credit facilities bear interest based upon the London Inter-Bank Offered Rate, or LIBOR. The senior secured credit facilities include a LIBOR floor of 1.00%. The interest period can be set at one, two, three or six months (or, to the extent available to all relevant lenders, twelve months or a shorter period) as selected by us in accordance with the terms of the senior secured credit facilities. An increase of 1.00% in LIBOR would result in a \$2.2 million increase in our annual interest expense associated with the senior secured credit facilities.

Table of Contents

Risks related to our ordinary shares

We qualify both as an “emerging growth company” and as a “smaller reporting company,” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenues of \$1.07 billion or more during any fiscal year before that time, in which cases, we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. In addition, we qualify as a “smaller reporting company,” which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding financial statements, executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them, and we cannot predict or estimate the amount or timing of such additional costs.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Investment funds affiliated with Avista Capital Partners, or Avista, and affiliates of Altchem Limited, or Altchem, have significant influence over us, including control over decisions that require the approval of shareholders, which could limit your ability to influence the outcome of matters submitted to shareholders for a vote.

We are currently controlled by Avista and Altchem, who we refer to as our Sponsors. As of March 1, 2021, investment funds affiliated with the Sponsors beneficially owned approximately 64.5% of our outstanding ordinary shares. For as long as the Sponsors own or control at least a majority of our outstanding voting power, they will have the ability to exercise substantial control over all corporate actions requiring shareholder approval, irrespective of how our other shareholders may vote, including over the election and removal of directors, any amendment to our Constitution, the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. Even if their ownership falls below 50%, they will continue to be able to strongly influence or effectively control our decisions so long as they continue to hold a significant portion of our ordinary shares. In addition, each of the Sponsors has a contractual right to nominate two directors for so long as such Sponsor owns at least 20% of our outstanding ordinary shares, and one director for so long as such Sponsor owns less than 20% but more than 10% of our outstanding ordinary shares.

Additionally, the Sponsors’ interests may not align with the interests of our other shareholders. Avista and Altchem are in the business of making investments in companies and may acquire and hold interests in businesses that compete directly or indirectly with us. The Sponsors may also pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us.

[Table of Contents](#)

We are a “controlled company” within the meaning of the rules of the Nasdaq Stock Market and, as a result, qualify for, and rely on, exemptions from certain corporate governance requirements. As a result, you do not have the same protections afforded to shareholders of companies that are subject to such requirements.

Because the Sponsors control a majority of the voting power of our outstanding ordinary shares, we are a “controlled company” within the meaning of the corporate governance standards of the Nasdaq Stock Market. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a “controlled company” and may elect not to comply with certain corporate governance requirements, including the requirements that, within one year of the date of the listing of our ordinary shares:

- we have a board of directors that is composed of a majority of “independent directors,” as defined under the rules of the Nasdaq Stock Market;
- we have a compensation committee that is composed entirely of independent directors; and
- we have a nominating and corporate governance committee that is composed entirely of independent directors.

We intend to continue to utilize all of these exemptions. Accordingly, for so long as we are a “controlled company,” you will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. Our status as a controlled company could make our ordinary shares less attractive to some investors or otherwise harm our share price.

Our directors who have relationships with Avista or Altchem may have conflicts of interest with respect to matters involving our company.

Two of our seven directors are affiliated with Avista and two directors are affiliated with Altchem. In addition, our Chief Executive Officer, Brian Markison, serves as an operating executive at Avista Capital Partners. Our directors have fiduciary duties to us and, in addition, have duties to Avista or Altchem, as applicable. As a result, these directors may face real or apparent conflicts of interest with respect to matters affecting both us and Avista or Altchem, as applicable, whose interests, in some circumstances, may be adverse to ours.

Your percentage ownership in us may be diluted in the future, which could reduce your influence over matters on which shareholders vote.

In the future, your percentage ownership in us may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we have granted or may grant in the future to directors, officers and employees. From time to time, we may issue additional options or other share based awards to our directors, officers and employees under our benefits plans.

Pursuant to our Articles of Association, our board of directors has the authority, without action or vote of our shareholders and on a non-pre-emptive basis, to issue all or any part of our authorized but unissued ordinary shares, and one or more classes or series of preferred shares having such powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. For example, our board of directors could grant the holders of preferred shares the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences our board of directors could assign to holders of preferred shares could affect the residual value of our ordinary shares.

Issuances of ordinary shares or voting preferred shares in the manner outlined above may reduce your influence over matters on which our shareholders vote.



[Table of Contents](#)

Currently there is a limited public market for our securities, which may limit your ability to sell your shares.

Although our ordinary shares are listed on the Nasdaq Global Select Market under the symbol “OSMT,” our shares have been thinly traded, and there may not be an active trading market for our shares. A public trading market having the desirable characteristics of depth, liquidity and orderliness depends upon the existence of willing buyers and sellers at any given time, such existence being dependent upon the individual decisions of buyers and sellers over which neither we nor any market maker has control. The failure of an active and liquid trading market to continue would likely have a material adverse effect on the value of our ordinary shares. The market price of our ordinary shares may decline and you may not be able to sell our ordinary shares at or above the price you paid for them, or at all. An inactive market may also impair our ability to raise capital to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Registration of the beneficial interests in our shares subjects us and the holders of such beneficial interests to certain risks.

We entered into a Depository Agreement, or DTC Agreement, with the Depository Trust Company, or DTC, in connection with the listing and trading of our shares on the Nasdaq Global Select Market. In accordance with the DTC Agreement, following completion of the initial public offering of our shares, DTC’s nominee, Cede & Co., was registered as the legal owner of certain of our ordinary shares in the Irish shareholder register that we are required to maintain pursuant to the Companies Act 2014 of Ireland, or the Irish Companies Act. Under the DTC Agreement, DTC credited the beneficial interests in those ordinary shares in book entry form to its participants. Accordingly, while the ordinary shares issued in accordance with Irish law are listed and traded on the Nasdaq Global Select Market, it is the beneficial interests in such ordinary shares that are settled and held in DTC. In accordance with market practice and system requirements of the Nasdaq Global Select Market, the ordinary shares are listed and traded on the Nasdaq Global Select Market under the category of “Common Share.” In respect of beneficial interests in ordinary shares held in DTC, such beneficial ownership would not necessarily be recognized by an Irish court. As such, investors holding beneficial interests in our ordinary shares within DTC may have no direct rights against us and our officers and directors and may be required to obtain the cooperation of DTC in order to assert claims against us and our officers and directors, and to look solely to DTC for the payment of any dividends, for exercise of voting rights attaching to the underlying ordinary shares and for all other rights arising in respect of the underlying ordinary shares. We cannot guarantee that DTC will be able to continue to execute its obligations under the DTC Agreement, including that the beneficial owners of the ordinary shares within DTC will receive notice of general meetings in time to instruct DTC to either effect registration of their ordinary shares or otherwise vote their ordinary shares in the manner desired by such beneficial owners. Any such failure may, inter alia, limit the access for, delay or prevent, such beneficial shareholders from being able to exercise the rights attaching to the underlying ordinary shares.

DTC has certain termination rights under the DTC Agreement. In the event that the DTC Agreement is terminated, we will use our reasonable best efforts to enter into a replacement agreement for purposes of permitting the uninterrupted listing of our ordinary shares on the Nasdaq Global Select Market. There can be no assurance, however, that it would be possible to enter into such a new agreement on substantially the same terms as the DTC Agreement or at all. A termination of the DTC Agreement could, therefore, have a material and adverse effect on us and the beneficial shareholders holding their ordinary shares within DTC. The DTC Agreement limits DTC’s liability for any loss suffered by us. DTC disclaims any liability for any loss attributable to circumstances beyond DTC’s control, including, but not limited to, errors committed by others. DTC is only liable for direct losses incurred as a result of events within DTC’s control. Thus, we may not be able to recover our entire loss if DTC does not perform its obligations under the DTC Agreement.

Our share price may be volatile, and the market price of our ordinary shares may drop below the price you pay.

Our share price has been and may continue to be volatile. Since our initial public offering in October 2018, the closing price of our ordinary shares as reported on the Nasdaq Global Select Market has ranged from a low of \$2.34 on June 10, 2019 to a high of \$9.20 on October 22, 2018. In addition,

securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic,

[Table of Contents](#)

market or political conditions, could subject the market price of our shares to wide price fluctuations regardless of our operating performance. The trading price of our shares may fluctuate in response to various factors, including:

- market conditions in the broader stock market;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- introduction of new products or services by us or our competitors;
- issuance of new or changed securities analysts' reports or recommendations;
- results of operations that vary from expectations of securities analysts and investors;
- results of operations that vary from those of our competitors;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- strategic actions by us or our competitors;
- announcement by us, our competitors or our vendors of significant contracts or acquisitions;
- sales, or anticipated sales, of large blocks of our shares;
- additions or departures of key personnel;
- regulatory, legal or political developments;
- public response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- litigation and governmental investigations;
- changing economic conditions;
- changes in accounting principles;
- default under agreements governing our indebtedness;
- exchange rate fluctuations; and
- other events or factors, including those from natural disasters, war, acts of terrorism or responses to these events.

These and other factors, many of which are beyond our control, may cause our market price and demand for our shares to fluctuate substantially. Fluctuations in our share price could limit or prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of shares have been volatile, holders of those shares have sometimes instituted securities class action litigation against the company that issued the shares. For example, on April 30, 2019 we were served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*, and on May 10, 2019, a complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19*

[Table of Contents](#)

was filed in the same court as the Shumacher action. The complaints name us, certain of our directors and officers and the underwriters of our initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for our initial public offering of ordinary shares. On July 22, 2019, the plaintiffs filed an Amended Complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. The parties participated in a mediation in December 2020 and agreed to settle the litigation. The parties are currently negotiating a settlement agreement which will need to be approved by the Court. We expect the settlement to be finalized and the litigation to be dismissed, the second quarter of 2021.

Since we have no current plans to pay regular cash dividends on our ordinary shares, you may not receive any return on investment unless you sell your ordinary shares for a price greater than that which you paid for it.

We do not anticipate paying any regular cash dividends on our ordinary shares for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. Our ability to pay dividends is, and may be, limited by covenants of existing and any future outstanding indebtedness we or our subsidiaries incur. In addition, our ability to pay cash dividends may be limited by Irish law, as discussed under the risk factor titled “The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our ordinary shares less attractive to investors.” Therefore, any return on investment in our ordinary shares is solely dependent upon the appreciation of the price of our ordinary shares on the open market, which may not occur.

Risks related to being an Irish corporation listing ordinary shares

Provisions contained in our Articles of Association, as well as provisions of Irish law, could impair a takeover attempt, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

Our Articles of Association, together with certain provisions of the Irish Companies Act could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors.

There are a number of approaches for acquiring an Irish public limited company, including a court-approved scheme of arrangement under the Irish Companies Act, through a tender offer by a third party, by way of a merger with a company incorporated in the European Economic Area, or EEA, under the EU Cross-Border Mergers Directive (EU) 2017/1132 as implemented in Ireland by the European Communities (Cross-Border Mergers) Regulations 2008 (as amended) and by way of a merger with a company incorporated in Ireland under the Irish Companies Act. Each method requires shareholder approval or acceptance and different thresholds apply.

The Irish Takeover Panel Act 1997 and the Irish Takeover Rules 2013 made thereunder, or the Irish Takeover Rules, govern a takeover or attempted takeover of our company by means of a court-approved scheme of arrangement or a tender offer. The Irish Takeover Rules contain detailed provisions for takeovers, including as to disclosure, process, dealing and timetable. The Irish Takeover Rules could discourage an investor from acquiring 30% or more of our outstanding ordinary shares unless such investor was prepared to make a bid to acquire all outstanding ordinary shares.

Our Articles of Association contain provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting and other rights of the holders of our ordinary shares. These provisions include:

- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions that allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;

[Table of Contents](#)

- establishing an advance notice procedure for shareholder proposals to be brought before shareholder meetings, including proposed nominations of persons for election to our board of directors;
- the ability of our board of directors to fill vacancies on our board in certain circumstances; and
- imposing particular approval and other requirements in relation to certain business combinations.

These provisions do not make us immune from takeovers. However, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our board of directors may be limited by the Irish Takeover Rules in its ability to defend an unsolicited takeover attempt.

We are subject to the Irish Takeover Panel Act 1997 and the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions, such as (i) the issue of shares, options, restricted share units or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in a jurisdiction of the United States.

The operation of the Irish Takeover Rules may affect the ability of certain parties to acquire our ordinary shares.

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of a company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. Under the Irish Takeover Rules, certain separate concert parties are presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of the company. The application of these presumptions resulted may continue to result in restrictions upon the ability certain concert parties and members of our board of directors to acquire more of our securities, including under the terms of any executive incentive arrangements. We have consulted and may consult again in future with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities, although we are unable to provide any assurance as to whether the Irish Takeover Panel will overrule this presumption in the future.

Our Articles of Association designate the courts of Ireland for all actions and proceedings, other than those relating to U.S. securities law, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees and require shareholders to pursue certain claims outside the United States.

Our Articles of Association provide that, unless our board of directors or one of its duly authorized committees approves the selection of an alternate forum and to the fullest extent permitted by applicable law, the courts of Ireland shall be the exclusive forum for all actions or proceedings, other than those related to U.S. securities law, but including (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty

[Table of Contents](#)

owed by any of our directors, officers or employees to us or our shareholders, (iii) any action asserting a claim against us arising pursuant to any provision of Irish law or our Articles of Association and (iv) any action to interpret, apply, enforce or determine the validity of our Articles of Association. Any person or entity purchasing or otherwise acquiring any interest in our shares shall be deemed to have notice of and to have consented to the provisions of our Articles of Association and waived any argument relating to the inconvenience of the forums described above. As a result, certain shareholder actions and proceedings may only be brought in Ireland and our shareholders would not have access to any U.S. courts with respect to such actions. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Articles of Association inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Irish law differs from the laws in effect in the United States and U.S. shareholders may have difficulty enforcing civil liabilities against us, our directors or members of senior management.

A number of our directors are non-residents of the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may not be possible to serve process on these directors, or us, in the United States or to enforce court judgments obtained in the United States against these individuals or us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. The United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland. A judgment obtained against us will be enforced by the courts of Ireland if the following general requirements are met:

- U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule); and
- the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it.

A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. But where the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether a final judgment given in default of appearance is final and conclusive. Irish courts may also refuse to enforce a judgment of the U.S. courts that meets the above requirements for one of the following reasons:

- the judgment is not for a definite sum of money;
- the judgment was obtained by fraud;
- the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice;
- the judgment is contrary to Irish public policy or involves certain U.S. laws that will not be enforced in Ireland; or
- jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Irish Superior Courts Rules.

[Table of Contents](#)

As an Irish company, we are principally governed by Irish law, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or other officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our ordinary shares may have more difficulty protecting their interests than would holders of shares of a corporation incorporated in a jurisdiction of the United States.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation and these differences may make our ordinary shares less attractive to investors.

We are incorporated under Irish law and, therefore, certain of the rights of holders of our shares are governed by Irish law, including the provisions of the Irish Companies Act, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations and these differences may make our ordinary shares less attractive to investors. The principal differences include the following:

- under Irish law, dividends may only be declared if we have, on an individual entity basis, profits available for distribution, within the meaning of the Irish Companies Act. In addition, no distribution or dividend may be paid or made by us unless our net assets are equal to, or exceed, the aggregate of our called up share capital plus non-distributable reserves and the distribution does not reduce our net assets below such aggregate;
- under Irish law, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of shares. Preemption rights may be disallowed under Irish law for renewable five-year periods by Irish companies by way of a provision in such companies' articles of association or a special resolution of their shareholders. We have opted out of these preemption rights in our Articles of Association as permitted under Irish law for the maximum period permitted of five years from the date of adoption of the Articles of Association;
- under Irish law, certain matters require the approval of holders of 75% of the votes cast at a general meeting of our shareholders, including amendments to our Articles of Association, which may limit our flexibility to manage our capital structure;
- under Irish law, a bidder seeking to acquire us would need, on a tender offer, to receive shareholder acceptance in respect of 80% of our outstanding shares. If this 80% threshold is not achieved in the offer, under Irish law, the bidder cannot complete a "second step merger" to obtain 100% control of us. Accordingly, tender of 80% of our outstanding shares will likely be a condition in a tender offer to acquire us, not 50% as is more common in tender offers for corporations organized under U.S. law; and
- under Irish law, shareholders may be required to disclose information regarding their equity interests upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on the transfer of the shares, as well as restrictions on voting, dividends and other payments.

Risks related to taxation

Changes in our effective tax rate may reduce our net income in future periods.

We cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions in which we operate and the varying applications of statutes, regulations and related interpretations.

A number of factors may increase our future effective tax rates, including: the jurisdictions in which profits are determined to be earned and taxed (which may vary depending on our taxable presence in such jurisdictions as may be

[Table of Contents](#)

determined by tax authorities in such jurisdictions); the resolution of issues arising from tax audits that may be undertaken by various tax authorities; changes in the valuation of our deferred tax assets and liabilities due to changes in applicable tax legislation; increases in expenses that are not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; changes in available tax credits; changes in share-based compensation; changes in tax laws or the interpretation of such tax laws changes to currently applicable tax treaties, including those resulting in a loss of treaty benefits; changes in GAAP; and challenges to the transfer pricing policies related to our structure undertaken by various tax authorities. Currently, jurisdictions within the Organization for Economic Co-Operation and Development, or the OECD, are reviewing OECD proposals relating to base erosion and profit shifting. Our effective tax rate could be adversely affected to the extent that countries adopt such OECD proposals.

U.S. tax legislation enacted in 2017 has significantly changed the U.S. federal income taxation of corporations and multinational consolidated groups, including by reducing the U.S. corporate income tax rate, limiting interest deduction, adopting elements of a territorial international tax system and introducing new anti-base erosion provisions. This legislation is unclear in many respects and could be subject to potential amendments and technical corrections and subject to differing interpretations and implementing regulations by the U.S. Department of Treasury and the Internal Revenue Service, any of which could lessen or increase certain adverse impacts of the legislation or affect our actual effective tax rate.

It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become tax resident in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a charge of Irish capital gains tax as a result of a deemed disposal of our assets. Our actual effective tax rate may vary from our expectation and that variance may be material. Additionally, the tax laws of Ireland and other jurisdictions in which we operate could change in the future, and such changes could cause a material adverse change in our effective tax rate.

If our tax rates or tax expenses were to increase as described above, such increases could cause a material and adverse change in our worldwide effective tax rate and we may have to take action, at potentially significant expense, to seek to mitigate the effect of such changes. In addition, any amendments to the current double taxation treaties between Ireland and other jurisdictions could subject us to increased taxation. Any such amendments to double taxation treaties or increases in taxation based on examinations by taxing authorities, if such increases are ultimately sustained, could result in increased charges, financial loss, including penalties, and reputational damage and materially and adversely affect our results, financial condition and prospects.

If we are a passive foreign investment company, U.S. investors in our ordinary shares could be subject to adverse U.S. federal income tax consequences.

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. federal income tax purposes. We would be classified as a PFIC for any taxable year in which either: (i) at least 75% of our gross income is classified as “passive income” for purposes of the PFIC rules, or (ii) at least 50% of the fair market value of our assets (determined on the basis of a quarterly average) is attributable to assets that produce or are held for the production of “passive income.” For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation we own, directly or indirectly, 25% or more (by value) of its stock.

We do not believe that we were a PFIC for the 2020 taxable year, and we do not anticipate becoming a PFIC for the 2021 taxable year; however, such a determination cannot be made until following the end of such taxable year.

The determination of whether we are a PFIC must be made annually after the close of each taxable year, depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the interpretation and application of the PFIC rules. The fair market value of our assets is expected to depend, in part, upon (a) the market price of our ordinary shares and (b) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. In light of the foregoing, no assurance can be provided that we are not a PFIC for the current taxable year or that we will not become a PFIC for any future taxable year.

Table of Contents

If we are a PFIC, U.S. holders of our ordinary shares would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. If we are classified as a PFIC in any taxable year with respect to which a U.S. holder owns ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless the U.S. holder makes a “deemed sale election.” Furthermore, whether or not U.S. holders of our ordinary shares make timely qualified electing fund, or QEF, elections, if we provide the necessary information to U.S. holders to make such elections, or mark-to-market elections may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and any distributions such U.S. holders may receive. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

U.S. holders of 10% or more of the voting power or value of our ordinary shares may be subject to U.S. federal income taxation at ordinary income tax rates on undistributed earnings and profits.

There is a risk that we will be classified as a “controlled foreign corporation,” or CFC, for U.S. federal income tax purposes. We will generally be classified as a CFC if more than 50% of our outstanding shares, measured by reference to voting power or value, are owned (directly, indirectly or by attribution) by “U.S. Shareholders.” For this purpose, a “U.S. Shareholder” is any U.S. person that owns directly, indirectly or by attribution, 10% or more of the total voting power or total value of our outstanding shares. If we are classified as a CFC, a U.S. Shareholder may be subject to U.S. income taxation at ordinary income tax rates on its proportionate share of our undistributed earnings and profits attributable to “subpart F income” or undistributed earnings and profits invested in certain U.S. property and may also be subject to tax at ordinary income tax rates on any gain realized on a sale of ordinary shares, to the extent of our current and accumulated earnings and profits attributable to such shares. A U.S. Shareholder of a CFC is also required to include in gross income for a taxable year, at a reduced effective tax rate, its proportionate share of certain non-U.S. active business income of a CFC not included in a CFC’s “subpart F income,” or “global intangible low-taxed income,” to the extent such CFC’s “tested income” is in excess of 10% of the adjusted U.S. federal income tax basis of depreciable tangible assets used in the CFC’s trade or business (reduced by a U.S. Shareholder’s allocable net interest expense) and is not otherwise offset by any “tested loss” attributable to other CFCs owned by such U.S. Shareholder. Foreign taxes paid by a CFC attributable to the CFC’s “subpart F income” and “global intangible low-taxed income” and any corresponding foreign tax credits may affect the amount of income includible in a U.S. Shareholder’s gross income for U.S. tax purposes. Even if we are not classified as a CFC, certain of our non-U.S. subsidiaries could be treated as CFCs due to the application of certain attribution rules that currently apply in determining CFC status. If certain non-U.S. subsidiaries are classified as CFCs, any U.S. Shareholder may be required to report annually and include in its U.S. taxable income its pro rata share of “subpart F income,” “global intangible low-taxed income” and investments in U.S. property attributable to those non-U.S. subsidiaries. The CFC rules are complex and U.S. Shareholders and U.S. holders of our ordinary shares are urged to consult their own tax advisors regarding the possible application of the CFC, “subpart F income,” and “global intangible low-taxed income” rules (including applicable direct and indirect attribution rules) to them based on their particular circumstances.

A future transfer of your ordinary shares, other than one effected by means of the transfer of book entry interests in DTC, may be subject to Irish stamp duty.

Transfers of ordinary shares effected by means of the transfer of book entry interests in the DTC should not be subject to Irish stamp duty where ordinary shares are traded through DTC, either directly or through brokers that hold such shares on behalf of customers through DTC. However, if you hold your ordinary shares as of record rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty to arise could adversely affect the price of our ordinary shares.



[Table of Contents](#)

General risk factors

We are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes.

We may be a party to legal proceedings, including matters involving securities liability, personnel and employment issues, intellectual property claims and other proceedings arising in the ordinary course of business. In addition, there are an increasing number of investigations and proceedings in the health care industry generally that seek recovery under the statutes and regulations identified in the section entitled “Business — Government Regulation and Approval Process.” We evaluate our exposure to these legal proceedings and establish reserves for the estimated liabilities in accordance with generally accepted accounting principles, or GAAP. Assessing and predicting the outcome of these matters involves substantial uncertainties. Unexpected outcomes in these legal proceedings, or changes in our evaluation or predictions and accompanying changes in established reserves, could have a material adverse impact on our financial results. For more information on our material pending litigation, see the risk factor under the caption “—Our competitors or other third parties may allege that we, our suppliers or partners are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to “at-risk” product launches, could have a material adverse effect on our business, financial position and results of operations” and the section entitled “Legal Proceedings” herein.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. As a global pharmaceutical company, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. Service interruptions could also result from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

Material weaknesses in our internal control over financial reporting have occurred in the past and could occur in the future.

We are required to comply with the SEC’s rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting.

Maintaining effective internal control over financial reporting is necessary for us to produce reliable financial reports and is important to help prevent financial fraud. We have in the past and may in the

future identify material weaknesses

[Table of Contents](#)

in our internal control over financial reporting. If we are unable to maintain adequate internal controls, our business and operating results could be harmed, we could be subjected to regulatory scrutiny, civil or criminal penalties or shareholder litigation, the defense of any of which could cause the diversion of management's attention and resources, we could incur significant legal and other expenses, and we could be required to pay damages as a result of such actions if any such actions were not resolved in our favor. Moreover, we may be the subject of negative publicity focusing on a material weakness and we may be subject to negative reactions from shareholders and others with whom we do business. Further, we may not be able to remediate a future material weakness in a timely manner and our management may be required to devote significant time and expense to remediate any such material weakness. Failure to maintain adequate internal control over financial reporting could also result in financial statements that do not accurately reflect our financial condition or results of operations, which could result in the need to restate previously issued financial statements. There can be no assurance that we will not identify any significant deficiencies or other material weaknesses in the future that will impair our ability to report our financial condition and results of operations accurately or on a timely basis. In addition, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting in future periods, investors may lose confidence in the accuracy and completeness of our financial reports.

We have in the past identified errors in our financial statements, which required us to restate those financial statements. If we identify errors in our financial reporting in the future, we may be required to restate previously issued financial statements and any such restatement may subject us to regulatory penalties and could cause investors to lose confidence in the accuracy and completeness of our financial statements.

In connection with the preparation of the prospectus for our initial public offering, we identified errors in our financial statements for the years ended December 31, 2016 and December 31, 2017 related to our accounting for certain aspects of the Business Combination. The required adjustments to address these errors led to restatements of those financial statements. In addition, we had to correct certain misstatements in our annual and interim financial statements for 2018 and 2019 related to misstatements associated with the tax treatment of certain intercompany transactions at the time of the Business Combination. Additionally, as previously reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2019, revisions were necessary to correct misstatements related to uncertain tax positions and prepaid taxes and certain other previously identified immaterial misstatements. If we are required to restate any of our financial statements in the future due to our inability to adequately remedy the issues that gave rise to these restatements or for any other reason, we may be subject to regulatory penalties and investors could lose confidence in the accuracy and completeness of our financial statements, which could cause our share price to decline.

Our operating results are affected by many factors and may fluctuate significantly on a quarterly basis.

Our operating results may vary substantially from quarter to quarter and may be greater or less than those achieved in the immediately preceding period or in the comparable period of the prior year. Factors that may cause quarterly results to vary include, but are not limited to, the following:

- our ability to create demand in the marketplace for products we promote;
- the number of new product introductions;
- losses related to inventory write-offs;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- price decreases and associated customer shelf stock adjustments;
- availability of raw materials and finished products from suppliers;

[Table of Contents](#)

- our ability to manufacture products at our manufacturing facilities;
- the scope and outcome of governmental regulatory actions;
- our dependence on a small number of products for a significant portion of total revenues or income; and
- legal actions asserting intellectual property rights against our products brought by competitors and legal challenges to our intellectual property rights brought against us by our competitors; price erosion and customer consolidation; and significant payments (such as milestones) payable by us under licensing and development agreements to our partners before the related product has received FDA approval.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to purchase products from third parties and our ability to manufacture our products in a cost-effective manner. If our total revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of total revenues could, therefore, significantly harm our business and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located in Bridgewater, New Jersey, where we lease approximately 18,000 square feet of office space pursuant to a lease that expires in March 2022. We also own a facility in Marietta, Georgia and lease facilities in Sayreville, New Jersey, Tampa, Florida, Wilmington, North Carolina, and Buenos Aires, Argentina. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to various legal proceedings. In addition, we have in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which exposes us to greater risks associated with litigation, regulatory or other proceedings, including significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our business, financial condition or results of operations.

On February 16, 2018, we received FDA approval for our amantadine extended release tablet product under the trade name Osmolex ER. On that same date we filed in the Federal District Court for the District of Delaware a Complaint for Declaratory Judgment of Noninfringement of certain patents owned by Adamas Pharmaceuticals, Inc. (Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals, LLC vs. Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC). Adamas was served with the complaint on February 21, 2018. Adamas filed an answer on April 13, 2018 denying the allegations in the complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to our Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in our complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. On December 2, 2020, we entered into an agreement to settle the litigation with Adamas. Under the terms of the agreement, both parties agreed to drop their respective claims relating to the patent litigation, and Adamas agreed to acquire the global rights to Osmolex ER from us for \$7.5 million. The sale of the global rights to Osmolex ER closed in January 2021. Additionally, in connection with the settlement and the sale of the global rights to Osmolex ER, the parties entered into a supply agreement pursuant to which we agreed to supply

[Table of Contents](#)

Adamas with amantadine extended release tablets for a six-year term, subject to possible two-year extensions and customary closing conditions.

On April 30, 2019, Osmotica Pharmaceuticals plc was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*. On May 10, 2019, a Complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints named us, certain of our directors and officers and the underwriters of our initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for our initial public offering of ordinary shares. On July 22, 2019, the plaintiffs filed an amended complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. The parties participated in a mediation and reached an agreement in principle to settle the litigation on December 15, 2020. The agreement in principle calls for a payment by the Company of \$5.25 million (a portion of which we expect would be covered by applicable insurance) and would fully resolve all claims asserted in the litigation against all defendants named in the litigation, including the Company. No party would admit any wrongdoing as part of the proposed settlement, which was reached to avoid the further cost and distraction of litigation. The agreement in principle contemplates the negotiation and execution of a final settlement agreement.

The settlement is also subject to preliminary approval by the Superior Court of New Jersey, notice to the putative class, and subsequent final approval by the Superior Court of New Jersey.

In general, we intend to continue to vigorously prosecute and defend any proceedings, as appropriate; however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations and legal proceedings, individually or in the aggregate, could have a material adverse effect on our business, results of operations and cash flows in any given accounting period or on our overall financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

[Table of Contents](#)

PART II

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

Market Information and Holders

Our ordinary shares began trading October 18, 2018. Our ordinary shares are listed on the Nasdaq Global Select Market under the symbol “OSMT.”

As of March 10, 2021, there were four registered holders of record of our ordinary shares.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Dividend Policy

We have never declared nor paid cash dividends on our ordinary shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our ordinary in the foreseeable future. Any future determination to pay cash dividends will be made at the discretion of our board of directors and will depend on restrictions and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table contains information regarding purchases of our ordinary shares made during the year ended December 31, 2020 by or on behalf of Osmotica Pharmaceuticals plc or any “affiliated purchaser,” as defined by Rule 10b-18(a)(3) of the Securities Exchange Act of 1934:

Period	Issuer Purchases of Equity Securities			Maximum number of shares that may yet be purchased under the plans or programs(1)
	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	
10/1/20 - 10/31/20	440,000	5.85	440,000	3,302,985
11/1/20 - 11/30/20	160,000	5.66	160,000	3,142,985
12/1/20 - 12/31/20	-	-	-	3,142,985
Total	600,000	\$ 5.44	600,000	

- (1) On September 3, 2019, our board of directors authorized the repurchase of up to 5,251,892 ordinary shares pursuant to a share repurchase program. Purchases under the ordinary share repurchase program can be made on the open market or in privately negotiated transactions, with the size and timing of these purchases based on a number of factors, including the price of our ordinary shares, our business and market conditions. We retired ordinary shares acquired under the repurchase program. The repurchase program expired November 28, 2020.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

[Table of Contents](#)

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

The statements in the discussion and analysis regarding industry outlook, our expectations regarding the performance of our business and the forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements.” Our actual results may differ materially from those contained in or implied by any forward-looking statements. You should read the following discussion together with the sections entitled “Risk Factors,” “Business” and the audited consolidated financial statements, including the related notes, appearing elsewhere in this Annual Report on Form 10-K. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. As used in this Annual Report on Form 10-K, unless the context suggests otherwise, “we,” “us,” “our,” “the Company” or “Osmotica” refer to Osmotica Pharmaceuticals plc. This discussion and analysis is based upon the historical financial statements of Osmotica Pharmaceuticals plc included in this Annual Report on Form 10-K. Prior to the Reorganization (as defined in the accompanying Notes to Consolidated Financial Statements), Osmotica Pharmaceuticals plc was a subsidiary of Osmotica Holdings S.C.S.p. and had no material assets and conducted no operations other than activities incidental to its formation, the Reorganization and its initial public offering.

We are a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. In 2020, we continued to transition our business to a specialty pharmaceutical company focused on proprietary products primarily in the eye care and neuroscience areas.

We generated total revenues in 2020 across our existing portfolio of promoted women’s health products, specialty neurology, as well as our non-promoted products, which are primarily complex formulations of generic drugs. In 2018, we received regulatory approval from the FDA for Osmolex ER (amantadine extended-release tablets) for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions, which are involuntary muscle movements caused by certain medications, in adults. We completed the launch of Osmolex ER in January 2019. In January 2021, we concluded the sale of Osmolex ER. In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution, 0.1%), for the treatment of acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 to a limited number of eyecare professionals.

Our core competencies span drug development, manufacturing and commercialization. Our sales representatives are fully engaged in the launch and in-person promotion of Upneeq, while we continue to maintain non-personal promotional efforts for certain other products in our portfolio, including M-72 in specialty neurology; OB Complete, our family of prescription prenatal dietary supplements, and Divigel (estradiol gel, 0.1%) in women’s health. As of December 31, 2020, our commercial portfolio of promoted and non-promoted products consists of approximately 35 products. Certain of our key products, particularly those that incorporate our proprietary Osmodex drug delivery system, are manufactured in our Marietta, Georgia facility. Some of our products benefit from intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as U.S. Drug Enforcement Administration, or DEA, regulation and quotas for API.

Many of our generic products compete in generic markets where barriers to entry are lower than markets in which certain of our promoted products compete. Generic products generally contribute most significantly to revenues and gross margins at the time of launch or in periods where no other or a limited number of competing products have been approved and launched. In the U.S., the consolidation of buyers in recent years has increased competitive pressures on the industry as a whole. As such, the timing of new product launches can have a significant impact on a company’s financial results. The entrance into the market of additional competition can have a negative impact on the pricing and volume of the affected products which are outside the company’s control. In particular, methylphenidate ER tablets, venlafaxine ER tablets, or VERT, and Lorzone have experienced, and are expected to continue to experience, significant pricing and market erosion due to additional competition from other generic pharmaceutical companies. This generic pricing erosion has resulted in lower net sales, revenue and profitability from methylphenidate ER tablets, VERT and Lorzone in 2020, and this erosion is expected to continue in subsequent years.

On July 8, 2020, the FDA approved our NDA for Upneeq for the treatment of acquired blepharoptosis in adults. Upneeq was approved based on three Phase III clinical studies that supported Upneeq's efficacy and safety. Results from

[Table of Contents](#)

Upneeq's first Phase III clinical trial showed that the formulation met its primary efficacy endpoint and was well-tolerated.

We believe Upneeq is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis. We currently make Upneeq available exclusively through RVL Pharmacy, Inc. our wholly-owned pharmacy.

We acquired Upneeq as part of our asset acquisition of RevitaLid, Inc., now known as RVL Pharmaceuticals, Inc., in 2017. As part of the acquisition, we agreed to make future earn-out, milestone and royalty payments based on net sales and regulatory developments with respect to Upneeq.

Upneeq is manufactured and supplied to us by Nephron Pharmaceuticals Corporation under an exclusive supply agreement that has a term of five years from the production of the initial commercial batches, and automatically renews for additional one-year periods unless either party provides at least 90 days' advance written notice of non-renewal.

On July 28, 2020, we entered into a license agreement with Santen Pharmaceutical Co. Ltd, or Santen, granting Santen the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Under the license agreement with Santen, we received an upfront license milestone payment of \$25.0 million and may receive additional milestone payments up to \$64.0 million based on regulatory and sales achievements in Santen's territories. We are also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories.

In addition, we are developing our late-stage product candidate arbaclofen extended-release, or ER, tablets designed for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, or MS, for which we have completed Phase III clinical trials. In June 2020, we resubmitted our NDA for arbaclofen ER tablets for the alleviation of spasticity in MS to the FDA. On July 17, 2020 we received notice from the FDA that it considered the resubmission a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020. On December 28, 2020 we received a complete response letter, or CRL indicating the FDA could not approve the NDA in its then current form. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, one of the co-primary endpoints. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL's recommendations and obtain advice on a path forward for the NDA. The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study.

On November 10, 2020, we and our board of directors announced that it is undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include divestitures of non-strategic assets, re-financings, commercialization or collaboration agreements.

Business Update Regarding COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, we have been able to continue to supply our products to our patients without significant disruptions. We do not currently anticipate significant interruptions in supply in the near term. However, we are continuing to monitor the potential impact of the COVID-19 pandemic on our business and operations, including our sales, expenses, manufacturing and clinical trials.

We and our third-party contract manufacturing partners have been able to operate our manufacturing facilities at or near normal levels. While we currently do not anticipate significant interruptions in our manufacturing supply chain, the

[Table of Contents](#)

COVID-19 pandemic and related mitigation efforts may have a negative impact in the future on our third party suppliers' and contract manufacturing partners' ability to manufacture our products or to have our products reach all markets.

We are monitoring the demand for our products, including the duration and degree to which we may see declines in customer orders or new prescriptions for our products, as health care providers are dedicating more resources for the treatment of COVID-19 patients. During the first quarter of 2020, we took action to reduce the size of our field sales force with the remaining sales personnel, in many cases, engaging with physicians remotely as we seek to continue to support healthcare professionals and patient care.

In the U.S. and in most other key markets, our office-based employees have been encouraged to work from home since mid-March 2020. During this time, we are ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories and manufacturing facilities.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in this Annual Report on Form 10-K.

Financial Operations Overview

Segment Information

We currently operate in one business segment focused on the development and commercialization of pharmaceutical products that target markets with underserved patient populations. We are not organized by market and are managed and operated as one business. We also do not operate any separate lines of business or separate business entities with respect to our products. A single management team reports to our chief operating decision maker who comprehensively manages our entire business. Accordingly, we do not accumulate discrete financial information with respect to separate product lines and do not have separately reportable segments. See Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Components of Results of Operations

Revenues

Our revenues consist of product sales, royalty revenues and licensing and contract revenue.

Net product sales—Our revenues consist primarily of product sales of our promoted products, principally Divigel and the OB Complete family of prescription prenatal dietary supplements, M-72, Lorzone, and our non-promoted products. We ship our products to our customers pursuant to purchase orders, which in certain cases are pursuant to a master agreement with that customer, and we invoice the customer upon shipment. For these sales we recognize revenue when control has transferred to the customer, which is typically on delivery to the customer. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which includes estimated chargebacks, commercial rebates, discounts and allowances at the time revenues are recognized.

Royalty revenue—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

Licensing and contract revenue—We have arrangements with commercial partners that allow for the purchase of product from the Company by the commercial partners for purpose of sub-distribution. Licensing revenue is recognized when the performance obligation identified in the arrangement is completed. Variable considerations, such as returns on product sales, government program rebates, price adjustments and prompt pay discounts associated with licensing revenue, are generally the responsibility of our commercial partners.



[Table of Contents](#)

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel expenses, including salaries and benefits for employees in executive, sales, marketing, finance, accounting, business development, legal and human resource functions. General and administrative expenses also include corporate facility costs, including rent, utilities, insurance, legal fees related to corporate matters and fees for accounting and other consulting services. We expect to continue to incur additional general and administrative expenses as a public company, including costs associated with the preparation of our SEC filings, increased legal and accounting costs, investor relations costs, incremental director and officer liability insurance costs, as well as costs related to compliance with the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Research and Development

Costs for research and development are charged as incurred and include employee-related expenses (including salaries and benefits, travel and expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies), costs associated with preclinical activities and development activities and costs associated with regulatory operations.

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 us by our 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 our consolidated financial statements as prepaid expenses or accrued expenses as applicable.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

Financial Operations Overview

The following table presents revenues and expenses for the years ended December 31, 2020 and 2019 (dollars in thousands):

	<u>Year Ended December 31,</u>	<u>2020</u>	<u>2019</u>	<u>% Change</u>
Net product sales	\$ 145,850	\$ 235,472		(38)%
Royalty revenue	4,107	3,641		13 %
Licensing and contract revenue	27,927	918		2,942 %
 Total revenues	 177,884	 240,031	 	 (26)%
Cost of goods sold (inclusive of amortization of intangibles)	74,480	111,630		(33)%
 Gross profit	 103,404	 128,401	 	 (19)%
Gross profit percentage	58 %	53 %		
Selling, general and administrative expenses	81,961	93,030		(12)%
Research and development expenses	19,696	32,319		(39)%
Impairment of intangibles	72,183	283,747		(75)%
 Total operating expenses	 173,840	 409,096	 	 (58)%
Interest expense and amortization of debt discount	14,396	18,211		(21)%
Other non-operating gain	(546)	(884)		(38)%
Total other non-operating expense	13,850	17,327		(20)%
 Loss before income taxes	 (84,286)	 (298,022)	 	 (72)%
Income tax benefit	4,697	27,121		(83)%
 Net loss	 <u>\$ (79,589)</u>	 <u>\$ (270,901)</u>	 	 (71)%

[Table of Contents](#)

Revenue

The following table presents total revenues for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,		% Change
	2020	2019	
Venlafaxine ER (VERT)	\$ 25,576	\$ 75,601	(66)%
Methylphenidate ER	31,699	73,205	(57)%
Divigel	31,629	26,794	18 %
Nitrofurantoin	10,443	5,726	82 %
Lorzone	4,058	15,004	(73)%
OB Complete	6,948	9,851	(29)%
Other	35,497	29,291	21 %
Net product sales	145,850	235,472	(38)%
Royalty revenue	4,107	3,641	13 %
Licensing and contract revenue	27,927	918	2,942 %
Total revenues	<u>\$177,884</u>	<u>\$240,031</u>	<u>(26)%</u>

Total revenues decreased by \$62.1 million to \$177.9 million for the year ended December 31, 2020, as compared to \$240.0 million for the year ended December 31, 2019 primarily due to a decrease in net product sales, partially offset by higher licensing and contract revenue.

Net Product Sales. Net product sales decreased by \$89.6 million to \$145.9 million for the year ended December 31, 2020, as compared to \$235.5 million for the year ended December 31, 2019. Approximately \$52.2 million of this decrease was attributable to lower realized prices, and approximately \$37.4 million was due to lower volumes of products sold. Net product sales of methylphenidate ER (including M-72), decreased 57% due to price erosion from generic competitors resulting in significantly lower net selling prices and lower volumes. Product sales from VERT decreased by 66% for the year ended December 31, 2020 due to additional generic competition resulting in lower volumes and net realized selling prices. During the first quarter of 2020 two competitors launched competing dosage strengths of VERT which negatively affected selling prices and volumes. We expect that the additional competition for both methylphenidate ER and VERT from these competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of these products in 2021 and future years. VERT sales were favorably impacted by \$6.4 million, in the aggregate related to product returns during the twelve months ended December 31, 2020 based on actual experience. There can be no assurance that actual product returns experience and other adjustments will continue to favorably impact net sales in 2021 and in future years.

Product sales from Lorzone declined 73% for the year ended December 31, 2020, reflecting lower volume due to the launch of generic competitors in late 2019 and 2020, and transition of sales to the Company's authorized generic product during the period. We expect that additional competition for Lorzone from current competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of Lorzone during 2021 and in future years. Product sales from Divigel increased by 18%, driven primarily by the launch of a new dosage strength in 2020 together with targeted promotional activities and strong patient access. Product sales from the OB Complete family of prescription prenatal dietary supplements decreased by \$2.9 million or 29% during 2020 due to lower volumes sold reflecting a shift of promotional resources to another product. Sales of Nitrofurantoin increased 82% as the 2020 represented the first full year of sales following the product's launch during 2019. Other product sales increased by 21%, largely due to other non-promoted products during the year.

Royalty Revenue. Royalty revenue increased by \$0.5 million for the year ended December 31, 2020, compared to the prior year period, primarily due to higher product sales by license partners during the year.

Licensing and Contract Revenue. Licensing and contract revenue increased by \$27.0 million in 2020 primarily reflecting license agreement with Santen Pharmaceutical Co. Ltd, granting the exclusive

development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Under the agreement, the Company received an upfront milestone payment of \$25.0 million.

[Table of Contents](#)

Cost of Goods Sold and Gross Profit Percentage

The following table presents a breakdown of total cost of goods sold for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,		% Change
	2020	2019	
Amortization of intangible assets	\$ 16,046	\$ 52,657	(70)%
Depreciation expense	1,492	2,343	(36)%
Royalty expense	9,283	10,198	(9)%
Other cost of goods sold	47,659	46,432	3 %
Total cost of goods sold	\$ 74,480	\$ 111,630	(33)%

Total cost of goods sold decreased \$37.2 million in the year ended December 31, 2020 to \$74.5 million as compared to \$111.6 million in the year ended December 31, 2019, primarily driven by a \$36.6 million decrease in amortization of intangible assets, due to lower amortization for methylphenidate ER and VERT. Royalty expense decreased by \$0.9 million due to decrease in net sales of certain royalty products. There was no material change in depreciation expense or other cost of goods sold.

Gross profit percentage increased to 58% for the year ended December 31, 2020 compared to 53% for the year ended December 31, 2019. Excluding amortization and depreciation, our gross profit percentage for the year ended December 31, 2020 was 68% as compared to 76% for the year ended December 31, 2019 largely due to higher unit production costs and sample costs associated with the launch of Upneeq, partially offset by lower inventory reserves and royalty expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased \$11.0 million in the year ended December 31, 2020 to \$82.0 million as compared to \$93.0 million in the year ended December 31, 2019. The decrease in our selling, general and administrative expenses reflects salesforce reductions in the third quarter of 2019 and the first quarter of 2020, partially offset by higher marketing expenses associated with the launch of Upneeq and higher general and administrative expenses largely due to costs associated with the Santen license transaction and legal expenses during the year.

Research and Development Expenses

Research and development expenses decreased by \$12.6 million in the year ended December 31, 2020 to \$19.7 million as compared to \$32.3 million in the year ended December 31, 2019. The decrease primarily reflects the completion of the Phase III clinical trials of both arbaclofen ER and RVL-1201 during the first and second quarters of 2019, respectively, and the NDA filing fees for RVL-1201 incurred in the third quarter of 2019.

The following table summarizes our research and development expenses incurred for the periods indicated (dollars in thousands):

	Year Ended December 31,		% Change
	2020	2019	
Arbaclofen ER	3,146	7,430	(58)%
RVL-1201	3,257	7,059	(54)%
Other	13,293	17,830	(25)%
Total	\$ 19,696	\$ 32,319	(39)%

[Table of Contents](#)

Impairment of Intangible Assets and Goodwill

Impairments of intangible assets and goodwill for the year-ended December 31, 2020 was \$72.2 million primarily consisting of write-downs to fair value for methylphenidate ER, VERT, arbaclofen ER and Oxybutynin of \$19.5 million, \$20.2 million, \$28.9 million and \$3.6 million, respectively, including an indefinite-lived In-Process R&D asset, arbaclofen ER, which resulted in an impairment charge of \$28.9 million due to a delay in the anticipated launch of the product candidate, if approved. The impairments of methylphenidate ER, VERT and Oxybutynin reflect the competitive generic environment which has continued to erode net realized pricing and volumes of these products, while the impairment of Onitnua ER reflects a delay in its anticipated commercialization should the product be approved by the FDA. In the fourth quarter of 2020 we recognized an impairment of finite-lived development technology and product rights for VERT of \$10.7 million and \$9.5 million, respectively due to the approval of a competing product and the anticipated deterioration of pricing and volumes, and an impairment of indefinite-lived intangible assets for arbaclofen ER of \$28.9 million.

Impairment of intangible assets was \$283.7 million during the year ended December 31, 2019 primarily consisting of write-downs to fair value of methylphenidate ER, VERT, Osmolex ER, and Corvite of \$128.1 million, \$137.7 million, \$17.7 million, and \$0.2 million, respectively. Methylphenidate ER tablets and VERT were impaired due to lower revenues reflecting an increasingly competitive environment which deteriorated pricing and volumes; Osmolex ER was impaired due to underperforming revenue expectations subsequent to the launch of the product; and Corvite was impaired due to the discontinuation of the product. In the third and fourth quarter of 2019, we also recognized an impairment of finite-lived development technology and product rights for VERT of \$73.0 million and \$64.7 million, respectively, due to approvals of competing products which deteriorated pricing and volumes.

[Table of Contents](#)

The following table details the impairment charges for such periods (in thousands):

Asset/Asset Group	Year Ended December 31, 2020	
	Impairment Charge	Reason For Impairment
<i>Product Rights</i>		
Methylphenidate ER	\$ 19,539	Lower revenue due to generic competition.
	<u>19,539</u>	
<i>Developed Technology</i>		
Venlafaxine ER	10,655	Lower revenue due to generic competition.
Oxybutynin	<u>3,618</u>	Lower revenue expectations
	<u>14,273</u>	Lower anticipated revenue due to generic competition.
<i>Distribution Rights</i>		
Venlafaxine ER	<u>9,461</u>	Lower revenue due to generic competition.
<i>In-Process R&D</i>		
Arbaclofen ER	<u>28,910</u>	Delay in anticipated commercialization of the product candidate, if approved.
Total Impairment Charges for year ended December 31, 2020	<u>\$ 72,183</u>	
Asset/Asset Group	Year Ended December 31, 2019	
	Impairment Charge	Reason For Impairment
<i>Product Rights</i>		
Osmolex ER	\$ 17,730	Lower than expected volume
Methylphenidate ER	<u>128,113</u>	Lower revenue due to generic competition.
Corvite	<u>190</u>	Discontinued formulation
	<u>146,033</u>	
<i>Product Rights</i>		
Venlafaxine ER	<u>72,995</u>	Revenue underperforming expectations due to new generic market entrants.
<i>Distribution Rights</i>		
Venlafaxine ER	<u>64,719</u>	Revenue underperforming expectations due to new generic market entrants.
Total Impairment Charges for year ended December 31, 2019	<u>\$ 283,747</u>	

Impairment of Fixed Assets

Fixed asset impairments for the years ended December 31, 2020 and 2019 were less than \$0.1 million and \$0.1 million, respectively, due to the abandonment of information technology in both 2020 and 2019 and warehouse assets in 2019.

Table of Contents

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by \$3.8 million in the year ended December 31, 2020 to \$14.4 million as compared to \$18.2 million in the year ended December 31, 2019. The decrease in borrowing costs reflects lower levels of indebtedness following the prepayment of debt in the third quarter of 2020, and lower interest rates.

Other Non-operating (Income) Expenses, net

Other non-operating (income) expense was \$(0.6) million and \$(0.9) million for the years ended December 31, 2020 and 2019, respectively.

Income Tax Benefit

	Year Ended December 31,	
	2020	2019
	(dollars in thousands)	
Income tax benefit	\$ 4,697	\$ 27,121
Effective tax rate	5.6 %	9.1 %

Income tax benefit decreased by \$22.4 million in the year ended December 31, 2020 to \$4.7 million as compared to \$27.1 million in the year ended December 31, 2019. The significant difference in the 2020 income tax benefit was the result of recording a valuation allowance in 2019.

Liquidity and Capital Resources

Our principal sources of liquidity are cash generated from operations and amounts available to be drawn under our Revolving Credit Facility, or Revolver. Our primary uses of cash are to fund operating expenses, product development costs, capital expenditures, debt service payments, as well as strategic business and product acquisitions.

As of December 31, 2020, we had cash and cash equivalents of \$114.1 million and borrowing availability under the Revolver of \$50.0 million. We also had \$221.3 million aggregate principal amount borrowed under our term loans. During the year ended December 31, 2020 we generated \$17.6 million of cash flows from operations, and during the year ended December 31, 2019, we generated cash flows from operations of \$33.6 million. We expect to generate positive cash flow from operations in the future through sales of our existing products; however, we expect our levels of cash flow generated to be lower or negative in the near term due to price erosion on our generic products and new product launch expenses associated with the launch of Upneeq and possible future price erosion on our other products.

As of December 31, 2020, the interest rate was 4.75% and 5.25% for our Term A Loan and Term B Loan, respectively. As of December 31, 2019, the interest rate was 5.79% and 6.29% for our Term A Loan and Term B Loan, respectively.

At December 31, 2020, there were no outstanding borrowings or outstanding letters of credit under the Revolver. Availability under the Revolver as of December 31, 2020 was \$50.0 million.

On January 13, 2020 we completed a follow-on equity offering and allotted 6,900,000 ordinary share at a public offering price of \$5.00 per share. The number of shares issued in this offering reflected the exercise in full of the underwriters' option to purchase 900,000 ordinary shares. The aggregate net proceeds from the follow-on offering were approximately \$31.8 million after deducting underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

On July 16, 2020 we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.4 million after deducting offering expenses. Proceeds from the offering will be used for working capital and general corporate purposes.



[Table of Contents](#)

Our non-promoted products, including methylphenidate ER and VERT compete in generic markets for which competition has eroded, and will continue to erode, profitability over time. During the year ended December 31, 2020, there were two launches of generic VERT, and as of December 31, 2020 there were six approved AB rated generic forms of Lorzone. Additionally, there was an additional approval of competing dosage strengths of VERT during 2020 which launched in early 2021. As a result, we have experienced, and anticipate that we will continue to experience, price erosion negatively affecting profitability of these products and possibly others in 2021 and future years.

The Company's future operating performance and adequacy of cash resources depends on many assumptions, including assumptions with respect to product sales and expenses, commercialization costs, research and development expenses as well as other factors. These assumptions may prove to be wrong or other factors may adversely affect the Company's operating results. As a result, the Company's operating results may fluctuate significantly quarter to quarter or year to year. The Company expects its near term levels of profitability and cash flow to be negatively affected by price competition on our generic products, and increased expenses associated with new product launches. As a result, it's possible the Company would not be able to comply with financial covenants in its credit agreement or generate sufficient cash to service its debt obligations. This could, among other things, force us to raise additional funds or force us to reduce our expenses through cost cutting measures either of which could have a material adverse affect on our business.

The Company is currently undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include asset disposals, re-financings and commercialization or collaboration agreements. In the event the Company is unable to generate sufficient proceeds from these strategic options such that it can reduce, retire or refinance its existing debt, the Company believes it has sufficient plans to effectively manage its expenses and avail itself of cure provisions provided for in its credit agreement, in order to maintain compliance with its debt covenants therein. The use of the cure provisions will result in the utilization cash to prepay debt.

A significant portion of the Company's expense base is discretionary and the Company has the ability to reduce or defer spending to reduce expenses and improve profitability and cash flow to maintain compliance with its debt covenants. This could include, among other things, significant reductions in its general and administrative expenses, research and development expenses, including deferral of clinical trial programs, and deferrals of certain promotional and capital spending programs which could negatively impact the Company's revenue growth and plans. The Company has previously demonstrated an ability to implement various cost reduction initiatives. During the third quarter of 2019 and continuing into 2020, the Company reduced its field force by an aggregate of 90 positions, generating annualized savings of approximately \$10 million, and took measures to realign its operating infrastructure to prepare for the launch of Upneeq and implemented other cost-savings measures to reduce its expenses.

Based on the current facts and circumstances, the use of the cure provisions provided for in the credit agreement, which will result in utilizing cash to prepay debt, and the Company's ability to implement spending reductions and program deferrals, we believe it is probable that the Company can effectively manage its spending to improve profitability in order to maintain compliance with the debt covenants and other obligations in our credit agreement for at least the next 12 months, even if the strategic review does not generate sufficient proceeds to reduce, retire or refinance our existing debt. As a result, the Company has concluded that, after consideration of management's plans our existing cash and cash equivalents, together with cash generated from operations, will be sufficient to meet our anticipated cash needs for the next 12 months.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Additionally, certain financings may require the consent of the lenders under our senior secured credit facilities. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. 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 intellectual property, technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

[Table of Contents](#)

Cash Flows

The following table provides information regarding our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		
	2020	2019	Change
Net cash provided by operating activities	\$17,590	\$33,567	\$(15,977)
Net cash used in investing activities	(3,084)	(4,020)	936
Net cash provided by (used in) financing activities	3,682	(4,691)	8,373
Effect on cash of changes in exchange rate	—	175	(175)
Net increase in cash and cash equivalents	\$18,188	\$25,031	\$ (6,843)

Net cash provided by operating activities

Cash flows from operating activities are primarily driven by earnings from operations (excluding the impact of non-cash items), the timing of cash receipts and disbursements related to accounts receivable and accounts payable and the timing of inventory transactions and changes in other working capital amounts. Net cash provided by operating activities was \$17.6 million and \$33.6 million for the years ended December 31, 2020 and 2019, respectively. The decrease in cash provided by operating activities in the year ended December 31, 2020, as compared to year ended December 31, 2019, was primarily as a result of lower net income after considering non-cash adjustments, partially offset by higher cash provided from operating assets and liabilities, particularly accounts receivable and inventories as compared to the year ended December 31, 2019.

Net cash used in investing activities

Our uses of cash in investing activities during the years ended December 31, 2020 and 2019 reflected purchases of property, plant and equipment and were \$3.1 million and \$4.0 million, respectively.

Net cash provided by (used in) financing activities

Net cash provided by financing activities of \$3.7 million during 2020 largely reflecting net proceeds raised from equity offerings in January and July, 2020, offset by prepayments of term loans in the third quarter of 2020, and share repurchases.

Net cash used by financing activities of \$4.7 million during the year ended December 31, 2019 primarily related to the \$1.8 million of net repayments of insurance premium financing and by \$2.8 million repurchase of ordinary shares.

Contractual Obligations

The following table lists our contractual obligations as of December 31, 2020.

	Payments due by period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations ⁽¹⁾	219,525	—	219,525	—	—
Interest expense ⁽²⁾	21,134	10,686	10,448	—	—
Capital lease obligations ⁽³⁾	44	40	4	—	—
Operating lease obligations ⁽⁴⁾	3,098	1,589	1,509	—	—
Royalty obligations ⁽⁵⁾	6,083	1,000	3,000	2,000	83
Total	249,884	13,315	234,486	2,000	83

[Table of Contents](#)

- (1) Represents the remaining principal amount under our senior secured credit facilities, which is due on December 21, 2022.
- (2) These amounts represent future cash interest payments related to our existing debt obligations based on variable interest rates specified in the senior secured credit facilities. Payments related to variable debt are based on applicable rates at December 31, 2020 plus the specified margin in the senior secured credit facilities for each period presented. As of December 31, 2020, the interest rate was 4.75% for Term A Loan and 5.25% for Term B Loan.
- (3) Includes minimum cash payments related to certain fixed assets, primarily office equipment.
- (4) Includes minimum cash payments related to our leased offices and warehouse facilities under non-cancelable leases in New Jersey, Florida, North Carolina, as well as in Argentina.
- (5) Includes obligations to make minimum annual royalty payments.

Our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. As of December 31, 2020, our liability for unrecognized tax benefits was \$0.2 million (excluding interest and penalties). We do not anticipate that the amount of our liability for unrecognized tax benefits will significantly change in the next 12 months.

Critical Accounting Estimates

The significant accounting policies and basis of presentation are described in Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Summary of Significant Accounting Policies. The preparation of our consolidated financial statements in accordance with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses and the related disclosures in the notes thereto. Some of these estimates can be subjective and complex. Although we believe that our estimates and assumptions are reasonable, there may be other reasonable estimates or assumptions that differ significantly from ours. Further, our estimates and assumptions are based upon information available at the time they were made. Actual results could differ from those estimates.

In order to understand our consolidated financial statements, it is important to understand our critical accounting estimates. We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made and (ii) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition, results of operations or cash flows. We believe the following accounting policies and estimates to be critical:

Revenue Recognition

Upon adoption of Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers* (ASC Topic 606) on January 1, 2018, we recognize revenue as described below. The implementation of the new revenue recognition standard did not have a material impact on our consolidated financial statements.

Product Sales—Revenue is recognized at the point in time when our performance obligations with our customers have been satisfied. At contract inception, we determine if the contract is within the scope of ASC Topic 606 and then evaluate the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue at the point in time when the Company satisfies a performance obligation.

Revenue is recorded at the transaction price, which is the amount of consideration we expect to receive in exchange for transferring products to a customer. We consider the unit of account for each purchase

order that contains more than one product. Because all products in a given purchase order are generally delivered at the same time and the method of

[Table of Contents](#)

revenue recognition is the same for each, there is no need to separate an individual order into separate performance obligations. In the event that we fulfilled an order only partially because a requested item is on backorder, the portion of the purchase order covering the item is generally cancelled, and the customer has the option to submit a new one for the backordered item. We determine the transaction price based on fixed consideration in our contractual agreements, which includes estimates of variable consideration, and the transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. In determining the transaction price, a significant financing component does not exist since the timing from when we deliver product to when the customers pay for the product is less than one year and the customers do not pay for product in advance of the transfer of the product.

We record product sales net of any variable consideration, which includes estimated chargebacks, commercial rebates, discounts and allowances and doubtful accounts. We utilize the expected value method to estimate all elements of variable consideration included in the transaction. The variable consideration is recorded as a reduction of revenue at the time revenues are recognized. We will only recognize revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration amount received and we will re-assess these estimates each reporting period to reflect known changes in factors.

Royalty Revenue—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or substantially satisfied).

Licensing and Contract Revenue—We have arrangements with commercial partners that allow for the purchase of product from us by the commercial partner for purposes of sub-distribution. We recognize revenue from an arrangement when control of such product is transferred to the commercial partner, which is typically upon delivery. In these situations the performance obligation is satisfied when product is delivered to our commercial partner. Licensing revenue is recognized in the period in which the product subject to the sublicensing arrangement is sold. Sales deductions, such as returns on product sales, government program rebates, price adjustments, and prompt pay discounts in regard to licensing revenue is generally the responsibility of our commercial partners and not recorded by us.

Freight—We record amounts billed to customers for shipping and handling as revenue, and record shipping and handling expenses related to product sales as cost of goods sold. We account for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. When shipping and handling costs are incurred after a customer obtains control of the products, we also have elected to account for these as costs to fulfill the promise and not as a separate performance obligation.

Sales Deductions

Product sales are recorded net of estimated chargebacks, commercial and governmental rebates, discounts, allowances, copay discounts, advertising and promotions and estimated product returns, or collectively, “sales deductions.”

Provision for estimated chargebacks, certain commercial rebates, discounts and allowances and doubtful accounts settled in sales credits at the time of sales are analyzed and adjusted, if necessary, monthly and recorded against gross trade accounts receivable. Estimated product returns, certain commercial and governmental rebates and customer coupons settled in cash are analyzed and adjusted, if necessary, monthly and recorded as a component of accrued expenses.

Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and estimated customer inventory levels. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are chargebacks, commercial and governmental rebates, product returns, discounts and allowances and advertising and promotions.

[Table of Contents](#)

Where available, we have relied on information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to days of sales outstanding, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we have evaluated market conditions for products primarily through the analysis of wholesaler and other third party sell-through, as well as internally-generated information, to assess factors that could impact expected product demand at December 31, 2020 and December 31, 2019. We believe that the estimated level of inventory held by our customers is within a reasonable range as compared to both: (i) historical amounts and (ii) expected demand for the products that represent a majority of the volume at December 31, 2020 and December 31, 2019.

If the assumptions we use to calculate our allowances for sales deductions do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted.

The following table presents the activity and ending balances for our product sales provisions for the years ended December 31, 2020 and 2019 (in thousands):

	Commercial Chargebacks	Commercial Rebates	Government and Managed Care Rebates	Product Returns	Discounts and Allowances	Total
Balance at December 31, 2018	\$ 38,861	\$ 49,232	\$ 9,981	\$ 48,464	\$ 3,510	\$ 150,048
Provision	345,366	147,173	20,092	(3,932)	15,719	524,418
Charges processed	(369,603)	(182,826)	(25,206)	(11,075)	(17,638)	(606,348)
Balance at December 31, 2019	\$ 14,624	\$ 13,579	\$ 4,867	\$ 33,457	\$ 1,591	\$ 68,118
Provision	122,592	22,488	18,211	2,825	7,003	173,119
Charges processed	(127,295)	(28,723)	(19,633)	(14,256)	(7,819)	(197,726)
Balance December 31, 2020	<u>\$ 9,921</u>	<u>\$ 7,344</u>	<u>\$ 3,445</u>	<u>\$ 22,026</u>	<u>\$ 775</u>	<u>\$ 43,511</u>

Total items deducted from gross product sales were \$173.1 million (excluding \$2.5 million in provisions for advertising and promotion), or 53.8% as a percentage of gross product sales, during the year ended December 31, 2020. Total items deducted from gross product sales were \$524.4 million (excluding \$4.4 million in provisions for advertising and promotion), or 68.6% as a percentage of gross product sales, during the year ended December 31, 2019.

Chargebacks—We enter into contractual agreements with certain third parties such as retailers, hospitals and group-purchasing organizations, or GPOs, to sell certain products at predetermined prices. Most of the parties have elected to have these contracts administered through wholesalers that buy the product from us and subsequently sell it to these third parties. When a wholesaler sells products to one of these third parties that are subject to a contractual price agreement, the difference between the price paid to us by the wholesaler and the price under the specific contract is charged back to us by the wholesaler. Utilizing this information, we estimate a chargeback percentage for each product and record an allowance for chargebacks as a reduction to gross sales when we record our sale of the products. We reduce the chargeback allowance when a chargeback request from a wholesaler is processed. Our provision for chargebacks is fully reserved for at the time when sales revenues are recognized.

We obtain product inventory reports from major wholesalers to aid in analyzing the reasonableness of the chargeback allowance and to monitor whether wholesaler inventory levels do not significantly exceed customer demand. We assess the reasonableness of our chargeback allowance by applying a product chargeback percentage that is based on a combination of historical activity and current price and mix expectations to the quantities of inventory on hand at the wholesalers according to wholesaler inventory reports. In addition, we estimate the percentage of gross sales that were generated through direct and indirect sales channels and the percentage of contract compared to non-contract revenue in the period, as these each affect the estimated reserve calculation. In accordance with our accounting policy, we estimate the percentage amount of wholesaler inventory that will ultimately be sold to third parties that are subject to contractual price agreements based on a trend of such sales through wholesalers. We use this percentage estimate until historical trends indicate that a revision should be

made. On an ongoing basis, we evaluate our actual chargeback rate experience, and new trends are factored into our estimates each quarter as market conditions change.

[Table of Contents](#)

Events that could materially alter chargebacks include: changes in product pricing as a result of competitive market dynamics or negotiations with customers, changes in demand for specific products due to external factors such as competitor supply position or consumer preferences, customer shifts in buying patterns from direct to indirect through wholesalers, which could either individually or in aggregate increase or decrease the chargebacks depending on the direction and trend of the change(s).

Chargebacks were \$122.6 million and \$345.4 million, or 38.1% and 45.2% as a percentage of gross product sales, for the years ended December 31, 2020 and 2019, respectively. Chargebacks as a percentage of gross product sales decreased in 2020 as compared with 2019, primarily due to a change in product mix and pricing. We expect that chargebacks will continue to significantly impact our reported net product sales.

Commercial Rebates—We maintain an allowance for commercial rebates that we have in place with certain customers. Commercial rebates vary by product and by volume purchased by each eligible customer. We track sales by product number for each eligible customer and then apply the applicable commercial rebate percentage, using both historical trends and actual experience to estimate our commercial rebates. We reduce gross sales and increase the commercial rebates allowance by the estimated rebate amount when we sell our products to eligible customers. We reduce the commercial rebate allowance when we process a customer request for a rebate. At each month end, we analyze the allowance for commercial rebates against actual rebates processed and make necessary adjustments as appropriate. Our provision for commercial rebates is fully reserved for at the time sales revenues are recognized.

The allowance for commercial rebates takes into consideration price adjustments which are credits issued to reflect increases or decreases in the invoice or contract prices of our products. In the case of a price decrease, a shelf-stock adjustment credit is given for product remaining in customer's inventories at the time of the price reduction. Contractual price protection results in a similar credit when the invoice or contract prices of our products increase, effectively allowing customers to purchase products at previous prices for a specified period of time. Amounts recorded for estimated shelf-stock adjustments and price protections are based upon specified terms with direct customers, estimated changes in market prices, and estimates of inventory held by customers. We regularly monitor these and other factors and evaluate the reserve as additional information becomes available.

We ensure that commercial rebates are reasonable through review of contractual obligations, review of historical trends and evaluation of recent activity. Furthermore, other events that could materially alter commercial rebates include: changes in product pricing as a result of competitive market dynamics or negotiations with customers, changes in demand for specific products due to external factors such as competitor supply position or consumer preferences, customer shifts in buying patterns from direct to indirect through wholesalers, which could either individually or in aggregate increase or decrease the commercial rebates depending on the direction and velocity of the change(s).

Commercial rebates were \$22.5 million and \$147.2 million, or 7.0% and 19.3% as a percentage of gross product sales, for the years ended December 31, 2020 and 2019, respectively. Commercial rebates as a percentage of gross product sales decreased in 2020 as compared to 2019 primarily due to the change in product mix and customer contracts. We expect that commercial rebates will continue to significantly impact our reported net sales.

Government Program Rebates—Federal law requires that a pharmaceutical distributor, as a condition of having federal funds being made available to the states for the manufacturer's drugs under Medicaid and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the distributor's covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement. CMS is responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are also due on the utilization of Medicaid managed care organizations, or MCOs. We also pay rebates to MCOs for the reimbursement of a portion of the sales price of prescriptions filled that are covered by the respective plans. The liability for Medicaid, Medicare and other government program rebates is settled in cash and is estimated based on historical and current rebate redemption and utilization rates contractually submitted by each state's program administrator and assumptions regarding future government program utilization for each product sold, and accordingly recorded as a reduction of product sales. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the

Medicaid participant. In addition to the estimates mentioned above, our calculation also requires other estimates, such as estimates

[Table of Contents](#)

of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, our estimates could differ from actual experience.

Government program rebates were \$18.2 million and \$20.1 million, or 5.7% and 2.6% as a percentage of gross product sales, during the years ended December 31, 2020 and 2019, respectively.

Product Returns—Certain of our products are sold with the customer having the right to return the product within specified periods. Estimated return accruals are made at the time of sale based upon historical experience. Our return policy generally allows customers to receive credit for expired products within six months prior to expiration and within one year after expiration. Our provision for returns consists of our estimates for future product returns.

Historical factors such as one-time recall events as well as pending new developments such as comparable product approvals or significant pricing movement that may impact the expected level of returns are taken into account monthly to determine the appropriate accrued expense. As part of the evaluation of the liability required, we consider actual returns to date that are in process, the expected impact of any product recalls and the amount of wholesaler's inventory to assess the magnitude of unconsumed product that may result in product returns to us in the future. The product returns level can be impacted by factors such as overall market demand and market competition and availability for substitute products which can increase or decrease the pull through for sales of our products and ultimately impact the level of product returns. In determining our estimates for returns and allowances, we are required to make certain assumptions regarding the timing of the introduction of new products. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments, we utilize market data for similar products as analogs for our estimations. We use our best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us. Product returns are fully reserved for at the time when sales revenues are recognized.

Our estimate for returns may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine whether we believe the increase is temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

- recently implemented or announced price increases for our products; and
- new product launches or expanded indications for our existing products.

Conversely, other-than-temporary increases in inventory levels may be an indication that future product returns could be higher than originally anticipated and, accordingly, we may need to adjust our provision for returns. Some of the factors that may be an indication that an increase in inventory levels will be other-than-temporary include:

- declining sales trends based on prescription demand;
- recent regulatory approvals to shorten the shelf life of our products, which could result in a period of higher returns;
- slow moving or obsolete product still in the distribution channel;
- introduction of new product(s) or generic competition;
- increasing price competition from generic competitors; and



[Table of Contents](#)

- changes to the National Drug Codes, or NDCs, of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

We ensure that product returns are reasonable through inspection of historical trends and evaluation of recent activity. Furthermore, other events that could materially alter product returns include: acquisitions and integration activities that consolidate dissimilar contract terms and could impact the return rate as typically we purchase smaller entities with less contracting power and integrate those product sales to our contracts; and consumer demand shifts by products, which could either increase or decrease the product returns depending on the product or products specifically demanded and ultimately returned.

Product returns were \$2.8 million and \$(3.9) million, or 0.9% and (0.5)% as a percentage of gross product sales, during the years ended December 31, 2020 and 2019, respectively. Product returns as a percentage of gross product sales decreased in 2020 as compared to 2019 primarily due to lower than expected returns processed. Product returns as a percentage of gross product sales are not expected to change materially for 2021.

Promotions and Co-Pay Discount Cards—From time to time we authorize various retailers to run in-store promotional sales of our products. We accrue an estimate of the dollar amount expected to be owed back to the retailer. Additionally, we provide consumer co-pay discount cards, administered through outside agents to provide discounted products when redeemed. Upon release of the cards into the market, we record an estimate of the dollar value of co-pay discounts expected to be utilized taking into consideration historical experience.

Advertising and promotions as a percentage of gross product sales did not change materially during the periods presented. Promotions and co-pay discount cards are included in advertising and promotions, which were \$2.5 million and \$4.4 million, or 0.86% and 0.6% as a percentage of gross product sales, during the years ended December 31, 2020 and 2019, respectively.

Discounts and allowances were \$7.0 million and \$15.7 million, or 2.2% and 2.1% as a percentage of gross product sales, during the years ended December 31, 2020 and 2019, respectively. Discounts and allowances as a percentage of gross product sales did not change materially during the periods presented and are not expected to change materially in 2021.

Valuation of long-lived assets

As of December 31, 2020, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is \$58.7 million.

Long-lived assets, other than goodwill and other indefinite-lived intangibles, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group.

Our long-lived intangible assets, which consist of distribution rights, product rights, tradenames and developed technology, are initially recorded at fair value upon acquisition. To the extent they are deemed to have finite lives, they are then amortized over their estimated useful lives using either the straight-line method or based on the expected pattern of cash flows. Factors giving rise to our initial estimate of useful lives are subject to change. Significant changes to any of these factors may result in a reduction in the useful life of the asset and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the

[Table of Contents](#)

asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations. Our reviews of long-lived assets during the two years ended December 31, 2020 and 2019 resulted in certain impairment charges. These charges relate to both finite and indefinite-lived intangible assets, which are described in Note 7, *Goodwill and Other Intangible Assets*, to our consolidated financial statements.

These impairment charges were generally based on fair value estimates determined using either discounted cash flow models or preliminary offers from prospective buyers. The discounted cash flow models include assumptions related to product revenue, growth rates and operating margin. These assumptions are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of future product cash flows. These estimates are subject to the economic environment in which we operate, demand for the products and competitor actions. The use of different assumptions would have increased or decreased our estimated discounted future cash flows and the resulting estimated fair values of these assets, causing increases or decreases in the resulting asset impairment charges. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted.

We recorded impairment charges of \$72.2 million and \$283.7 million, regarding definite-lived and indefinite-lived intangible assets for the years ended December 31, 2020 and 2019, respectively.

Goodwill and indefinite-lived intangible assets

Goodwill and indefinite-lived intangible assets are assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired.

Goodwill Impairment Assessment—We are organized in one reporting unit and evaluate goodwill for our company as a whole. Under the authoritative guidance issued by the Financial Accounting Standards Board, or FASB, we have the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. As further described in Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, effective January 1, 2017, we early adopted Accounting Standards Update (ASU) No. 2017-04 “*Intangibles — Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*” (ASU 2017-04). Subsequent to adoption, we perform our goodwill impairment tests by comparing the fair value and carrying amount of our reporting unit. Any goodwill impairment charges we recognize for our reporting unit are equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

The goodwill impairment test requires us to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the carrying value exceeds its fair value, an impairment charge is recorded for the difference. If the carrying value recorded is less than the fair value calculated then no impairment loss is recognized. The fair value of our reporting unit is determined using an income approach that utilizes a discounted cash flow model or, where appropriate, the market approach, or a combination thereof. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. Our estimates of future cash flows are based on a comprehensive product by product forecast over a ten-year period and involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amounts, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions, all which may differ from actual future cash flows.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of the future results of our operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which we operate, demand for the products and competitor actions. Estimated future

cash flows are discounted to present value using a market participant, weighted average cost of capital. The financial and credit market volatility directly impacts certain

[Table of Contents](#)

inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any. The discount rates applied to the estimated cash flows for our October 1, 2020 and 2019 annual goodwill impairment test were 19.5% and 16.5%, respectively, depending on the overall risk associated with the particular asset and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

Based on the quantitative goodwill impairment assessment performed, we determined that there was no impairment of goodwill as of October 1, 2020 and for the year ended December 31, 2020. An increase of 50 basis points to our assumed discount rate used in our goodwill assessment would not have materially changed the results of our analyses.

IPR&D Intangible Asset Impairment Assessment—IPR&D, which are indefinite-lived intangible assets representing the value assigned to acquired Research and Development, or R&D, projects that principally represent rights to develop and sell a product that we have acquired which has not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. We have the option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of the asset is less than its carrying value. If we elect not to conduct the qualitative assessment or if indications of a potential impairment exist, the determination of whether an impairment has occurred requires the determination of the fair value of the asset being assessed. Under the qualitative assessment, we consider several qualitative factors, including the results from the last quantitative test, changes, if any, in the status of regulatory and commercial success risks, and competitive trends impacting each asset and changes in the related cash flow stream projections.

Under a qualitative assessment, the fair value of our indefinite-lived intangible assets is determined using an income approach that utilizes a discounted cash flow model and requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. Indefinite-lived intangible assets classified as in-process research and development, or IPRD, are subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development. During the period ended, December 31, 2020, the POS factor applied to the IPRD asset was 69.6% and the discount rate was 9.5%. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D product, the assets are reduced to zero. Upon approval of the products in development for sale and placement into service, the associated IPR&D intangible assets are transferred to Product Rights amortizing intangible assets. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated.

If the fair value of the IPR&D is less than its carrying amount, an impairment loss is recognized for the difference. Based on results of the impairment assessment performed, we did recognize an impairment change to IPR&D of \$28.9 million for the year ended December 31, 2020 and we did not recognize an impairment charge of IPR&D for the year ended December 31, 2019. The 2020 impairment charge reflects the delay in our anticipated commercialization date if this product candidate is approved.

Income Taxes

Income taxes are recorded under the asset and liability method of accounting. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled.

[Table of Contents](#)

Deferred income tax assets are reduced, as is necessary, by a valuation allowance when we determine it is more-likely-than-not that some or all of the tax benefits will not be realizable in the future.

Realization of the deferred tax assets is dependent on a variety of factors, some of which are subjective in nature, including the generation of future taxable income, the amount and timing of which are uncertain. In evaluating the ability to recover the deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, the forecast of future taxable income exclusive of certain reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, management is responsible for assumptions utilized including, but not limited to, the amount of U.S. federal, state and international pre-tax operating income, the reversal of certain temporary differences, carryforward periods available to us for tax reporting purposes, the implementation of feasible and prudent tax planning strategies and other relevant factors. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying business. We assess the need for a valuation allowance each reporting period, and would record any material changes that may result from such assessment to income tax expense in that period.

We account for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The evaluation of unrecognized tax benefits is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate unrecognized tax benefits and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. The liabilities for unrecognized tax benefits can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax benefit.

The most significant tax jurisdictions are Ireland, the United States, Argentina and Hungary. Significant estimates are required in determining the provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on the future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, changes in the international organization, likelihood of settlement, and changes in overall levels of income before taxes.

As of December 31, 2020 and 2019, the Company has a federal net operating loss carryover of \$29.1 million and \$2.2 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of \$3.8 million and \$9.9 million, respectively which will begin to expire in 2022. At December 31, 2020 and 2019, the Company had total tax credit carryovers of approximately \$6.7 million and \$4.6 million, respectively, primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers are expected to be fully realized prior to their expiration, beginning in 2035.

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. While we have concluded in the past that some of such undistributed earnings are indefinitely reinvested, facts and circumstances may change in the future. Changes in facts and circumstances may include a change in the estimated capital needs of our subsidiaries, or a change in our corporate liquidity requirements. Such changes could result in our management determining that some or all of such undistributed earnings are no longer indefinitely reinvested. In that event, we would be required to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely reinvested outside the relevant tax jurisdiction.

[Table of Contents](#)

Share-based compensation

Prior to the consummation of the IPO, our employees were eligible to receive equity awards from the 2016 Plan (as defined below). Following the consummation of the IPO, employees are eligible to receive equity awards from the 2018 Equity Incentive Plan.

Effective February 3, 2016, Osmotica Holdings S.C.Sp. adopted the 2016 Equity Incentive Plan, or the 2016 Plan, under which, the Company's officers and key employees were granted options to purchase common units. The options awards were made up of two components: 50% of options granted were Time Awards, or Time Based Options, and 50% were Performance Awards, or Performance Based Options. The Time Based Options vested 25% annually from original grant date. The Performance Based Options were to vest immediately upon the achievement by the majority investors in the Company having received (on a cumulative basis) aggregate net proceeds exceeding certain return on investment targets. The Time Awards and Performance Awards contained a sales restriction in the form of a liquidity event and subsequent disposal of common units by the Major Limited Partners (as defined in the 2016 Plan) before the employee was able to sell vested and exercised common units and were required to remain employed to avoid Company's call option on such common units at a lower of cost or fair market value.

Prior to the Company's IPO on October 22, 2018, the Company amended the 2016 Plan effective upon the IPO. Under the amended 2016 Plan at the IPO, the Time Based Options and the Performance Based Options converted to options to purchase our ordinary shares on the same basis as common units of Osmotica Holdings S.C.Sp. were converted to ordinary shares, with corresponding adjustments to the exercise price and the number of the options as well as the removal of existing sales restriction. In connection with this modification, the Time Based Options continued to vest in accordance with their original vesting schedule while the Performance Based Options were converted into options which vest with the passage of time, in equal annual installments on the first four anniversaries of the IPO, subject to the continued employment on each vesting date.

In addition, prior to the IPO the Company adopted the 2018 Equity Incentive Plan, or the 2018 Plan effective upon the IPO. During 2018, the Company granted Time Based Options vesting in a single installment on the fourth anniversary of the Company's IPO, generally subject to the employee's continued employment on the vesting date. During 2020, the Company granted performance stock units ("PSUs") under its existing 2018 Incentive Plan (the "2018 Plan") to certain key employees of the Company that gives holders the potential to receive a certain number of earned PSUs at the end of a pre-determined term. Unless earlier terminated, forfeited, relinquished or expired, the earned PSUs will vest in full on the vesting date, subject to the grantee remaining in continuous employment from the date of grant through the vesting date. The PSUs will vest on the third and fifth anniversary of the grant date. The number of PSUs that become earned PSUs as of the end of the performance period shall be equal to the number of PSUs multiplied by the applicable percentage based on Stock Price Hurdle attainment, as set forth in the PSU Award Agreement and 2018 Plan.

We account for share-based compensation awards in accordance with the FASB Accounting Standards Codification, or ASC, Topic 718, *Compensation — Stock Compensation*, or ASC 718. ASC 718 requires service-based and equity settled share-based awards issued to employees to be recognized as expense based on their grant date fair values. We use the Black-Scholes option pricing model to value our share option awards and the Monte Carlo model to value our performance stock options. We account for forfeitures of share option awards as they occur in accordance with ASU No. 2016-09. For option and performance awards issued to employees, we recognize compensation expense on a graded vesting basis over the requisite service period, which is generally the vesting period of the award.

The conversion of the Performance Based Options to new Time Based Options upon IPO was accounted for as a modification under ASC 718 where the fair value of such awards determined on the modification date, or the IPO date will be recognized over their remaining vesting period.

Each award was approved by our directors at a per share exercise price not less than the per share fair value in effect as of that award date.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our ordinary shares, the exercise price, the expected option term, share price volatility, the risk-free interest rate and

[Table of Contents](#)

expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our share-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Option Term.* Due to the lack of sufficient company-specific historical exercise data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB), Topic 14.D.2, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.
- *Expected Volatility.* Due to lack of a public market for the trading of our ordinary shares, the expected volatility is based on historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB 14.D.6.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- *Expected Dividends.* The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our ordinary shares.

Historically for all periods prior to the IPO, our board of directors has determined the fair value of the common unit underlying our options with assistance from management and based upon information available at the time of grant. Given the absence of a public trading market for our common units, estimating the fair value of our common units has required complex and subjective judgments and assumptions, including the most recent valuations of our common units based on the actual operational and financial performance, current business conditions and discounted cash flow projections. The estimated fair value of our common unit was adjusted for lack of marketability and control existing at the grant date.

For valuations after the consummation of the IPO, the board of directors determines the fair value of each share of underlying ordinary shares based on the closing price of our ordinary shares as reported on the date of grant.

During the years ended December 31, 2020 and 2019, we recognized \$4.9 million and \$4.9 million, respectively, of stock compensation expense.

Recently Issued Accounting Standards

For a discussion of recent accounting pronouncements, please see Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

Through the operation of our subsidiaries based in Argentina and Hungary, we are exposed to foreign exchange rate risks. In addition to the operations of our foreign subsidiaries, we also contract with vendors that are located outside the United States, and in some cases make payments denominated in foreign currencies. We are subject to fluctuations in



Table of Contents

foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2020, our liabilities denominated in foreign currencies were not material.

We are exposed to fluctuations in interest rates on our senior secured credit facilities. An increase in interest rates could have a material impact on our cash flow. As of December 31, 2020, a 100 basis point increase in assumed interest rates for our variable interest credit facilities would have an annual impact of approximately \$2.2 million on interest expense.

As of December 31, 2020, we had cash and cash equivalents of \$114.1 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

Inflation generally affects us by increasing our cost of labor, API costs and costs of clinical trials. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2020 and 2019.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm – Ernst & Young, LLP</u>	112
<u>Consolidated Balance Sheets as of December 31, 2020 and 2019</u>	113
<u>Consolidated Statements of Operational and Comprehensive Loss for the Years Ended December 31, 2020 and 2019</u>	114
<u>Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2020 and 2019</u>	115
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019</u>	116
<u>Notes to Consolidated Financial Statements</u>	117

[Table of Contents](#)

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Osmotica Pharmaceuticals plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Osmotica Pharmaceuticals plc (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

I selin, New Jersey
March 30, 2021



[Table of Contents](#)

OSMOTICA PHARMACEUTICALS PLC
Consolidated Balance Sheets
(In thousands, except share and per share data)

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 114,053	\$ 95,865
Trade accounts receivable, net	26,412	43,914
Inventories, net	17,934	21,305
Prepaid expenses and other current assets	14,755	11,546
Total current assets	173,154	172,630
Property, plant and equipment, net	28,054	30,238
Operating lease assets	2,755	4,983
Intangibles, net	65,758	153,986
Goodwill	100,855	100,855
Other non-current assets	373	563
Total assets	<u>\$ 370,949</u>	<u>\$ 463,255</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 6,768	\$ 8,495
Accrued liabilities	47,517	65,253
Current portion of obligation under finance leases	40	127
Current portion of lease liability	1,457	2,062
Income taxes payable - current portion	2	—
Total current liabilities	55,784	75,937
Long-term debt, net of non-current deferred financing costs	219,525	267,950
Long-term portion of obligation under finance leases	4	44
Long-term portion of lease liability	1,436	3,116
Deferred taxes	344	1,500
Total liabilities	<u>277,093</u>	<u>348,547</u>
Commitments and contingencies (See Note 14)		
Shareholders' equity:		
Ordinary shares (\$0.01 nominal value 400,000,000 shares authorized, 62,545,832 and 51,845,742 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively)	625	518
Preferred shares (\$0.01 nominal value 40,000,000 shares authorized, no shares issued and outstanding)	—	—
Euro deferred shares (€1.00 nominal value 25,000 shares authorized, no shares issued and outstanding)	—	—
Additional paid in capital	548,070	489,440
Accumulated deficit	(452,610)	(373,021)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	<u>93,856</u>	<u>114,708</u>
Total liabilities and shareholders' equity	<u>\$ 370,949</u>	<u>\$ 463,255</u>

See accompanying notes to consolidated financial statements.

[Table of Contents](#)

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Net product sales	\$ 145,850	\$ 235,472
Royalty revenue	4,107	3,641
Licensing and contract revenue	27,927	918
Total revenues	177,884	240,031
Cost of goods sold (inclusive of amortization of intangibles)	74,480	111,630
Gross profit	103,404	128,401
Selling, general and administrative expenses	81,961	93,030
Research and development expenses	19,696	32,319
Impairment of intangibles	72,183	283,747
Total operating expenses	173,840	409,096
Operating loss	(70,436)	(280,695)
Interest expense and amortization of debt discount	14,396	18,211
Other non-operating gain	(546)	(884)
Total other non-operating expense	13,850	17,327
Loss before income taxes	(84,286)	(298,022)
Income tax benefit	4,697	27,121
Net loss	\$ (79,589)	\$ (270,901)
Other comprehensive loss, net		
Change in foreign currency translation adjustments	—	(383)
Comprehensive loss	\$ (79,589)	\$ (271,284)
Loss per share attributable to shareholders		
Basic and Diluted	\$ (1.31)	\$ (5.17)
Weighted average shares basic and diluted		
Basic and Diluted	60,652,999	52,367,444

See accompanying notes to consolidated financial statements.

[Table of Contents](#)

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Changes in Shareholders' Equity/Partners' Capital
(In thousands, except share data)

	Ordinary shares	Additional paid in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount			
Balance at January 1, 2019	52,518,924	\$ 525	\$ 487,288	\$ (102,120)	\$ 383,847
Repurchase of ordinary shares	(673,182)	(7)	(2,780)	—	(2,787)
Net loss	—	—	—	(270,901)	(270,901)
Share compensation	—	—	4,932	—	4,932
Change in foreign currency translation	—	—	—	(383)	(383)
Balance at December 31, 2019	<u>51,845,742</u>	<u>\$ 518</u>	<u>\$ 489,440</u>	<u>\$ (373,021)</u>	<u>\$ (2,229)</u>
Proceeds from issuance of ordinary shares, net of offering costs	11,900,000	119	62,321	—	62,440
Repurchase of ordinary shares	(1,435,725)	(15)	(8,086)	—	(8,101)
Payments for taxes related to the net share settlement of equity awards	—	—	(749)	—	(749)
Net loss	—	—	—	(79,589)	(79,589)
Share compensation	<u>235,815</u>	<u>3</u>	<u>5,144</u>	<u>—</u>	<u>5,147</u>
Balance at December 31, 2020	<u><u>62,545,832</u></u>	<u><u>\$ 625</u></u>	<u><u>\$ 548,070</u></u>	<u><u>\$ (452,610)</u></u>	<u><u>\$ (2,229)</u></u>
					<u><u>\$ 93,856</u></u>

See accompanying notes to consolidated financial statements.

[Table of Contents](#)

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (79,589)	\$ (270,901)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	21,026	57,015
Share compensation	4,925	4,932
Impairment of intangibles	72,183	283,747
Deferred income tax benefit	(1,156)	(26,794)
Loss on sale of fixed and leased assets	287	173
Bad debt provision	6	(164)
Amortization of deferred financing and loan origination fees	1,269	1,337
Write off of deferred financing fees in connection with prepayment	496	—
Change in operating assets and liabilities:		
Trade accounts receivable, net	17,496	12,674
Inventories, net	3,371	3,078
Prepaid expenses and other current assets	(3,209)	9,177
Trade accounts payable	(1,723)	(16,375)
Accrued and other current liabilities	(17,792)	(24,332)
Net cash provided by operating activities	<u>17,590</u>	<u>33,567</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	50	17
Payments on disposal of leased assets	(214)	(74)
Purchase of property, plant and equipment	(2,920)	(3,963)
Net cash used in investing activities	<u>(3,084)</u>	<u>(4,020)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on finance lease obligations	(127)	(130)
Proceeds from public offering, net of issuance costs	62,440	—
Proceeds from purchases of stock under ESPP	219	—
Debt repayment	(50,000)	—
Repurchases of ordinary shares	(8,101)	(2,787)
Payments for taxes related to net share settlement of equity awards	(749)	—
Proceeds from insurance financing loan	—	1,314
Repayment of insurance financing loan	—	(3,088)
Net cash provided by (used in) financing activities	<u>3,682</u>	<u>(4,691)</u>
Net change in cash and cash equivalents	18,188	24,856
Effect on cash of changes in exchange rate	—	175
Cash and cash equivalents, beginning of period	95,865	70,834
Cash and cash equivalents, end of period	<u>\$ 114,053</u>	<u>\$ 95,865</u>
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	\$ 14,745	\$ 15,181
Cash paid for taxes	<u>\$ 2,044</u>	<u>\$ 1,290</u>

See accompanying notes to consolidated financial statements.

[Table of Contents](#)

OSMOTICA PHARMACEUTICALS PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Nature of Operations

Osmotica Pharmaceuticals plc, together with its subsidiaries, is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. The Company generates revenues across an existing portfolio of promoted specialty neurology and women's health products, as well as non-promoted products, many of which are primarily complex formulations of generic drugs.

Osmotica Pharmaceuticals plc (formerly known as Lilydale Limited and Osmotica Pharmaceuticals Limited) is an Irish public limited company. Osmotica Holdings S.C.Sp. acquired Osmotica Pharmaceuticals plc on April 30, 2018 for the purpose of facilitating an offering of ordinary shares in an initial public offering. On October 22, 2018, Osmotica Pharmaceuticals plc completed its initial public offering (the "IPO"), in which it issued and allotted 7,647,500 ordinary shares at a public offering price of \$7.00 per share. The number of shares issued in the IPO reflected the exercise in full of the underwriters' option to purchase 997,500 additional ordinary shares. In addition, the Company issued and allotted 2,014,285 ordinary shares at the public offering price in a private placement to investment funds affiliated with Avista Capital Partners, Altchem Limited and an entity controlled by the Company's Chief Financial Officer. The aggregate net proceeds from the IPO and the private placement were approximately \$58.1 million after deducting underwriting discounts and commissions and estimated offering expenses.

Immediately prior to the IPO and prior to the commencement of trading of Osmotica Pharmaceuticals plc's ordinary shares on the Nasdaq Global Select Market, Osmotica Holdings S.C.Sp. undertook a series of restructuring transactions that resulted in Osmotica Pharmaceuticals plc becoming the direct parent of Osmotica Holdings S.C.Sp with each holder of common units of Osmotica Holdings S.C.Sp. receiving approximately 42.84 ordinary shares of Osmotica Pharmaceuticals plc in exchange for each such common unit. In addition, each holder of an option to purchase common units of Osmotica Holdings S.C.Sp. received an option to purchase the number of ordinary shares of Osmotica Pharmaceuticals plc determined by multiplying the number of units underlying such option by approximately 42.84 (rounded down to the nearest whole share) and dividing the exercise price per unit for such option by approximately 42.84 (rounded up to the nearest whole cent). These transactions are referred to as the "Reorganization". Accordingly, all share and share amounts for all periods presented in the accompanying financial statements have been adjusted retroactively, where applicable, to reflect the Reorganization.

Until the Reorganization on October 17, 2018, Osmotica Pharmaceuticals plc did not conduct any operations (other than activities incidental to its formation, the Reorganization and the pursuit of an initial public offering). Upon the completion of the Reorganization, the historical consolidated financial statements of Osmotica Holdings S.C.Sp. became the historical financial statements of Osmotica Pharmaceuticals plc. Accordingly, the accompanying consolidated financial statements included herein reflect the financial information of Osmotica Holdings S.C.Sp.

Osmotica Holdings S.C.Sp. is a Luxembourg special limited partnership, formed on January 28, 2016. Osmotica Holdings US LLC, a subsidiary of Osmotica Holdings S.C.Sp. entered into a fifty-fifty partnership (the "Merger"), effective February 3, 2016, pursuant to a definitive agreement between Vertical/Trigen Holdings, LLC ("Vertical/Trigen") and members, and Osmotica Holdings Corp Limited and Subsidiaries. Osmotica Holdings S.C.Sp. and several other holding companies and partnerships were formed as a result of the Merger. Pursuant to the Merger, Vertical/Trigen was deemed to be the accounting acquirer. Osmotica is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations.

Unless otherwise indicated or required by the context, references throughout to "Osmotica," or the "Company," refer to (i) prior to the completion of the Reorganization, Osmotica Holdings S.C.Sp. and its consolidated subsidiaries, including, from and after April 30, 2018, Osmotica Pharmaceuticals plc,

and (ii) following the completion of the Reorganization, Osmotica Pharmaceuticals plc and its consolidated subsidiaries, including Osmotica Holdings S.C.Sp.

[Table of Contents](#)

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Significant Accounting Policies

Going Concern Evaluation

The Company devotes significant financial resources to the manufacture, marketing and commercialization of its approved products, and support of its research and development efforts. The Company's future operating performance depends on many assumptions, including assumptions with respect to product sales and expenses, commercialization costs, research and development expenses as well as other factors. These assumptions may prove to be wrong or other factors may adversely affect the Company's operating results. As a result, the Company's operating results may fluctuate significantly quarter to quarter or year to year. The Company expects its near term levels of profitability to be negatively affected by price competition on our generic products, and increased expenses associated with new product launches. As a result, it's possible it would not be able to comply with financial covenants in its credit agreement or generate sufficient cash to service its debt obligations.

The Company is currently undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include divestitures of non-strategic assets, refinancings and commercialization or collaboration agreements. In the event the Company is unable to generate sufficient proceeds from these strategic options such that it can reduce, retire or refinance its existing debt, the Company believes it has sufficient plans to effectively manage its expenses and avail itself of cure provisions provided for in its credit agreement, in order to maintain compliance with its debt covenants therein. The use of the cure provisions will result in utilization cash to pay down the debt balance.

A significant portion of the Company's expense base is discretionary and the Company has the ability to reduce or defer spending to reduce expenses and improve profitability and cash flow to maintain compliance with its debt covenants. This could include, among other things, significant reductions in its general and administrative expenses, research and development expenses, including deferral of clinical trial programs, and deferrals of certain promotional and capital spending programs which could negatively impact the Company's revenue growth and plans. The Company has previously demonstrated an ability to implement various cost reduction initiatives. During the third quarter of 2019 and continuing into 2020, the Company reduced its field force by an aggregate of 90 positions, generating annualized savings of approximately \$10 million, and took measures to realign its operating infrastructure to prepare for the launch of Upneeq and implemented other cost-savings measures to reduce its expenses.

Based on the current facts and circumstances, the use of the cure provisions provided for in the credit agreement, which will result in utilizing cash to prepay debt, and the Company's ability to implement spending reductions and program deferrals, we believe it is probable that the Company can effectively manage its spending to improve profitability in order to maintain compliance with the debt covenants and other obligations in our credit agreement for at least the next 12 months, even if the strategic review does not generate sufficient proceeds to reduce, retire or refinance our existing debt. As a result, the Company has concluded that, after consideration of management's plans it has sufficient liquidity to meet its obligations within one year after the issuance date of its Consolidated Financial Statements, and it does not have substantial doubt about its ability to continue as a going concern.

Basis of Presentation—The accompanying consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Principles of Consolidation—The accompanying consolidated financial statements include the accounts of Osmotica Pharmaceuticals plc and its wholly-owned domestic and foreign subsidiaries. All inter-company transactions and balances have been eliminated in consolidation. The Company is not involved with variable interest entities.

Use of Estimates—The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates

[Table of Contents](#)

on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Foreign Currency Translation—The financial position and results of operations of the Company’s non-U.S. subsidiaries are generally determined using U.S. Dollars as the functional currency. Our subsidiary in Argentina is currently operating in a highly inflationary environment, as a result, we account for translation in accordance with US GAAP. Foreign currency transaction gains and losses are included in selling, general and administrative expenses in the Company’s statements of operations.

Cash and Cash Equivalents—The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents.

Fair Value of Financial Instruments—The Company applies Accounting Standards Committee or ASC 820, *Fair Value Measurement* (“ASC 820”), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company’s principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity’s own assumptions based on market data and the entity’s judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The Company’s financial instruments include cash and cash equivalents, accounts receivable, accounts payable and short and long-term debt. The fair values of these financial instruments approximate book value because of the short maturity of these instruments.

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Inventories—Inventories are stated at the lower of cost or net realizable value at approximate costs determined on the first-in first-out basis. The Company maintains an allowance for excess and obsolete inventory as well as inventory where the cost is in excess of its net realizable value (“NRV”) based on management’s assessments. The Company capitalizes inventory costs associated with its products prior to regulatory approval when, based on management judgement, future commercialization is considered probable and future economic benefit is expected to be realized. As of December 31, 2020 and 2019, there were no capitalized inventory costs associated with products that had not yet achieved regulatory approval. The Company assesses the regulatory approval process and where the product stands in relation to that approval process including any known constraints or impediments to approval. The Company also considers the shelf life of the product in relation to the product timeline for approval. Sample inventory utilized for promoting the Company’s products are expensed and included in cost of goods sold when the sample units are purchased or manufactured.

[Table of Contents](#)

Property, Plant and Equipment—Property, plant and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs are charged to expense when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized and depreciated over the remaining useful lives of the assets. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings. Depreciation is provided using the straight-line method in amounts considered to be sufficient to amortize the cost of the assets to operations over their estimated useful lives or lease terms, as follows:

<u>Asset category</u>	<u>Depreciable life</u>
Buildings	20 - 30 years
Leasehold improvements	Lesser of the useful life of the improvement or the terms of the underlying lease
Machinery	3 - 15 years
Furniture, fixtures and equipment	3 - 10 years
Computer hardware and software	3 - 12 years

Long-Lived Assets, Including Definite-Lived Intangible Assets—Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis or based on the expected pattern of cash flows over estimated useful lives ranging from 5 to 20 years. The Company periodically reviews the estimated useful lives of intangible assets and makes adjustments when events indicate that a shorter life is appropriate.

Long-lived assets, other than goodwill and other indefinite-lived intangibles, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets.

Factors that the Company considers in deciding when to perform an impairment review include significant changes in the Company's forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes, or planned changes in the Company's use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations.

The Company recorded impairment charges of \$72.2 million and \$283.7 million, in regard to definite-lived and indefinite-lived intangible assets for the years ended December 31, 2020 and 2019, respectively (see Note 7).

Goodwill and Indefinite Lived Intangible Assets—Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company is organized in one reporting unit and evaluates the goodwill for the Company as a whole. Goodwill is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. Under the authoritative guidance issued by the Financial Accounting Standards Board (the "FASB"), the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying value, then no impairment is recognized. If the carrying value recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The

judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's

[Table of Contents](#)

financial condition and results of operations. There was no impairment of goodwill for the year ended December 31, 2020 and 2019, respectively. (see Note 7).

In-Process Research and Development (“IPR&D”) intangible assets represent the value assigned to acquired Research & Development (“R&D”) projects that principally represent rights to develop and sell a product that the Company has acquired which have not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. Impairment testing requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset’s life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D product, the assets are reduced to zero. IPR&D is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. If the fair value of the IPR&D is less than its carrying amount, an impairment is recognized for the difference. The Company recognized an impairment charge to IPR&D of \$28.9 million for the year ended December 31, 2020 and we recognized no impairment charges of IPR&D for the year ended December 31, 2019 (see Note 7).

Product Sales—Revenue is recognized at the point in time when the Company’s performance obligations with the applicable customers have been satisfied. At contract inception, the Company determines if the contract is within the scope of ASC Topic 606 and then evaluates the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue at the point in time when the entity satisfies a performance obligation.

Revenue is recorded at the transaction price, which is the amount of consideration the Company expects to receive in exchange for transferring products to a customer. The Company considered the unit of account for each purchase order that contains more than one product. Because all products in a given purchase order are generally delivered at the same time and the method of revenue recognition is the same for each, there is no need to separate an individual order into separate performance obligations. The Company determines the transaction price based on fixed consideration in its contractual agreements, which includes estimates of variable consideration, and the transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. In determining the transaction price, a significant financing component does not exist since the timing from when the Company delivers product to when the customers pay for the product is less than one year and the customers do not pay for product in advance of the transfer of the product.

The Company records product sales net of any variable consideration, which includes estimated chargebacks, certain commercial rebates, and discounts and allowances. The Company utilizes the expected value method to estimate all elements of variable consideration included in the transaction price. The variable consideration is recorded as a reduction of revenue at the time revenues are recognized. The Company will only recognize revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration amount received and the Company will re-assess these estimates each reporting period to reflect known changes in factors.

Royalty Revenue—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

Licensing and Contract Revenue—The Company has arrangements with commercial partners that allow for the purchase of product from the Company by the commercial partners for purposes of sub-

distribution. The Company recognizes revenue from an arrangement when control of such product is transferred to the commercial partner, which is typically upon delivery. In these situations, the performance obligation is satisfied when product is delivered to the Company's

[Table of Contents](#)

commercial partner. Licensing revenue is recognized in the period in which the product subject to the sublicensing arrangement is sold by the Company to its commercial partner. Sales deductions, such as returns on product sales, government program rebates, price adjustments, and prompt pay discounts in regard to licensing revenue is generally the responsibility of the Company's commercial partners and not recorded by the Company.

The transfer of the license is a performance obligation satisfied at a point in time. For arrangements that include non-sales based milestones, including milestone payments based on regulatory approvals or other activities, and the license is deemed to be the predominant item to which the milestones relate, the Company recognizes revenue at the later of a) when the milestone activity is achieved, or b) when the performance obligation to which some or all the milestone has been allocated has been satisfied (or partially satisfied). For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

Freight—The Company records amounts billed to customers for shipping and handling as revenue, and records shipping and handling expenses related to product sales as cost of goods sold. The Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. When shipping and handling costs are incurred after a customer obtains control of the products, the Company also has elected to account for these as costs to fulfill the promise and not as a separate performance obligation.

Chargebacks—The Company enters into contractual agreements with certain third parties such as retailers, hospitals, and group-purchasing organizations (“GPOs”) to sell certain products at predetermined prices. Similarly, the Company maintains an allowance for rebates and discounts related to chargebacks, wholesaler fees for service contracts, GPO administrative fees, government programs, prompt payment and other adjustments with certain customers. Most of the parties have elected to have these contracts administered through wholesalers that buy the product from the Company and subsequently sell it to these third parties. As noted elsewhere, these wholesalers represent a significant percentage of the Company's gross sales. When a wholesaler sells products to one of these third parties that are subject to a contractual price agreement, the difference between the price paid to the Company by the wholesaler and the price under the specific contract is charged back to the Company by the wholesaler. Utilizing this information, the Company estimates a chargeback percentage for each product and records an allowance as a reduction to gross sales when the Company records its sale of the products. The Company reduces the chargeback allowance when a chargeback request from a wholesaler is processed. The Company's provision for chargebacks is fully reserved for at the time when sales revenues are recognized.

The Company obtains product inventory reports from major wholesalers to aid in analyzing the reasonableness of the chargeback allowance and to monitor whether wholesaler inventory levels do not significantly exceed customer demand. The Company assesses the reasonableness of its chargeback allowance by applying a product chargeback percentage that is based on a combination of historical activity and current price and mix expectations to the quantities of inventory on hand at the wholesalers according to wholesaler inventory reports. In addition, the Company estimates the percentage of gross sales that were generated through direct and indirect sales channels and the percentage of contract vs. non-contract revenue in the period, as these each affect the estimated reserve calculation. In accordance with its accounting policy, the Company estimates the percentage amount of wholesaler inventory that will ultimately be sold to third parties that are subject to contractual price agreements based on a trend of such sales through wholesalers. The Company uses this percentage estimate until historical trends indicate that a revision should be made. On an ongoing basis, the Company evaluates its actual chargeback rate experience, and new trends are factored into its estimates each quarter as market conditions change.

The Company ensures that chargebacks are reasonable through review of contractual obligations, historical trends and evaluation of recent activity. Furthermore, other events that could materially alter chargebacks include: changes in product pricing as a result of competitive market dynamics or negotiations with customers, changes in demand for specific products due to external factors such as

competitor supply position or consumer preferences, customer shifts in buying patterns from direct to indirect through wholesalers, which could either individually or in aggregate increase or decrease the chargebacks depending on the direction and trend of the change(s).

[Table of Contents](#)

Commercial Rebates—The Company maintains an allowance for commercial rebates that it has in place with certain customers. Commercial rebates vary by product and by volume purchased by each eligible customer. The Company tracks sales by product number for each eligible customer and then applies the applicable commercial rebate percentage, using both historical trends and actual experience to estimate its commercial rebates. The Company reduces gross sales and increases the commercial rebates allowance by the estimated commercial rebates when the Company sells its products to eligible customers. The Company reduces the commercial rebate allowance when it processes a customer request for a rebate. At each month end, the Company analyzes the allowance for commercial rebates against actual rebates processed and makes necessary adjustments as appropriate. The Company's provision for commercial rebates is fully reserved for at the time when sales revenues are recognized.

The allowance for commercial rebates takes into consideration price adjustments which are credits issued to reflect increases or decreases in the invoice or contract prices of the Company's products. In the case of a price decrease, a credit is given for products remaining in customer's inventories at the time of the price reduction. Contractual price protection results in a similar credit when the invoice or contract prices of the Company's products increase, effectively allowing customers to purchase products at previous prices for a specified period of time. Amounts recorded for estimated shelf-stock adjustments and price protections are based upon specified terms with direct customers, estimated changes in market prices, and estimates of inventory held by customers. The Company regularly monitors these and other factors and evaluates the reserve as additional information becomes available. The Company ensures that commercial rebates are reasonable through review of contractual obligations, review of historical trends and evaluation of recent activity. Furthermore, other events that could materially alter commercial rebates include: changes in product pricing as a result of competitive market dynamics or negotiations with customers, changes in demand for specific products due to external factors such as competitor supply position or consumer preferences, customer shifts in buying patterns from direct to indirect through wholesalers, which could either individually or in aggregate increase or decrease the commercial rebates depending on the direction and velocity of the change(s).

Product Returns—Certain of the Company's products are sold with the customer having the right to return the product within specified periods. Estimated return accruals are made at the time of sale based upon historical experience. Historical factors such as one-time recall events as well as pending new developments like comparable product approvals or significant pricing movement that may impact the expected level of returns are taken into account monthly to determine the appropriate accrued expense. As part of the evaluation of the liability required, the Company considers actual returns to date that are in process, the expected impact of any product recalls and the amount of wholesaler's inventory to assess the magnitude of unconsumed product that may result in product returns to the Company in the future. The product returns level can be impacted by factors such as overall market demand and market competition and availability for substitute products which can increase or decrease the pull through for sales of the Company's products and ultimately impact the level of product returns. Product returns are fully reserved for at the time when sales revenues are recognized.

The Company ensures that product returns are reasonable through review of historical trends and evaluation of recent activity. Furthermore, other events that could materially alter product returns include: acquisitions and integration activities that consolidate dissimilar contract terms and could impact the return rate as typically the Company purchases smaller entities with less contracting power and integrates those product sales to Company contracts; and consumer demand shifts by products, which could either increase or decrease the product returns depending on the product or products specifically demanded and ultimately returned.

Accrual for Promotions and Co-Pay Discount Cards—From time to time the Company authorizes various retailers to run in-store promotional sales of its products. The Company accrues an estimate of the dollar amount expected to be owed back to the retailer. Additionally, the Company provides consumer co-pay discount cards, administered through outside agents to provide discounted products when redeemed. Upon release of the cards into the market, the Company records an estimate of the dollar value of co-pay discounts expected to be utilized taking into consideration historical experience.

Government Program Rebates—Federal law requires that a pharmaceutical distributor, as a condition of having federal funds being made available to the States for the manufacturer's drugs under Medicaid

and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the distributor's covered outpatient drugs that are

[Table of Contents](#)

dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement. The Centers for Medicare and Medicaid Services (“CMS”) are responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are also due on the utilization of Medicaid managed care organizations (“MMCOs”).

The Company also pays rebates to managed care organizations (“MCOs”) for the reimbursement of a portion of the sales price of prescriptions filled that are covered by the respective plans. The liability for Medicaid, Medicare, and other government program rebates is settled in cash and is estimated at the time when sales revenues are recognized based on historical and current rebate redemption and utilization rates contractually submitted by each state’s program administrator and assumptions regarding future government program utilization for each product sold; and accordingly recorded as a reduction of product sales.

Business Combinations—The Company accounts for its business combinations under the provisions of ASC Topic 805, *Business Combinations* (“ASC 805”), which requires that the purchase method of accounting be used for all business combinations. Assets acquired, and liabilities assumed, are recorded at the date of acquisition at their respective fair values. Amounts allocated to acquire IPR&D are capitalized at the date of an acquisition and are not amortized. As products in development are approved for sale, amounts are allocated to product rights and licenses and amortized over their estimated useful lives. Definite-lived intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill represents the excess purchase price over the fair value of the tangible net assets and intangible assets acquired in a business combination. Acquisition-related expenses are recognized separately from business combinations and are expensed as incurred. If the business combination provides for contingent consideration, the Company records the contingent consideration at fair value at the acquisition date. Changes in fair value of contingent consideration resulting from events after the acquisition date, such as earn-outs, are recognized as follows: 1) if the contingent consideration is classified as equity, the contingent consideration is not re-measured and its subsequent settlement is accounted for within equity, or 2) if the contingent consideration is classified as a liability, the changes in fair value are recognized in earnings.

Purchases of developed products and licenses that are accounted for as an asset acquisition are capitalized as intangible assets and amortized over an estimated useful life. IPR&D assets acquired as part of an asset acquisition are expensed immediately if they have no alternative future uses.

In-Process Research and Development—In-process research and development represent the fair value assigned to incomplete research projects that the Company acquires through business combinations or developed internally which, at that time, have not reached technological feasibility. Intangible assets associated with IPR&D projects are not amortized until regulatory approval is obtained and product is launched, subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated. During the years ended December 31, 2020 and 2019, \$0 million and \$19.7 million, respectively, of IPR&D was transferred to Product Rights as the products in development are approved for sale and placed into service (see Note 7). Such amounts will be amortized over their respectful estimated useful lives. At that time an evaluation of fair value was performed immediately prior to such transfer and no impairments were recognized at that time. Assets are subsequently evaluated for indicators of impairment.

Research and Development Costs—Research and development costs are expensed as incurred. These expenses include the costs of proprietary efforts, as well as costs incurred in connection with certain licensing arrangements. Upfront payments are recorded when incurred, and milestone payments are recorded when the specific milestone has been achieved.

Advertising—Advertising expense consists primarily of print media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2020 and 2019 amounted to \$9.3 million and \$8.5 million, respectively.

[Table of Contents](#)

Share-based Compensation—The Company recognizes share-based compensation expense for all options and other arrangements within the scope of ASC 718, *Stock Compensation*. Share-based compensation expense is measured at the date of grant, based on the fair value of the award. Compensation for share-based awards with vesting conditions other than service are recognized at the time that those conditions will be achieved. Forfeitures are recognized as they are incurred.

Income Taxes—Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position. These tax benefits are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

Comprehensive income (loss)—Comprehensive income (loss) refers to revenues, expenses, gains and losses that under U.S. GAAP are included in comprehensive loss but are excluded from net loss as these amounts are recorded directly as an adjustment to accumulated other comprehensive income (loss). The Company's other comprehensive loss is comprised of foreign currency translation adjustments.

Basic and Diluted Loss per Share—Basic and diluted net loss per share is determined by dividing net loss by the weighted average ordinary shares outstanding during the period. For all periods presented with a net loss, the shares underlying the common share options have been excluded from the calculation because their effect would have been anti-dilutive. Therefore, the weighted average shares outstanding used to calculate both basic and diluted loss per share are the same for periods with a net loss.

Segment Reporting—The Company operates in one business segment which focuses on developing and commercializing pharmaceutical products that target markets with underserved patient populations. The chief operating decision maker (“CODM”) reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions. The consolidated financial statements reflect the financial results of the Company's one reportable operating segment. The Company has no significant revenues or tangible assets outside of the United States.

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which introduces a new methodology for accounting for credit losses on financial instruments, including available-for-sale debt securities. The guidance establishes a new “expected loss model” that requires entities to estimate current expected credit losses on financial instruments by using all practical and relevant information. The estimate of credit losses must be based on all relevant information including historical information, current conditions, and reasonable and supportable forecasts that affect the collectability of the amounts. The Company adopted this standard on January 1, 2020, and there was no material impact to the Company's consolidated financial statements. The Company has provided additional disclosures as required by the standard upon adoption. Refer to Note 4 for additional details.

Note 3. Revenues

The Company's performance obligations are to provide its pharmaceutical products based upon purchase orders from distributors. The performance obligation is satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. The Company invoices

its customers after the products have been delivered and invoice payments are generally due within 30 to 60 days of invoice date.

[Table of Contents](#)

The following table disaggregates revenue from contracts with customers by pharmaceutical products (in thousands):

Pharmaceutical Product	Year Ended December 31,	
	2020	2019
Venlafaxine ER (VERT)	\$ 25,576	\$ 75,601
Methylphenidate ER	31,699	73,205
Divigel	31,629	26,794
Nitrofurantoin	10,443	5,726
Lorzone	4,058	15,004
OB Complete	6,948	9,851
Other	35,497	29,291
Net product sales	145,850	235,472
Royalty revenue	4,107	3,641
License and contract revenue	27,927	918
Total revenues	<u>\$ 177,884</u>	<u>\$ 240,031</u>

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of products to the customer under the terms of a contract, the Company records a contract liability. The Company classifies contract liabilities as deferred revenue. The Company had no material deferred revenue as of December 31, 2020 and 2019. The Company has elected to apply the exemption under paragraph 606-10-50-14(a) related to remaining performance obligations as all open purchase orders are expected to be satisfied with a period of one year from the date of the purchase order.

Contract assets primarily relate to rights to consideration for goods or services transferred to the customer when the right is conditional on something other than the passage of time. Contract assets are transferred to accounts receivable when the rights become unconditional. The Company had no contract assets as of December 31, 2020 and 2019, respectively. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs*.

Note 4. Accounts Receivable, Sales and Allowances

The nature of the Company's business inherently involves, in the ordinary course, significant amounts and substantial volumes of transactions and estimates relating to allowances for product returns, chargebacks, rebates, doubtful accounts and discounts given to customers. This is typical of the pharmaceutical industry and not necessarily specific to the Company. Depending on the product, the end-user customer, the specific terms of national supply contracts and the particular arrangements with the Company's wholesale customers, certain rebates, chargebacks and other credits are deducted from the Company's accounts receivable. The process of claiming these deductions depends on wholesalers reporting to the Company the amount of deductions that were earned under the terms of the respective agreement with the end-user customer (which in turn depends on the specific end-user customer, each having its own pricing arrangement, which entitles it to a particular deduction). This process can lead to partial payments against outstanding invoices as the wholesalers take the claimed deductions at the time of payment.

Accounts receivable result primarily from sales of pharmaceutical products, amounts due under revenue sharing, license and royalty arrangements, which inherently involves, in the ordinary course of business, estimates relating to allowances for product returns, chargebacks, rebates, credit losses and discounts given to customers. Credit is extended based on the customer's financial condition, and, generally, collateral is not required. The Company ages its accounts receivable using the corresponding sale date of the transaction and considers accounts past due based on terms agreed upon in the transaction, which is generally 30 to 60 days for branded and generic sales, depending on the customer and the products purchased.

The Company is exposed to credit losses primarily through sales of its products. Prior to January 1, 2020, accounts receivable were recorded at cost less an allowance for doubtful accounts. Subsequent to January 1, 2020, accounts receivable are recorded at amortized cost less an allowance for expected

credit losses that are not expected to be recovered. The Company's expected loss methodology for accounts receivable is developed using historical collection

[Table of Contents](#)

experience, a review of the current status of customer's trade receivables, and current and future market conditions. Due to the short-term nature of such receivables, the estimate of accounts receivable that may not be collected is based on the aging of accounts receivable balances and the financial condition of customers. The Company's monitoring activities include timely account reconciliations, dispute resolution, payment confirmation, consideration of customers' financial condition and macroeconomic conditions. Balances are written-off when determined to be uncollectible. The Company considered the current and expected future economic and market conditions surrounding a novel strain of the coronavirus, referred to as 2019-ncov, COVID-19 coronavirus epidemic, or COVID-19, and determined that the estimate of credit losses was not significantly impacted.

With the exception of the allowance for credit losses, which is reflected as part of selling, general and administrative expense, the provisions for the following customer reserves are reflected as a reduction of revenues in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

Trade accounts receivable, net consists of the following (in thousands):

	December 31, 2020	December 31, 2019
Gross trade accounts receivable		
Trade accounts receivable	\$ 38,546	\$ 70,958
R ^{oyalty} accounts receivable	1,267	702
Other receivable	4,639	2,186
Less reserves for:		
Chargebacks	(9,921)	(14,624)
Commercial rebates	(7,344)	(13,579)
Discounts and allowances	(775)	(1,591)
Allowance for credit losses	—	(138)
Total trade accounts receivable, net	<u>\$ 26,412</u>	<u>\$ 43,914</u>

For the years ended December 31, 2020 and 2019, the Company recorded the following adjustments to gross product sales (in thousands):

	Year Ended December 31,	
	2020	2019
Gross product sales	\$ 321,493	\$ 764,267
Less provisions for:		
Chargebacks	(122,592)	(345,366)
Government and managed care rebates	(18,211)	(20,092)
Commercial rebates	(22,488)	(147,173)
Product returns	(2,825)	3,932
Discounts and allowances	(7,003)	(15,719)
Advertising and promotions	(2,524)	(4,377)
Net product sales	<u>\$ 145,850</u>	<u>\$ 235,472</u>

[Table of Contents](#)

For the years ended December 31, 2020 and 2019, the activity in the Company's allowance for customer deductions against trade accounts receivable is as follows (in thousands):

	Chargebacks	Commercial Rebates	Discounts and Allowances	Credit Losses	Total
Balance at December 31, 2018	\$ 38,861	\$ 49,232	\$ 3,510	\$ 194	\$ 91,797
Provision	345,366	147,173	15,719	(190)	508,068
Charges processed	(369,603)	(182,826)	(17,638)	134	(569,933)
Balance at December 31, 2019	\$ 14,624	\$ 13,579	\$ 1,591	\$ 138	\$ 29,932
Provision	122,592	22,488	7,003	6	152,089
Charges processed	(127,295)	(28,723)	(7,819)	(144)	(163,981)
Balance at December 31, 2020	<u>\$ 9,921</u>	<u>\$ 7,344</u>	<u>\$ 775</u>	<u>\$ —</u>	<u>\$ 18,040</u>

The annual activity in the Company's accrued liabilities for customer deductions by account for the years ended December 31, 2020 and 2019, is as follows (in thousands):

	Product Returns	Government and Managed Care Rebates	Total
Balance at December 31, 2018	\$ 48,464	\$ 9,981	\$ 58,445
Provision	(3,932)	20,092	16,160
Charges processed	(11,075)	(25,206)	(36,281)
Balance at December 31, 2019	<u>\$ 33,457</u>	<u>\$ 4,867</u>	<u>\$ 38,324</u>
Provision	2,825	18,211	21,036
Charges processed	(14,256)	(19,633)	(33,889)
Balance at December 31, 2020	<u>\$ 22,026</u>	<u>\$ 3,445</u>	<u>\$ 25,471</u>

Provisions and utilizations of provisions activity in the current period which relate to the prior period revenues are not provided because to do so would be impracticable. The Company's current systems and processes do not capture the chargeback and rebate settlements by the period in which the original sales transaction was recorded. The Company uses a combination of factors and applications to estimate the dollar amount of reserves for chargebacks and rebates at each month end. Variable consideration is included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. The Company regularly monitors the reserves based on an analysis of the Company's product sales and most recent claims, wholesaler inventory, current pricing, and anticipated future pricing changes. If amounts are different from the estimate due to changes from estimated rates, accrual rate adjustments are considered prospectively when determining provisions in accordance with authoritative U.S. GAAP. During the year ended December 31, 2020 and 2019, adjustments due to changes in estimates were necessary based on actual product returns experience, resulting in a decrease of \$7.1 million and \$25.3 million, respectively, to the product returns reserve and a corresponding benefit to the net product sales recognized.

Note 5. Inventories

The components of inventories, net of allowances, are as follows (in thousands):

	December 31, 2020	December 31, 2019
Finished goods	\$ 13,352	\$ 15,319
Work in process	618	778
Raw materials and supplies	3,964	5,208
	<u>\$ 17,934</u>	<u>\$ 21,305</u>

Table of Contents

The Company maintains an allowance for excess and obsolete inventory, as well as inventory where its cost is in excess of its net realizable value. The activity in the allowance for excess and obsolete inventory account for the years ended December 31, 2020 and 2019, was as follows (in thousands):

	Year Ended	
	December 31, 2020	December 31, 2019
Balance at beginning of period	\$ 1,069	\$ 1,561
Provision	1,001	2,322
Charges processed	(1,144)	(2,814)
Balance at end of period	\$ 926	\$ 1,069

Note 6. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following (in thousands):

	Year Ended	
	December 31, 2020	December 31, 2019
Land	\$ 2,120	\$ 2,120
Buildings	11,671	11,643
Leasehold improvements	3,580	3,423
Machinery	17,399	16,034
Furniture, fixtures and equipment	1,368	1,388
Computer hardware and software	9,014	8,508
	45,152	43,116
Accumulated depreciation	(18,980)	(14,292)
	26,172	28,824
Construction in progress	1,882	1,414
	\$ 28,054	\$ 30,238

Depreciation expense was \$5.0 million and \$4.4 million for the years ended December 31, 2020 and 2019, respectively. There is approximately \$2.8 million of remaining construction in progress expenditures to substantially complete the projects.

Note 7. Goodwill and Other Intangible Assets

The Company tests goodwill and indefinite-lived intangible assets for impairment annually as of October 1st, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. Goodwill is net of accumulated impairment charges of \$86.3 million at December 31, 2020 and 2019. The following table sets forth the carrying value of goodwill as of December 31, 2019 and 2020, respectively (in thousands).

	Goodwill
January 1, 2019	\$ 100,855
Impairments	—
December 31, 2019	\$ 100,855
Impairments	—
December 31, 2020	\$ 100,855

[Table of Contents](#)

The following tables sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of December 31, 2020 and 2019, for those assets that are not already fully amortized (in thousands):

	December 31, 2020				Weighted Average Remaining Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	
Distribution Rights	\$ 33,714	\$ (23,893)	\$ (9,461)	\$ 360	0.8
Product Rights	202,567	(164,336)	(19,539)	18,692	2.1
Tradenames	13,485	(3,741)	—	9,744	14.0
Developed Technology	52,466	(36,321)	(14,273)	1,872	8.6
IPR&D	64,000	—	(28,910)	35,090	Indefinite Lived
	<u>\$366,232</u>	<u>\$(228,291)</u>	<u>\$(72,183)</u>	<u>\$65,758</u>	

The table above is inclusive of a gross carrying amount of \$85.9 million and \$62.1 million of accumulated amortization for assets that have been fully impaired.

	December 31, 2019				Weighted Average Remaining Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	
Distribution Rights	\$ 98,433	\$ (22,291)	\$ (64,719)	\$ 11,423	10.1
Product Rights	348,600	(152,348)	(146,033)	50,219	3.1
Tradenames	13,485	(3,035)	—	10,450	15.0
Developed Technology	125,461	(34,572)	(72,995)	17,894	10.9
IPR&D	64,000	—	—	64,000	Indefinite Lived
	<u>\$649,979</u>	<u>\$(212,246)</u>	<u>\$(283,747)</u>	<u>\$153,986</u>	

The table above is inclusive of a gross carrying amount of \$28.3 million and \$10.4 million of accumulated amortization for assets that have been fully impaired.

Changes in intangible assets during the years ended December 31, 2019 and 2020, were as follows (in thousands):

	Distribution Rights	Product Rights	Tradenames	Developed Technology	IPR&D	Total
January 1, 2019	\$ 81,204	\$ 217,473	\$ 11,156	\$ 96,857	\$ 83,700	\$ 490,390
Amortization	(5,062)	(40,921)	(706)	(5,968)	—	(52,657)
Impairments	(64,719)	(146,033)	—	(72,995)	—	(283,747)
Reclassifications(A)	—	19,700	—	—	(19,700)	—
December 31, 2019	<u>\$ 11,423</u>	<u>\$ 50,219</u>	<u>\$ 10,450</u>	<u>\$ 17,894</u>	<u>\$ 64,000</u>	<u>\$ 153,986</u>
Amortization	(1,602)	(11,988)	(706)	(1,749)	—	(16,045)
Impairments	(9,461)	(19,539)	—	(14,273)	(28,910)	(72,183)
December 31, 2020	<u>\$ 360</u>	<u>\$ 18,692</u>	<u>\$ 9,744</u>	<u>\$ 1,872</u>	<u>\$ 35,090</u>	<u>\$ 65,758</u>

(A) IPR&D in the amount of \$19.7 million related to Osmolex ER was reclassified to Product Rights in the first quarter of 2019 when the product was launched. Osmolex ER was fully impaired during the second quarter of 2019.

As part of the Company's goodwill and intangible asset impairment assessments performed on the annual assessment date, when indicators of impairment are identified and when IPR&D assets are put into service, when a qualitative assessment is performed, the Company estimates the fair values of the intangible assets using an income approach that utilizes a discounted cash flow model, or, where

appropriate, a market approach. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve

[Table of Contents](#)

assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amounts, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. As of October 1, 2020, the Company performed a qualitative assessment for goodwill and for the IPR&D assets and concluded that the assets were not impaired. The discount rates applied to the estimated cash flows for the Company's 2019 annual goodwill and indefinite-lived intangible assets impairment test was 16.5%, based on the overall risk associated with the particular assets and other market factors. Indefinite-lived intangible assets classified as in-process research and development, or IPRD, are subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development. The POS factor applied to the IPRD asset on a subsequent assessment as of December 31, 2020 was 69.6% and the discount rate was 9.5%. The Company believes the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments, if any, are recorded to Impairment of intangible assets in the Consolidated Statements of Operations and Comprehensive Loss.

Impairments of intangible assets and goodwill for the year-ended December 31, 2020 was \$72.2 million primarily consisting of write-downs to fair value for methylphenidate ER, VERT and Oxybutynin of \$19.5 million, \$20.2 million and \$3.6 million, respectively, including an indefinite-lived In-Process R&D asset, arbaclofen ER, which resulted in an impairment charge of \$28.9 million due to a delay in the anticipated commercialization date of the product, if approved. These impairments reflect the competitive generic environment which has continued to erode net realized pricing and volumes of these products. In the fourth quarter of 2020 we recognized an impairment of finite-lived development technology and product rights for VERT of \$10.7 million and \$9.5 million, respectively due to the approval of a competing product and the anticipated deterioration of pricing and volumes.

During 2019, we recognized impairments of finite-lived intangible assets of \$283.7 million, consisting primarily of write-downs to fair value of methylphenidate ER, VERT, Osmolex ER, and Corvite of \$128.1 million, \$137.7 million, \$17.7 million, and \$0.2 million, respectively. Methylphenidate ER tablets and VERT were impaired due to lower revenues reflecting an increasingly competitive environment which deteriorated pricing and volumes; Osmolex ER was impaired due to underperforming revenue expectations subsequent to the launch of the product; and Corvite due to the discontinuation of the product. In the third and fourth quarter of 2019 we also recognized an impairment of finite-lived development technology and distribution rights for VERT of \$73.0 million and \$64.7 million, respectively, due to approvals of competing products which deteriorated pricing and volumes.

Amortization expense was \$16.0 million and \$52.7 million for the years ended December 31, 2020 and 2019, respectively and is recorded to Cost of goods sold (inclusive of amortization of intangibles) in the Consolidated Statements of Operations and Comprehensive Loss.

The amortization expense of acquired intangible assets for each of the following five years are expected to be as follows (in thousands):

Years ending December 31	Amortization Expense
2021	\$ 10,193
2022	5,625
2023	4,739
2024	2,790
Thereafter	7,321
Total	\$ 30,668



Table of Contents

Note 8. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued product returns	\$ 22,026	\$ 33,457
Accrued royalties	2,246	3,649
Accrued compensation	8,022	10,998
Accrued government and managed care rebates	3,445	4,867
Accrued research and development	1,000	3,028
Accrued expenses and other liabilities	10,550	8,477
Customer coupons	200	777
Deferred revenue	28	—
Total	\$ 47,517	\$ 65,253

In the ordinary course of business, the Company enters into contractual agreements with wholesalers pursuant to which the wholesalers distribute sales of Company products to customers and provide sales data to the Company. In return the wholesalers charge the Company a fee for services and other customary rebates and chargebacks based on distribution sales of Company products through the wholesalers and downstream customers.

Note 9. Leases

The Company leases office space in Bridgewater, New Jersey for its principal offices under two non-cancelable leases that expire in July 2022 and November 2023, in addition to office and warehouse space in various domestic and international locations. The Company also leases certain vehicles under operating leases. As of December 31, 2020, the Company's operating leases had remaining lease terms ranging from 0.99 years to 3.00 years.

We assess whether an arrangement is a lease or contains a lease at inception. For arrangements considered leases or that contain a lease that is accounted for separately, we determine the classification and initial measurement of the right-of-use asset and lease liability at the lease commencement date, which is the date that the underlying asset becomes available for use. The Company has elected to account for non-lease components associated with our leases and lease components as a single lease component.

The Company recognizes a right-of-use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments are calculated using either the implicit interest rate in the lease or an incremental borrowing rate.

[Table of Contents](#)

Our lease assets and liabilities were classified as follows on our Condensed Consolidated Balance Sheet at December 31, 2020 (in thousands):

Leases	Classification	Balance at December 31, 2020	Balance at December 31, 2019
Assets			
Operating	Operating Lease Assets	\$ 2,755	\$ 4,983
Finance	Property, plant and equipment, net	58	188
Total leased assets		<u>\$ 2,813</u>	<u>\$ 5,171</u>
Liabilities			
Current			
Operating	Current portion of lease liability	\$ 1,457	\$ 2,062
Finance	Current portion of obligations under finance leases	40	127
Non-current			
Operating	Long-term portion of lease liability	1,436	3,116
Finance	Long-term portion of obligations under finance leases	4	44
Total lease liabilities		<u>\$ 2,937</u>	<u>\$ 5,349</u>

The Company recognizes lease expense on a straight-line basis over the lease term. The components of lease cost are as follows (in thousands):

Lease Cost	Classification	Year Ended December 31, 2020	Year Ended December 31, 2019
		2020	2019
Operating lease cost	SG&A expenses	\$ 1,525	\$ 1,926
	R&D expenses	104	139
	Cost of goods sold	392	366
Finance lease cost			
Amortization of leased assets	Depreciation and amortization	130	130
Interest on lease liabilities	Interest expense	2	4
Total lease cost		<u>\$ 2,153</u>	<u>\$ 2,565</u>

The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the leases as follows (in thousands):

Years ending December 31	Operating Leases
2021	\$ 1,589
2022	955
2023	554
Total lease payments	3,098
Less: interest	207
Present value of lease payments	<u>\$ 2,891</u>

The Company has future minimum lease payments required under the finance leases of less than \$0.1 million less interest expense of less than \$0.1 million for total present value lease payments of less than \$0.1 million for the years ended December 31, 2021 through December 31, 2022.



[Table of Contents](#)

The weighted-average remaining lease term and the weighted-average discount rate of our leases were as follows (in thousands):

Lease Term and Discount Rate	December 31, 2020	December 31, 2019
Weighted average remaining lease term (years)		
Operating leases	2.24	2.86
Finance leases	1.47	1.33
Weighted average discount rate		
Operating leases	5.60 %	5.26 %
Finance leases	1.99 %	1.81 %
<hr/>		
Other Information	December 31, 2020	December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ (1,927)	\$ (2,431)
Operating cash flows for finance leases	(2)	(4)
Financing cash flows for finance leases	(127)	(130)

For the years ended December 31, 2020 and 2019, the Company recorded \$0.2 million and \$1.4 million, respectively, of leased assets obtained in exchange for new operating lease liabilities and \$0.0 million and less than \$0.1 million, respectively, of leased assets obtained in exchange for new finance lease liabilities. During the years ended December 31, 2020 and 2019, the Company disposed of \$0.6 million and \$0.4 million, respectively, of leased assets.

Note 10. Financing Arrangements

The composition of the Company's debt and financing obligations are as follows (in thousands):

	December 31, 2020	December 31, 2019
CIT Bank, N.A. Term Loan due December 21, 2022, net of deferred financing costs of \$1.8 million and \$3.4 million as of December 31, 2020 and December 31, 2019, respectively	\$ 219,525	\$ 267,950
Total debt	219,525	267,950
Less: current portion	—	—
Long-term debt	<u>\$ 219,525</u>	<u>\$ 267,950</u>

Term Loan

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a \$160.0 million Term Loan (the "Term Loan") pursuant to a Credit Agreement dated February 3, 2016 (as amended, supplemented or otherwise modified, the "Term Loan Agreement") between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent. The Term Loan is secured by certain assets of the Company, excluding certain intangibles and foreign property.

The Term Loan Agreement required quarterly principal repayments equal to 0.625% of the initial aggregate Term Loan amount beginning on the last day of the first full fiscal quarter following the closing of the Term Loan Agreement, with final payment of the remaining principal balance due at maturity six years from the date of closing of the Term Loan Agreement. At the Company's election, interest accrues on a Prime Rate/Federal Funds Effective Rate ("ABR Loan") or a LIBOR ("LIBOR Loan") rate, plus a margin of 4.00% for ABR Loan, and 5.00% for LIBOR Loan.

On November 10, 2016, the Company amended the Term Loan Agreement (the "First Amendment to the Term Loan Agreement") in conjunction with the reacquisition of venlafaxine distribution rights. Pursuant to the First Amendment to

[Table of Contents](#)

the Term Loan Agreement, CIT Bank and certain other lenders agreed to make available to the Company, an Incremental Term Loan in the aggregate principal amount of \$117,500,000, which was added to the Term Loan; there were no other modifications to the Term Loan Agreement.

On April 28, 2017, the Company amended the Term Loan Agreement (the "Second Amendment to the Term Loan Agreement"), in which the due date of the Company's annual financial statements was modified for the first fiscal year after the closing of the Second Amendment to Term Loan Agreement.

On December 21, 2017, the Company amended the Term Loan Agreement (the "Third Amendment to the Term Loan Agreement"). Pursuant to the Third Amendment to the Term Loan Agreement, CIT Bank and certain other lenders agreed to increase the principal amount of the Term Loan to an aggregate principal amount of \$327,500,000. Of the aggregate principal amount, \$277,500,000 was designated as the Term A Loan and \$50,000,000 was designated as the Term B Loan.

On December 11, 2020, the Company amended the Term Loan Agreement (the "Fourth Amendment to the Term Loan Agreement"). Pursuant to the Fourth Amendment to the Term Loan Agreement, the Term Loan Agreement was amended to, among other things, remove a limit on the exercise of the Company's right to cure a breach of the financial covenant under the Term Loan Agreement and providing that any proceeds received by the company as a result of the exercise of such cure right will be applied to repay term loans under the Term Loan Agreement.

The Term Loan Agreement requires quarterly principal repayments to 0.6925% of the original principal amount of the Term A Loan and in the case of the Term B Loan 0.25% of the original principal amount of the Term B Loan, with final payment of the remaining principal balance due at maturity five years from the date of closing of the Term Loan Agreement.

At the Company's election, for the Term A Loan, interest accrues on a Prime Rate/Federal Funds Effective Rate ("ABR Loan") or a LIBOR ("LIBOR Loan") rate in which the applicable rate per annum set forth below under the caption "ABR Spread" or "LIBOR Rate Spread," based upon the Total Leverage Ratio (as defined in the Term Loan Agreement) as of last day of the most recently ended fiscal quarter is as follows:

Total Leverage Ratio	LIBOR Rate Margin	ABR Margin
Category 1	3.75 %	2.75 %
Greater than 2.00 to 1.00		
Category 2	3.25 %	2.25 %
Equal to or less than 2.00 to 1.00		

For Term B Loan, interest accrues with respect to any ABR Loan, 3.25% per annum, and with respect to any LIBOR Rate Loan, 4.25% per annum. As of December 31, 2020 and 2019, the interest rates were 4.75% and 5.79% for Term A Loan and 5.25% and 6.29% for Term B Loan, respectively.

The Term Loan Agreement contains covenants that require the Company to deliver quarterly and annual financial statements along with certain supplementary financial information and schedules and ratios. The Term Loan Agreement also contains covenants that limit the ability of the Company to, among other things: incur additional indebtedness; incur liens; make investments; make payments on indebtedness; dispose of assets; enter into merger transactions; and make distributions. In addition, the Company shall not permit the total leverage ratio to be greater than 4.75:1.00 until March 31, 2020 at which time the total leverage ratio remains constant at a required 4.50:1.00. The total leverage ratio is the ratio, as of any date of determination, of (a) consolidated total debt, net of unrestricted cash and cash equivalents as of such date to (b) consolidated adjusted earnings before income taxes, depreciation and amortization ("Consolidated EBITDA") for the test period then most recently ended for which financial statements have been delivered. Also, the Company will not permit the fixed charge coverage ratio to fall below 1.25:1.0 beginning on March 31, 2018 through the final maturity date. The fixed charge coverage ratio, as of the date of determination, is the ratio of (x) Consolidated EBITDA net of capital expenditures and cash taxes paid to (y) interest payments, scheduled principal payments, restricted payments and management fees paid to related parties. The Company obtained a waiver from CIT Bank in regard to its non-compliance of its covenant to deliver annual financial statements by April 2, 2018. The Company did

[Table of Contents](#)

not incur a waiver fee as a condition to the waiver. The Company was in compliance with all covenants of the Term Loan Agreement as of December 31, 2020 and 2019.

As a result, of payments made in 2018, as of both December 31, 2020 and 2019, there are no remaining scheduled installments of principal due in respect of the Term Loans until the final maturity date.

During the year ended December 31, 2020, the Company prepaid \$50.0 million in aggregate of the outstanding principal amount. The prepayments consisted of \$42.3 million of Term A Loan outstanding principal and \$7.7 million of Term B Loan outstanding principal. As required by the Third Amendment, the prepayments were made on a pro rata basis between the Term A Loan and the Term B Loan. The Company intends to continue to make interest payments accrued on the outstanding remaining balance through the date of maturity.

In accordance with ASC 470, when debt is prepaid within its contractual terms and the terms of the remaining debt are not modified, the prepayment should be treated as a partial extinguishment rather than a modification. This conclusion is reached without regard to consideration of the 10% cash flow test since no change to terms of the original debt instrument was modified in connection with the prepayment. The Third Agreement allows for partial prepayments without creating changes to the terms of Term Loan A or Term Loan B.

The Company incurred debt issuance costs associated with the Third Amendment. Pursuant to ASC 835-30-35-2, with respect to a note for which the imputation of interest is required, the difference between the present value and the face amount shall be treated as a discount or premium and amortized as interest expense or income over the life of the note in such a way as to result in a constant rate of interest when applied to the amount outstanding at the beginning of any given period. As such, in accordance with ASC 835-30-35-2, the Company deferred and amortized the debt issuance costs amortized over the length of the Term Loan using the effective interest method.

As a result of the partial extinguishment, the Company has elected, as an accounting policy in accordance with ASC 470-50-40-2, to write off a proportionate amount of the unamortized fees at the time that the financing was partially settled in accordance with the terms of the Third Amendment. The unamortized debt issuance costs are allocated between the remaining original loan balance and the portion of the loan paid down on a pro-rata basis. The Company wrote off \$0.5 million in debt issuance costs relating to the prepayment which occurred during the year ended December 31, 2020, and recorded the expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

Revolving Facility

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a Revolving Facility in an aggregate amount of \$30.0 million (the "Revolving Facility") pursuant to a Credit Agreement dated February 3, 2016 between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent, as discussed above. The Company incurred closing costs associated with the Revolving Facility in the amount of \$1.1 million, which were deferred and amortized over the length of the Revolving Facility on a straight-line basis.

On December 21, 2017, the Company amended the Revolving Facility (the "Amended Revolving Facility"). Pursuant to the Amended Revolving Facility, CIT Bank and certain other lenders agreed to increase the revolving credit commitments up to \$50.0 million. The Company accounted for the Amended Revolving Facility as a modification of debt in accordance with ASC 470-50, Debt — Modifications and Extinguishments and ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line of Credit Arrangements. Lender fees incurred in the amount of \$0.4 million were deferred and are amortized over the length of the Amended Revolving Facility on a straight-line basis.

The total amount available under the Revolving Facility includes a Swingline Loan and Letter of Credit subfacility, respectively, in an aggregate principal amount at any time outstanding not to exceed the

lesser of (x) in the case of each of the Swingline Loan and Letter of Credit, \$5.0 million and (y) the total revolving commitment, based on certain terms and conditions of the Credit Agreement.

[Table of Contents](#)

The Company will be required to repay the Revolving Facility upon its expiration five years from issuance, subject to permitted extension, and will pay interest on the outstanding balance monthly based, at the Company's election, on an adjusted prime/federal funds rate ("ABR") or an adjusted LIBOR ("LIBOR"), in which the applicable rate per annum set forth below under the caption "ABR Spread" or "LIBOR Rate Spread," based upon the Total Leverage Ratio (as defined in the Credit Agreement) as of last day of the most recently ended fiscal quarter. Additionally, the Company will pay a Commitment Fee based on the average daily unused revolving credit commitment. The LIBOR Rate Margin, the ABR Margin and Commitment Fee are as follows:

Total Leverage Ratio	LIBOR Rate Margin	ABR Margin	Commitment Fee
Category 1	3.75 %	2.75 %	0.50 %
Greater than 2.00 to 1.00			
Category 2	3.25 %	2.25 %	0.38 %
Equal to or less than 2.00 to 1.00			

At December 31, 2020 and 2019, there were no outstanding borrowings or outstanding letters of credit. Availability under the Revolving Facility as of December 31, 2020, was \$50.0 million.

Aggregated cumulative maturities of long-term obligations (including the incremental and existing Term Loan and the Revolving Facility), excluding deferred financing costs of \$1.8 million, as of December 31, 2020 were (in thousands):

Years ending December 31,	Maturities of Long-term Obligations
2021	\$ —
2022	219,525
Total	\$ 219,525

Note 11. Concentrations and Credit Risk

For the years ended December 31, 2020 and 2019, a significant portion of the Company's gross product sales reported were through three customers, and a significant portion of the Company's accounts receivable as of December 31, 2020 and 2019 were due from these customers as well. The following table sets forth the percentage of the Company's gross sales and accounts receivable attributable to these customers for the periods indicated:

	Gross Product Sales	
	Year Ended December 31,	
	2020	2019
Amerisource Bergen	31 %	12 %
Cardinal Health	20 %	47 %
McKesson	43 %	38 %
Combined Total	94 %	97 %

	Gross Account Receivables	
	December 31,	
	2020	2019
Amerisource Bergen	21 %	21 %
Cardinal Health	20 %	22 %
McKesson	52 %	51 %
Combined Total	93 %	94 %

Purchasing

For the year ended December 31, 2020, two suppliers accounted for more than 86% of the Company's purchases of raw materials for products that are manufactured by the Company.



Table of Contents

Three suppliers accounted for more than 92% of the Company's purchases of raw materials manufactured by the Company for the year ended December 31, 2019.

The Company purchases various API of finished products at contractual minimum levels through agreements with third parties. Individually, none of these agreements are material to the Company, therefore, the Company does not believe at this time that any of the purchase obligations represent levels above the normal course of business.

Sales by Product

For the years ended December 31, 2020 and 2019, one product accounted for 33% and 57%, respectively, of the Company's total gross product sales.

Royalty Sales

The following tables set forth the percentage of the revenues and accounts receivable recognized in connection with Company's royalty contracts for the years ended December 31, 2020 and 2019, respectively:

	Year Ended December 31, 2020	
	Gross	Gross Royalty
	Royalty Revenue	Accounts Receivable
Customer 4	53 %	54 %
Customer 5	24 %	12 %
Combined Total	77 %	66 %

	Year ended December 31, 2019	
	Gross	Gross Royalty
	Royalty Revenue	Accounts Receivable
Customer 4	54 %	93 %
Customer 5	12 %	NM %
Combined Total	66 %	93 %

NM – Not Meaningful

Note 12. Shareholders' Equity

Osmotica Pharmaceuticals plc 2018 Equity Incentive Plan

Prior to the IPO, the Company adopted the 2018 Incentive Plan (the "2018 Plan") which became effective upon our IPO and allows for the issuance of up to 4,100,000 ordinary shares of the Company ("Shares") in satisfaction of awards under the 2018 Plan. The 2018 Plan provides for the grant of share options, SARs, restricted and unrestricted share and share units, performance awards, and other awards that are convertible into or otherwise based on the Company's shares to employees and non-employee directors, consultants and advisors to the Company. The Company's compensation committee shall determine the time at which an award vests or becomes exercisable. In connection with the IPO, the Company granted share options under the 2018 Plan that will vest on the fourth anniversary of the grant date, subject to the employee's continued employment through such vesting date.

Osmotica Holdings S.C.Sp. 2016 Equity Incentive Plan

Effective February 3, 2016, Osmotica Holdings S.C.Sp. adopted the 2016 Equity Incentive Plan (the "2016 Plan") which allows for the issuance of up to 75,000 Units in Osmotica Holdings S.C.Sp. Options to purchase common units granted under the 2016 Plan vest and become exercisable in whole or in part, in accordance with vesting conditions set by the

[Table of Contents](#)

Company's board of directors. Each option award had a maximum term of ten years from the date of grant. The option awards granted under the 2016 Plan were made up of two components: Time Awards and Performance Awards. The Time Awards vested 25% annually from original grant date, subject to continuous employment on each vesting date. The vesting of the Performance awards was subject to performance criteria, requiring the majority investors in the Company to receive (on a cumulative basis) aggregate net proceeds exceeding certain return on investment targets. The Time Awards and Performance Awards contained a sales restriction in the form of a liquidity event and subsequent disposal of common units by the Major Limited Partners (as defined in the 2016 Plan) before the employee was able to sell vested and exercised common units and were required to remain employed to avoid Company's call option on such common units at a lower of cost or fair market value.

Amended and Restated Osmotica Pharmaceuticals plc. 2016 Equity Incentive Plan

On August 14, 2018, the board of directors amended and restated the 2016 Plan in connection with the Reorganization. The Amended and Restated 2016 Equity Incentive Plan (the "Amended 2016 Plan") became effective upon our IPO which closed on October 22, 2018. In connection with the Reorganization, options to purchase common units of Osmotica Holdings S.C.Sp. were converted into options to purchase shares of the Company and existing sales restriction was removed. In connection with the IPO, the number of shares issuable pursuant to the Amended 2016 Plan and the corresponding exercise prices of options were adjusted to reflect a stock split initiated prior to the IPO. Additionally, effective upon the IPO, the Amended 2016 Plan modified the terms of Performance Awards previously issued under the 2016 Plan by converting these awards to time based awards vesting in equal annual installments on the first four anniversaries of the IPO, subject to continuous employment. There were 3,015,572 ordinary shares issuable upon exercise of options issued and outstanding as of December 31, 2018 under the Amended 2016 Plan. Prior to the modification date, there was no share based compensation recognized for the Performance Awards due to a performance condition based upon the majority investors in the Company receiving aggregate net proceeds exceeding certain return on investment targets.

Ordinary Share Repurchase Program

In September 2019, the Company's board of directors authorized the repurchase of up to 5,251,892 ordinary shares pursuant to a share repurchase program. Purchases under the ordinary share repurchase program can be made on the open market or in privately negotiated transactions, with the size and timing of these purchases based on a number of factors, including the price of our ordinary shares, our business and market conditions. The Company has retired ordinary shares acquired under the repurchase program. For the years ended December 31, 2020 and 2019, the Company repurchased 1,435,725 ordinary shares for an aggregate of \$8.1 million and 673,182 ordinary shares for an aggregate of \$2.8 million, respectively.

2019 Employee Share Purchase Plan

In September 2019, the Company's board of directors adopted and approved, the Employee Share Purchase Plan (the "ESPP"). The ESPP allows each eligible employee who is participating in the plan to purchase shares by authorizing payroll deductions of up to \$2,000 per payroll period. Unless the participating employee has previously withdrawn from the offering, accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85 percent of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of ordinary shares, valued at the start of the purchase period, under the ESPP in any calendar year. There is no minimum holding period associated with shares purchased pursuant to this plan. An employee's purchase rights terminate immediately upon termination of employment.

The Company accounts for employee stock purchases made under its ESPP using the estimate grant date fair value of accounting in accordance with ASC 718, Stock Compensation. The purchase price discount and the look-back feature cause the ESPP to be compensatory and the Company to recognize compensation expense. The compensation cost is recognized on a straight-line basis over the requisite service period. The Company recognized \$113,860 and \$31,619 of compensation expense for the years

ended December 31, 2020 and 2019, respectively. The Company values ESPP shares using the Black-Scholes model.

[Table of Contents](#)

As of December 31, 2020 and 2019, there were no unrecognized ordinary share compensation expense related to the ESPP. There were 51,905 ordinary shares issued under the ESPP during the year ended December 31, 2020. There were no ordinary shares issued under the ESPP during the year ended December 31, 2019. On January 4, 2021, the Company issued 39,321 ordinary shares to the employees who participated in the ESPP during the offering period ended December 31, 2020.

Share-based Compensation

The compensation cost that has been charged against income for all incentive plans was \$4.8 million for the year ended December 31, 2020 and \$4.9 million for the year ended December 31, 2019. The conversion of the Performance Awards issued under the 2016 Plan to Time Awards upon IPO under the Amended 2016 Plan was accounted for as a modification where the fair value of such awards determined on a modification date, or the IPO date is being recognized over their remaining vesting period.

Share-Based Award Activity

A summary of option activity granted under the 2016 Plan and the Amended 2016 Plan as of December 31, 2020, and changes during the year then ended is presented below:

2016 Equity Incentive Plan	Number of Shares	Weighted Average Exercise Price		Weighted Average Contractual Term
		Time	Price	
Outstanding at January 1, 2019	3,015,572	\$	14.96	7.5 years
Granted	—	—	—	
Exercised	—	—	—	
Expired / Forfeited	(55,686)	\$	14.95	
Outstanding at December 31, 2019	2,959,886	\$	14.96	6.4 years
Vested Options at December 31, 2019	1,459,005	\$	14.96	6.4 years
Granted	—	—	—	
Exercised	—	—	—	
Expired / Forfeited	(132,786)	\$	15.21	
Outstanding at December 31, 2020	2,827,100	\$	14.95	5.4 years
Vested Options at December 31, 2020	2,099,950	\$	14.95	5.4 years

There were no options granted during 2020 and 2019, respectively, under the 2016 Plan. The intrinsic value of options under the 2016 Plan outstanding at December 31, 2020 and 2019, respectively, was \$0. The fair value of options vested under the 2016 Plan during the years ended December 31, 2020 and 2019 were \$8,832 and \$6,431, respectively.

[Table of Contents](#)

A summary of option activity granted under the 2018 Plan as of December 31, 2020, and changes during the year then ended is presented below:

2018 Equity Incentive Plan

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Contractual Term</u>
	<u>Time</u>		
Outstanding at January 1, 2019	178,600	\$ 7.00	9.8 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(44,400)	\$ 7.00	
Outstanding at December 31, 2019	<u>134,200</u>	<u>\$ 7.00</u>	8.7 years
Vested Options at December 31, 2019	—	0	
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(37,800)	\$ 7.00	
Outstanding at December 31, 2020	<u>96,400</u>	<u>\$ 7.00</u>	
Vested Options at December 31, 2020	—	—	7.7 years

There were no options granted during 2020 and 2019, respectively.

The estimated fair value of the options is expensed over the requisite service period, which is generally the vesting period on a graded vesting basis. As of December 31, 2020 and 2019, there was \$0.8 million and \$2.2 million of total unrecognized compensation cost related to nonvested options granted under the Incentive Plans. That cost is expected to be recognized over a weighted-average period of 1.3 years and 1.5 years, respectively.

The fair value of option awards is estimated using the Black-Scholes option-pricing model. Exercise price of each award is generally not less than the per share fair value in effect as of that award date. The determination of fair value using the Black-Scholes model is affected by the Company's share fair value as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, risk-free interest rate and projected employee share option exercise behaviors. There were no options granted during 2020 and 2019, respectively.

For all periods prior to the IPO, our Board of Directors has determined the fair value of the common unit underlying our option with assistance from management and based upon information available at the time of grant. Prior to our IPO, given the absence of a public trading market for our common units, estimating the fair value of our common units was based on the actual operational and financial performance, current business conditions and discounted cash flow projections. The estimated fair value of our common units, prior to our IPO was adjusted for lack of marketability and control existing at the grant date.

Restricted and Performance Stock Units

On May 18, 2020 and May 20, 2020, the Company granted performance stock units ("PSUs") under its existing 2018 Incentive Plan (the "2018 Plan") to certain key employees of the Company that gives holders the potential to receive a certain number of earned PSUs at the end of a pre-determined term. Unless earlier terminated, forfeited, relinquished or expired, the earned PSUs will vest in full on the vesting date, subject to the grantee remaining in continuous employment from the date of grant through the vesting date. The vesting date is the third anniversary from the grant date for the PSUs granted on May 18, 2020 and the fifth anniversary from the grant date for the PSUs granted on May 20, 2020. The number of PSUs that become earned PSUs as of the end of the performance period shall be equal to the number of PSUs multiplied by the applicable percentage based on Stock Price Hurdle attainment, as set forth in the PSU Award Agreement and 2018 Plan. The fair value of these market-based awards is estimated on the date of grant using a Monte Carlo simulation model with the following assumptions:

Years Ended

[Table of Contents](#)

	<u>December 31, 2020</u>
Expected volatility	90 %
Risk-free interest rate	.21% - .24 %
Expected dividend yield	— %
Performance period in years	3.00

The Company estimates its expected volatility by using a combination of historical share price volatilities of similar companies within our industry. The risk-free interest rate assumption is based on observed interest rates for the appropriate term of the Company's options on a grant date.

As of December 31, 2020 total compensation cost not yet recognized related to unvested PSUs \$3.2 million which is expected to be recognized over a weighted average period of 3.0 years.

The following table summarizes the information as of December 31, 2020 and activity during 2020 related to our PSUs:

	<u>Number of PSUs</u>	<u>Weighted- Average Grant Date Fair Value</u>	<u>Average Remaining Contractual Term (Years)</u>
Outstanding at January 1, 2020	—	\$ —	—
PSUs granted	825,997	4.99	—
PSUs vested	—	—	—
PSUs forfeited	(36,198)	4.90	—
Outstanding at December 31, 2020	<u>789,799</u>	<u>\$ 4.99</u>	3.01

During 2020 and 2019 we granted restricted stock units, or RSUs, covering an equal number of our ordinary shares to employees and certain directors with a weighted average grant date fair value of \$4.46 and \$7.19, respectively. The fair value of RSUs are determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized ratably over the vesting period of four years for employees and one to three years for directors. As of December 31, 2020 and 2019 total compensation cost not yet recognized related to unvested RSUs was \$8.5 million and \$8.0 million which is expected to be recognized over a weighted average period of 2.8 years and 3.2 years, respectively.

The following table summarizes the information as of December 31, 2020 and activity during 2020 related to our RSUs:

	<u>Number of RSUs</u>	<u>Weighted- Average Grant Date Fair Value</u>	<u>Average Remaining Contractual Term (Years)</u>
Outstanding at January 1, 2019	—	\$ —	—
RSUs granted	1,486,020	7.19	—
RSUs vested	—	—	—
RSUs forfeited	(51,787)	7.18	—
Outstanding at December 31, 2019	<u>1,434,233</u>	<u>\$ 7.19</u>	3.20
RSUs granted	976,429	4.46	—
RSUs vested	(300,788)	6.73	—
RSUs forfeited	(118,317)	6.07	—
Outstanding at December 31, 2020	<u>1,991,557</u>	<u>\$ 5.99</u>	2.11

[Table of Contents](#)

2020 Equity Offering

On January 13, 2020 we completed a follow-on equity offering and allotted 6,900,000 ordinary share at a public offering price of \$5.00 per share. The number of shares issued in this offering reflected the exercise in full of the underwriters' option to purchase 900,000 ordinary shares. The aggregate net proceeds from the follow-on offering were approximately \$31.8 million after deducting underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

On July 16, 2020 we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.6 million after deducting offering expenses. Proceeds from the offering will be used for working capital and general corporate purposes.

Note 13. Earnings (Loss) per Ordinary Share

Basic net income (loss) per ordinary share is computed by dividing net income (loss) by the weighted-average number of shares of ordinary shares outstanding during the period. Diluted net income per ordinary shares is computed by dividing net income by the weighted average number of shares of ordinary shares and potentially dilutive outstanding shares of ordinary shares during the period to reflect the potential dilution that could occur from ordinary shares issuable through contingent share arrangements, share options and warrants.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares and units outstanding as they would have been anti-dilutive at December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Performance and restricted stock units	2,781,356	1,434,233
Options to purchase ordinary shares	2,923,500	3,093,786
Shares to be purchased through employee stock purchase plan	39,321	29,550

Note 14. Commitments and Contingencies

Contingent Milestone Payments

The Company has entered into strategic business agreements for the development and marketing of finished dosage form pharmaceutical products with various pharmaceutical development companies. Each strategic business agreement includes a future payment schedule for contingent milestone payments and in certain strategic business agreements, minimum royalty payments. The aggregate amount of future potential milestone payments payable in connection with such agreement are currently not material to the Company's financial statements. The Company will be responsible for contingent milestone payments and minimum royalty payments to these strategic business partners based upon the occurrence of future events. Each strategic business agreement defines the triggering event of its future payment schedule, such as meeting product development progress timelines, successful product testing and validation, successful clinical studies, and various U.S. Food and Drug Administration and other regulatory approvals. The aggregate amount of future potential milestone payments are currently not material to our financial statements.

Royalty Obligations

The Company has agreements with third parties that require the Company to make minimum royalty payments on a calendar year basis.

Table of Contents

The following table lists the Company's enforceable and legally binding royalty obligations as of December 31, 2020 (in thousands):

	Royalty Obligations
Less than 1 year	\$ 1,000
1 to 3 years	3,000
3 to 5 years	2,000
More than 5 years	83
Total	<u>\$ 6,083</u>

Supply Agreement Obligations

The Company is engaged in various supply agreements with third parties which obligate the Company to purchase various API or finished products at contractual minimum levels. None of these agreements are individually in the aggregate material to the Company. Further, the Company does not believe at this time that any of the purchase obligations represent levels above that of normal business demands.

The Company has no enforceable and legally binding purchase obligations as of December 31, 2020.

Defined Contribution Plan

Vertical/Trigen and Legacy Osmotica both had a defined contribution plan under Section 401(k) of the Internal Revenue Code ("IRC") as of December 31, 2016 pursuant to the Merger (the "Contribution Plans"). The employees of the respective companies are eligible to participate in the Contribution Plans. Participants may contribute amounts through payroll deductions not to exceed IRC limitations. For the year ended December 31, 2016, the Vertical/Trigen Plan provided for nonelective employer contributions equal to 3% of basic compensation. The separate Contribution Plans were merged into one plan effective January 1, 2017. Effective January 1, 2017, the plan provides for employer matching contributions equal to 100% of each employee's elective deferrals up to 3% of base salary, plus 50% of each employee's elective deferrals between 3% and 5% of base salary. For the years ended December 31, 2020 and 2019, the Company recognized expenses related to its contributions under the Plan of \$0.5 million and \$1.3 million, respectively.

Legal Proceedings

The Company is a party in legal proceedings and potential claims arising from time to time in the ordinary course of its business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, management of the Company believes that the ultimate disposition of such proceedings and exposures will not have a material adverse impact on the financial condition, results of operations, or cash flows of the Company.

On February 16, 2018, the Company received FDA approval for its amantadine extended release tablets under the trade name Osmolex ER. On that same date the Company filed in the Federal District Court for the District of Delaware a Complaint for Declaratory Judgment of Noninfringement of certain patents owned by Adamas Pharmaceuticals, Inc. (Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals, LLC vs. Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC). Adamas was served with the Complaint on February 21, 2018. Adamas filed an answer on April 13, 2018 denying the allegations in the Complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. On December 2, 2020, we entered into an agreement to settle the litigation with Adamas. Under the terms of the agreement, both parties agreed to drop their respective claims relating to the patent litigation, and Adamas agreed to acquire the global rights to Osmolex ER from the Company for \$7.5 million. The sale of the global rights to Osmolex ER closed in January 2021 at which time the related gain was recorded.



[Table of Contents](#)

Additionally, in connection with the settlement and the sale of the global rights to Osmolex ER, the parties entered into a supply agreement pursuant to which the Company agreed to supply Adamas with amantadine extended release tablets for a six-year term, subject to possible two-year extensions and customary closing conditions.

On April 30, 2019, the Company was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*. On May 10, 2019, a Complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints named the Company, certain of the Company's directors and officers and the underwriters of the Company's initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for the Company's initial public offering of ordinary shares. On July 22, 2019, the plaintiffs filed an amended complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. The parties participated in a mediation and reached an agreement in principle to settle the litigation on December 15, 2020. The agreement in principle calls for a payment by the Company of \$5.25 million (a portion of which we expect would be covered by applicable insurance) and would fully resolve all claims asserted in the litigation against all defendants named in the litigation, including the Company. No party would admit any wrongdoing as part of the proposed settlement, which was reached to avoid the further cost and distraction of litigation. The agreement in principle contemplates the negotiation and execution of a final settlement agreement. The settlement is also subject to preliminary approval by the Superior Court of New Jersey, notice to the putative class, and subsequent final approval by the Superior Court of New Jersey.

Note 15. Income Taxes

Osmotica Pharmaceuticals plc (formerly known as Lilydale Limited and Osmotica Pharmaceuticals Limited) is an Irish public limited company. Osmotica Holdings S.C.Sp. acquired Osmotica Pharmaceuticals plc on April 30, 2018 for the purpose of facilitating an offering of ordinary shares in an initial public offering. On October 22, 2018, Osmotica Pharmaceuticals plc completed its initial public offering (the "IPO"). Immediately prior to the IPO and prior to the commencement of trading of Osmotica Pharmaceuticals plc's ordinary shares on the Nasdaq Global Select Market, Osmotica Holdings S.C.Sp. undertook a series of restructuring transactions that resulted in Osmotica Pharmaceuticals plc being the direct parent of Osmotica Holdings S.C.Sp. Osmotica Holdings S.C.Sp. is a Luxembourg special limited partnership, formed on January 28, 2016. Osmotica Holdings US LLC, a subsidiary of Osmotica Holdings S.C.Sp. entered into a fifty-fifty partnership (the "Merger"), effective February 3, 2016, pursuant to a definitive agreement between Vertical/Trigen Holdings, LLC ("Vertical/Trigen") and members, and Osmotica Holdings Corp Limited and Subsidiaries. Osmotica Holdings S.C.Sp. and several other holding companies and partnerships were formed as a result of the Merger. Vertical/Trigen Holdings, LLC became a wholly-owned subsidiary of certain U.S. corporations that are directly or indirectly owned by Osmotica Holdings U.S. LLC. These subsidiaries are included in the consolidated financial statements and are designated as C Corp filers for U.S. tax purposes. As such, the activity of Vertical/Trigen Holdings, LLC is subject to federal income tax at the level of its U.S. corporate parents beginning in 2016. In addition, the Company's foreign entities are subject to income tax in various foreign jurisdictions.

The Company follows the Income Taxes topic of ASC 740, which prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of a tax position taken or expected to be taken

[Table of Contents](#)

in a tax return, as well as guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The loss before income taxes and the related tax benefit are as follows (in thousands):

	December 31, 2020	December 31, 2019
Loss before income taxes		
U.S. operations	\$ 66,836	\$ 140,664
Non-U.S. operations	<u>17,450</u>	<u>157,358</u>
Total loss before income taxes	<u>84,286</u>	<u>298,022</u>
Current tax benefit (provision)		
Federal	4,541	(1,387)
State	(232)	292
Foreign	<u>(985)</u>	<u>(791)</u>
Total current tax benefit (expenses)	<u>3,324</u>	<u>(1,886)</u>
Deferred tax benefit (provision)		
Federal	(82)	15,396
State	—	712
Foreign	<u>1,455</u>	<u>12,899</u>
Total deferred tax benefit	<u>1,373</u>	<u>29,007</u>
Total benefit for income taxes	<u>\$ 4,697</u>	<u>\$ 27,121</u>

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2020 and 2019 respectively are as follows:

	December 31, 2020	December 31, 2019
Federal tax at 21% statutory rate	21.00 %	21.00 %
State and local income taxes, net of federal benefit	1.11 %	0.91 %
Differences in tax effects on foreign income	(3.38)%	(6.43)%
Federal tax credits	1.35 %	0.59 %
Uncertain tax positions	1.40 %	0.04 %
NOL carryback rate differential	3.87 %	0.00 %
Tax audit adjustment	(3.65)%	0.00 %
Change in valuation allowance	(15.52)%	(7.02)%
Permanent adjustments	(0.79)%	0.00 %
Other	0.18 %	0.01 %
Effective tax rate	<u>5.57 %</u>	<u>9.10 %</u>

[Table of Contents](#)

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial statement purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at December 31, 2020 and 2019 respectively are as follows (in thousands):

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Accounts receivable	\$ —	\$ 31
Accrued expenses	5,921	9,535
Inventory	295	243
Investment in partnership	2,393	8,696
Net operating losses	1,285	2,627
Operating lease liabilities	657	1,121
Tax credits	6,486	3,249
Share compensation	1,816	1,399
Intangible assets	19,082	—
Other	3,328	1,685
Less: valuation allowance	(27,811)	(21,216)
Deferred tax liabilities:		
Prepaid expenses	(658)	(689)
Property plant & equipment	(3,261)	(3,252)
Operating lease assets	(623)	(1,115)
Intangible assets	(9,254)	(3,814)
Total deferred income taxes	<u>\$ (344)</u>	<u>\$ (1,500)</u>

Included in the deferred tax balances above is a net deferred tax asset of \$14.9 million and deferred tax liability of \$4.6 million, respectively for 2020 and 2019 related to the assets and liabilities in Vertical/Trigen Holdings, LLC, which is a partnership for Federal income tax purposes. The Company owns in aggregate 100% of Vertical/Trigen Holdings, LLC and the assets and liabilities of this entity are included in the consolidated financial statements of the Company.

As of December 31, 2020 and 2019, the Company had a federal and state net operating loss carryover of \$29.1 million and \$2.2 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of \$3.8 million and \$9.9 million, respectively which will begin to expire in 2022. At December 31, 2020 and 2019, the Company had total tax credit carryovers of approximately \$6.7 million and \$4.6 million primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers begin to expire in 2035. The Company assesses the realizability of the deferred tax assets at each balance sheet date based on actual and forecasted operating results in order to determine the proper amount, if any, required for a valuation allowance. As of December 31, 2020 and 2019, the Company maintains valuation allowances on deferred tax assets applicable to entities in the United States and foreign jurisdictions for which separate income tax returns are filed, where realization of the related deferred tax assets from future profitable operations is not reasonably assured. In 2020, the valuation allowance increased by \$6.6 million.

The Coronavirus Aid Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020 in the United States. The CARES Act and related notices include several significant provisions, including delaying certain payroll tax payments, mandatory transition tax payments under the Tax Cuts and Jobs Act, and estimated income tax payments that we expect to defer to future periods. The Cares Act provides a five year carryback for losses generated in 2018-2020. The Company incurred losses in the current period that will be carried back to the earliest year, 2015. The loss generated in 2020 will be carried back to a tax year with a higher tax rate providing a benefit of \$3.2 million. The impact to the Company's effective tax rate is 3.8%. The Cares Act made the business interest limitation less restrictive in that it increased the deduction limit for business interest to 50% of adjusted taxable income as well as allowing taxpayers to elect to utilize 2019 adjusted taxable income when computing the limitation in 2020. The Company utilized this clause in the CARES ACT when computing the current period income tax benefit.

The Company files income tax returns in U.S. federal, state and certain international jurisdictions. For federal and certain state income tax purposes, the Company's 2015 through 2018 tax years remain open for examination by the tax

[Table of Contents](#)

authorities under the normal statute of limitations. For certain international income tax purposes, the Company's 2015 through 2019 tax years remain open for examination by the tax authorities under the normal statute of limitations.

Two of the Company's subsidiaries, Osmotica Pharmaceutical Corp. and Valkyrie Group Holding Inc., finalized audits by the Internal Revenue Service for tax years 2016 and 2017. The Company agreed to an IRS adjustments and correspondingly recorded tax expense of \$1.9 million which includes \$1.4 million of income tax \$0.5 million of interest and penalty expense.

No provision is made for foreign withholding or income taxes associated with the cumulative undistributed earnings of the foreign subsidiaries. Any future foreign withholding or income taxes associated with the undistributed earnings are not anticipated to be material.

A reconciliation was completed of the beginning and ending amounts of unrecognized tax benefits, excluding accrued interest, for December 31, 2020 and 2019. It is not anticipated that the amount of unrecognized tax benefits will materially change in the next 12 months. If recognized, the total amount of unrecognized benefits of \$0.2 million would an immaterial impact on the effective tax rate.

	December 31, 2020	December 31, 2019
Unrecognized tax benefits beginning balance	\$ 2,677	\$ 2,218
Additions related to current period tax positions	171	459
Releases related to prior period tax positions	(2,677)	—
Unrecognized tax benefits ending balance	<u><u>\$ 171</u></u>	<u><u>\$ 2,677</u></u>

The Company classifies interest expense related to unrecognized tax benefits as components of the tax provision for income taxes. Interest and penalties recognized in the consolidated income statement as of December 31, 2020 resulted in an immaterial amount of interest and penalties as of December 31, 2020 and in a decrease of \$0.1 million as of December 31, 2019. As of December 31, 2020 and 2019 the Company has recorded accrued interest of an immaterial amount and \$0.2 million, respectively. The current year release of unrecognized tax benefits is due to an accounting method change which eliminated the need for an uncertain tax position.

Note 16. Related Parties

On August 22, 2018, the Company entered into a Master Service Agreement with United Biosource, LLC or UBC, an Avista portfolio company, for prescription processing and patient access services. In November 2018, the Company and UBC entered into a Statement of Work for services through the end of 2019 valued at approximately \$2.4 million. During 2019, we amended the initial Statement of Work to add approximately \$275,000 of additional services for 2019. On January 1, 2020, we entered into an additional Statement of Work for services during 2020 valued at approximately \$1.7 million. The Company had accrued \$0.2 million of liabilities related to this agreement as of December 31, 2020 and had recognized \$1.0 million of related expense for the year ended December 31, 2020. The Company had accrued less than \$0.1 million of liabilities related to this agreement as of December 31, 2019 and had recognized \$1.9 million of related expense for the year ended December 31, 2019.

[Table of Contents](#)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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 cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Annual 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 a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the 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 and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and

[Table of Contents](#)

monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain information regarding our executive officers is set forth at the end of Part I, Item 1 of this Form 10-K under the heading, "Information about our Executive Officers." The remaining information required with respect to this Item 10 is incorporated by reference to the information to be contained in our Proxy Statement for the 2020 Annual Meeting of Shareholders, or the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the information to be contained in our definitive Proxy Statement.

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

The information required by this Item 12 is incorporated by reference to the information to be contained in our Proxy Statement.

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

The information required by this Item 13 is incorporated by reference to the information to be contained in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated by reference to the information to be contained in our Proxy Statement.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

None

[Table of Contents](#)

Financial Statement Schedules

None

ITEM 16. FORM 10-K SUMMARY

None

Table of Contents

Exhibits

Exhibit No.	Description
2.1#	<u>Business Combination Agreement, dated as of December 3, 2015, among Osmotica Holdings Corp Limited, the shareholders of Osmotica Holdings Corp Limited party thereto, Altchem Limited, Vertical/Trigen Holdings, LLC, the shareholders of Vertical/Trigen Holdings, LLC party thereto, Avista Capital Partners III GP, LP, and Osmotica Holdings S.C.Sp.</u> (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
3.1	<u>Memorandum and Articles of Association Osmotica Pharmaceuticals plc</u> (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 28, 2019, Commission File No. 001-38709)
4.1	<u>Shareholders' Agreement</u> (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 28, 2019, Commission File No. 001-38709)
4.2	<u>Amendment No. 1, dated as of November 20, 2020, to the Shareholders Agreement, dated as of October 17, 2018, by and among, Osmotica Pharmaceuticals plc, ACP Holdco (Offshore), L.P., ACP III AIV, L.P., Altchem Limited, Orbit Co-Invest A-I LLC, Orbit Co-Invest I LLC, Orbit Co-Invest III LLC, and the management shareholders identified therein</u>
4.3	<u>Form of Ordinary Share Certificate</u> (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
4.4	<u>Description of Osmotica Securities</u>
10.1†	<u>License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of November 24, 2003, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation</u> (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.2	<u>First Amendment to License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of May 20, 2004, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation</u> (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.3	<u>Second Amendment to License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of June 30, 2004, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation</u> (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.4†	<u>Third Amendment to License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of May 20, 2010, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation</u> (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.5†	<u>Fourth Amendment to License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of August 1, 2013, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation</u> (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

[Table of Contents](#)

- 10.6† [Fifth Amendment to License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of January 1, 2018, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation](#) (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.7† [Distribution and Supply Agreement, dated as of June 28, 2011, by and between Cipher Pharmaceuticals Inc. and Vertical Pharmaceuticals Inc.](#) (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.8† [First Amendment to Distribution and Supply Agreement, dated as of March 27, 2012, by and between Cipher Pharmaceuticals Inc. and Vertical Pharmaceuticals Inc.](#) (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.9† [Second Amendment to Distribution and Supply Agreement, dated as of November 21, 2013, by and between Cipher Pharmaceuticals Inc. and Vertical Pharmaceuticals Inc.](#) (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.10† [Third Amendment to Distribution and Supply Agreement, dated as of January 1, 2015, by and between Cipher Pharmaceuticals Inc. and Vertical Pharmaceuticals Inc. \(incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357\)](#)
- 10.11† [Methylphenidate Supply Agreement, effective as of March 16, 2017, by and among Mallinckrodt LLC, Osmotica Kereskedelmi es Szolgálati Kft and Osmotica Pharmaceutical Corporation](#) (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.12† [Manufacturing and Supply Agreement, effective as of March 8, 2010, by and between Mikart, Inc. and Vertical Pharmaceuticals, Inc.](#) (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.13† [Tablets Marketing Rights Agreement, dated as of March 10, 2010, by and between Argent Development Group, LLC and Vertical Pharmaceuticals, Inc.](#) (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.14† [Master Manufacturing Services Agreement, dated as of August 21, 2014, by and between Patheon Pharmaceuticals Inc. and Osmotica Pharmaceutical Corp.](#) (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357) (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.15 [First Amendment to Master Manufacturing Services Agreement, dated as January 1, 2017, by and between Patheon Pharmaceuticals Inc. and Osmotica Pharmaceutical US, LLC](#) (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.16† [Product Agreement, dated as of October 1, 2014, by and between Patheon Pharmaceuticals Inc. and Osmotica Pharmaceutical Corp.](#) (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)

[Table of Contents](#)

- 10.17† [License Agreement dated as of August 31, 2011 by and between VOOM, LLC and Revitalid, Inc.](#) (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.18† [Exclusive Supply Agreement, dated as of February 7, 2013, by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc.](#) (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.19† [First Amendment to Exclusive Supply Agreement, dated as October 24, 2017 by and between Nephron Pharmaceuticals Corporation and Revitalid, Inc.](#) (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.20† [License Agreement dated as of July 28, 2020, by and between RVL Pharmaceuticals, Inc. and Santen Pharmaceutical Co. Ltd.](#) (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on July 31, 2020, Commission File No. 001-38709)
- 10.21 [Credit Agreement, dated February 3, 2016, by and among Osmotica Pharmaceutical Corp., Orbit Blocker I LLC, Orbit Blocker II LLC, Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the lenders party thereto, and CIT Bank, N.A. as administrative agent and swingline lender](#) (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.22 [First Amendment to Credit Agreement, dated November 10, 2016, by and among Osmotica Pharmaceutical Corp., Orbit Blocker I LLC, Orbit Blocker II LLC, Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the lenders party thereto, and CIT Bank, N.A. as administrative agent and swingline lender](#) (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.23 [Second Amendment to Credit Agreement, dated April 28, 2017, by and among Osmotica Pharmaceutical Corp., Orbit Blocker I LLC, Orbit Blocker II LLC, Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the lenders party thereto, and CIT Bank, N.A. as administrative agent and swingline lender](#) (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.24 [Third Amendment to Credit Agreement, dated December 21, 2017, by and among Osmotica Pharmaceutical Corp., Orbit Blocker I LLC, Orbit Blocker II LLC, Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the lenders party thereto, and CIT Bank, N.A. as administrative agent and swingline lender](#) (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.25 [Fourth Amendment to Credit Agreement, dated December 11, 2020, by and among Osmotica Pharmaceutical Corp., Orbit Blocker I LLC, Orbit Blocker II LLC, Valkyrie Group Holdings, Inc., Osmotica Holdings US LLC, the lenders party thereto, and CIT Bank, N.A. as administrative agent and swingline lender](#)
- 10.26+ [Form of Director and Officer Indemnification Agreement](#) (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.27+ [Form of Osmotica Holdings US LLC Director and Corporate Secretary Indemnification Agreement](#) (incorporated by reference to Exhibit 10.25 to the Company's Registration

[Table of Contents](#)

- 10.28+ [Form of Nonqualified Option Award Agreement under the Osmotica Pharmaceuticals plc 2018 Incentive Plan](#) (incorporated by reference to Exhibit 10.26 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.29+ [Osmotica Pharmaceuticals plc 2018 Employee Share Purchase Plan](#) (incorporated by reference to Exhibit 10.27 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.30+ [Form of Nonqualified Option Award Agreement under the Amended and Restated Osmotica Pharmaceuticals plc 2016 Equity Incentive Plan](#) (incorporated by reference to Exhibit 10.28 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.31+ [Amended and Restated Osmotica Pharmaceuticals plc 2016 Equity Incentive Plan](#) (incorporated by reference to Exhibit 10.29 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.32+ [Osmotica Pharmaceuticals plc 2018 Incentive Plan](#) (incorporated by reference to Exhibit 10.30 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.33+ [Osmotica Pharmaceuticals plc 2018 Annual Cash Incentive Plan](#) (incorporated by reference to Exhibit 10.31 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.34+ [Employment Agreement, dated December 3, 2015, by and between Vertical/Trigen Holdings, LLC and Brian A. Markison](#) (incorporated by reference to Exhibit 10.32 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.35+ [Employment Agreement, dated December 16, 2013, by and between Vertical/Trigen Opc, LLC and James Schaub](#) (incorporated by reference to Exhibit 10.33 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.36+ [Employment Agreement, dated May 2, 2016, by and between Vertical/Trigen Opc, LLC and Tina deVries](#) (incorporated by reference to Exhibit 10.34 to the Company’s Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
- 10.37+ [Employment Agreement, dated December 16, 2013, by and between Vertical/Trigen Opc, LLC and Christopher Klein](#) (incorporated by reference to Exhibit 10.35 to the Company’s Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)
- 10.38+ [Form of Initial Retainer Agreement \(In Lieu of Equity Awards\) with Osmotica Pharmaceuticals plc Directors](#) (incorporated by reference to Exhibit 10.36 to the Company’s Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)
- 10.39+ [Form of Additional Annual Retainer Agreement \(In Lieu of Equity Awards\) with Osmotica Pharmaceuticals plc Directors](#) (incorporated by reference to Exhibit 10.37 to the Company’s Annual Report on Form 10-K filed on March 19, 2020, Commission File No. 001-38709)
- 21.1 [Subsidiaries of Osmotica Pharmaceuticals plc](#)
- 23.1 [Consent of Ernst & Young LLP independent registered public accounting firm](#)

Table of Contents

- 31.1 [Principal Executive Officer Certification Pursuant to Securities Exchange Act Rules13a-14 and 15d-14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- 31.2 [Principal Financial Officer Certification Pursuant to Securities Exchange Act Rules13a-14 and 15d-14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- 32.1 [Principal Executive Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 32.2 [Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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- # The Company agrees to furnish supplementally to the SEC a copy of any omitted schedule or exhibit to such agreement upon request by the SEC.
 - + Indicates management contract or compensatory plan.
 - † Portions of this exhibit have been omitted pursuant to a confidential treatment request.

[Table of Contents](#)

SIGNATURES

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

Osmotica Pharmaceuticals plc

Dated: March 30, 2021

By: /s/ Brian Markison

Brian Markison
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 30, 2021.

<u>Signatures</u>	<u>Capacity in Which Signed</u>
<u>/s/ Brian Markison</u> Brian Markison	Chief Executive Officer and Director (Chairman) (Principal Executive Officer)
<u>/s/ Andrew Einhorn</u> Andrew Einhorn	Chief Financial Officer (Principal Financial Officer and Accounting Officer)
<u>/s/ Michael DeBiasi</u> Michael DeBiasi	Director
<u>/s/ David Burgstahler</u> David Burgstahler	Director
<u>/s/ Gregory L. Cowan</u> Gregory L. Cowan	Director
<u>/s/ Joaquin Benes</u> Joaquin Benes	Director
<u>/s/ Sriram Venkataraman</u> Sriram Venkataraman	Director
<u>/s/ Juan Vergez</u> Juan Vergez	Director
<u>/s/ Fred Weiss</u> Fred Weiss	Director