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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, 2018

☐ **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	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(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	**Name of Each Exchange on Which Registered**
Ordinary shares, $0.01 nominal value per share	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 if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definite proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☐	Accelerated filer ☐	Non-accelerated filer ☒	Smaller reporting company ☒ Emerging growth company ☒

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

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

The aggregate market value of the voting shares held by non-affiliates of the Registrant on October 22, 2018, based upon the closing price of $9.20 of the Registrant's ordinary shares as reported on the Nasdaq Global Select Market, was approximately $75.1 million. The Registrant has elected to use October 22, 2018, which was the closing date of the Registrant's initial public offering, as the calculation date, because the Registrant was a privately-held company on June 30, 2018 (the last business day of the Registrant's second fiscal quarter).

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

Class	**Outstanding at March 27, 2019**
Ordinary shares, $0.01 nominal value per share	52,518,924 shares

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2019 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.

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PART I

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, 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 operate our business under our new capital and operating structure; 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, 2018, we had total outstanding indebtedness of approximately $268.6 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 significantly limit our growth and materially adversely affect our financial results;
- 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;

- 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 23 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.

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. We generate total revenues across our existing portfolio of promoted specialty neurology and women's health products, as well as our non-promoted products, which are primarily complex formulations of generic drugs. In July 2017, we received regulatory approval from the FDA, for 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 launched M-72 in the second quarter of 2018. In February 2018, we received FDA approval of 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 and completed commercial launch of Osmolex ER in January 2019. In addition, we have a late-stage development pipeline highlighted by two new drug application, or NDA, candidates in Phase III clinical trials: Ontinua™ ER (arbaclofen extended-release tablets) for muscle spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid. Many of our products use our proprietary osmotic-release drug delivery system, Osmodex®, which we believe offers advantages over alternative extended-release, or ER, technologies.

Our core competencies span drug development, manufacturing and commercialization. Our specialized neurology and women's health sales teams support the ongoing commercialization of our existing promoted product portfolio as well as the launch of new products. As of December 31, 2018, we actively promoted five products: M-72, Lorzone® (chlorzoxazone scored tablets) and ConZip® (tramadol hydrochloride extended-release capsules) in specialty neurology; and OB Complete®, our family of prescription prenatal dietary supplements, and Divigel® (estradiol gel, 0.1%) in

women's health. We launched M-72 in the second quarter of 2018, and completed the launch of Osmolex ER, in January, 2019. As of December 31, 2018, we sold a portfolio consisting of approximately 37 non-promoted products. The cash flow from these non-promoted products has contributed to our investments in research and development and business development activities. Many of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as U.S. Drug Enforcement Administration, or DEA, regulation and quotas for active pharmaceutical ingredients, or API. Certain of our key products, particularly those that incorporate our proprietary Osmodex drug delivery system, are or are expected to be manufactured in our Marietta, Georgia facility.

We are focused on progressing our pipeline, which is highlighted by two Phase III candidates under clinical development — arbaclofen ER and RVL-1201. We developed arbaclofen ER using our proprietary Osmodex drug delivery system and believe this formulation will provide an efficacious and safe treatment for spasticity in multiple sclerosis patients. Arbaclofen ER has been designated by the FDA as an Orphan Drug in this indication. We recently received topline data from our second Phase III clinical trial of arbaclofen in multiple sclerosis patients with spasticity. The 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 Total Numeric-transformed Ashworth Scale, or TNmAS, and Clinician Global Impression of Change, or CGIC, on day 84. Arbaclofen did not demonstrate superiority to placebo as measured by the CGIC; however, a statistically significant improvement in spasticity relative to placebo was demonstrated by the TNmAS for both doses of arbaclofen (p=0.0482 and 0.0118) for 40 mg and 80 mg per day, respectively. Upon preliminary review, it appears that CGIC failed to recognize the improvement demonstrated by the TNmAS. However, the CGIC values indicated both treatment groups improved from baseline. Further, it appears that there is a dose-response relationship between the two strengths with the 80 mg exhibiting a stronger signal of efficacy as assessed by the TNmAS scale. Though arbaclofen 80 mg per day had a higher discontinuation rate in the study, the safety and tolerability profile was in line with previously reported results, most notably a somnolence incidence of 9.5% and 14.5% for the 40-mg and 80-mg treatment arms, respectively, compared to 9.6% for the placebo treatment arm. Somnolence is one of the most frequently reported dose-limiting adverse events associated with baclofen treatment today. Based on the efficacy and safety exhibited for arbaclofen, the Company remains encouraged and plans to proceed with its clinical and regulatory strategy to file an NDA. At this time, however, it is unclear whether or not the Company will be required to conduct an additional clinical trial which may delay our submission past 2019. Additionally, we continue to explore opportunities for arbaclofen in other indications, such as opioid withdrawal symptoms.

We acquired the rights to RVL-1201 in 2017 and are conducting a second Phase III clinical trial of RVL-1201 for droopy eyelid. If approved, RVL-1201 would be the first non-surgical treatment option approved by the FDA for droopy eyelid. We have completed enrollment in the Phase III clinical trials for RVL-1201 and we anticipate submitting an NDA for RVL-1201 in the second half of 2019. We plan to invest selectively in expanding our product portfolio by leveraging both our proprietary Osmodex drug delivery system to develop differentiated products as well as our management team's operating experience to pursue external business development opportunities.

Our Strengths

We believe our principal competitive strengths include:

Diversified Portfolio of Pharmaceutical Products. As of December 31, 2018, we sold an attractive and diversified portfolio of five promoted products and approximately 37 non-promoted products. Through our specialized sales teams we promote a portfolio of specialty neurology and women's health products that we believe are differentiated from competing products and provide meaningful benefits to patients due to their formulation or pharmacokinetic profiles. In addition, we believe that our promoted products are protected by a combination of patent protection, data exclusivity and our proprietary formulation and manufacturing know-how. Our key non-promoted products are comprised of complex formulations of generic drugs that incorporate our proprietary Osmodex drug delivery system.

Efficient Research and Development Organization Generating a Targeted Pipeline. We have a history of developing commercially successful pharmaceutical products. As of December 31, 2018, we employed 104 professionals with extensive regulatory and drug development experience in our research and development organization. As of December

31, 2018 we had 36 U.S. patents, 79 patents outside the United States and 28 pending patent applications, the last of which expires in 2037. Our pipeline is highlighted by two NDA candidates in Phase III clinical trials: Ontinua ER, which we are evaluating for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity; and RVL-1201, which we are studying for the treatment of blepharoptosis.

Demonstrated Commercialization Capabilities. We have built a robust infrastructure for the commercialization of our pharmaceutical products. As of December 31, 2018 our sales force was comprised of two dedicated teams that totaled 193 professionals targeting approximately 18,000 physicians across the specialty neurology and women's health therapeutic areas. Our non-promoted products are supported by a team with extensive experience commercializing generic products in attractive markets.

Experience Driving Patient Access in Order to Facilitate Penetration of Key Markets. We support patients' access to our medications through careful research and a deep understanding of the changing reimbursement landscape. We have developed capabilities across the market access continuum underscored by successful payor contracting strategies and supplemental patient assistance programs. Patient access is central to the commercialization strategy for our recent and near-term product launches. We expect that our pricing of these products will facilitate strong managed-care coverage and reimbursement, which we believe will improve patient access to our products.

Product Portfolio and Pipeline That Benefit from Multiple Potential Barriers to Entry. Many of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as DEA regulation and quotas for API. Our proprietary Osmodex drug delivery system uses osmotic pressure to provide a controlled drug release and is adaptable to many different combinations of immediate-release, extended-release and controlled- or delayed-release formulations that contain one or more drugs. We seek to identify and develop drug candidates that are well-suited to our proprietary Osmodex drug delivery system, which we believe can deliver a differentiated and favorable pharmacokinetic profile and may provide meaningful benefits to patients. We believe that third parties attempting to compete with our products that use our proprietary Osmodex drug delivery system may face difficulties in developing a comparable product. Likewise, we believe that formulation complexities and manufacturing challenges may limit the number of viable competitors in the markets for our key generic products.

Cash Flow from Existing Product Portfolio Enhances Research and Development Investment and Opportunistic Business Development Activities. Our current commercial success and historical cash flow generation allow us to invest in our pipeline to support the next stage of our growth. Additionally, we opportunistically pursue strategic acquisitions and business development initiatives to augment our internal development pipeline.

Experienced and Accomplished Management Team with a Proven Track Record. Our management team brings a wealth of experience navigating changes in the pharmaceutical industry and delivering financial success. Led by our Chief Executive Officer, Brian Markison, our management team possesses expertise in many areas of the pharmaceutical industry, including drug development, manufacturing, commercial operations and finance.

Our Strategy

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

Target Specialty Therapeutic Markets. We intend to continue developing innovative products targeting specialty markets with underserved patient populations that we believe we can commercialize efficiently. We may expand into additional specialty markets where we believe there are attractive opportunities to use our expertise and proprietary Osmodex drug delivery system to develop and commercialize differentiated products.

Grow Our Existing Product Sales. We plan to leverage our existing sales force to grow our promoted product portfolio including M-72 and Osmolex ER. We anticipate opportunistically expanding our sales force to support future growth

and focus on products, such as M-72 and Osmolex ER, where we believe there is an attractive market. We intend to support our non-promoted products through our national account team that manages relationships with major drug-buying consortia, pharmaceutical wholesalers and retailers in the United States.

Successfully Develop Our Late-Stage Product Candidates. We are focused on advancing the development of our late-stage clinical programs to further diversify our revenue base and sustain our future growth. If successfully developed, we believe Ontinua ER represents an attractive product candidate with an addressable multiple sclerosis spasticity market of up to $3.5 billion in the United States. If successfully developed and approved, we believe that RVL-1201 would become the first pharmacological treatment for blepharoptosis in the United States and would represent an important therapy in the continuum of care for patients with mild or moderate blepharoptosis. Our research and development efforts also include activities related to seeking additional indications for Ontinua ER.

Expand Our Pipeline by Leveraging Our Proprietary Technology to Develop Differentiated Products. We plan to expand our pipeline of product candidates through the application of our technology, research infrastructure and development expertise. Our research and development efforts are focused on identifying commercially viable products that are well suited to benefit from our proprietary Osmodex drug delivery system. Our technology is designed to produce an extended-release formulation with a differentiated pharmacokinetic profile that we believe can, in certain circumstances, meaningfully improve upon the efficacy or side effect profiles of currently approved therapies. We plan to continue to apply our drug development criteria to make capital efficient investments in promising product candidates.

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.

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. Scientific staff in Buenos Aires, Argentina, Wilmington, North Carolina, Bridgewater, New Jersey, Marietta, Georgia and Budapest, Hungary use their expertise in our proprietary Osmodex drug delivery system, chemistry and material science to focus on identifying drug compounds for re-formulation to either achieve new therapeutic attributes (e.g., extended release) or indications in the case of branded products, or to achieve bioequivalence in the case of generic products. Additionally, we perform early-stage manufacturing and technology transfer engineering and evaluate any unique intellectual property arising from these activities. If we elect to progress a development candidate forward, scale-up process engineering is performed at our manufacturing plant in Marietta, Georgia. 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.

As of December 31, 2018, we had 104 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 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 abbreviated new drug applications, or 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, 2018, we had 36 U.S. patents, 79 patents outside the United States and 28 pending patent applications, the last of which expires in 2037.

Our Technology

Osmodex: Our Proprietary Drug Delivery System

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.

We believe that brands using osmotic extended-release technology can benefit from longer life cycles as compared to brands delivered in conventional extended-release dosage forms due to the complexities of mimicking extended-release profiles of products using osmotic technologies. Moreover, we believe there are only a limited number of competitors with experience using osmotic technology. Given these dynamics, we estimate, based on market research, that osmotic extended-release brands have generally retained higher market share following loss of exclusivity as compared to other ER brands. We further estimate that generic versions of osmotic extended-release brands have tended to exhibit greater price stability as compared to generic versions of other extended-release branded formulations, as pricing declines over time.

Our Portfolio

As of December 31, 2018, we sold a diverse portfolio consisting of five promoted products and approximately 37 non-promoted products, several of which incorporate our proprietary Osmodex drug delivery system. We also have a development pipeline that is highlighted by two NDA candidates in Phase III clinical trials, one of which we believe has the potential for indication expansion over time. Our non-promoted product portfolio includes methylphenidate ER and VERT as well as smaller volume ANDAs and prescription dietary supplements. As of December 31, 2018 our non-promoted pipeline included 16 products in various stages of development.

Many of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as DEA regulation and quotas for API. The following table shows our promoted and non-promoted product portfolio at December 31, 2018.

Promoted Products	Indication	Osmodex Technology	U.S. Regulatory Status
Specialty Neurology			
M-72	ADHD in patients aged 13 to 65	Yes	Approved
Osmolex ER	Parkinson's and drug-induced extrapyramidal reactions in adults	Yes	Approved
Lorzone	Muscle spasms	No	Approved
ConZip	Pain	No	Approved
Ontinua ER	Multiple sclerosis spasticity	Yes	Phase III
	Opioid withdrawal symptoms	Yes	Phase II Ready
Women's Health			
Divigel	Menopause	No	Approved
OB Complete	Various dietary needs during prenatal, pregnancy and postnatal periods	No	Dietary Supplement
Ophthalmology			
RVL-1201	Blepharoptosis (droopy eyelid)	No	Phase III

Non-Promoted Products	Indication	Osmodex Technology	U.S. Regulatory Status
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
Osmodex ANDAs	Various	Yes	In Development (3)
Other ANDAs	Various	No	Filed (9) In Development (4) Approved (1)

* Out-licensed ANDAs with a commercial partner.

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.

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 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, 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.

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 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.

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

Ontinua ER has received Orphan Drug Designation for the treatment of muscle spasticity in multiple sclerosis patients.

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.

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 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.

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.

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.

Under the Trump administration, there have been 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 eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called "individual mandate"). In a May 2018 report, the Congressional Budget Office estimated that, compared to 2018, the number of uninsured will increase by three million in 2019 and six million in 2028, in part due to the elimination of the individual mandate. The ACA has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the ACA is still operational in all respects.

There have also been other reform initiatives under the Trump Administration, including initiatives focused on drug pricing. For example, in May of 2018, President Trump and the Secretary of the Department of Health and Human Services released a "blueprint" to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in October 2018, the Centers for Medicare & Medicaid Services, or CMS, solicited public comments on potential changes to payment for certain Medicare Part B drugs, including reducing the Medicare payment amount for selected Medicare Part B drugs to more closely align with international drug prices. As another example, in November of 2018, CMS issued an advance notice of proposed rulemaking that proposed revisions to Medicare Part D to support health plans' negotiation of lower drug prices with manufacturers and reduce health plan members' out-of-pocket costs. The Office of Inspector General, or OIG, within the Department of Health and Human Services, or HHS, issued a proposed rule in February of 2018 that would revise the federal Anti-Kickback Statute to limit protection for discounts offered by pharmaceutical manufacturers to pharmacy benefit managers, or PBMs, Medicare Part D plans, and Medicaid managed care plans that are not reflected in the price charged to the patient at the pharmacy counter and to provide protection only for certain types of service fees paid by pharmaceutical manufacturers to PBMs.

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 prescribers, purchasers and formulary managers 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 $100,000 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 reimbursed by private health plans as well as government health care programs. Criminal sanctions (up to $200,000 fine and 10 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 $11,181 to $22,363 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 practioner providing Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $20,000 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 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 $169,170 per year (or up to an aggregate of $127,799 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 healthcare providers, such as physicians, hospitals, pharmacies and laboratories, as well as 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 the Health Information Technology for Economic and Clinical Health Act of 2009, or 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 or finds ambiguity with regard to 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 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, 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 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.

Employees

As of December 31, 2018, we had a total of 466 full time employees (including 47 employees in Argentina and five employees in Hungary). 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.

Reorganization and Our Structure

On April 30, 2018, Osmotica Holdings S.C.Sp. acquired Lilydale Limited, an Irish private company with limited liability that was organized in Ireland on July 13, 2017, and renamed such entity Osmotica Pharmaceuticals Limited, effective May 1, 2018. On July 31, 2018, Osmotica Pharmaceuticals Limited re-registered under the Irish Companies Act of 2014 as a public limited company and was renamed Osmotica Pharmaceuticals plc. In addition, immediately prior to our initial public offering and prior to the commencement of trading of our ordinary shares on the Nasdaq Global Select Market, we undertook a series of restructuring transactions that resulted in Osmotica Pharmaceuticals plc becoming the direct parent company 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). Prior to this time, Osmotica Pharmaceuticals plc did not conduct any operations (other than activities incidental to its formation, this reorganization and our initial public offering). Upon the completion of this reorganization, the historical consolidated financial statements of Osmotica Holdings S.C.Sp. became the historical financial statements of Osmotica Pharmaceuticals plc. Except as otherwise indicated, all information contained in this Annual Report on Form 10-K gives effect to this reorganization.

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.

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 our industry," "Risks related to our indebtedness," "Risks related to our ordinary shares," "Risks related to being an Irish corporation listing ordinary shares" and "Risks related to taxation." 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

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. 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
- 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 branded products because of the 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, after reviewing with the FDA the topline data from our second Phase III clinical trial of arbaclofen in multiple sclerosis patients with spasticity, the FDA may require additional clinical trials before approving arbaclofen for commercial use, if they approve the product at all. The FDA's review, as well as any subsequent clinical testing, could delay the commercial launch of this product and increase our operating expenses, which could have a material adverse effect on our business, financial position and results of operations.

In addition, more than 79% and 65% of our total revenues in 2018 and 2017 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 percentage decline, often significantly and rapidly. Accordingly, our total revenues and future profitability are dependent, in part, upon our ability or the ability of our development partners to file ANDAs with the FDA and gain approvals timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. No assurances can be given that we will be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our total revenues, gross profit percentage and operating results may decline significantly and our prospects and business may be materially adversely affected.

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 $48.8 million and $42.7 million on research and development expenses in 2018 and 2017, 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. As a result, we may be unable to reasonably determine the total research and development costs required to develop a particular product. Finally, 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 cost-effectively commercialize new products, our business, financial position and results of operations may be materially adversely affected.

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 also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience failures of or delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. 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; delays in reaching agreement with the FDA or equivalent foreign regulatory authorities on final trial design; 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 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.

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.

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. We also rely on contract laboratories and other third parties, such as CROs, to conduct or otherwise support our nonclinical laboratory 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 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.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

Although we have received orphan drug designation for Ontinua ER for treatment for muscle spasticity in multiple sclerosis patients, we may not receive the full set of benefits potentially associated with orphan drug designation. Under the Orphan Drug Act, the first product with orphan drug designation to receive FDA approval for a specific disease or condition will be entitled to a seven-year period of market exclusivity in the United States. The FDA has previously approved another form of baclofen for the treatment of intractable muscle spasticity in multiple sclerosis patients. If the FDA determines that our product 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, the FDA could subsequently approve a competing drug for the same condition if the FDA concludes that the later drug is clinically superior to our product. A competitor also may receive approval of different products for the same indication for which our 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.

Our products or product candidates may cause adverse effects or have other 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.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result. For example, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution, the FDA may require implementation of REMS,

regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, we may be required to change the way the product is administered or conduct additional clinical studies, we could be sued and held liable for harm caused to patients, and our reputation may suffer.

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 our products or product candidates do not produce the effects intended or if they cause undesirable side effects, our business may suffer.

If our products or product candidates do not have the effects intended or cause undesirable side effects, our business may suffer. For example, although many of the ingredients in our current dietary supplement products are vitamins, minerals and other substances for which there is a history of human consumption, they also contain innovative ingredients or combinations of ingredients. These products and the combinations of ingredients could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions, such as the potential effect of high doses of folic acid masking pernicious anemia. In addition, our products may not have the effect intended if they are not taken in accordance with applicable instructions, which may include certain dietary restrictions. 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 or will not have harmful side effects in an unforeseen way or on an unforeseen patient population. 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 side effects are identified with our marketed products, or if manufacturing problems occur, changes in labeling of products may be required, which could have a material adverse effect on our sales of the affected products. We or regulatory authorities, including the FDA, could decide that changes to the product labeling are needed to ensure the safety and effectiveness of the products. 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. Under the Food and Drug Administration Amendments Act of 2007, the FDA has broad authority to force drug manufacturers to take any number of actions if previously unknown safety or drug interaction problems arise, including but not limited to, mandating labeling changes to a product based on new safety information (safety labeling changes). Our products, including ConZip, Divigel and VERT, have been subject to safety labeling changes, which we have addressed and incorporated into relevant product labeling. These products and others, including 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, alter or terminate current or planned trials for additional uses of products, 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 results of operations.

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 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 Corruption Offences Act 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, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes.

We are a party to legal proceedings, including matters involving 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 "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."

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 percentage from the sale of a limited number of products. For the years ended December 31, 2018 and 2017, our top ten products by product sales accounted for approximately 99% and approximately 90%, 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 percentage. For example, we expect increased pricing and market share pressure on methylphenidate ER due to additional market entrants.

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;
- availability of raw materials and finished products from suppliers;
- 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.

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 and indefinite 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 the year ended December 31, 2018, we recorded non-cash impairment charges of $104.2 million related to adjustments to the forecasted operating results for certain of our acquired generic, developed technology and in-process research and development assets 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 (in some instances of generic entry, price declines have exceeded 90%). 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 result 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 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, health maintenance organizations, or HMOs, 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 $109.3 million for the year ended December 31, 2018. Our net losses 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, including Osmolex ER;
- conduct clinical trials and seek regulatory approval for Ontinua ER and RVL-1201;
- continue development of our pipeline product candidates;
- conduct preclinical studies for product candidates;
- incur litigation expenses related to Osmolex ER;
- add personnel to support our marketing, commercialization and sales of approved products, and continue clinical and preclinical product development efforts; and
- 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, our business, financial condition, prospects and results of operations could materially suffer.

As of December 31, 2018, we had approximately 22 customers, some of which are part of larger buying groups. Our three largest customers accounted for approximately 96% of our total revenues for the year ended December 31, 2018, as follows: Cardinal Health, Inc. 55%; McKesson Corporation 34%; and AmerisourceBergen Corporation 7%. The loss of 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.

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 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 percentage. This price competition has led to an increase in customer demands for downward price adjustments by pharmaceutical distributors. There can be no 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 Osmolex ER, 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.

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 percentage. 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.

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

Revenues and gross profit percentage 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. We cannot provide assurance that we will be able to continue to develop such products or that the number of 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 percentage.

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.

A business interruption at our manufacturing facility in Marietta, Georgia, our warehouses in Sayreville, New Jersey and Tampa, Florida 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.

We produce all of the products that we manufacture at our manufacturing facility in Marietta, Georgia, and our inventory passes through our warehouses in Sayreville, New Jersey and Tampa, Florida. 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, 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. 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 may experience declines in the sales volume and prices of our products as a result of the continuing trend of consolidation of certain customer groups, which could have a material adverse effect on our business, financial position and results of operations.

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.

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, Nephron Pharmaceuticals Corporation is our only supplier of RVL-1201 and Mallinckrodt LLC is our only supplier of the API used in methylphenidate ER (including M-72). 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. For example, we have been engaged in discussions with Albion Laboratories, Inc. regarding potential disputes over the fulfillment of obligations under agreements for the supply of raw materials. 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.

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.

We have broadened our product offering by entering into a variety of third-party agreements covering a combination of joint development, supply, marketing and distribution of products. For example, we have entered into an agreement with Mallinckrodt LLC for the development and supply of API used in methylphenidate ER (including M-72) products that we manufacture at our manufacturing facility in Marietta, Georgia. For the year ended December 31, 2018, 50% 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 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.

For the years ended December 31, 2018 and 2017, we spent $42.5 million and $33.1 million, respectively, on sales and marketing. As we gain approval and launch new products, we will invest in expanding our sales and marketing organization into new areas such as Parkinson's disease, multiple sclerosis and ophthalmology. We face a number of 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;
- the cost of establishing a marketing and sales force capability may not be justified in light of the total revenues generated from our products; and
- our direct sales and marketing efforts 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.

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. 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 FTC;
- our inability to achieve expected total revenues and gross profit percentage 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 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.

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;
- 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 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.

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 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. 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 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.

Upon receipt of approval for Osmolex ER from the FDA, we filed a declaratory judgment action against Adamas Pharmaceuticals, Inc. and Adamas LLC, which we collectively refer to as Adamas, on February 16, 2018 in the U.S. District Court for the District of Delaware seeking a declaratory judgment that Osmolex ER does not infringe, directly or indirectly, any valid and enforceable claim of any of the 11 patents enumerated in our complaint. On September 20, 2018, Adamas filed an amended answer with counterclaims alleging infringement of certain patents included in our complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. Adamas commercializes a different amantadine product, an extended-release capsule marketed and sold as Gocovri®. We intend to vigorously defend our rights to commercialize Osmolex ER free and clear of any of these patents. However, this litigation is at an early stage. If Adamas's counterclaims for infringement are successful, we could be subject to liability for damages, potentially including lost profits damages or reasonable royalties, and also injunctive relief, as discussed above, and the other risks associated with patent litigation, which could have an adverse effect on our business, financial position 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 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.

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.

Risks related to our industry

Our profitability depends on coverage and reimbursement by governmental authorities, HMOs, 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, or 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 offer our products, or of the terms of any such coverage, or that covered drugs will be reimbursed at amounts that reflect current or historical levels. The Medicare Part D Prescription Drug Benefit, established a voluntary outpatient prescription drug benefit for Medicare beneficiaries (primarily the elderly over 65 and the disabled). These beneficiaries may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The Medicare Part D program is administered by the CMS within HHS.

Since Medicare Part D was first established in 2006, CMS has issued extensive regulations and other sub-regulatory guidance documents implementing the Medicare Part D benefit, and the HHS Office of Inspector General, or OIG, has issued regulations and other guidance in connection with the Medicare Part D program. The federal government may continue to issue guidance and regulations regarding the obligations of Part D sponsors and their subcontractors that affect program coverage of pharmaceutical products or their reimbursement levels. In addition, participating drug plans may establish drug formularies that exclude coverage of specific drugs, and payment levels for drugs negotiated with Part D drug plans may be lower than reimbursement levels available through private health plans or other payors. Moreover, beneficiary co-insurance requirements could influence which products are recommended by physicians and selected by patients. See “Business – Government Regulation and Approval Process – Healthcare Reform.

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 action to lower the pharmaceutical costs of the program are possible. 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 are currently 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 intend to defend ourselves vigorously in these proceedings, an adverse determination of this or 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, the growth of organizations such as HMOs and MCOs, 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. The Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced the discontinuance of the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. In December 2018 a federal and district court found the ACA unconstitutional in its entirety. Pending appeals, the ACA remains operational.

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.

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, or the Budget Control Act includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2027. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues.

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 federal level, Congress and the Trump Administration have each indicated an intent to continue to seek new legislative or administrative measures to control drug costs. And federal agencies have proposed various reforms to address drug costs. See "Business – Government Regulation and Approval Process – Healthcare Reform." 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 issued subpoenas to pharmaceutical companies, seeking information about the sales, marketing and pricing of certain generic drugs. 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 providers 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. On April 9, 2018, First Databank announced that it is proceeding with a reclassification of non-prenatal dietary supplements to non-prescription which may affect some of our products. First Databank has temporarily delayed implementing this reclassification for prenatal dietary supplements. If First Databank or 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.

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. For example, we had three active recalls of methylphenidate ER to the wholesale level. These recalls were each based on a complaint that indicated that a bottle had contained one tablet with the incorrect dosage strength. Our investigation revealed that the incorrect tablets were likely introduced at the first coating step of the manufacturing process and determined that the issue poses no potential risk to patients. Final status reports for these three recalls have been sent to the FDA Recall Coordinator. In addition, in August 2017, we initiated a recall to the retail level of the prescription dietary supplement product, Zatean pN DHA. We initiated the recall because the product labeling listed an incorrect food coloring as one of the excipient ingredients. In May 2018, the recall was converted to a market withdrawal, and we did not have any reports of adverse reactions associated with the use of the affected product; the event is considered closed.

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, New Jersey and North Carolina, and in overseas jurisdictions including Argentina and Hungary, and we are required to comply with the laws and regulations of those states or 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. Namely, the Trump Administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will affect the FDA's ability to exercise its regulatory authority. If these executive 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.

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

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 (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 HITECH and its implementing regulations, which imposes certain obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as certain health plans, healthcare clearinghouses and healthcare providers as well as the covered entities' business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of 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

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, teaching hospitals, and, beginning with transfers of value occurring in 2021, other healthcare practitioners 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, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; 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.

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 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. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, 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 EU-U.S. Privacy Shield (Privacy Shield) or the European Commission approved standard contractual clauses, or if very narrow legal exceptions (such as data subject consent) apply. The Privacy Shield framework (which permits transfers of personal data from the EEA to the U.S.) is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (e.g. the standard contractual clauses). It is uncertain whether the Privacy Shield framework or the standard contractual clauses will be invalidated by the European courts. 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 the current 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.

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. 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, should there be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may 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 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, HMOs and others, reimburse doctors and others for 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, 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 settle 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, 2018, our opioid products represented 2% of our total revenues. Aggressive enforcement, 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. Such negative publicity could 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 the substantial majority of states have announced a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. Attorneys general from several states, including Kentucky, Florida, New Mexico, and New York have also individually filed cases and issued subpoenas to 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, 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 1,400 of these lawsuits have been consolidated in multi-district litigation in the Northern District of Ohio in *In re: National Prescription Opiate Litigation*, 1:17md2804, or Federal Opioid MDL. On January 29, 2019, the Federal Opioid MDL Court issued a case management schedule setting a trial date for October 21, 2019 for three bellwether cases brought by counties and cities in the Northern District of Ohio. 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. 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.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.

In addition, for some methylphenidate ER products when a patient switches from one medication to another, there may be an actual or perceived lack of efficacy or increase in side effects. For example, this could happen if a patient starts taking our methylphenidate ER product instead of the branded product. These lack of efficacy reports are submitted to the FDA and may result in the FDA reviewing previously submitted data, or generating data on its own, to confirm whether or not our product is therapeutically equivalent to the reference listed drug. If the FDA finds that our product is not therapeutically equivalent to the reference listed drug, FDA could change the designation of the product from AB to BX rated and request that we remove the product from the market. Either result would adversely affect our business and financial condition.

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 chemical compounds 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.

Litigation is common in our industry, can be protracted and expensive, and could delay or prevent entry of our products into the market, which could have a material adverse effect on our business.

Litigation concerning intellectual property rights in the pharmaceutical industry 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, 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.

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

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 confirming that they completed an evaluation of our corrective actions and that we have 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;

(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 operating subsidiaries' 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, 2018, our total indebtedness was $268.6 million (net of deferred financing costs), with unused commitments of $50.0 million under the senior secured credit facilities. We may also incur significant additional indebtedness in the future.

Subject to the limits contained in our senior secured credit facilities, we may be able to incur substantial additional debt 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.

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, commencing with the fiscal quarter ending March 31, 2018, our operating subsidiaries must (i) maintain a Total Leverage Ratio (as defined in the Credit Agreement) no greater than 4.75:1.00, which shall be reduced to 4.50:1.00 for the fiscal quarter ending March 31, 2020 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

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.

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 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 or refinance all or a portion of our indebtedness on or before maturity. Significant delays in our planned capital expenditures 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 and Osmotica Pharmaceutical US LLC. As a result, notwithstanding any restrictions on payment of dividends under our existing indebtedness and 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 $2.7 million increase in our annual interest expense associated with the senior secured credit facilities.

Risks related to our ordinary shares

We are eligible to be treated as an "emerging growth company," as defined in the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth 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. In addition, as an emerging growth

company, we are only required to provide three years of audited financial statements and three years of selected financial data in this Annual Report on Form 10-K.

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 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 December 31, 2018, investment funds affiliated with the Sponsors beneficially owned approximately 81.6% 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 the election and removal of directors, any amendment to our Memorandum and Articles of Association, 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.

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; 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 may grant 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.

As a public company, we are subject to additional laws, regulations and stock exchange listing standards, which impose additional costs on us and may strain our resources and divert our management's attention.

Prior to our initial public offering, we operated our company on a private basis. We are now subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the Nasdaq Stock Market and other applicable securities laws and regulations. Compliance with these laws and regulations increases our legal and financial compliance costs and makes some activities more difficult, time-consuming or costly. Being a public company and being subject to new rules and regulations also makes it more expensive for us to obtain director and officer liability insurance, and we may be required

to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors may therefore strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

We have identified a material weakness in our internal control over financial reporting. If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and therefore are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires 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. Although we are required to disclose changes that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until our second annual report required to be filed with the SEC.

To comply with the requirements of being a public company, we may need to undertake various actions to develop, implement and test additional processes and other controls, including compliance training for our directors, officers and employees, hiring of additional finance, accounting and other personnel and modifications to our existing accounting systems, any of which could entail substantial cost or take a significant period of time to complete. Testing and maintaining internal controls can divert our management's attention from other matters related to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate resulting in our management being unable to assert that our internal control over financial reporting is effective.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our audited consolidated financial statements as of and for the years ended December 31, 2017 and 2016, we identified a material weakness in our internal control over financial reporting. This material weakness related to our failure to maintain an effective control environment around our period-end financial closing and reporting process.

Maintaining effective internal control over financial reporting is necessary for us to produce reliable financial reports and is important to help prevent financial fraud. If we are unable to maintain adequate internal controls, our business and operating results could be harmed. While we believe that we have remediated the material weakness identified in connection with the preparation of our audited consolidated financial statements as of and for the years ended December 31, 2017 and 2016, if we fail to maintain the adequacy of our internal control over financial reporting or our disclosure controls and procedures, 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 to settle 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 comply with the requirements of Section 404 in a timely manner or 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. In the event that any of the foregoing occurs, the market price of our ordinary shares could be negatively affected.

We have 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, 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, which could cause the price of our ordinary shares to decline.

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. 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.

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 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 new agreements 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 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.

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 $6.25 on November 27, 2018 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, 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 has been volatile, holders of those shares have sometimes instituted securities class action litigation against the company that issued the shares. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

A significant portion of our total outstanding ordinary shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our ordinary shares to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our ordinary shares in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our ordinary shares. As of December 31, 2018 we had 52,518,924 ordinary shares outstanding. This includes shares that we sold in our initial public offering, which may be freely sold in the public market. Substantially all of the shares that were not sold in our initial public offering are subject to a 180-day lock-up period provided under agreements executed in connection with our initial public offering. These shares will, however, be able to be resold after the expiration of these lock-up agreements on April 15, 2019. As restrictions on resale end, the market price of our shares could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them. We also filed a Form S-8 under the Securities Act to register all of our ordinary shares that we may issue under our equity compensation plans. In addition, Avista and Altchem have certain demand registration rights that could require us in the future to file registration statements in connection with sales of our shares by them. Such sales could be significant. Once we register these shares, they can be freely sold in the public market upon issuance.

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.

If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our shares or if our results of operations do not meet their expectations, our share price and trading volume could decline.

The trading market for our shares is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Moreover, if one or more of the analysts who covers us downgrades our ordinary shares, or if our results of operations do not meet their expectations, our share price could decline.

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 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;
- 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 may result in restrictions upon the ability of any of the 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 may consult 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.

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 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.

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 disapplied 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, which is an option we availed ourselves of prior to the completion of our initial public offering;

- 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 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 (including in respect of new U.S. tax legislation passed last year); 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 affected to the extent that countries adopt such OECD proposals.

Recently enacted U.S. tax legislation 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. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions and may affect our actual effective tax rate. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as 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. Further, it is reasonable to expect that non-U.S. taxing authorities will be reviewing current law for potential modifications in reaction to the implementations of the new U.S. tax legislation.

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 are currently a PFIC, and we do not anticipate becoming a PFIC for the 2019 taxable year, however such a determination cannot be made until following the end of such taxable year. Notwithstanding the foregoing, 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, including our initial public offering. 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.

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. 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. U.S. Shareholders of a CFC are 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 "global intangible low-taxed 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). 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 new 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located in Bridgewater, New Jersey, where we lease approximately 25,000 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, Buenos Aires, Argentina and Budapest, Hungary. 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, upon receipt of approval for Osmolex ER from the FDA, we filed suit against Adamas in the U.S. District Court for the District of Delaware seeking a declaratory judgment that Osmolex ER does not infringe, directly or indirectly, any valid and enforceable claim of any of the 11 patents enumerated in our complaint. On September 20, 2018, Adamas filed an amended answer with counterclaims alleging infringement of certain patents included in our complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. Adamas commercializes a different amantadine product, an extended-release capsule marketed and sold as Gocovri®. We intend to vigorously defend our rights to commercialize Osmolex ER free and clear of any of these patents. However, this litigation is at an early stage. If Adamas's counterclaims for infringement are successful, we could be exposed to

injunctive relief, invalidity or damages, any of which could materially and adversely affect our business, financial condition and results of operations.

In general, we intend to continue to vigorously prosecute and defend these 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.

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 27, 2019, there were 11 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.

Use of Proceeds from Initial Public Offering of Ordinary Shares

On October 17, 2018, our Registration Statement on Form S-1, as amended (File No. 333-227357), relating to our IPO, was declared effective by the SEC. The offering commenced on October 17, 2018 and, on October 22, 2018, we closed the issuance and allotment of the 7,647,500 ordinary shares at a price of $7.00 per ordinary 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. Jefferies, Barclays, RBC Capital Markets and Wells Fargo Securities acted as joint lead book-running managers for the offering. In addition, we issued and allotted 2,014,285 ordinary shares at the public offering price in a private placement to certain existing shareholders.

We raised a total of $67.6 million in gross proceeds in the IPO and concurrent private placement, or approximately $58.1 million in net proceeds, after deducting underwriting discounts of $4.6 million, net of reimbursement and estimated expenses of approximately $4.9 million. On October 31, 2018, the net proceeds from the IPO were used to repay $42.3 million of our Term A Loan and $7.7 million of our Term B Loan, together with accrued and unpaid interest.

Recent Sales of Unregistered Securities

In addition, we issued and allotted 2,014,285 ordinary shares on October 17, 2018 at the IPO price in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended, to certain existing shareholders. The aggregate net proceeds of the private placement were approximately $14.1 million, which, as reference above, were used to repay indebtedness under our senior secured credit facility, to pay fees and expenses associated with the IPO and the private placement and for working capital and other general corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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.Sp. 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 2017, we generated total revenues across our existing portfolio of promoted specialty neurology and women's health products, as well as our non-promoted products, which are primarily complex formulations of generic drugs. In 2018 we received regulatory approval from the U.S. Food and Drug Administration, or the FDA, for 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, as well as 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 launched M-72 in the second quarter of 2018 and launched Osmolex ER in January 2019. In addition, we have a late-stage development pipeline highlighted by two new drug application or NDAs, candidates in Phase III clinical trials: Ontinua ER (arbaclofen extended-release tablets) for muscle spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid. Many of our products use our proprietary osmotic-release drug delivery system, Osmodex, which we believe offers advantages over alternative extended-release, or ER, technologies.

Our core competencies span drug development, manufacturing and commercialization. Our specialized neurology and women's health sales teams support the ongoing commercialization of our existing promoted product portfolio as well as the launch of new products. As of December 31, 2018, we actively promoted five products: M-72, Lorzone (chlorzoxazone scored tablets) and ConZip (tramadol hydrochloride extended-release capsules) in specialty neurology; and OB Complete, our family of prescription prenatal dietary supplements, and Divigel (estradiol gel, 0.1%) in women's health. We launched M-72 in the second quarter of 2018, and Osmolex ER, which was approved by the FDA on February 16, 2018, was fully launched in January 2019. As of December 31, 2018, we sold a portfolio consisting of approximately 37 non-promoted products, which has generated strong cash flow. The cash flow from these non-promoted products has contributed to our investments in research and development and business development activities. Certain of our key products, particularly those that incorporate our proprietary Osmodex drug delivery system, are or are expected to be manufactured in our Marietta, Georgia facility. Many of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as U.S. Drug Enforcement Administration, or DEA, regulation and quotas for API. Our non-promoted products compete in generic markets where barriers to entry are lower than markets in which certain of our promoted products compete. In particular, both methylphenidate ER tablets and venlafaxine ER tablets, or VERT have experienced, and are expected to continue to experience pricing erosion due to additional competition from other generic pharmaceutical companies. It is anticipated that this pricing erosion will result in lower net sales, revenue and profitability in 2019 and subsequent years.

We are focused on progressing our pipeline, which is highlighted by two Phase III candidates under clinical development — arbaclofen ER and RVL-1201. We developed arbaclofen ER using our proprietary Osmodex drug

delivery system and believe this formulation will provide an efficacious and safe treatment for spasticity in multiple sclerosis patients. We recently received topline data from our second Phase III clinical trial of arbaclofen in multiple sclerosis patients with spasticity. The initial review of the preliminary topline data indicates that both doses of arbaclofen demonstrated superiority to placebo in one of the two co-primary endpoints. In addition, there were numerous signals of efficacy and the safety profile was in line with previously reported results. Based on the efficacy and safety exhibited for arbaclofen, the Company remains encouraged and plans to proceed with its clinical and regulatory strategy to submit an NDA. At this time, however, it is unclear whether or not the Company will be required to conduct an additional clinical trial which may delay our submission past 2019. If we are required to conduct any such additional clinical trial, our development costs may increase, our regulatory approval process could be denied or delayed and we may not be able to commercialize and commence sales of arbaclofen ER in the time frame currently contemplated, if at all.

We acquired the rights to RVL-1201 in 2017 and are conducting a second Phase III clinical trial of RVL-1201 for droopy eyelid. If approved, RVL-1201 would be the first non-surgical treatment option approved by the FDA for droopy eyelid. We plan to invest selectively in expanding our product portfolio by leveraging both our proprietary Osmodex drug delivery system to develop differentiated products as well as our management team's operating experience to pursue external business development opportunities.

Financial Operations Overview

Recent Transactions

RevitaLid Acquisition

On October 24, 2017, we entered into a stock purchase agreement to acquire the outstanding stock of RevitaLid, Inc., or RevitaLid. RevitaLid is the owner of RVL-1201, an ophthalmic product that treats blepharoptosis, which had been licensed from one of the sellers in the transaction. Osmotica obtained all rights under the license agreement and is undertaking the clinical development and, if approved, the commercialization of RVL-1201, which includes conducting clinical trials and filing an NDA with the FDA. The transaction was accounted for as an asset acquisition of acquired in-process research and development, or IPR&D, and because there was no alternative future use for the acquired asset, the purchase price, including net deferred tax assets and liabilities, was expensed and included in research and development expenses.

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 service 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 M-72, Lorzone, Divigel and the OB Complete family of prescription prenatal dietary supplements, and our non-promoted products, principally methylphenidate ER and venlafaxine ER, or VERT. We ship product to a customer pursuant to a purchase order, which in certain cases is 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, 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 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel expenses, including salaries and benefits for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expenses also include corporate facility costs, including rent, utilities, legal fees related to corporate matters and fees for accounting and other consulting services. We expect 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, 2018 and 2017

Financial Operations Overview

The following table presents revenues and expenses for the years ended December 31, 2018 and 2017 (dollars in thousands):

	Year Ended December 31,		
	2018	2017	% Change
Net product sales	$ 261,398	$ 237,671	10 %
Royalty revenue	1,959	6,449	(70)%
Licensing and contract revenue	344	1,629	(79)%
Total Revenue	263,701	245,749	7 %
Cost of goods sold (inclusive of amortization of intangibles)	135,014	125,188	8 %
Gross profit	128,687	120,561	7 %
Gross profit percentage	49 %	49 %	
Selling, general and administrative expenses	74,244	56,955	30 %
Research and development expenses	48,761	42,688	14 %
Impairment of intangibles and fixed assets	17,903	72,986	(75)%
Impairments of goodwill	86,318	—	%
Total operating expenses	227,225	172,629	32 %
Interest expense and amortization of debt discount	20,791	29,052	(28)%
Other non-operating (income) expenses, net	(665)	4,522	(115)%
Total other non-operating expenses, net	20,126	33,574	(40)%
Loss before income taxes	(118,664)	(85,643)	(39)%
Income tax benefit	9,268	44,501	(79)%
Net loss	$ (109,396)	$ (41,142)	166 %

Revenue

The following table presents total revenues for the years ended December 31, 2018 and 2017 (dollars in thousands):

	Year Ended December 31,		
	2018	2017	% Change
Venlafaxine ER (VERT)	$ 66,039	$ 96,054	(31)%
Methylphenidate ER	129,469	43,711	196 %
Lorzone	17,172	22,276	(23)%
Divigel	23,314	18,542	26 %
OB Complete	10,510	10,446	1 %
Other	14,894	46,642	(68)%
Net product sales	261,398	237,671	10 %
Royalty revenue	1,959	6,449	(70)%
Licensing and contract revenue	344	1,629	(79)%
Total revenues	$ 263,701	$ 245,749	7 %

Total revenues increased by $18.0 million to $263.7 million for the year ended December 31, 2018, as compared to $245.7 million for the year ended December 31, 2017.

Net Product Sales. Net product sales increased by $23.7 million to $261.4 million for the year ended December 31, 2018, as compared to $237.7 million for the year ended December 31, 2017, primarily due to methylphenidate ER, which was approved and launched in the third quarter of 2017, and M-72, which was launched in the second quarter of 2018. While we experienced significant growth in methylphenidate ER during 2018, this trend is expected to reverse in

2019. Two new competitors received FDA approval for AB-rated methylphenidate ER products in the first and fourth quarters of 2018, and we anticipate additional competitors in 2019. Accordingly, we anticipate average selling prices will decline which will negatively affect our net sales of methylphenidate ER in 2019 and in future years.

Product sales from VERT decreased by 31% for the year ended December 31, 2018, reflecting additional competition and a greater proportion of sales from our lower priced authorized generic product, which accounted for substantially all VERT unit volume during the year. Prior to 2018, one other company sold competing dosage strengths of VERT. During the third quarter of 2018, another company launched competing dosage strengths of VERT. We expect that these competing products as well as additional generic product launches in the future, if any, will continue to negatively affect our sales of VERT for 2019 and future years.

Product sales from Lorzone declined 23% for the year ended December 31, 2018, reflecting the shift of promotional efforts to M-72 which was launched in the second quarter of 2018, partially offset by price increases instituted during 2018. Product sales from Divigel increased by 26%, driven primarily by targeted promotional activities and strong patient access. Product sales from the OB Complete family of prescription prenatal dietary supplements increased by 1% as sales levels rebounded after initially falling following the discontinuation of our OB Complete Gold prenatal vitamin line during 2017. Other non-promoted product sales decreased by 68%, largely due to the termination in the second quarter of 2017 of a marketing and distribution relationship with the ANDA holder of a portfolio of products, including aripiprazole together with a favorable resolution in late 2017 of disputed gross sales deductions taken by a wholesale customer.

Royalty Revenue. Royalty revenue decreased by $4.5 million for the year ended December 31, 2018, compared to the prior year period, primarily due to lower product sales by third parties.

Licensing and Contract Revenue. Licensing and contract revenue decreased by $1.3 million in 2018 primarily due to the discontinuation in April 2017 of promotional activities for Monistat, a women's health product, on behalf of a third party, and a decline in sales on other contract revenue products.

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, 2018 and 2017 (dollars in thousands):

	Year Ended December 31,		
	2018	2017	% Change
Amortization of intangible assets	$ 76,896	$ 43,381	77 %
Depreciation expense	2,626	1,978	33 %
Royalty expense	11,949	31,386	(62)%
Other cost of goods sold	43,543	48,443	(10)%
Total cost of goods sold	$ 135,014	$ 125,188	8 %

Cost of goods sold increased $9.8 million in the year ended December 31, 2018 to $135.0 million as compared to $125.2 million in the year ended December 31, 2017. The increase was primarily driven by a $33.5 million increase in amortization of intangible assets, largely attributable to a full year of amortization for methylphenidate ER following its approval and launch in the third quarter of 2017. The increase in depreciation expense is largely attributable to a full year of depreciation related to an expansion project for our manufacturing facility in Marietta, Georgia which was completed during the second quarter of 2017. Royalty expense decreased by $19.4 million primarily reflecting the termination in the second quarter of 2017 of the distribution and marketing arrangement with the ANDA holder for a portfolio of products, including aripiprazole, for which we paid a significant royalty rate on our net sales. The $4.9 million decrease in other cost of goods sold is mostly due to lower API costs for methylphenidate ER during 2018.

Gross profit percentage remained at 49% for the year ended December 31, 2018 compared to the year ended December 31, 2017. Excluding amortization and depreciation, our gross profit percentage increased to 79% for the year ended

December 31, 2018 as compared with 68% for the year ended December 31, 2017, primarily as a result of the termination in the second quarter of 2017 of the distribution and marketing relationship with the ANDA holder for a portfolio of products, including aripiprazole, for which we paid a significant royalty rate on net sales.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $17.2 million in the year ended December 31, 2018 to $74.1 million as compared to $57.0 million in the year ended December 31, 2017. The increase in our selling, general and administrative expenses reflects additions to salesforce headcount and marketing costs associated with the launches of M-72 and Osmolex ER, together with costs we incurred related to our initial public offering and severance expenses due to restructuring of our sales force.

Research and Development Expenses

Research and development expenses increased by $6.1 million in the year ended December 31, 2018 to $48.8 million as compared to $42.7 million in the year ended December 31, 2017. The increase was largely attributable to clinical trial costs of arbaclofen ER and RVL-1201, each of which are in Phase III clinical trials, together with additional headcount. Partially offsetting this increase, research and development expenses for the year ended December 31, 2017 included approximately $16.4 million related to the acquisition of RevitaLid, Inc., owner of the rights to RVL-1201. The purchase of RevitaLid was accounted for as an acquisition of in-process R&D with no alternative future use and expensed at the time of acquisition.

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

	Year Ended December 31,		
	2018	2017	% Change
Osmolex ER	$ 1,732	$ 3,235	(46)%
Arbaclofen ER	19,679	5,976	229 %
RVL 1201	7,225	16,372	(56)%
Other	20,125	17,105	18 %
Total	$ 48,761	$ 42,688	14 %

Impairment of Intangible Assets and Goodwill

Impairment of intangible assets and goodwill was $104.2 million during the year ended December 31, 2018. During 2018 we recognized impairments of finite-lived developed technology assets of $10.3 million consisting of the write down to fair value of nifedipine and Khadezla of $6.2 million and $4.1 million, respectively. Nifedipine was impaired due to a greater competitive environment which reduced the anticipated royalty revenue from our license partner, and in late 2018, we made the decision to discontinue commercialization of Khedezla and recognized an impairment charge of $4.1 million. In December 2018, we made the decision to cease development of Generic Product A, an indefinite-lived In-Process R&D asset which resulted in an impairment charge of $7.6 million. In December 2018, circumstances and events related to pricing on certain of our generic assets, together with our decision to discontinue development and commercialization of Khedezla and Generic Product A, made it more likely than not that goodwill had become impaired. As a result, we performed an assessment of goodwill as of December 31, 2018. Based on the results of this assessment, we recognized an impairment charge of $86.3 million for the year ended December 31, 2018.

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

	Year Ended December 31, 2018	
Asset/Asset Group	**Impairment Charge**	**Reason For Impairment**
Developed Technology		
Nifedipine	$ 6,173	Lower royalty revenue due to competition
Khedezla	4,130 (1)	Discontinued commercialization
	10,303	
In-Process R&D		
Generic Product "A"	7,600 (1)	Suspension of development activities
Goodwill	86,318	Discontinued products and price erosion on generic assets
Total Impairment Charges for year ended December 31, 2018	$ 104,221	

	Year Ended December 31, 2017	
Asset/Asset Group	**Impairment Charge**	**Reason For Impairment**
Product Rights		
Hydromorphone ER	$ 6,567 (1)	Sales underperforming expectations due to competition
Other Product Rights	561 (1)	Discontinued products/lower sales expectations
	7,128	
Developed Technology		
Oxybutinin License Royalty	8,767	Revenue underperforming expectations due to a new generic market entrant
In-Process R&D		
Ontinua ER	23,100	Delay in commencement of Phase III trial
Osmolex ER	8,900	Delay in approval date and product launch
Generic Product "A"	18,600	Delay in finalizing formulation development
Other Generic Products in Development	6,025 (1)	Discontinued products/lower sales expectations post launch
	56,625	
Total Impairment Charges for year ended December 31, 2017	$ 72,520	

(1) - Assets were fully impaired as of December 31, 2018 and December 31, 2017, as applicable.

Impairment of Fixed Assets

Fixed asset impairments for the years ended December 31, 2018 and 2017 were $0.1 million and $0.5 million, respectively, due to the abandonment of assets at a warehouse we ceased leasing, the termination of a capital project that had not reached completion, and the fair market value for equipment being lower than its carrying value.

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by $8.3 million in the year ended December 31, 2018 to $20.8 million as compared to $29.1 million in the year ended December 31, 2017. The decrease in borrowing costs reflects lower costs associated with a refinancing concluded in December 2017 which refinanced our LIBOR-based term loan, senior subordinated note, and junior subordinated PIK note borrowings.

Other Non-operating (Income) Expenses, net

Other non-operating (income) expense was $0.7 million and $(4.5) million for the years ended December 31, 2018 and 2017, respectively. On December 21, 2017, we amended our senior secured credit facilities to increase the principal amount by $59.0 million. Proceeds from these incremental borrowings were used to fully repay our senior subordinated notes and PIK notes. On October 31, 2018, we prepaid $50.0 million of term loans under our senior secured credit facility. Other non-operating income (expense) included $0.9 million and $4.9 million of debt extinguishment costs for years ended December 31, 2018 and 2017, respectively, offset by interest and other miscellaneous income.

Income Tax Benefit

	Year Ended December 31,	
	2018	2017
	(dollars in thousands)	
Income tax benefit	$ 9,268	$ 44,501
Effective tax rate	7.8 %	51.9 %

Income tax benefit decreased by $35.2 million in the year ended December 31, 2018 to $9.3 million as compared to $44.5 million in the year ended December 31, 2017.

The income tax benefit for the year ended December 31, 2018 and 2017 reflect significant differences in the usual relationship of income tax benefit before income taxes. The primary cause of this, as well as the change in the effective income tax rate period over period, relates to the following items: the decrease in the U.S. statutory income tax rate to 21% from 34% for the year ended December 31, 2018 compared to the same period in 2017; a disproportionate change in the income tax rate for the year ended December 31, 2018 as a result of credits from research and development when compared to the loss before income taxes; and the fact that in both periods there were ordinary losses in certain foreign tax jurisdictions in which we operate where no tax benefit is expected to be recognized, which subsequently requires that these jurisdictions not be included in the calculation of the interim annual effective income tax rate. In addition, during the year ended December 31, 2018 there was a discrete item of expense included in the income tax provision related to a decrease in the Argentinian statutory rate as a result of a law change.

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, 2018, we had cash and cash equivalents of $70.8 million and borrowing availability under the Revolver of $50.0 million. We also had $271.4 million aggregate principal amount borrowed under our term loans and $1.8 million under our note payable for insurance financing. During the year ended December 31, 2018 we generated

$37.6 million of cash from operations, and during the year ended December 31, 2017, we generated cash flows from operations of $57.8 million. We expect to generate positive cash flow from operations in the future through sales of our existing products, launches of approved products currently in our development pipeline and sales derived from in-licenses or acquisitions of other products; however, we expect our levels of cash flow generated to be lower due to price erosion on methylphenidate ER and VERT.

As of December 31, 2018, the interest rate was 6.09% and 6.59% for our Term A Loan and Term B Loan, respectively. As of December 31, 2017, the interest rate was 5.25% and 5.75% for our Term A Loan and Term B Loan, respectively.

At December 31, 2018, there were no outstanding borrowings or outstanding letters of credit under the Revolver. Availability under the Revolver as of December 31, 2018 was $50.0 million.

On October 22, 2018, we completed our IPO, in which we 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, we issued and allotted 2,014,285 ordinary shares at the public offering price in a private placement to certain existing shareholders. The aggregate net proceeds of the IPO and the private placement were approximately $58.1 million after deducting underwriting discounts and commissions and offering expenses. Shortly after the IPO, we prepaid $50 million of our Term A loan and Term B loan.

During the year ended December 31, 2018, we benefited from the commercial launch of methylphenidate ER and M-72 in September 2017 and April 2018, respectively. Methylphenidate ER competes in generic markets for which future competition will erode profitability over time. In late 2018, we became aware of several companies launching competing versions of methylphenidate ER. As a result, we anticipate price erosion which will negatively affect profitability of methylphenidate in 2019 and future years. During 2017 and 2018, we made significant investments in research and development, primarily for Ontinua ER and RVL-1201, both of which are in Phase III clinical trials.

We believe that our existing cash balances, cash we expect to generate from operations from our existing product portfolio, our near-term product launches and our product pipeline, as well as funds available under the Revolver, will be sufficient to fund our operations and to meet our existing obligations for at least the next 12 months.

The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as other factors, such as successful development and launching of new products and strategic product or business acquisitions. Our assumptions may prove to be wrong or other factors may adversely affect our business, and 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 which could, among other things, force us to raise additional funds or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to internal product development, clinical trials of product candidates, expansion of our commercial, manufacturing and other operations and product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. Any equity financing would be dilutive to our shareholders, and the consent of the lenders under our senior secured credit facilities could be required for certain financings.

Cash Flows

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

	Year Ended December 31,		
	2018	2017	Change
Net cash provided by operating activities	$ 37,558	57,837	$ (20,279)
Net cash used in investing activities	(4,134)	(19,395)	15,261
Net cash provided by (used in) financing activities	3,604	(23,314)	26,918
Effect on cash of changes in exchange rate	(938)	57	(995)
Net increase in cash and cash equivalents	$ 36,090	$ 15,185	$ 20,905

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 $37.6 million and $57.8 million for the years ended December 31, 2018 and 2017, respectively.

The decrease in cash provided by operating activities in the year ended December 31, 2018, as compared to year ended December 31, 2017, was due to changes in working capital, primarily as a result of greater level of accounts receivable and inventories and, a lower level of accounts payable, partially offset by prepaid assets and higher accrued expenses.

Net cash outflow related to operating assets and liabilities was $25.0 million for the year ended December 31, 2018 as compared with the net cash inflow of $9.5 million for the year ended December 31, 2017. The change was largely driven by greater levels of accounts receivable and inventories related to methylphenidate ER, which was launched late in the third quarter of 2017, and lower levels of accounts payable, offset by lower levels of prepaid assets and higher accrued expenses during the period.

During the year ended December 31, 2018, accounts receivable was a $17.0 million use of funds, due to greater levels of accounts receivable from product sales, and lower reserves for chargebacks, commercial rebates and doubtful accounts. Inventories were also a use of funds of $7.4 million primarily due to increased methylphenidate ER inventories to meet customer demand. Prepaid expenses and other current assets were a $4.7 million source of funds while accounts payable, represented a $11.3 million use of funds.

Net cash used in investing activities

Our uses of cash in investing activities during the years ended December 31, 2018 and 2017 reflected purchases of property, plant and equipment and were $4.1 million and $6.9 million, respectively. In 2017 we invested $12.5 million in the acquisition of RevitaLid, Inc., owner of rights to RVL-1201. Purchases of property, plant and equipment in the year ended December 31, 2017 included the costs of completion of the expansion construction project for our Marietta, Georgia manufacturing facility, and the purchase of other property, plant and equipment.

Net cash provided by (used in) financing activities

Net cash provided by financing activities of $3.6 million during the year ended December 31, 2018 primarily related to the $58.1 million of net proceeds from our IPO and a $2.7 million net increase in insurance financing loans, partially offset by $56.1 million of repayments of our term loans under our senior secured credit facility.

Net cash used in financing activities of $23.3 million during the year ended December 31, 2017 primarily related to debt repayments and payment of contingent consideration related to the 2014 in-license of a portfolio of women's health products, including Divigel and distributions to partners.

Contractual Obligations

The following table lists our contractual obligations as of December 31, 2018.

	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]	271,360	—	271,360	—	—
Interest expense[2]	70,028	17,632	52,396	—	—
Capital lease obligations[3]	257	119	138	—	—
Operating lease obligations[4]	5,803	1,998	3,314	491	—
Purchase obligations[5]	4,000	4,000	—	—	—
Royalty obligations[6]	8,646	1,375	3,188	3,000	1,083
Insurance premium financing obligations[7]	1,774	1,774	—	—	—
Total	361,868	26,898	330,396	3,491	1,083

(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, 2018 plus the specified margin in the senior secured credit facilities for each period presented. As of December 31, 2018, the interest rate was 6.09% for Term A Loan and 6.59% 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 and Hungary.

(5) Includes obligations to purchase API with minimum required annual amounts.

(6) Includes obligations to make minimum annual royalty payments.

(7) Includes obligations to make minimum insurance premium financing 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, 2018, our liability for unrecognized tax benefits was $1.5 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. The information presented for the periods prior to January 1, 2018 has not been restated and is reported under ASC Topic 605.

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 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 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 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. 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.

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, 2018 and December 31, 2017. 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 majority of the volume at December 31, 2018 and December 31, 2017.

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, 2018 and 2017 (in thousands):

	Chargebacks	Commercial Rebates	Government Rebates	Product Returns	Discounts and Allowances	Total
Balance at January 1, 2017	$ 24,311	$ 30,553	$ 6,486	$ 30,341	$ 3,632	$ 95,323
Provision	202,367	134,526	26,007	26,300	15,387	404,587
Charges processed	(194,336)	(125,845)	(18,342)	(13,341)	(15,534)	(367,398)
Balance at December 31, 2017	32,342	39,234	14,151	43,300	3,485	132,512
Provision	365,043	257,917	18,582	20,492	20,245	682,279
Charges processed	(358,524)	(247,920)	(22,752)	(15,328)	(20,220)	(664,744)
Balance December 31, 2018	$ 38,861	$ 49,231	$ 9,981	$ 48,464	$ 3,510	$ 150,047

Total items deducted from gross product sales were $682.3 million (excluding $4.9 million in provisions for advertising and promotion), or 71.9% as a percentage of gross product sales, during the year ended December 31, 2018. Total items deducted from gross product sales were $404.6 million, or 62.6% as a percentage of gross product sales, in 2017.

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.

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 $365.0 million and $202.4 million, or 38.5% and 31.3% as a percentage of gross product sales, for the years ended December 31, 2018 and 2017, respectively. Chargebacks as a percentage of gross product sales increased in 2018 as compared with 2017, 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 $257.9 million and $134.5 million, or 27.2% and 20.8% as a percentage of gross product sales, for the years ended December 31, 2018 and 2017, respectively. Commercial rebates as a percentage of gross product sales increased in 2018 as compared to 2017 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 MMCOs. 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 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 $18.6 million and $26.0 million, or 2.0% and 4.0% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, 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
- 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 $20.5 million and $26.3 million, or 2.2% and 4.1% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively. Product returns as a percentage of gross product sales decreased in 2018 as compared to 2017 primarily due to the launch of methylphenidate ER in September, 2017, and product recalls which were not present in 2018. Product returns as a percentage of gross product sales are not expected to change materially for 2019.

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 $4.9 million and $4.4 million, or 0.5% and 0.7% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively.

Discounts and allowances were $20.2 million and $15.4 million, or 2.1% and 2.4% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, 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 for the remainder of 2018.

Valuation of long-lived assets

As of December 31, 2018, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is $437.9 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 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, 2018 and 2017 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 $10.3 million and $15.9 million, regarding definite-lived intangible assets for the years ended December 31, 2018 and 2017, 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 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, 2018 and 2017 annual goodwill impairment test were 14% and 9.0%, 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, 2018 and for the year ended December 31, 2017. 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.

In December 2018, we determined that, subsequent to our annual impairment testing, circumstances and events related to pricing on certain of our generic assets, together with our decision to discontinue commercialization of a developed technology asset, and discontinue development of an IPR&D asset, made it more likely than not that goodwill had become impaired. As a result, we performed an assessment of goodwill as of December 31, 2018. Based on the results of this assessment, it was determined that the carrying value of goodwill exceeded its fair value by $86.3 million and an impairment charge was recognized for the year ended December 31, 2018.

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. 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. The discount rates applied to the estimated cash flows for our October 1, 2018 and 2017 indefinite-lived intangible asset impairment test were 14% and

9.0%, respectively. 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 recognized impairment charges to IPR&D of $7.6 million and $56.6 million for the years ended December 31, 2018 and 2017, respectively. The 2018 impairment charge reflects our decision to cease development activities on a generic asset thereby reducing its fair value to zero.

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.

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, 2018 and 2017, the Company has a federal net operating loss carryover of $3.3 million and $4.4 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of approximately $30.5 million and $90.2 million, respectively which will begin to expire in 2022. At December 31, 2018 and 2017, the Company had total tax credit carryovers of approximately $4.6 million and $9.1 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 2036.

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.

For the year ended December 31, 2018, we have not recorded any measurement period adjustments to the provisional estimates recorded as of December 31, 2017 in accordance with the SEC's Staff Accounting Bulletin No. 118, or SAB 118. We analyzed the impact of the U.S. Tax Cuts and Jobs Act under SAB 118 and do not believe that any additional adjustments were required.

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.

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 we account for forfeitures of share option awards as they occur in accordance with ASU No. 2016-09. For 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 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 year end December 31, 2018 we recognized $1.9 million 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 foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2018, 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, 2018, a 100 basis point increase in assumed interest rates for our variable interest credit facilities would have an annual impact of approximately $2.7 million on interest expense.

As of December 31, 2018, we had cash and cash equivalents of $70.8 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 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, 2018 and 2017.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Osmotica Pharmaceuticals plc
Dublin, Ireland

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Osmotica Pharmaceuticals plc (the "Company") and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity/partners' capital, and cash flows for each of the two years in the period ended December 31, 2018, 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 and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Method Related to Revenue

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for revenue during the year ended December 31, 2018 due to the adoption of Accounting Standards Codification 606, *"Revenue from Contracts with Customers."*

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

Woodbridge, New Jersey
March 27, 2019

OSMOTICA PHARMACEUTICALS PLC
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 70,834,496	$ 34,743,152
Trade accounts receivable, net	56,423,866	37,637,957
Inventories, net	24,383,021	16,946,870
Prepaid expenses and other current assets	20,743,685	25,498,092
Total current assets	172,385,068	114,826,071
Property, plant and equipment, net	31,263,432	31,410,133
Intangibles, net	490,389,723	585,388,710
Goodwill	100,854,816	187,172,816
Other non-current assets	751,927	942,419
Total assets	$ 795,644,966	$ 919,740,149
Liabilities and Shareholders' Equity/Partners' Capital		
Current liabilities:		
Trade accounts payable	$ 24,869,593	$ 36,069,936
Accrued liabilities	87,236,940	81,926,390
Current portion of long-term debt, net of deferred financing costs	1,774,199	6,655,604
Current portion of obligation under capital leases	119,344	24,245
Income taxes payable - current portion	393,552	—
Total current liabilities	114,393,628	124,676,175
Long-term debt, net of non-current deferred financing costs	266,802,911	313,949,581
Long-term portion of obligation under capital leases	137,949	57,059
Income taxes payable - long term portion	1,803,512	1,334,645
Deferred taxes	26,237,841	42,891,444
Other long-term liabilities	—	1,047,477
Total liabilities	409,375,841	483,956,381
Commitments and contingencies (See Note 14)		
Shareholders' equity/partners' capital:		
Ordinary shares ($0.01 nominal value 400,000,000 shares authorized, 52,518,924 shares issued and outstanding)	525,189	—
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	489,949,791	—
Accumulated deficit	(102,359,672)	—
Partners' capital	—	436,416,914
Accumulated other comprehensive loss	(1,846,183)	(633,146)
Total shareholders' equity/partners' capital	386,269,125	435,783,768
Total liabilities and shareholders' equity/partners' capital	$ 795,644,966	$ 919,740,149

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2018	2017
Net product sales	$ 261,398,205	$ 237,671,178
Royalty revenue	1,958,571	6,449,095
Licensing and contract revenue	344,573	1,628,759
Total revenues	263,701,349	245,749,032
Cost of goods sold (inclusive of amortization of intangibles)	135,013,998	125,188,435
Gross profit	128,687,351	120,560,597
Selling, general and administrative expenses	74,242,509	56,954,513
Research and development expenses	48,761,494	42,688,062
Impairment of intangibles and fixed assets	17,903,208	72,986,303
Impairment of goodwill	86,318,000	—
Total operating expenses	227,225,211	172,628,878
Operating loss	(98,537,860)	(52,068,281)
Interest expense and amortization of debt discount	20,790,714	29,052,363
Other non-operating (income) loss, net	(664,391)	4,521,898
Total other non-operating expense, net	20,126,323	33,574,261
Loss before income taxes	(118,664,183)	(85,642,542)
Income tax benefit	9,267,917	44,500,731
Net loss	$ (109,396,266)	$ (41,141,811)
Other comprehensive loss, net		
Change in foreign currency translation adjustments	(1,213,036)	(907,927)
Comprehensive loss	$ (110,609,302)	$ (42,049,738)
Loss per share attributable to shareholders		
Basic	$ (2.42)	$ (0.96)
Diluted	$ (2.42)	$ (0.96)
Weighted average shares basic and diluted		
Basic and Diluted	45,276,278	42,855,722

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Changes in Shareholders' Equity/Partners' Capital

	Ordinary shares		Additional paid in capital	Accumulated deficit	Partners' capital	Accumulated other comprehensive loss	Total
	Shares	Amount					
Balance at December 31, 2016	$ —	—	$ —	$ —	$ 477,430,725	$ 274,781	$ 477,705,506
Net loss	—	—	—	—	(41,141,811)	—	(41,141,811)
Change in foreign currency translation	—	—	—	—	—	(907,927)	(907,927)
Partners' contributions	—	—	—	—	128,000	—	128,000
Balance at December 31, 2017	—	$ —	$ —	$ —	$ 436,416,914	$ (633,146)	$ 435,783,768
Cumulative effect of change in accounting standard (See Note 2)	—	—	—	—	1,047,477	—	1,047,477
Net loss	—	—	—	—	(7,036,594)	—	(7,036,594)
Change in foreign currency translation	—	—	—	—	—	(1,169,244)	(1,169,244)
Share compensation	—	—	—	—	1,248,023	—	1,248,023
Partners' distributions	—	—	—	—	(2,026)	—	(2,026)
Balance at October 17, 2018	—	$ —	$ —	$ —	$ 431,673,794	$ (1,802,390)	$ 429,871,404
Effect of reorganization	42,857,139	428,571	431,245,223	—	(431,673,794)	—	—
Issuance of ordinary shares in initial public offering and private placement, net of offering costs	9,661,785	96,618	57,987,245	—	—	—	58,083,863
Share compensation	—	—	717,323	—	—	—	717,323
Net loss	—	—	—	(102,359,672)	—	—	(102,359,672)
Change in foreign currency translation	—	—	—	—	—	(43,793)	(43,793)
Balance at December 31, 2018	52,518,924	$525,189	$489,949,791	$(102,359,672)	$ —	$ (1,846,183)	$ 386,269,125

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (109,396,266)	$ (41,141,811)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	81,572,591	46,450,146
Share compensation	1,965,346	—
Impairment of intangibles and fixed assets	17,903,208	72,986,303
Impairment of goodwill	86,318,000	
Deferred income tax benefit	(16,653,604)	(48,506,649)
Loss on sale of fixed assets	93,652	—
Bad debt provision	(1,771,487)	832,388
Non-cash interest expense and amortization of deferred financing and loan origination fees	1,651,536	7,506,359
Write off of deferred financing fees in connection with prepayment	875,576	4,981,624
Expensed IPR&D	—	16,372,476
Change in fair value of contingent consideration	—	182,396
Payment for contingent consideration	—	(1,991,288)
Payment of In-kind interest	—	(9,321,500)
Change in operating assets and liabilities:		
Trade accounts receivable, net	(17,040,991)	5,268,883
Inventories, net	(7,436,151)	2,892,119
Prepaid expenses and other current assets	4,686,449	(14,569,647)
Other non-current assets	—	1,512,082
Trade accounts payable	(11,325,623)	588,238
Accrued and other current liabilities	6,116,094	13,794,939
Net cash provided by operating activities	37,558,330	57,837,058
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	10,000	—
Payment for asset acquisition	—	(12,500,000)
Purchase of property, plant and equipment	(4,143,723)	(6,895,332)
Net cash used in investing activities	(4,133,723)	(19,395,332)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	(2,026)	—
Contributions from Partners	—	128,000
Payments on capital lease obligations	(111,554)	(113,842)
Proceeds from issuances of debt	—	327,500,000
Debt financing costs	—	(3,563,499)
Proceeds from insurance financing loan	2,744,852	—
Repayment of insurance financing loan	(970,653)	—
Proceeds from initial public offering and private placement, net of issuance costs	58,083,863	—
Debt repayment	(56,140,063)	(338,756,329)
Payment for contingent consideration	—	(8,508,712)
Net cash provided by (used in) financing activities	3,604,419	(23,314,382)
Net change in cash and cash equivalents	37,029,026	15,127,344
Effect on cash of changes in exchange rate	(937,682)	57,237
Cash and cash equivalents, beginning of period	34,743,152	19,558,571
Cash and cash equivalents, end of period	$ 70,834,496	$ 34,743,152
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 19,618,614	$ 25,272,842
Income taxes paid	$ 2,637,560	$ 17,592,965
Purchase of fixed assets by entering into capital lease	$ 287,542	$ —

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Nature of Operations

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 stock split.

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.

Immaterial Correction of Errors

Subsequent to the issuance of the unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2018 and 2017 in the Company's Quarterly Report on Form 10-Q, the Company determined that a revision was required to correct misstatements associated with the business combination between

Osmotica Holdings Limited and subsidiaries and Vertical/Trigen Holdings LLC which occurred on February 3, 2016. For the year ended December 31, 2017, the correction resulted in an increase in Goodwill of $34,357,100; a decrease in Prepaid Expenses of $316,197; an increase in Deferred Tax Liability of $17,527,389; an increase in Partners' Capital of $16,513,514; and an increase in Income Tax Benefit and corresponding decrease in Net Loss of $4,013,161. The Company has corrected these amounts in the periods presented in these consolidated financial statements with an adjustment to the Company's consolidated financial statements for the year ended December 31, 2016 and the adjustments were determined to be immaterial to the Company's financial position as previously reported.

For the statement of changes in partners' capital/shareholders equity, the correction resulted in an increase of $12,500,353 in the balance of Partners' Capital at December 31, 2016.

For the consolidated statement of cash flows for the year ended December 31, 2017, within the Cash Flows from Operating Activities section, Net loss decreased by $4,013,161, deferred income tax benefit increased by $4,013,161.

The impacts of the corrections have been reflected throughout the consolidated financial statements, including the applicable notes, as appropriate.

The following table presents the amounts originally reported, net correction adjustments, and corrected amounts for items affected by the corrections for the three months and nine months ended on September 30, 2018 and 2017, and year-to-date periods ended December 31, 2017:

	Year ended December 31, 2017		
	As originally reported	Net adjustments	As corrected
Partners' capital as of 12/31/2016	$ 465,205,153	$ 12,500,353	$ 477,705,506
Goodwill	152,815,716	34,357,100	187,172,816
Prepaid expenses	25,814,289	(316,197)	25,498,092
Total assets	885,699,246	34,040,903	919,740,149
Deferred taxes	25,364,055	17,527,389	42,891,444
Total liabilities	466,428,992	17,527,389	483,956,381
Partners' capital as of 12/31/2017	419,270,254	16,513,514	435,783,768
Total liabilities and partners' capital	885,699,246	34,040,903	919,740,149
Income tax benefit	40,487,570	4,013,161	44,500,731
Net loss	(45,154,972)	4,013,161	(41,141,811)
Comprehensive loss	(46,062,899)	4,013,161	(42,049,738)
Loss per share	(1.05)	0.09	(0.96)

	Nine months ended September 30, 2018		
	As originally reported	Net adjustments	As corrected
Goodwill	$ 152,815,716	$ 34,357,100	$ 187,172,816
Prepaid expense and other current assets	18,802,004	5,628,370	24,430,374
Total assets	855,472,388	39,985,470	895,457,858
Deferred taxes	13,124,607	22,048,491	35,173,098
Total liabilites	439,969,303	22,048,491	462,017,794
Partners' capital as of 9/30/2018	417,374,758	17,936,979	435,311,737
Total liabilities and partners' capital	855,472,388	39,985,470	895,457,858
Income tax benefit	1,999,323	1,423,465	3,422,788
Net loss	(3,574,093)	1,423,465	(2,150,628)
Comprehensive loss	(4,812,620)	1,423,465	(3,389,155)
Loss per share	(0.08)	0.03	(0.05)

	Nine months ended September 30, 2017		
	As originally reported	Net adjustments	As corrected
Income tax benefit	$ 16,785,658	$ (644,853)	$ 16,140,805
Net loss	(42,332,512)	(644,853)	(42,977,365)
Comprehensive loss	(41,915,544)	(644,853)	(42,560,397)
Loss per share	(0.99)	(0.02)	(1.01)

	Three months ended September 30, 2017		
	As originally reported	Net adjustments	As corrected
Income tax benefit	$ 12,046,928	$ (1,704,498)	$ 10,342,430
Net loss	(12,272,821)	(1,704,498)	(13,977,319)
Comprehensive loss	(11,979,971)	(1,704,498)	(13,684,469)
Loss per share	(0.29)	(0.04)	(0.33)

	Three months ended September 30, 2018		
	As originally reported	Net adjustments	As corrected
Income tax benefit	$ 2,489,029	$ 1,557,842	$ 4,046,871
Net loss	(4,988,310)	1,557,842	(3,430,468)
Comprehensive loss	(5,136,493)	1,557,842	(3,578,651)
Loss per share	(0.12)	0.04	(0.08)

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

Significant Accounting Policies

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 it estimates 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, except our subsidiary in Argentina which uses the local currency as its functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at the exchange rate in effect at each year end. Income statement accounts are translated into U.S. dollars at the average rate of exchange prevailing during the year. Adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive loss in shareholders' equity. Foreign currency transaction gains and losses are included in foreign exchange (loss) gain 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, 2018 and 2017, 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.

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:

Asset category	Depreciable life
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 3 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 $10,303,208 and $15,894,843, in regard to definite-lived intangible assets for the years ended December 31, 2018 and 2017, respectively (see Note 8).

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 financial condition and results of operations. There was no impairment of goodwill for the year ended December 31, 2017. For the year ended December 31, 2018 it was determined that the carrying value of goodwill exceeded its fair value. Accordingly, the Company recognized a goodwill impairment charge of $86,318,000 for the year ended December 31, 2018 (see Note 8).

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 impairment charges to IPR&D of $7,600,000 and $56,625,436 for the years ended December 31, 2018 and 2017, respectively (see Note 8).

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 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.

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).

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 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, 2018 and 2017, $0 and $264,100,000 of IPR&D was transferred to Product Rights as the products in development are approved for sale and placed into service (see Note 8). Such amounts will be amortized over their respectful estimated useful lives of 7 and 10 years. At that time an evaluation of fair value was performed immediately prior to such transfer.

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, 2018 and 2017 amounted to $6,193,610 and $2,650,540, respectively.

Share-based Compensation—The Company recognizes share-based compensation expense for all options and other arrangements within the scope of ASC 718, *Stock Compensation,* that are expected to vest. Share-based compensation expense is measured at the date of grant, based on the fair value of the award, and is recognized using the straight-line method over the employee's requisite service period. Compensation for share-based awards with vesting conditions other than service are recognized at the time that those conditions will be achieved.

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 Company's business offerings have similar economic and other characteristics, including the nature of products, manufacturing and acquiring processes, types of customers, distribution methods and regulatory environment. 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 May 2014, the FASB issued ASC Topic 606, which, along with amendments issued in 2015, 2016 and 2017, supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* (ASC Topic 605), including most industry-specific revenue recognition guidance throughout the Industry Topics of the Accounting Standards Codification. ASC Topic 606 provides a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer in an amount that reflects the consideration it expects to receive in exchange for those goods or services. On January 1, 2018, the Company adopted the new revenue recognition standard for all contracts not completed as of the adoption date using the modified retrospective method. The implementation of the new revenue recognition standard did not have a material impact on the Company's consolidated financial statements. The information presented for the periods prior to January 1, 2018 has not been restated and is reported under ASC Topic 605.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. The Company adopted ASU 2016-01 as of January 1, 2018, and there was no material impact on the Company's consolidated financial statements resulting from the adoption of this guidance.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The Company adopted this standard on January 1, 2018 and adoption did not have a material impact on the consolidated financial statements.

In October of 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*, ASU 2016-16 requires recognition of the current and deferred income tax effects of an intra-entity asset

transfer, other than inventory, when the transfer occurs, as opposed to current GAAP, which requires companies to defer the income tax effects of intra-entity asset transfers until the asset has been sold to an outside party. The income tax effects of intra-entity inventory transfers will continue to be deferred until the inventory is sold. The standard is required to be adopted on a modified retrospective basis with a cumulative-effect adjustment recorded to retained earnings as of the beginning of the period of adoption. The Company adopted this standard on January 1, 2018. Subsequent to the issuance of the condensed consolidated financial statements as of and for the six months ended June 30, 2018, the Company determined that a revision was required to correct for the adoption of this accounting standard resulting in an increase to Partners' capital and decrease to Other long-term liabilities in the amount of $1,047,477. These adjustments were not considered to be material to the Company's condensed consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718).* This standard requires that an entity must apply modification accounting to changes in the terms or conditions of a share-based payment award unless all of the following criteria are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the modification provided that if the modification does not affect any of the inputs to the valuation technique used to value the award, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the modification; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the modification. The Company adopted this standard on January 1, 2018 and there was no impact to the Company's consolidated financial statements.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740) — Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU 2018-05"). This standard amends Accounting Standards Codification 740, *Income Taxes* ("ASC 740") to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the Tax Act) pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Act enactment date. The amendments are effective upon addition to the FASB Accounting Standards Codification. This standard was effective upon issuance. The Company has evaluated the impact from the Tax Cut and Jobs Act pursuant to SAB 118, see Note 14 for further disclosures.

Recent Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which is effective for annual reporting periods beginning after December 15, 2019 and early adoption is permitted. Under ASU 2016-02, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and 2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2016-02 must be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. In July 2018, the FASB issued ASU 2018-11, *Leases: Targeted Improvements*. Among other things, this ASU provides entities with a transition option to recognize the cumulative-effect adjustment from the modified retrospective application to the opening balance of retained earnings in the period of adoption rather than the earliest period presented in the financial statements. We will adopt ASU 2016-02 on a modified retrospective basis at the adoption date of January 1, 2019. The adoption of ASU 2016-02 will result in the recognition of right-of-use assets and lease liabilities of approximately $4.5 million on the consolidated balance sheet as of January 1, 2019. The right-of-use assets and lease liabilities primarily relate to real estate lease. We will provide additional lease-related disclosures in the notes to the consolidated financial statements commencing with our consolidated financial statements for the quarter ending March 31, 2019.

In February 2018, the FASB issued ASU 2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220) — Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.* This standard allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act and requires certain disclosures about stranded tax effects. This standard will be effective for the Company for annual periods beginning after December 15, 2018 and should be applied either in the

period of adoption or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of the new accounting standard.

Note 3. Other Strategic Investments

RevitaLid Asset Acquisition

On October 24, 2017, the Company entered into a stock purchase agreement with Nephron Pharmaceuticals Corporation, Point Guard Partners, LLC, VOOM LLC, Tom Riedhammer, Avery Family Trust, and Vision Quest Holdings, LLC (collectively, the "Sellers") to purchase the outstanding stock of RevitaLid, Inc. ("RevitaLid"). RevitaLid is the owner of RVL-1201, an ophthalmic product that treats blepharoptosis, or droopy eyelid, which had been licensed from VOOM LLC. Osmotica obtained all rights to the VOOM LLC License Agreement and will be undertaking future development and commercialization of RVL-1201, which includes conducting clinical trials and filing a new drug application with the Food and Drug Administration ("FDA").

The acquisition of RevitaLid included the license to intellectual property from VOOM LLC dated August 31, 2011 which contains future regulatory and sales milestone payments and royalties payable to VOOM LLC as well as a liability payable to Oculos Clinical Research and unpaid Seller transaction expenses.

The minimum purchase price for the transaction was $12,500,000 which was payable less the liability payable to Oculos Clinical Research less all Sellers' transaction expenses, plus an earn-out based on specified percentages of net sales once regulatory approval has been given regarding commercialization, the Company determined that the earn-out was not probable on October 24, 2017 or as of December 31, 2017.

The Company evaluated the acquisition of the RevitaLid assets under ASC 805, *Business Combinations* and ASU 2017-01 and concluded that as substantially all of the fair value of the gross assets acquired is concentrated in an identifiable group of similar assets, the transaction did not meet the requirements to be accounted for as a business combination and therefore was accounted for as an asset acquisition. Accordingly, the purchase price of the RevitaLid assets, along with transaction costs of $681,952 were allocated over the relative fair value of the identified group of assets as follows:

In-process research and development	$ 12,500,000
Net deferred tax assets and liabilities	3,872,476
Total assets acquired	$ 16,372,476

The acquired IPR&D was deemed to have no alternative future uses, thus, pursuant to ASC 730, *Research and Development*, $16,372,476 was recorded as an expense after the acquisition date and included in Research and development expenses in the Consolidated Statements of Operations and Comprehensive Loss. The deferred tax liability of $5,566,642, a component of the net deferred tax assets and liabilities acquired, was subsequently removed and included as a component of the income tax benefit for the year ended December 31, 2017.

Note 4. 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 60 days of invoice date.

The following table disaggregates revenue from contracts with customers by pharmaceutical products:

	Year Ended December 31,	
Pharmaceutical Product	**2018**	**2017**
Venlafaxine ER	$ 66,039,604	$ 96,054,161
Methylphenidate ER	129,468,673	43,711,097
Lorzone	17,171,894	22,275,831
Divigel	23,313,679	18,541,774
OB Complete	10,509,824	10,446,364
Other	14,894,531	46,641,951
Net product sales	261,398,205	237,671,178
Royalty revenue	1,958,571	6,449,095
License and contract revenue	344,573	1,628,759
Total revenues	$ 263,701,349	$ 245,749,032

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 deferred revenue as of December 31, 2018 and 2017. Upon adoption of ASC Topic 606, the Company did not have any contract assets or liabilities. 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, 2018. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs.*

Note 5. 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, doubtful accounts 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.

With the exception of the provision for doubtful accounts, 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:

	December 31, 2018	December 31, 2017
Gross trade accounts receivable		
Trade accounts receivable	$ 146,419,682	$ 110,592,198
Royalty accounts receivable	238,960	25,712
Other receivable	1,562,287	4,161,368
Less reserves for:		
Chargebacks	(38,861,232)	(32,342,377)
Commercial rebates	(49,231,445)	(39,233,419)
Discounts and allowances	(3,510,242)	(3,484,587)
Doubtful accounts	(194,144)	(2,080,938)
Total trade accounts receivable, net	$ 56,423,866	$ 37,637,957

Subsequent to the issuance of the 2017 consolidated financial statements, the Company determined that a reclassification was required to correct disclosure of the components of the royalty and other accounts receivable. These reclassifications had no effect on net earnings, cash flows or the Company's financial position as previously reported.

For the years ended December 31, 2018 and 2017, the Company recorded the following adjustments to gross product sales:

	Year Ended December 31,	
	2018	2017
Gross product sales	$ 948,560,626	$ 646,701,628
Less provisions for:		
Chargebacks	(365,042,883)	(202,366,801)
Government rebates	(18,582,352)	(26,007,632)
Commercial rebates	(257,916,721)	(134,525,716)
Product returns	(20,492,281)	(26,299,811)
Discounts and allowances	(20,245,486)	(15,387,024)
Advertising and promotions	(4,882,698)	(4,443,466)
Net product sales	$ 261,398,205	$ 237,671,178

For the years ended December 31, 2018 and 2017, the activity in the Company's allowance for customer deductions against trade accounts receivable is as follows:

	Chargebacks	Commercial Rebates	Discounts and Allowances	Doubtful Accounts	Total
Balance at January 1, 2017	$ 24,311,153	$ 30,552,734	$ 3,631,326	$ 4,910,478	$ 63,405,691
Provision	202,366,801	134,525,716	15,387,024	832,388	353,111,929
Charges processed	(194,335,577)	(125,845,031)	(15,533,763)	(3,661,928)	(339,376,299)
Balance at December 31, 2017	32,342,377	39,233,419	3,484,587	2,080,938	77,141,321
Provision	365,042,883	257,916,721	20,245,486	(1,771,487)	641,433,603
Charges processed	(358,524,028)	(247,918,695)	(20,219,831)	(115,307)	(626,777,861)
Balance at December 31, 2018	$ 38,861,232	$ 49,231,445	$ 3,510,242	$ 194,144	$ 91,797,063

The annual activity in the Company's accrued liabilities for customer deductions by account for the years ended December 31, 2018 and 2017, is as follows:

	Product Returns	Government Rebates	Total
Balance at January 1, 2017	$ 30,340,749	$ 6,485,749	$ 36,826,498
Provision	26,299,811	26,007,632	52,307,443
Charges processed	(13,341,236)	(18,341,667)	(31,682,903)
Balance at December 31, 2017	$ 43,299,324	$ 14,151,714	$ 57,451,038
Provision	20,492,281	18,582,352	39,074,633
Charges processed	(15,328,096)	(22,753,190)	(38,081,286)
Balance at December 31, 2018	$ 48,463,509	$ 9,980,876	$ 58,444,385

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. Chargeback, rebate claims and certain other gross to net items are not submitted by customers with sufficient details to link the accrual recorded at the point of sale with the settlement of the accrual. As a result, the Company is unable to reasonably determine the dollar amount of the change in estimate in its gross to net reporting reflected in its results of operations for each period presented, and, those changes could be significant. However, the Company uses a combination of factors and applications to estimate the dollar amount of reserves for chargebacks and rebates at each month end. 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.

Note 6. Inventories

The components of inventories, net of allowances, are as follows:

	December 31, 2018	December 31, 2017
Finished goods	$ 15,577,104	$ 10,467,243
Work in process	1,138,906	789,413
Raw materials and supplies	7,667,011	5,690,214
	$ 24,383,021	$ 16,946,870

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, 2018 and 2017, was as follows:

	Year Ended	
	December 31, 2018	December 31, 2017
Balance at beginning of year	$ 3,066,620	$ 7,754,596
Provision	2,926,472	9,183,372
Charges processed	(4,432,010)	(13,871,348)
Balance at end of year	$ 1,561,082	$ 3,066,620

Note 7. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following:

	Year Ended December 31,	
	2018	2017
Land	$ 2,120,000	$ 2,120,000
Buildings	11,567,677	11,363,109
Leasehold improvements	2,109,106	2,095,784
Machinery	13,851,886	11,495,856
Furniture, fixtures and equipment	1,447,819	266,314
Computer hardware and software	6,984,055	5,838,823
	38,080,543	33,179,886
Accumulated depreciation	(10,235,900)	(5,852,660)
	27,844,643	27,327,226
Construction in progress	3,418,789	4,082,907
	$ 31,263,432	$ 31,410,133

Depreciation expense was $4,476,813 and $3,069,223 for the years ended December 31, 2018 and 2017, respectively. There is approximately $1,502,000 of remaining construction in progress expenditures to substantially complete the projects.

Note 8. 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. As further described below, in December 2018, changes in events and circumstances made it more likely than not goodwill had been impaired. As a result we recognized a goodwill impairment charge of $86,318,000. The following table sets forth the carrying value of goodwill as of December 31, 2018 and 2017, respectively.

	Goodwill
January 1, 2017	$ 187,172,816
Impairments	—
December 31, 2017	187,172,816
Impairments	(86,318,000)
December 31, 2018	$ 100,854,816

The following table sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of December 31, 2018 and 2017, for those assets that are not already fully amortized:

	December 31, 2018					
	Gross Carrying Amount	Accumulated Amortization	Reclassifications	Impairment	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Distribution Rights	$ 98,433,377	$ (17,229,374)	$ —	$ —	$ 81,204,003	12.0
Product Rights	326,530,149	(109,056,754)	—	—	217,473,395	4.0
Tradenames	13,485,000	(2,329,284)	—	—	11,155,716	16.0
Developed Technology	138,133,333	(30,973,516)	—	(10,303,208)	96,856,609	12.6
IPR&D	91,300,000	—	—	(7,600,000)	83,700,000	Indefinite Lived
	$667,881,859	$(159,588,928)	$ —	$(17,903,208)	$490,389,723	

The gross carrying amount and accumulated amortization in the table above is inclusive of $6,156,564 of accumulated amortization for assets that have been fully impaired as of December 31, 2018.

	December 31, 2017					
	Gross Carrying Amount	Accumulated Amortization	Reclassifications	Impairment	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Distribution Rights	$ 98,433,377	$ (9,890,282)	$ —	$ —	$ 88,543,095	13.0
Product Rights	69,558,325	(49,902,094)	264,100,000	(7,128,176)	276,628,055	5.4
Tradenames	13,485,000	(1,623,368)	—	—	11,861,632	17.1
Developed Technology	146,900,000	(21,077,405)	—	(8,766,667)	117,055,928	13.1
IPR&D	412,025,436	—	(264,100,000)	(56,625,436)	91,300,000	Indefinite Lived
	$740,402,138	$(82,493,149)	$ —	$(72,520,279)	$585,388,710	

The gross carrying amount and accumulated amortization in the table above is inclusive of $3,786,772 of accumulated amortization for assets that have been fully impaired in 2017.

Changes in intangible assets during the years ended December 31, 2018 and 2017, were as follows:

	Distribution Rights	Product Rights	Tradenames	Developed Technology	IPR&D	Total
January 1, 2017	$95,741,106	$ 44,091,974	$12,759,363	$136,672,033	$ 412,025,436	$701,289,912
Acquisitions	—	—	—	—	16,372,476	16,372,476
Amortization	(7,198,011)	(24,435,743)	(897,731)	(10,849,438)	—	(43,380,923)
Impairments	—	(7,128,176)	—	(8,766,667)	(56,625,436)	(72,520,279)
Reclassifications (A)	—	264,100,000	—	—	(264,100,000)	—
Expensed (B)	—	—	—	—	(16,372,476)	(16,372,476)
December 31, 2017	$88,543,095	$276,628,055	$11,861,632	$117,055,928	$ 91,300,000	$585,388,710
Amortization	(7,339,092)	(59,154,660)	(705,916)	(9,896,111)	—	(77,095,779)
Impairments	—	—	—	(10,303,208)	(7,600,000)	(17,903,208)
December 31, 2018	$81,204,003	$217,473,395	$11,155,716	$ 96,856,609	$ 83,700,000	$490,389,723

(A) IPR&D related to the methylphenidate ER asset group was reclassified to Product Rights at the time the product was launched. The amount will be amortized over the estimated useful life of 7 years which was determined to be the period in which the Product Rights are expected to contribute to cash flow. The amount will be amortized on an accelerated method based on estimated pattern of cash flows.

(B) The amount acquired for IPR&D in the RevitaLid Asset Acquisition was deemed to have no alternative future uses, thus the full amount was expensed (see Note 3).

The Company tests goodwill and indefinite-lived intangible assets for impairment annually on October 1st, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired.

As part of the Company's goodwill and intangible asset impairment assessments and when IPR&D assets are put into service, the Company estimates the fair values of the reporting unit and 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 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. The discount rates applied to the estimated cash flows for the Company's October 1, 2018 and 2017 annual goodwill and indefinite-lived intangible assets impairment test ranged from 14.0% to 9.0%, respectively, depending on the overall risk associated with the particular assets and other market factors. 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.

In December 2018, we determined that, subsequent to our annual impairment testing, circumstances and events related to pricing on certain of our generic assets together with our decision to discontinue commercialization of a developed technology asset, and discontinue development of an IPR&D asset, made it more likely than not that goodwill had become impaired. As a result, we performed an assessment of goodwill as of December 31, 2018. Based on the results of this assessment, it was determined that the carrying value of goodwill exceeded its fair value by approximately $86.3 million and an impairment charge was recognized for the year end December 31, 2018.

During the fourth quarter of 2017, the Company performed an evaluation of the carrying value of the intangible assets acquired. After completing the valuations, the Company realized the net present value of the intangible assets had decreased below the net book value and thus impaired the intangible assets. Product Rights, Developed Technologies, and IPR&D had been impaired by $7,128,176, $8,766,667, and $56,625,436 respectively due to lower than expected cash flows and, in the case of IPR&D, delays in the anticipated timing of development.

Amortization expense was $77,095,779 and $43,380,923 for the years ended December 31, 2018 and 2017, respectively.

The amortization expense of acquired intangible assets for each of the following five years are expected to be as follows:

Years ending December 31	Amortization Expense
2019	$ 68,899,197
2020	67,512,249
2021	65,348,168
2022	43,107,441
2023	38,906,920
Thereafter	122,915,748
Total	$ 406,689,723

Note 9. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2018	December 31, 2017
Accrued product returns	$ 48,463,509	$ 43,299,324
Accrued royalties	3,597,957	12,325,232
Accrued compensation	8,672,913	6,342,731
Accrued government rebates	9,980,876	14,151,714
Accrued research and development	8,337,812	1,248,800
Accrued expenses and other liabilities	7,362,941	3,904,556
Customer coupons	719,578	425,911
Deferred revenue	101,354	228,122
Total	$ 87,236,940	$ 81,926,390

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 10. Financing Arrangements

The composition of the Company's debt and financing obligations are as follows:

	December 31, 2018	December 31, 2017
CIT Bank, N.A. Term Loan, net of deferred financing costs of $4,557,025 and $6,894,816 as of December 31, 2018 and December 31, 2017, respectively	$ 266,802,911	$ 320,605,185
Note payable — insurance financing	1,774,199	—
	268,577,110	320,605,185
Less: current portion	(1,774,199)	(6,655,604)
Long-term debt	$ 266,802,911	$ 313,949,581

Term Loan

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a $160,000,000 Term Loan (the "Term Loan") pursuant to a Credit Agreement dated February 3, 2016 (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. As of December 31, 2016, this rate was 6.00%.

For the year ended December 31, 2016, the Company incurred debt issuance costs associated with the Term Loan Agreement in the amount of $5,734,332, which were deferred and are amortized over the length of the Term Loan using the effective interest method.

On November 10, 2016, the Company amended the Term Loan Agreement (the "Amended Term Loan Agreement") in conjunction with the reacquisition of venlafaxine distribution rights. Pursuant to the Amended 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.

The Company accounted for the Amended Term Loan Agreement as a modification of debt in accordance with ASC 470-50, Debt — Modifications and Extinguishments. In accordance with modification guidance detailed in ASC 470-50, lender fees incurred in the amount of $4,000,000 were deferred and are amortized over the length of the Term Loan using the effective interest rate method. In addition, the Company incurred third party fees associated with the Amended Term Loan Agreement in the amount of $398,558, which were expensed as professional fees in accordance with modification guidance and included in selling, general and administrative expense during the year ended December 31, 2016.

On April 28, 2017, the Company amended the Amended Term Loan Agreement (the "Second Amended 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 Amended Term Loan Agreement.

Furthermore, on December 21, 2017, the Company amended the Second Amended Term Loan Agreement (the "Third Amended Term Loan Agreement"). Pursuant to the Third Amended 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 will be designated as the Term A Loan and $50,000,000 will be designated as the Term B Loan.

The Third Amended 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 Third Amended 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 an 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 Third Amended 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, 2018 and 2017, the interest rates were 6.09% and 5.25% for Term A Loan and 6.59% and 5.75% for Term B Loan, respectively.

The Company accounted for the Third Amended Term Loan Agreement as a modification of debt in accordance with ASC 470-50, Debt — Modifications and Extinguishments. In accordance with modification guidance detailed in ASC 470-50, lender fees incurred in the amount of $3,126,000 were deferred and are amortized over the length of the Term Loan using the effective interest rate method. In addition, deferred financing fees and a prepayment premium in the total amount of $4,981,624 were charged to other non-operating (loss)/income, net during the year ended December 31, 2017, as certain previous lenders did not participate in the Third Amended Term Loan. In addition, the Company incurred third party fees associated with the Third Amended Term Loan Agreement in the amount of $389,234, which were expensed as professional fees in accordance with modification guidance and included in selling, general and administration expense during the year ended December 31, 2017.

The Third Amended 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 Third Amended 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 1.25:1.00 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 not incur a waiver fee as a condition to the waiver. The Company was in compliance with all covenants of the Third Amended Term Loan Agreement as of December 31, 2018.

On October 31, 2018, the Company used a portion of the proceeds resulting from the IPO on October 22, 2018 to repay $50,000,000 in aggregate of the outstanding principal amount and $1,787,924 of accrued interest of indebtedness under the Company’s senior secured credit facilities.

The prepayments made on October 31, 2018 were as follows: (1) $42,278,907 and $1,492,597 on Term Loan A outstanding principal and accrued interest, respectively, and (2) $7,721,093 and $295,327 on Term Loan B outstanding principal and accrued interest respectively. The prepayments were made on a pro rata basis which is consistent with the requirements of the Third Amendment. The prepayments were applied to the remaining scheduled installments of principal due in respect of the Term Loans of such class in direct order of maturity. As a result, there are no remaining scheduled installments of principal due in respect of the Term Loans until the final maturity date. The Company will 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. The balance of the debt issuance costs as of the date of the partial prepayment made on October 31, 2018 was $5,627,508.

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. At the time of repayment, the Company wrote off $875,576 in debt issuance costs 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 $30,000,000 (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 $1,075,187, 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 $50,000,000. 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 $437,500 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, $5,000,000 and (y) the total revolving commitment, based on certain terms and conditions of the Credit Agreement.

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 is as follows:

Total Leverage Ratio	LIBOR Rate Margin	ABR Margin
Category 1 Greater than 2.00 to 1.00	3.75 %	2.75 %
Category 2 Equal to or less than 2.00 to 1.00	3.25 %	2.25 %

At December 31, 2018 and 2017, there were no outstanding borrowings or outstanding letters of credit. Availability under the Revolving Facility as of December 31, 2018, was $50,000,000.

Subordinated Note

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a $40,000,000 Subordinated Note Purchase Agreement (the "Subordinated Note") between the Company as borrower and Newstone Capital Partners, LLC. Interest on the outstanding principal balance of the Subordinated Note accrues, at the Company's election, at a rate equal to ABR plus a margin of 9.00% or LIBOR plus a margin of 10.00%. As of December 31, 2016, the effective interest rate on the Subordinated note was 11.00%. The Subordinated Note was to mature on February 3, 2023. As part of the Third Amended Term Loan Agreement, the Subordinated Note was paid in full including associated accrued interest. $1,159,557 and $800,000 of deferred financing and prepayment costs, respectively, associated with the Subordinated Note was expensed in accordance with ASC 470-50, Debt — Modifications and Extinguishments and included in the total amount of $4,981,624 as a component of other non-operating (loss) income, net on the accompanying Consolidated Statement of Operations and Comprehensive Loss.

Promissory Notes

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into four promissory note agreements (collectively the "PIK Notes") for total proceeds of $25,000,000. The PIK Notes are identical to each other with exception for the Lender (as identified below) and principal sum. Interest accrued on a

daily basis at a rate equal to 18% per annum on the unpaid principal balance of the PIK Notes outstanding. The lenders and principal sum of the PIK Notes are below:

Lender	Principal Sum
Altchem Limited (Cyprus)	$ 12,500,000
ACP III AIV, L.P.	7,661,834
ACP Holdco (Offshore), L.P.	4,272,166
Newstone Capital Partners II, L.P.	566,000
	$ 25,000,000

As part of the Third Amended Term Loan Agreement, the PIK Notes were paid in full including associated accrued in-kind interest that had been accrued and capitalized in a total amount of $9,321,500.

Aggregated cumulative maturities of long-term obligations (including the incremental and existing Term Loan and the Revolving Facility), excluding deferred financing costs of $4,557,025, as of December 31, 2018 are:

Years ending December 31,	Maturities of Long-term Obligations
2019	$ 1,774,199
2020	—
2021	—
2022	271,359,936
Total	$ 273,134,135

Note 11. Concentrations and Credit Risk

For the years ended December 31, 2018 and 2017, 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, 2018 and 2017 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,	
	2018	2017
Amerisource Bergen	7 %	23 %
Cardinal Health	55 %	37 %
McKesson	34 %	32 %
Combined Total	96 %	92 %

	Gross Account Receivables	
	December 31, 2018	December 31, 2017
Amerisource Bergen	6 %	7 %
Cardinal Health	61 %	57 %
McKesson	29 %	29 %
Combined Total	96 %	93 %

Purchasing

For the year ended December 31, 2018, four suppliers accounted for more than 96% of the Company's purchases of raw materials for products that are manufactured by the Company.

Three suppliers accounted for more than 91% of the Company's purchases of raw materials manufactured by the Company for the year ended December 31, 2017.

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, 2018 and 2017, one product accounted for 66% and 15%, 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, 2018 and 2017, respectively:

	Year ended December 31, 2018	
	Gross Royalty Revenue	Gross Royalty Accounts Receivable
Customer 4	36 %	43 %
Customer 5	31 %	30 %
Customer 6	— %	— %
Combined Total	67 %	73 %

	Year ended December 31, 2017	
	Gross Royalty Revenue	Gross Royalty Accounts Receivable
Customer 4	54 %	NM %
Customer 5	14 %	NM %
Customer 6	21 %	NM %
Combined Total	89 %	— %

Note 12. Incentive Plans

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

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.

Share-based Compensation

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. The compensation cost that has been charged against income for those incentive plans was $1,965,346 for the year ended December 31, 2018, $1.2 million of which related to share based compensation incurred prior to the IPO related to the fiscal year 2018. The total income tax benefit recognized in the statement of operations and comprehensive loss for share-based compensation arrangements was $439,318 for the year ended December 31, 2018. 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, 2018, and changes during the year then ended is presented below:

2016 Equity Incentive Plan	Number of Units			Weighted Average Exercise Price	Weighted Average Contractual Term
	Time	Performance	Total		
Outstanding at December 31, 2016	35,650	35,650	71,300	$ —	
Granted	3,150	3,150	6,300	646	
Exercised	—	—	—	—	
Expired / Forfeited	(2,700)	(2,700)	(5,400)	640	
Outstanding at December 31, 2017	36,100	36,100	72,200	$ —	8.3 years
Granted	—	—	—	—	
Exercised	—	—	—	—	
Expired / Forfeited	(900)	(900)	(1,800)	640	
Outstanding at date of conversion	35,200	35,200	70,400	641	
Unit options converted to share options	1,507,786	1,507,786	3,015,572	14.96	
Performance options modified to time options	1,507,786	(1,507,786)	—	14.96	
Granted	—	—	—	—	
Exercised	—	—	—	—	
Expired / Forfeited	—	—	—	—	
Outstanding at December 31, 2018	3,015,572	—	3,015,572	—	7.5 years
Vested Options at December 31, 2018	720,131	—	720,131	$ 14.96	

There were no options granted during 2018 under the 2016 Plan. The weighted-average grant-date fair value of options granted during 2018 under the 2016 Plan was $184.69.

A summary of option activity granted under the 2018 Plan as of December 31, 2018, and changes during the year then ended is presented below:

	Number of Shares			Weighted Average Exercise Price	Weighted Average Contractual Term
	Time	Performance	Total		
Outstanding at December 31, 2017	—	—	—	$ 7.00	
Granted	179,700	—	179,700	—	
Exercised	—	—	—	—	
Expired / Forfeited	(1,100)	—	(1,100)	7.00	
Outstanding at December 31, 2018	178,600	—	178,600	$ —	9.8 years
Vested Options at December 31, 2018	—	—	—	$ 7.00	

The weighted-average grant-date fair value of options granted during 2018 under the 2018 Plan was $3.82.

As of December 31, 2018, there was $5,062,986 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 9.8 years.

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. Options granted or modified under the 2016 Plan and 2018 Plan during the years ended December 2018 and 2017 were valued using the Black-Scholes option-pricing model with the following assumptions:

	Years ended December 31,	
	2018	2017
Expected volatility	50% - 63.1 %	50% - 55 %
Risk-free interest rate	3.03% - 3.11 %	1.94% - 2.27 %
Expected dividend yield	— %	— %
Expected life of options in years	5.02 - 7.00	6.25

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. The expected option term assumption is estimated using the simplified method and is based on the mid-point between vest date and the remaining contractual term of the option, since the Company does not have sufficient exercise history to estimate expected term of its historical option awards.

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 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.

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, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
Unit options to purchase units	—	74,200
Options to purchase ordinary shares	3,193,072	—

Note 14. Commitments and Contingencies

The Company leases its New Jersey office and warehouse facilities under non-cancelable leases that expire in July 2022 and December 2023, respectively. On September 6, 2018, the Company entered into a sublease agreement to lease additional office space in its New Jersey location that expires November 2023. The Company also leases office and warehouse facilities in Tampa, Florida, under a non-cancelable lease that expires in October 2023. The Company also leases its Argentina office and warehouse facilities which originally expired in December 31, 2014, but the contract was amended to extend to December 31, 2020. The Company also leases its Hungary office and warehouse facilities which expired on February 15, 2017 and automatically renewed for a two-year term. The lease will continue to renew for successive two-year periods unless either party elects not to renew. The Company also leases its North Carolina office and warehouse facilities that expires on July 31, 2019. In 2018, the Company began leasing vehicles under a cancelable fleet lease that has successive one-year renewal terms. The lease may be terminated by either party by providing written notice to the other.

Total rent expense charged to selling, general and administrative expenses was $1,000,994 and $598,159 for the years ended December 31, 2018 and 2017, respectively. Total rent expense charged to research and development was $229,448 and $273,706 for the years ended December 31, 2018 and 2017, respectively. The rent expense charged to cost of goods sold was $343,793 and $372,429 the years ended December 31, 2018 and 2017, respectively. The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the leases as of December 31, 2018:

Years ending December 31	Operating Leases
2019	$ 1,997,564
2020	1,371,444
2021	1,084,566
2022	859,184
2023	490,514
Thereafter	—
Total	$ 5,803,272

Capital Leases

Amortization of assets held under the capital lease is included in depreciation expense as a component of selling, general and administrative expenses. The Company has future minimum lease payments for the year ended December 31, 2018 required under the capital leases together with its present value of the net minimum lease payments of $257,293.

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 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.

Royalty Obligations

The Company has agreements with third parties that require the Company to make minimum royalty payments on a calendar year basis.

The following table lists the Company's enforceable and legally binding royalty obligations as of December 31, 2018:

	Royalty Obligations
Less than 1 year	$ 1,375,000
1 to 3 years	3,188,000
3 to 5 years	3,000,000
More than 5 years	1,083,000
Total	$ 8,646,000

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 following table lists the Company's enforceable and legally binding purchase obligations as of December 31, 2018:

	Purchase Obligations
Less than 1 year	$ 4,000,000
1 to 3 years	—
3 to 5 years	—
Total	$ 4,000,000

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, 2018 and 2017, the Company recognized expenses related to its contributions under the Plan of $1,076,677 and $896,632, 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.

Osmotica was a party to patent infringement litigation in the U.S. District Court for the Northern District of Georgia with Shire Development, LLC ("Shire") over the Company's proposed delayed-release mesalamine abbreviated new drug application ("ANDA") product which is a generic version of Shire's LIALDA®. (*Shire Development LLC et al. v. Osmotic Pharmaceutical Corp.*, No. 1-12-cv-00904 (N.D. Georgia, filed March 16, 2012)). The litigation over the mesalamine product was limited to one (1) patent, U.S. Patent No. 6,773,720 (the "720 Patent"), which is directed to a particular controlled-release formulation. Absent invalidation by a generic challenger, the '720 Patent will expire on June 8, 2020.

On March 29, 2017, Osmotica sent a notice to the FDA requesting that their ANDA be withdrawn, and on March 31, 2017, Osmotica received confirmation from FDA that the ANDA was withdrawn. On May 5, 2017, Osmotica was dismissed from the litigation, as such no loss or accrual was deemed necessary.

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. 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.

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 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:

	December 31, 2018	December 31, 2017
Loss before income taxes		
U.S. operations	$ (52,758,931)	$ (41,276,187)
Non-U.S. operations	(65,905,252)	(44,366,355)
Total loss before income taxes	(118,664,183)	(85,642,542)
Current provision		
Federal	4,039,243	2,198,256
State	1,537,683	212,416
Foreign	1,808,761	1,595,246
Total current tax expenses	7,385,687	4,005,918
Deferred (benefit) provision		
Federal	(8,962,037)	(41,477,737)
State	(4,005,413)	(3,282,520)
Foreign	(3,686,154)	(3,746,392)
Total deferred tax benefit	(16,653,604)	(48,506,649)
Total benefit for income taxes	$ (9,267,917)	$ (44,500,731)

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2018 and 2017 respectively are as follows:

	December 31, 2018	December 31, 2017
Federal tax at 34% statutory rate	21.00 %	34.00 %
State and local income taxes, net of federal benefit	1.68 %	2.37 %
Differences in tax effects on foreign income	(10.08)%	(14.79)%
Federal tax credits	4.54 %	8.69 %
Uncertain tax positions — interest & penalties	(0.08)%	(0.07)%
Enacted change in statutory rates	0.00 %	22.24 %
Change in valuation allowance	0.00 %	0.00 %
Permanent adjustments	(8.70)%	0.09 %
Other	(0.55)%	(0.57)%
Effective tax rate	7.81 %	51.96 %

For the year ended December 31, 2018 differences between the Federal statutory income tax rate of 21% and the effective tax rate are primarily due to the foreign tax rate differential and Orphan Drug/Research & Development federal credits.

For the year ended December 31, 2017, differences between the Federal statutory income tax rate of 34% and the effective tax rate are primarily due to the enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act ("TCJA"), foreign tax rate differential and a change in estimate with regard to the prior year Orphan Drug credit. In December 2017, the Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allowed us to record provisional amounts during a measurement period not to exceed beyond one year of the enactment date. In the fourth quarter of 2018, we completed our analysis to determine the effect of the 2017 Tax Act, which did not require any adjustments as of December 31, 2018.

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, 2018 and 2017 respectively are as follows:

	December 31, 2018	December 31, 2017
Deferred tax assets:		
Accounts receivable	$ 44,241	$ 495,373
Accrued expenses	12,640,052	11,259,586
Inventory	490,574	341,539
Investment in partnership	9,536,754	7,730,044
Net operating losses	3,742,237	5,716,378
Tax credits	4,616,722	9,091,441
Share compensation	439,318	—
Other	2,634,429	1,932,521
Less: valuation allowance	(298,219)	(137,061)
Deferred tax liabilities:		
Prepaid expenses	(828,216)	(9,200,249)
Property plant & equipment	(3,002,215)	(2,827,186)
Intangible assets	(56,253,518)	(67,293,830)
Total deferred income taxes	$ (26,237,841)	$ (42,891,444)

On December 22, 2017, the U.S. enacted the TCJA, which resulted in the revaluation of the Company's U.S. related deferred tax assets and liabilities and had an impact on the Company's total 2017 tax benefit.

Included in the deferred tax balances above is a net deferred tax liability of $30,289,469 and $44,655,585 respectively for 2018 and 2017 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, 2018 and 2017, the Company had a federal net operating loss carryover of $3.3 million and $4.4 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of approximately $30.5 million and $90.2 million, respectively which will begin to expire in 2022. At December 31, 2018 and 2017, the Company had total tax credit carryovers of approximately $4.6 million and $9.1 million primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers begin to expire in 2036. 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, 2018 and 2017, the Company maintains valuation allowances on deferred tax assets applicable to entities in 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 2018, the valuation allowance increased by $1.8 million due to incremental net operating losses applicable to entities in foreign jurisdictions.

The Company leverages its significant resources in research and development and proprietary drug delivery technology to address the growing need of the global patient population. The Company completed a tax evaluation project for its year ended December 31, 2017 to determine its appropriate research and development credits for the Orphan Drug and Research & Development credit. This project resulted in the engagement of professional technical experts and the investment in significant time to evaluate historical records to identify the maximum credits as permitted by the relevant tax law. This project was concluded in connection with the preparation of the current year financial statements. As a result of the significant effort required to attain, validate and conclude on the appropriate credits, the Company considers the results of the tax project to be new information and therefore the results of such project are recorded in the current year as a change in accounting estimate. In the year ended December 31, 2017, the adjustment recorded was an increase in tax credits of approximately $5.7 million net of a reduction in income tax expense of approximately $2.7 million for a net tax effect of $3.0 million.

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 2014 through 2017 tax years remain open for examination by the tax authorities under the normal statute of limitations. For certain international income tax purposes, the Company's 2010 through 2017 tax years remain open for examination by the tax authorities under the normal statute of limitations.

No provision is made for foreign withholding or income taxes associated with the cumulative undistributed earnings of the foreign subsidiaries. The cumulative undistributed earnings, if any, are expected to be reinvested in working capital and other business needs indefinitely. 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, 2018 and 2017. 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 $1.5 million would have no impact on the effective tax rate.

Note 16. Related Parties

As of December 31, 2018 and 2017, respectively, the Company had a $83,818 and $125,000 accrued liability which comprised of quarterly advisory and monitoring fees payable to shareholders. Further, the Company leases its Argentina office and warehouse space facilities through a related party lease. The term of the operating lease is through December 31, 2020. For the years ended December 31, 2018 and 2017, the Company incurred rent expense of $246,092 and $325,838, respectively.

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 valued at approximately $2.4 million.

In 2016 the Company entered into a two-year consulting agreement with two Vertical/Trigen shareholders. The term of the agreement requires a compensation rate of $20,833 per month and is a component of the selling, general and administrative expenses. This agreement terminated in January 2018.

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, 2018. 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, 2018, 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

On January 1, 2018, we adopted Accounting Standards Codification 606, *Revenue from Contracts with Customers*, and as a result, we have incorporated internal controls over significant process changes for revenue recognition that we believe to be appropriate and necessary in consideration of the related integration of the new standard.

In connection with the preparation of our audited financial statements as of and for the years ended December 31, 2017 and 2016, we identified a material weakness in our period-end financial closing process related to our lack of sufficient available resources in our accounting and financial reporting functions with sufficient experience and expertise with respect to the application of GAAP and related financial reporting to ensure that we identified, accumulated and timely prepared and reviewed all required supporting information to establish the completeness and accuracy of our consolidated financial statements and disclosures.

We have identified and implemented the actions described below to remediate the underlying causes of the control deficiencies that gave rise to the material weakness. To address the material weakness, we:

- hired additional personnel and engaged external consultants who possess the requisite skills in certain technical areas important to our financial reporting;

- assessed the required training needs to provide for the continued development of our finance personnel;

- performed a comprehensive review of current procedures to ensure compliance with our accounting policies and GAAP;

- improved the process of reviewing the consolidation, supporting schedules and related reconciliations in our financial reporting;

- enhanced existing and continue developing additional monitoring controls to provide reasonable assurance that we maintain sufficient oversight of the performance of internal control over financial reporting responsibilities;

- reassessed our existing framework used to identify and implement corrective actions on a timely, prioritized basis with defined accountability; and

- designed and implemented enhanced controls over the preparation, analysis and review of significant accounts that operate at the appropriate level of precision to prevent or detect a material misstatement of such balances at period end.

Based on the aforementioned actions, management has therefore concluded that the previously reported material weakness in internal controls over financial reporting related to our lack of sufficient available resources in our accounting and financial reporting functions with sufficient experience and expertise with respect to the application of GAAP and related financial reporting for our period-end financial closing process had been remediated as of December 31, 2018.

Except as described above, 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, 2018 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

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Brian Markison, 59, 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 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., 58, 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, 59, 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, 37, 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, 55, 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.

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 2018 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

Financial Statement Schedules

None

ITEM 16. FORM 10-K SUMMARY

None

Exhibits

Exhibit No.	Description
2.1#	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. (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)
2.2#†	Stock Purchase Agreement, dated as of October 24, 2017, by and between Revitalid, Inc. and Osmotica Pharmaceutical Corp. (incorporated by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
3.1	Memorandum and Articles of Association Osmotica Pharmaceuticals plc
4.1	Shareholders' Agreement
4.2	Form of Ordinary Share Certificate (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)
10.1†	License, Supply, Marketing, Distribution and Collaboration Agreement, dated as of November 24, 2003, by and between Upsher-Smith Laboratories, Inc. and Orion Corporation (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	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 (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	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 (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†	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 (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†	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 (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)
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 Szolgalato 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)
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	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)
10.21	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)
10.22	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)
10.23	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)
10.24	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)
10.25	Form of Osmotica Holdings US LLC Director and Corporate Secretary Indemnification Agreement (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1/A filed on October 17, 2018, Commission File No. 333-227357)
10.26	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)
10.27	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)
10.28	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)

10.29	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)
10.30	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)
10.31	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)
10.32+	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)
10.33+	Employment Agreement, dated December 16, 2013, by and between Vertical/Trigen Opco, 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)
10.34+	Employment Agreement, dated May 2, 2016, by and between Vertical/Trigen Opco, 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)
21.1	Subsidiaries of Osmotica Pharmaceuticals plc
23.1	Consent of BDO USA, LLP independent registered public accounting firm
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 Exension 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

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.

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 27, 2019

By: /s/ Brian Markison
Brian Markison
Chief Executive Officer

Dated: March 27, 2019

By: /s/ Andrew Einhorn
Andrew Einhorn
Chief Financial 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 27, 2019.

Signatures	Capacity in Which Signed
/s/ Brian Markison Brian Markison	Chief Executive Officer and Director (Chairman) (Principal Executive Officer)
/s/ Andrew Einhorn Andrew Einhorn	Chief Financial Officer (Principal Financial Officer and Accounting Officer)
/s/ David Burgstahler David Burgstahler	Director
/s/ Gregory L. Cowan Gregory L. Cowan	Director
/s/ Carlos Sielecki Carlos Sielecki	Director
/s/ Sriram Venkataraman Sriram Venkataraman	Director
/s/ Juan Vergez Juan Vergez	Director
/s/ Fred Weiss Fred Weiss	Director

Exhibit 3.1

A PUBLIC COMPANY LIMITED BY SHARES

CONSTITUTION

OF

OSMOTICA PHARMACEUTICALS PUBLIC LIMITED COMPANY

(adopted on 17 October 2018)

COMPANIES ACT 2014

A PUBLIC COMPANY LIMITED BY SHARES

MEMORANDUM OF ASSOCIATION

OF

OSMOTICA PHARMACEUTICALS PUBLIC LIMITED COMPANY

1. The name of the Company is Osmotica Pharmaceuticals public limited company.

2. The Company is a public limited company for the purposes of Part 17 of the Companies Act 2014.

3. The objects for which the Company is established are:

   3.1. To carry on the business of a holding company and to coordinate the administration, finances and activities of any subsidiary companies or associated companies, to do all lawful acts and things whatsoever that are necessary or convenient in carrying on the business of such a holding company and in particular to carry on, in all its branches, the business of a management services company, to act as managers and to direct or coordinate the management of other companies or of the business, property and estates of any company or person and to undertake and carry out all such services in connection therewith as may be deemed necessary or appropriate by the Company's board of directors and to exercise its powers as a shareholder of other companies.

   3.2. To carry on the business of a pharmaceuticals company and to research, develop, design, manufacture, produce, supply, buy, sell, distribute, import, export, provide, promote and otherwise deal in pharmaceuticals, active pharmaceutical ingredients and dosage pharmaceuticals and other devices or products of a pharmaceutical, medicinal or healthcare character and to hold intellectual property rights and to do all things usually done by persons carrying on the above mentioned activities or any of them or likely to be required in connection with any such activities.

   3.3. To invest in pharmaceutical and related assets, including, amongst other items, investments in pharmaceutical companies, products, businesses, divisions, technologies, devices, sales force and other marketing capabilities, development projects and related activities, licences, intellectual and similar property rights, premises and equipment, royalty rights and all other assets needed to operate a pharmaceuticals business.

   3.4. To establish, maintain and operate laboratories for the purposes of carrying on chemical, physical and other research in medicine, chemistry, industry or other unrelated or related fields.

   3.5. To invest (including long-term investments in, and acquisitions of, the shares or other securities or ownership interests in other companies) any monies of the Company in such investments and in such manner as may from time to time be determined, and to hold, sell or deal with such investments and generally to purchase, take on lease or in exchange or otherwise acquire any real and personal property and rights or privileges.

   3.6. To develop and turn to account any land acquired by the Company or in which it is interested and in particular by laying out and preparing the same for building purposes, constructing, altering, pulling down, decorating, maintaining, fitting up and improving buildings and conveniences, and by planting, paving, draining, farming, cultivating, letting on building lease or building agreement and by advancing money to and entering into contracts and arrangements of all kinds with builders, tenants and others.

3.7. To acquire and hold shares and stocks of any class or description, debentures, debenture stocks, bonds, bills, mortgages, obligations, investments, partnership interests, limited partnership interests, trust interests, membership interests and other securities or ownership interests of all descriptions and of any kind issued or guaranteed by any company or undertaking of whatever nature and wheresoever constituted or carrying on business or issued or guaranteed by any government, state, dominion, colony, sovereign ruler, commissioners, trust, public, municipal, local or other authority or body of whatever nature and wheresoever situated and investments, securities and property of all descriptions and of any kind, including real and chattel real estates, mortgages, reversions, assurance policies, contingencies and choses in action.

3.8. To remunerate by cash payments or allotment of shares or securities or other ownership interests (including rights to acquire shares or securities or other ownership interests) of the Company credited as fully paid up or otherwise any person or company for services rendered or to be rendered to the Company or any parent or subsidiary body corporate whether in the conduct or management of its business, or in placing or assisting to place or guaranteeing the placing of any of the shares of the Company's capital, or any debentures or other securities of the Company or in or about the formation or promotion of the Company.

3.9. To purchase for investment property of any tenure and any interest therein, and to make advances upon the security of land or other similar property or any interest therein.

3.10. To acquire by purchase, exchange, lease, fee, farm grant or otherwise, either for an estate in fee simple or for any less estate or other estate or interest, whether immediate or reversionary and whether vested or contingent, any lands, tenements or hereditaments of any tenure, whether subject or not to any charges or encumbrances, and to hold, farm, work and manage and to let, sublet, mortgage or charge land and buildings of any kind, reversions, interests, annuities, life policies, and any other property real or personal, movable or immovable, either absolutely or conditionally, and either subject or not to any mortgage, charge, ground rent or other rents or encumbrances.

3.11. To erect or secure the erection of buildings or other structures of any kind with a view of occupying or letting them or otherwise utilising them and to enter into any contracts or leases and to grant any licences necessary to effect the same.

3.12. To maintain and improve any lands, tenements or hereditaments acquired by the Company or in which the Company is interested, in particular by decorating, maintaining, furnishing, fitting up and improving houses, shops, flats, maisonettes and other buildings and structures and to enter into contracts and arrangements of all kinds with tenants and others.

3.13. To sell, exchange, mortgage (with or without power of sale), assign, turn to account or otherwise dispose of and generally deal with the whole or any part of the property, shares, stocks, securities, estates, rights or undertakings of the Company, real property, chattels real or personal, movable or immovable, either in whole or in part.

3.14. To take part in the management, supervision, or control of the business or operations of any company or undertaking, and for that purpose to appoint and remunerate any directors, accountants, or other experts or agents to act as consultants, supervisors and agents of other companies or undertakings and to provide managerial, advisory, technical, design, purchasing and selling services and any other services deemed appropriate by the Company.

3.15. To make, draw, accept, endorse, negotiate, issue, execute, discount and otherwise deal with bills of exchange, promissory notes, letters of credit, circular notes, and other negotiable or non-negotiable or transferable or non-transferrable instruments.

3.16. To redeem, purchase, or otherwise acquire in any manner permitted by law any shares in the Company's capital or other securities or ownership interests of any kind issued by the Company.

3.17. To guarantee, support or secure whether by personal covenant or by mortgaging or charging all or any part of the undertaking, property and assets (present and future) and uncalled capital of the Company or by both such methods, or by any other method whatsoever, the performance of the obligations of, and the repayment or payment of the principal amounts of and the premiums, interest, dividends and other amounts due on or with respect to any security of any person, firm or company, including any company which is for the time being the Company's holding company (as defined by section 8 of the Companies Act 2014) or subsidiary (as defined by section 7 of the Companies Act 2014) or another subsidiary as defined by the said section of the Company's holding company (as defined by section 8 of the Companies Act 2014) or otherwise associated with the Company in business notwithstanding the fact that the Company may not receive any consideration, advantage or benefit, direct or indirect from entering into such guarantee or other arrangement or transaction contemplated herein.

3.18. To lend the funds of the Company with or without security and at interest or free of interest.

3.19. To raise or borrow or secure the payment of money, including by the issue of bonds, debentures or debenture stock, perpetual or redeemable, or by mortgage, charge, lien or pledge upon the whole or any part of the undertaking, property, assets or rights of the Company, present or future, including its uncalled capital and generally in any other manner as the directors shall from time to time determine and to enter into or issue interest and currency hedging and swap agreements, forward rate agreements, interest and currency futures or options and other forms of financial instruments, and to purchase, redeem or pay off any of the foregoing and to guarantee any or all of the liabilities of the Company, any other company or any other person, and any debentures, debenture stock or other securities may be issued at a discount, premium or otherwise, and with any special privileges as to redemption, surrender, transfer, drawings, allotments of shares, attending and voting at general meetings of the Company, appointment of directors and otherwise.

3.20. To accumulate capital for any of the purposes of the Company, and to appropriate any of the Company's assets to specific purposes, either conditionally or unconditionally, and to admit any class or section of those who have any dealings with the Company to any share in the profits thereof or in the profits of any particular branch of the Company's business or to any other special rights, privileges, advantages or benefits.

3.21. To reduce the share capital of the Company in any manner permitted by law.

3.22. To make gifts or grant bonuses to officers or other persons who are or have been in the employment of the Company and to allow any such persons to have the use and enjoyment of such property, chattels or other assets belonging to the Company upon such terms as the Company shall think fit.

3.23. To establish and maintain or procure the establishment and maintenance of any pension or superannuation fund (whether contributory or otherwise) for the benefit of and to give or procure the giving of donations, gratuities, pensions, annuities, allowances, emoluments or charitable aid to any persons who are or were at any time in the employment or service of the Company or any of its predecessors in business, or of any company which is a subsidiary of the Company or who may be or have been directors or officers of the Company, or of any such other company as aforesaid, or any persons in whose welfare the Company or any such other company as aforesaid may be interested and the wives, husbands, widows, widowers, families, relatives or dependants of any such persons, and to make payments towards insurance and assurance and to form and contribute to provident and benefit funds for the benefit of any such persons and to remunerate any person, firm or company rendering services to the Company or of any company which is a subsidiary of the Company, whether by cash payment, gratuities, pensions, annuities, allowances, emoluments or by the allotment of shares or securities of the Company credited as paid up in full or in part or otherwise.

3.24. To employ experts to investigate and examine into the conditions, prospects, value, character and circumstances of any business concerns, undertakings, assets, property or rights.

3.25. To insure the life of any person who may, in the opinion of the Company, be of value to the Company, as having or holding for the Company interests, goodwill, or influence or otherwise and to pay the premiums on such insurance.

3.26. To distribute either upon a distribution of assets or division of profits among the Members of the Company in kind any property of the Company, and in particular any shares, debentures or securities of other companies belonging to the Company or of which the Company may have the power of disposing.

3.27. To give, whether directly or indirectly, and whether by means of a loan, guarantee, the provision of security or otherwise, any financial assistance for the purpose of or in connection with a purchase or subscription made or to be made by any person of or for any shares in the Company, or, where the Company is a subsidiary company, in its holding company.

3.28. To do and carry out all or any of the foregoing or following objects in any part of the world and either as principals, agents, contractors, trustees or otherwise, and either by or through agents, trustees or otherwise and either alone or in partnership or in conjunction with any other company, firm or person, provided that nothing herein contained shall empower the Company to carry on the business of insurance.

3.29. To apply for, purchase or otherwise acquire any patents, brevets d'invention, licences, trademarks, trade names, copyrights, industrial designs, know-how, concessions and other forms of intellectual property rights and the like conferring any exclusive or non-exclusive or limited or contingent rights to use, or any secret or other information as to any invention or process of the Company, or the acquisition of which may seem calculated directly or indirectly to benefit the Company, and to use, exercise, develop, or grant licences in respect of, or otherwise turn to account the property, rights or information so acquired.

3.30. To enter into partnership or into any arrangement for sharing profits, union of interests, co-operation, joint venture, reciprocal concession or otherwise with any person or company.

3.31. To acquire and undertake the whole or any part of the undertaking, business, property and liabilities of any person or company.

3.32. To adopt such means of making known the Company and its products and services as may seem expedient.

3.33. To acquire and carry on any business carried on by a subsidiary or a holding company of the Company or another subsidiary of a holding company of the Company.

3.34. To promote any company or companies for the purpose of acquiring all or any of the property and liabilities of this Company or for any other purpose which may seem directly or indirectly calculated to benefit this Company.

3.35. To amalgamate with, merge with or otherwise become part of or associated with any other company or association in any manner permitted by law.

3.36. To make voluntary dispositions of all or any part of the property and rights of the Company and to make gifts thereof or gratuitous payments either for no consideration or for a consideration less than the market value of such property or rights or the amount of cash payment or by all or any such methods.

3.37. To receive voluntary dispositions of all or any part of the undertakings, properties, assets or rights of any other corporation and to receive gifts thereof or gratuitous payments either for no

consideration or for a consideration less than the market value of such property or rights or the amount of cash payment or by all or any such methods.

3.38. To do and carry out all such other things, except the issuing of policies of insurance, as may be deemed by the Company capable of being carried on in connection with the above objects or any of them or calculated to enhance the value of or render profitable any of the Company's undertakings, properties, assets or rights.

And it is hereby declared that (i) the word "company" in this clause, except where used in reference to this Company, shall be deemed to include any person, partnership, limited partnership, limited liability partnership, limited liability company, other corporate body, trust or other body of persons whether incorporated or not incorporated and whether domiciled in Ireland or elsewhere and that the objects of the Company as specified in each of the foregoing paragraphs of this clause shall be separate and distinct objects and shall not be in anyway limited or restricted by reference to or inference from the terms of any other paragraph or the name of the Company and (ii) any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

4. The liability of each Member is limited to the amount from time to time unpaid on such Member's Shares.

5. The authorised share capital of the Company is €25,000 and US$4,400,000 divided into 25,000 Euro Deferred Shares of €1.00 each, 400,000,000 Ordinary Shares of US$0.01 each and 40,000,000 Preferred Shares of US$0.01 each.

6. Notwithstanding any other provision of these Memorandum and Articles of Association, amendments to this paragraph of the Memorandum of Association, and amendments to Articles 17, 67.1, 76, 90, 92, 112, 156-159 (inclusive), 194, and 196-198 (inclusive) may only be made with the prior approval of the holders of at least 75% in nominal value of the issued Ordinary Shares of the Company which carry an entitlement to vote at a general meeting of the Company.

7. The shares forming the capital, increased or reduced, may be increased or reduced and be divided into such classes and issued with any special rights, privileges and conditions or with such qualifications as regards preference, dividend, capital, voting or other special incidents, and be held upon such terms as may be attached thereto or as may from time to time be provided by the original or any substituted or amended Articles of Association and regulations of the Company for the time being, but so that where shares are issued with any preferential or special rights attached thereto such rights shall not be alterable otherwise than pursuant to the provisions of the Company's Articles of Association for the time being.

COMPANIES ACT 2014

A PUBLIC COMPANY LIMITED BY SHARES

ARTICLES OF ASSOCIATION

OF

OSMOTICA PHARMACEUTICALS PUBLIC LIMITED COMPANY

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PRELIMINARY

1. Sections 43(2), 43(3), 65(2)-(7), 77-81, 83(3), 94(1), 95(1), 96(2)-(11), 124, 125, 126(2) to (8), 144(3)-(4), 148(2), 158-165, 178(2), 180(5), 181(1), 181(6), 182(2), 182(5), 183(3), 186(c)(i), 187, 188, 218(3)-(5), 229, 230, 338(5)-(6), 618(1)(b), 620(8), 1090, 1092, and 1113 of the Companies Act shall not apply to the Company. The provisions of the Companies Act which are stated therein to apply to a public limited company, save to the extent that its constitution is permitted to provide or state otherwise, will apply to the Company subject to the alterations contained in these Articles, and will, so far as not inconsistent with these Articles, bind the Company and its Members.

2.

2.1. In these Articles:

"1990 Regulations"	The Companies Act 1990 (Uncertificated Securities) Regulations 1996 (S.I. No. 68 of 1996) as may be amended from time to time.
"address"	includes any number or address used for the purposes of communication by way of electronic mail or other electronic communication.
"Adoption Date"	means 17 October 2018.
"Articles" or **"Articles of Association"**	means these articles of association of the Company, as amended from time to time by Special Resolution or in accordance with paragraph 6 of the Memorandum.
"Assistant Secretary"	means any person appointed by the Board from time to time to assist the Secretary.
"Auditors"	means the persons for the time being performing the duties of the statutory auditors of the Company.
"Board"	means the board of Directors for the time being of the Company.
"Chairperson"	means the chairperson of the Board from time to time and/or chairperson of a general meeting of the Company as the context may require.
"clear days"	means, in relation to a period of notice, that period excluding the day when the notice is given or deemed to be given and the day for which notice is being given or on which an action or event for which notice is being given is to occur or take effect.

"Companies Act"	means the Irish Companies Act 2014 and every statutory modification, replacement and re-enactment thereof for the time being in force.
"Company"	means Osmotica Pharmaceuticals plc.
"Court"	means the Irish High Court.
"CSD Regulation"	means any regulation of the European Parliament and of the Council on improving securities settlement in the European Union and on central securities depositories and amending Directive 98/26/EC.
"Derivative Transaction"	means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial: (A) the value of which is derived in whole or in part from the value of any class or series of Shares or other securities of the Company, (B) which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the Company, (C) the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes with respect to any securities of the Company, or (D) which provides the right to vote or increase or decrease the voting power of such Proponent, or any of its affiliates or associates, with respect to any securities of the Company, which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position, profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the Company held by any general or limited partnership, or any limited liability company, of which such Proponent is, directly or indirectly, a general partner or managing member.
"Directors"	means the directors for the time being of the Company.
"dividend"	includes dividends, final dividends, interim dividends and bonus dividends.
"electronic communication"	shall have the meaning given to those words in the Electronic Commerce Act 2000.

"electronic signature"	shall have the meaning given to those words in the Electronic Commerce Act 2000.
"Enterprise"	means the Company and any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise or entity which a person is or was serving at the request of the Company.
"Exchange"	means any securities exchange or other system on which the Shares of the Company may be listed or otherwise authorised for trading from time to time.
"Exchange Act"	means the Securities Exchange Act of 1934 of the United States of America.
"IAS Regulation"	means Regulation (EC) No. 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of internal accounting standards.
"Member"	means a person who has agreed to become a member of the Company and whose name is entered in the Register of Members as a registered holder of Shares.
"Memorandum"	means the memorandum of association of the Company as amended from time to time by Special Resolution or in accordance with paragraph 6 of the Memorandum.
"month"	means a calendar month.
"Official"	means a director, officer, secretary, employee, trustee, agent, partner, managing member, fiduciary or other official of the Company or another Enterprise.
"Ordinary Resolution"	means an ordinary resolution of the Company's Members within the meaning of section 191 of the Companies Act.
"paid-up"	means paid-up in accordance with the Companies Act as to the nominal value and any premium payable in respect of the issue of any Shares and includes credited as paid-up.
"Proponent"	shall have the meaning given to that term in Article 90.4.
"Redeemable Shares"	means redeemable shares in accordance with the Companies Act.

"Register of Members" or **"Register"**	means the register of Members of the Company maintained by or on behalf of the Company, in accordance with the Companies Act.
"registered office"	means the registered office for the time being of the Company.
"Seal"	means the seal of the Company, if any, and includes every duplicate seal.
"Secretary"	means the person appointed by the Board to perform any or all of the duties of secretary of the Company and includes an Assistant Secretary and any person appointed by the Board or the Secretary to perform the duties of secretary of the Company, in each case, when acting in the capacity of the secretary of the Company.
"Share" and **"Shares"**	means a share or shares in the capital of the Company.
"Special Resolution"	means a special resolution of the Company's Members within the meaning of section 191 of the Companies Act.
"Sponsor Holders"	means each of Avista Capital Holdings, L.P. and Altchem Limited and their respective affiliates, and **Sponsor Holder** means either of them.

2.2. In these Articles (unless otherwise specified):

2.2.1. words importing the singular number include the plural number and vice-versa;

2.2.2. words importing the feminine gender include the masculine gender and the neuter and vice-versa;

2.2.3. words importing persons include any company, partnership or other body of persons, whether corporate or not, any trust and any government, governmental body or agency or public authority, whether of Ireland or elsewhere and references to a company, except where used in reference to the Company, shall be deemed to include any person, partnership, limited partnership, limited liability partnership, limited liability company, other corporate body, trust or other body of persons whether incorporated or not incorporated and whether domiciled in Ireland or elsewhere;

2.2.4. expressions referring to "written" and "in writing" shall be construed, unless the contrary intention appears, as including references to printing, lithography, photography and any other modes of representing or reproducing words in a visible form except as provided in these Articles and/or where it constitutes writing in electronic form sent to the Company;

2.2.5. expressions referring to execution of any document shall include any mode of execution whether under seal or under hand or any mode of electronic signature;

2.2.6. references to provisions of any law or regulation shall be construed as references to those provisions as amended, modified, re-enacted or replaced from time to time;

2.2.7. any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

2.2.8. reference to "officer" or "officers" in these Articles means any executive that has been designated by the Company as an "officer" and, for the avoidance of doubt, shall not have the meaning given to such term in the Companies Act and any such officers shall not constitute officers of the Company within the meaning of section 2(1) of the Companies Act;

2.2.9. headings are inserted for reference only and shall be ignored in construing these Articles; and

2.2.10. references to US$, USD, $ or dollars shall mean United States dollars, the lawful currency of the United States of America and references to €, euro, or EUR shall mean the euro, the lawful currency of Ireland.

REGISTERED OFFICE

3. The registered office shall be at such place in Ireland as the Board from time to time shall decide.

SHARE CAPITAL; ISSUE OF SHARES

4. The authorised share capital of the Company is €25,000 and US$4,400,000 divided into 25,000 Euro Deferred Shares of €1.00 each, 400,000,000 Ordinary Shares of US$0.01 each and 40,000,000 Preferred Shares of US$0.01 each.

5. Subject to the provisions of these Articles relating to new Shares, the Shares shall be at the disposal of the Directors, and they may (subject to the provisions of the Companies Act) allot, issue, grant options over or otherwise dispose of them to such persons, on such terms and conditions and at such times as they may consider to be in the best interests of the Company and its Members, but so that no Share shall be issued at a discount save in accordance with sections 71(4) and 1026 of the Companies Act, and so that, in the case of Shares offered to the public for subscription, the amount payable on application on each such Share shall not be less than one-quarter of the nominal amount of the Share and the whole of any premium thereon. To the extent permitted by the Companies Act, Shares may also be allotted by a committee of the Directors or by any other person where such committee or person is so authorised by the Directors.

6. Subject to any requirement to obtain the approval of Members under any laws, regulations or the rules of any Exchange, the Board is authorised, from time to time, to grant such persons, for such periods and upon such terms as the Board deems advisable, options or awards to purchase or subscribe for any number of Shares of any class or classes or of any series of any class and other securities or ownership interests of the Company as the Board may deem advisable, and to cause warrants or other appropriate instruments evidencing such options or awards to be issued.

7.

7.1. The Directors are, for the purposes of section 1021 of the Companies Act, generally and unconditionally authorised to exercise all powers of the Company to allot and issue relevant securities (as defined by the said section 1021) up to the amount of the Company's authorised but unissued share capital and to allot and issue any Shares acquired by or on behalf of the Company pursuant to the provisions of the Companies Act and held as treasury shares and,

unless it is renewed or a longer period of time is allowed under applicable law, this authority shall expire five years from the Adoption Date.

7.2. The Directors are hereby empowered pursuant to sections 1022 and 1023(3) of the Companies Act to allot equity securities (as defined by the said section 1023) for cash pursuant to the authority conferred by Article 7.1 as if section 1022 of the Companies Act did not apply to any such allotment.

7.3. The Company may before the expiry of the authorities conferred by Articles 7.1 and/or 7.2 make an offer or agreement which would or might require relevant securities (as defined in section 1021 of the Companies Act) and/or equity securities (as defined in section 1023 of the Companies Act), as the case may be, to be allotted after such expiry and the Board may allot relevant securities and/or equity securities in pursuance of such an offer or agreement as if the authorities conferred by Articles 7.1 and/or 7.2 had not expired.

7.4. The Company may issue permissible letters of allotment (as defined by section 1019 of the Companies Act) to the extent permitted by the Companies Act.

8. The Company may pay commission to any person in consideration of any person subscribing or agreeing to subscribe, whether absolutely or conditionally, for the Shares in the Company or procuring or agreeing to procure subscriptions, whether absolute or conditional, for any Shares in the Company on such terms and, subject to the provisions of the Companies Act and to such conditions as the Board may determine including by paying cash or allotting and issuing fully or partly paid Shares or any combination of the two. The Company may also on any issue of Shares pay such brokerage as may be lawful.

ORDINARY SHARES

9. The rights and restrictions attaching to the Ordinary Shares shall be as follows:

9.1. subject to the right of the Company to set record dates for the purposes of determining the identity of Members entitled to notice of and/or to vote at a general meeting and any rules or regulations applicable to the conduct of any general meeting of the Company, the right to attend and speak at any general meeting of the Company and to exercise one vote per Ordinary Share held at any general meeting of the Company;

9.2. the right to participate pro rata in all dividends declared by the Company with respect to the Ordinary Shares; and

9.3. the right, in the event of the Company's winding up, to participate pro rata with all other Ordinary Shares in the total assets of the Company.

10. The rights attaching to the Ordinary Shares shall be subject to the terms of issue of any series or class of Preferred Shares allotted by the Directors from time to time in accordance with Article 17.

11. Unless the Board specifically resolves to treat such acquisition as a purchase for the purposes of the Companies Act, an Ordinary Share shall be deemed to be a Redeemable Share on, and from the time of, the existence or creation of an agreement, transaction or trade between the Company (including any agent or broker acting on behalf of the Company) and any third party pursuant to which the Company acquires or will acquire Ordinary Shares, or an interest in Ordinary Shares, from such third party and the Company is hereby authorised to enter into any such agreement, transaction or trade. In these circumstances, the acquisition of such Shares or interest in Shares by the Company shall constitute the redemption of a Redeemable Share in accordance with the Companies Act. No resolution, whether special or otherwise, shall be required to be passed to deem any Ordinary Share a Redeemable Share, or to authorise the redemption of such a Redeemable Share and once deemed to be a Redeemable Share such share shall be redeemable at the instance of the Company.

12. All Ordinary Shares shall rank *pari passu* with each other in all respects.

EURO DEFERRED SHARES

13. The holders of the Euro Deferred Shares shall not be entitled to receive any dividend or distribution and shall not be entitled to receive notice of, nor to attend, speak or vote at, any general meeting of the Company. On a return of assets, whether on liquidation or otherwise, the Euro Deferred Shares shall entitle the holder thereof only to the repayment of the amounts paid up on such shares after repayment of the capital paid up on the Ordinary Shares plus the payment of $5,000,000 on each of the Ordinary Shares and the holders of the Euro Deferred Shares (as such) shall not be entitled to any further participation in the assets or profits of the Company.

14. The Company has the irrevocable authority at any time after the Adoption Date to:

14.1. acquire all or any of the fully paid Euro Deferred Shares otherwise than for valuable consideration in accordance with section 102 of the Companies Act and without obtaining the sanction of the holders thereof;

14.2. appoint any person to execute on behalf of the holders of the Euro Deferred Shares remaining in issue (if any) a transfer thereof and/or an agreement to transfer the same otherwise than for valuable consideration to the Company or to such other person as the Company may nominate;

14.3. cancel any acquired Euro Deferred Shares; and

14.4. pending such acquisition and/or transfer and/or cancellation, retain the certificate (if any) for such Euro Deferred Shares.

15. In accordance with section 1040(3) of the Companies Act, the Company shall, not later than three (3) years after any acquisition by it of any Euro Deferred Shares as aforesaid, cancel such shares (except those which, or any interest of the Company in which, it shall have previously disposed of) and reduce the amount of the share capital by the nominal value of the shares so cancelled and the Board may take such steps as are required to enable the Company to carry out its obligations under that section without complying with sections 84 and 85 of the Companies Act, including passing resolutions in accordance with section 1040(5) of the Companies Act.

16. Neither the acquisition by the Company otherwise than for valuable consideration of all or any of the Euro Deferred Shares nor the redemption thereof nor the cancellation thereof by the Company in accordance with these Articles shall constitute a variation or abrogation of the rights or privileges attached to the Euro Deferred Shares, and accordingly the Euro Deferred Shares or any of them may be so acquired, redeemed and cancelled without any such consent or sanction on the part of the holders thereof. The rights conferred upon the holders of the Euro Deferred Shares shall not be deemed to be varied or abrogated by the creation of further Shares ranking in priority thereto or *pari passu* therewith.

PREFERRED SHARES

17.

17.1. The Directors are authorised to issue all or any of the authorised but unissued Preferred Shares from time to time in one or more classes or series, and to fix for each such class or series such voting power, full or limited, or no voting power, and such designations, preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Directors providing for the issuance of such class or series, including (but not limited to) the authority to provide that any such class or series may be:

17.1.1. redeemable at the option of the Company, or the holders, or both, with the manner of the redemption to be set by the Directors, and redeemable at such time or times, including upon a fixed date, and at such price or prices as the Directors may determine;

17.1.2. entitled to receive dividends (which may be cumulative or non-cumulative) at such rates, on such conditions and at such times as the Directors may determine, and which may be payable in preference to, or in such relation to, the dividends payable on any other class or classes of Shares or any other series as the Directors may determine;

17.1.3. entitled to such rights upon the dissolution of, or upon any distribution of the assets of, the Company as the Directors may determine; or

17.1.4. convertible into, or exchangeable for, Shares of any other class or classes of Shares, or of any other series of the same or any other class or classes of Shares, of the Company at such price or prices or at such rates of exchange and with such adjustments as the Directors may determine.

17.2. The Directors may at any time before the allotment of any Preferred Share by further resolution in any way amend the designations, preferences, rights, qualifications, limitations or restrictions, or vary or revoke the designations of such Preferred Shares.

18. The rights conferred upon the holder of any pre-existing Shares in the share capital of the Company shall be deemed not to be varied by the creation, issue and allotment of Preferred Shares in accordance with Article 17.

ISSUE OF WARRANTS

19. The Board may issue warrants to subscribe for any class of Shares or other securities of the Company on such terms as it may from time to time determine.

CERTIFICATES FOR SHARES

20. Unless otherwise provided for by the Board or the rights attaching to or by the terms of issue of any particular Shares, or to the extent required by any Exchange, depository or any operator of any clearance or settlement system or by law, no person whose name is entered as a Member in the Register of Members shall be entitled to receive a share certificate for any Shares of any class held by him or her (nor on transferring a part of holding, to a certificate for the balance).

21. Any share certificate, if issued, shall specify the number of Shares in respect of which it is issued and the amount paid thereon or the fact that they are fully paid, as the case may be, and may otherwise be in such form as shall be determined by the Board. Such certificates may be under Seal. All certificates for Shares shall be consecutively numbered or otherwise identified and shall specify the Shares to which they relate. The name and address of the person to whom the Shares represented thereby are issued, with the number of Shares and date of issue, shall be entered in the Register of Members. All certificates surrendered to the Company for transfer shall be cancelled and no new certificate shall be issued until the former certificate for a like number of Shares shall have been surrendered and cancelled. The Board may authorise certificates to be issued with the Seal and authorised signature(s) affixed by some method or system of mechanical or electronic process. In respect of a Share or Shares held jointly by several persons, the Company shall not be bound to issue a certificate or certificates to each such person, and the issue and delivery of a certificate or certificates to one of several joint holders shall be sufficient delivery to all such holders.

22. If a share certificate is defaced, worn out, lost or destroyed, it may be renewed on such terms (if any) as to evidence and indemnity and on the payment of such expenses reasonably incurred by the Company in investigating such evidence, as the Board may prescribe, and, in the case of defacement or wearing out, upon delivery of the old certificate.

REGISTER OF MEMBERS

23. The Company shall maintain or cause to be maintained a Register of its Members in accordance with the Companies Act.

24. If the Board considers it necessary or appropriate, the Company may establish and maintain a duplicate Register or Registers of Members at such location or locations within or outside Ireland as the Board thinks fit. The original Register of Members shall be treated as the Register of Members for the purposes of these Articles and the Companies Act.

25. The Company, or any agent(s) appointed by it to maintain any duplicate Register of Members in accordance with these Articles shall, as soon as practicable and on a regular basis record, or procure the recording of, in the original Register of Members, all transfers of Shares effected on any duplicate Register of Members and shall at all times maintain the original Register of Members in such manner as to show at all times the Members for the time being and the Shares respectively held by them, in all respects in accordance with the Companies Act.

26. The Company shall not be bound to register more than four (4) persons as joint holders of any Share. If any Share shall stand in the names of two (2) or more persons, the person first named in the Register of Members shall be deemed the sole holder thereof as regards service of notices and, subject to the provisions of these Articles, all or any other matters connected with the Company.

TRANSFER OF SHARES

27. Subject to such of the restrictions of these Articles and to such of the conditions of issue or transfer as may be applicable, all transfers of Shares shall be effected by an instrument in writing (an "**instrument of transfer**") in such form as the Board or the Secretary may approve. All such instruments of transfer must be left at the registered office or at such other place as the Board or the Secretary may specify and all such instruments of transfer shall be retained by the Company.

28.

28.1. In the case of transfers to Cede & Co (or to any successor thereto, or to any other affiliate or nominee of The Depositary Trust Company or of any successor to The Depositary Trust Company) the instrument of transfer shall not be effective until executed by:

28.1.1. the Secretary (or such person as may be nominated by the Secretary for this purpose) on behalf of the Company; and

28.1.2. by the transferor or alternatively by or on behalf of the transferor by the Secretary (or such person as may be nominated by the Secretary for this purpose) on behalf of the Company, and the Company shall be deemed to have been irrevocably appointed agent for the transferor of such Share or Shares with full power to execute, complete and deliver in the name of and on behalf of the transferor of such Share or Shares all such transfers of Shares held by the Members in the share capital of the Company.

28.2. In the case of transfers other than those to Cede & Co (or to any successor thereto, or to any other affiliate or nominee of The Depositary Trust Company or of any successor to The Depositary Trust Company), the instrument of transfer of any Share shall be executed by the transferor or alternatively for and on behalf of the transferor by the Secretary (or such other person as may be nominated by the Secretary for this purpose) on behalf of the Company, and the Secretary (or relevant nominee), acting on behalf of the Company shall be deemed to have been irrevocably appointed agent for the transferor of such Share or Shares with full power to execute, complete and deliver in the name of and on behalf of the transferor of such Share or Shares all such transfers of Shares held by the Members in the share capital of the Company.

28.3. An instrument of transfer need not be executed by the transferee except to the extent required by the Companies Act. Any document which records the name of the transferor, the name of the transferee, the class and number of Shares agreed to be transferred and the date of the agreement to transfer the Shares, shall, once executed in accordance with this Article, be deemed to be a proper instrument of transfer for the purposes of section 94 of the Companies Act.

28.4. The transferor shall be deemed to remain the holder of the Share until the name of the transferee is entered on the Register in respect thereof, and neither the title of the transferee nor the title of the transferor shall be affected by any irregularity or invalidity in the proceedings in reference to the sale should the Board so determine.

28.5. The Company, at its absolute discretion and insofar as the Companies Act or any other applicable law permits, may, or may procure that a subsidiary of the Company shall, pay Irish stamp duty arising on a transfer of Shares on behalf of the transferor or transferee of such Shares of the Company. If stamp duty resulting from the transfer of Shares in the Company which would otherwise be payable by the transferor or transferee is paid by the Company or any subsidiary of the Company on behalf of the transferor or transferee, then in those circumstances, the Company shall, on its behalf or on behalf of its subsidiary (as the case may be), be entitled, but not required, to (i) seek reimbursement of the stamp duty from the transferor or transferee, (ii) set-off the stamp duty against any dividends payable to the transferor or transferee of those Shares or (iii) claim a first and permanent lien on the Shares on which stamp duty has been paid by the Company or its subsidiary for the amount of stamp duty paid. The Company's lien shall extend to all dividends paid on those Shares.

28.6. Notwithstanding the provisions of these Articles and subject to any CSD Regulation or any regulations made under section 1086 of the Companies Act or the 1990 Regulations (including any modification thereof or any regulations in substitution therefor made under the Companies Act or otherwise), title to any Shares may also be evidenced and transferred without a written instrument in accordance with any CSD Regulation or section 1086 of the Companies Act or any regulations made thereunder or the 1990 Regulations (including any modification thereof or any regulations in substitution therefor made under the Companies Act or otherwise). The Board shall have power to permit any class of Shares to be held in uncertificated form and to implement any arrangements they think fit for such evidencing and transfer which accord with such regulations and in particular shall, where appropriate, be entitled to disapply or modify all or part of the provisions in these Articles with respect to the requirement for written instruments of transfer and share certificates (if any), in order to give effect to such regulations.

29. The Board may, without assigning any reason for its decision, decline to register any transfer of any Share which is not a fully paid Share. The Board may also, without assigning any reason, refuse to register a transfer of any Share unless:

29.1. the instrument of transfer is fully and properly completed and is lodged with the Company at the registered office or at such other place as the Board or the Secretary may specify, accompanied by the certificate(s) for the Shares (if any) to which it relates (which shall upon registration of the transfer be cancelled) and such other evidence as the Board may reasonably require to show the right of the transferor to make the transfer;

29.2. the instrument of transfer is in respect of only one class of Shares;

29.3. a registration statement under the Securities Act of 1933 (as amended) of the United States of America is in effect with respect to such transfer or such transfer is exempt from registration and, if requested by the Board, a written opinion from counsel reasonably acceptable to the Board is obtained to the effect that such transfer is exempt from registration;

29.4. the instrument of transfer is properly stamped (in circumstances where stamping is required);

29.5. in the case of a transfer to joint holders, the number of joint holders to which the Share is to be transferred does not exceed four;

29.6. it is satisfied, acting reasonably, that all applicable consents, authorisations, permissions or approvals of any governmental body or agency in Ireland or any other applicable jurisdiction required to be obtained under relevant law prior to such transfer have been obtained; and

29.7. it is satisfied, acting reasonably, that the transfer would not violate the terms of any agreement to which the Company (or any of its subsidiaries) and the transferor are party or subject.

30. If the Board shall refuse to register a transfer of any Share, it shall, within two (2) months after the date on which the transfer was lodged with the Company, send to each of the transferor and the transferee notice of such refusal.

31. The Company shall not be obligated to register any transfer to an individual under 18 years of age or to a person in respect of whom an order has been made by a competent court or official on the grounds that he or she is or may be suffering from mental disorder or is otherwise incapable of managing his or her affairs or under other legal disability.

32. Upon every transfer of Shares, the certificate (if any) held by the transferor shall be given up to be cancelled, and shall forthwith be cancelled accordingly, and subject to Article 20 a new certificate may be issued without charge to the transferee in respect of the Shares transferred to him or her, and if any of the Shares included in the certificate so given up shall be retained by the transferor, a new certificate in respect thereof may be issued to him or her without charge.

REDEMPTION AND REPURCHASE OF SHARES

33. Subject to the provisions of Chapter 6 of Part 3 and Chapter 5 of Part 17 of the Companies Act and the other provisions of this Article 33, and without prejudice to Article 17, the Company may:

33.1. pursuant to section 66(4) of the Companies Act, allot and issue any Shares of the Company which are to be redeemed or are liable to be redeemed at the option of the Company or the Member on such terms and in such manner as may be determined by the Board;

33.2. redeem Shares of the Company on such terms as may be contained in, or be determined pursuant to the provisions of, these Articles. Subject as aforesaid, the Company may cancel any Shares so redeemed or may hold them as treasury shares (as defined in section 106(1) of the Companies Act) and re-issue such treasury shares as Shares of any class or classes or cancel them;

33.3. subject to or in accordance with the provisions of the Companies Act and without prejudice to any relevant special rights attached to any class of Shares, pursuant to section 105 and Chapter 5 of Part 17 of the Companies Act, acquire any of its own Shares (including any Redeemable Shares and without any obligation to acquire on any *pro rata* basis as between Members or Members of the same class) and may cancel any Shares so acquired or hold them as treasury shares (as defined in section 106(1) of the Companies Act) and may re-issue any such Shares as Shares of any class or classes or cancel them; or

33.4. convert any of its Shares into Redeemable Shares provided that the total number of Shares which shall be redeemable pursuant to this authority shall not exceed the limit in section 1071(b) of the Companies Act. No resolution of Members, whether special or otherwise, shall be required to be passed to convert any of the Shares into Redeemable Shares.

34. The Company may make a payment in respect of the redemption or purchase of its own Shares in any manner permitted by the Companies Act.

35. The holder of the Shares being redeemed or purchased shall be bound to deliver up to the Company, at its registered office or such other place as the Board shall specify, the certificate(s) (if any) thereof for cancellation and thereupon the Company shall pay to him or her the purchase or redemption monies or consideration in respect thereof.

VARIATION OF RIGHTS OF SHARES

36. Without prejudice to the authority conferred on the Directors pursuant to Article 17 to issue Preferred Shares in the capital of the Company, if at any time the share capital of the Company is divided into different classes or series of Shares, the rights attached to any class or series (unless otherwise provided by the terms of issue of the Shares of that class or series) may be varied or abrogated with the consent in writing of the holders of a majority of the issued Shares of that class or series entitled to vote on such variation or abrogation, or with the sanction of an Ordinary Resolution passed at a general meeting of the holders of the Shares of that class or series.

37. The provisions of these Articles relating to general meetings of the Company shall apply *mutatis mutandis* to every such general meeting of the holders of one class or series of Shares except that the necessary quorum shall be one or more persons holding or representing by proxy at least a majority of the issued Shares of the class or series.

38. The rights conferred upon the holders of the Shares of any class or series issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the Shares of that class or series, be deemed to be varied by (i) the creation or issue of further Shares ranking *pari passu* therewith; (ii) a purchase or redemption by the Company of its own Shares; or (iii) the creation or issue for value (as determined by the Board) of further Shares ranking as regards participation in the profits or assets of the Company or otherwise in priority to them. For the avoidance of doubt:

38.1. the issue, redemption or purchase of any of the 25,000 Euro Deferred Shares of €1.00 each or the 40,000,000 Preferred Shares of US$0.01 each shall not constitute a variation of the rights of the holders of Ordinary Shares; and

38.2. the issue of Preferred Shares or any class or series of Preferred Shares which rank *pari passu* with, or junior to, any existing Preferred Shares or class or series of Preferred Shares shall not constitute a variation of the existing Preferred Shares or class or series of Preferred Shares.

LIEN ON SHARES

39. The Company shall have a first and paramount lien on every Share (not being a fully paid Share) for all monies (whether presently payable or not) payable at a fixed time or called in respect of that Share. The Board, at any time, may declare any Share to be wholly or in part exempt from the provisions of this Article 39. The Company's lien on a Share shall extend to all monies payable in respect of it.

40. The Company may sell in such manner as the Board determines any Share on which the Company has a lien if a sum in respect of which the lien exists is presently payable and is not paid within fourteen (14) clear days after notice demanding payment, stating that if the notice is not complied with the Share may be sold, has been given to the holder of the Share or to the person entitled to it by reason of the death, bankruptcy or insolvency of the holder or otherwise by operation of law or regulation (whether of Ireland or otherwise).

41. To give effect to a sale, the Board may authorise some person to execute an instrument of transfer of the Share(s) sold to, or in accordance with the directions of, the transferee. The transferee shall be entered in the Register as the holder of the Share(s) comprised in any such transfer and he or she shall not be bound to see to the application of the purchase monies nor shall his or her title to the Share(s) be affected by any irregularity in, or invalidity of, the proceedings in reference to the sale, and after the name of the transferee has been entered in the Register, the remedy of any person aggrieved by the sale shall be in damages only and against the Company exclusively.

42. The net proceeds of the sale, after payment of the costs, shall be applied in payment of so much of the sum for which the lien exists as is presently payable and any residue (upon surrender to the Company for cancellation of the certificate for the Shares sold and subject to a like lien for any monies not presently payable as existed upon the Shares before the sale) shall be paid to the person entitled to the Shares at the date of the sale.

43. Whenever any law for the time being of any country, state or place imposes or purports to impose any immediate or future or possible liability upon the Company to make any payment or empowers any government or taxing authority or government official to require the Company to make any payment in respect of any Shares registered in the Register as held either jointly or solely by any Member or in respect of any dividends, bonuses or other monies due or payable or accruing due or which may become due or payable to such Member by the Company on, or in respect of, any Shares registered as mentioned above or for or on account or in respect of any Member and whether in consequence of:

(a) the death of such Member;

(b) the non-payment of any income tax or other tax by such Member;

(c) the non-payment of any estate, probate, succession, death, stamp or other duty by the executor or administrator of such Member or by or out of his or her estate; or

(d) any other act or thing,

in every such case (except to the extent that the rights conferred upon holders of any class of Shares renders the Company liable to make additional payments in respect of sums withheld on account of the foregoing):

43.1. the Company shall be fully indemnified by such Member or his or her executor or administrator from all liability;

43.2. the Company shall have a lien upon all dividends and other monies payable in respect of the Shares registered in the Register as held either jointly or solely by such Member for all monies paid or payable by the Company as referred to above in respect of such Shares or in respect of any dividends or other monies thereon or for or on account or in respect of such Member under or in consequence of any such law, together with interest at the rate of fifteen percent (15%) per annum (or such other rate as the Board may determine) thereon from the date of payment to the date of repayment, and the Company may deduct or set off against such dividends or other monies so payable any monies paid or payable by the Company as referred to above together with interest at the same rate;

43.3. the Company may recover as a debt due from such Member or his or her executor or administrator (wherever constituted) any monies paid by the Company under or in consequence of any such law and interest thereon at the rate and for the period referred to above in excess of any dividends or other monies then due or payable by the Company; and

43.4. the Company may, if any such money is paid or payable by it under any such law as referred to above, refuse to register a transfer of any Shares by any such Member or his or her executor or administrator until such money and interest is set off or deducted as referred to above or, in the case that it exceeds the amount of any such dividends or other monies then due or payable by the Company, until such excess is paid to the Company.

44. Subject to the rights conferred upon the holders of any class of Shares, nothing in Article 43 will prejudice or affect any right or remedy which any law may confer or purport to confer on the Company. As between the Company and every such Member as referred to above (and, his or her executor, administrator and estate, wherever constituted), any right or remedy which such law shall confer or purport to confer on the Company shall be enforceable by the Company.

CALLS ON SHARES

45. Subject to the terms of allotment, the Board may make calls upon the Members in respect of any monies unpaid on their Shares and each Member (subject to receiving at least fourteen (14) clear days' notice specifying when and where payment is to be made) shall pay to the Company as required by the notice the amount called on his or her Shares. A call may be required or permitted to be paid in instalments. A call may be revoked before receipt by the Company of a sum due thereunder, in whole or in part, and payment of a call may be postponed in whole or in part.

46. A call shall be deemed to have been made at the time when the resolution of the Board authorising the call was passed.

47. A person on whom a call is made shall (in addition to a transferee) remain liable notwithstanding the subsequent transfer of the Share in respect of which the call is made.

48. The joint holders of a Share shall be jointly and severally liable to pay all calls in respect thereof.

49. If a call remains unpaid after it has become due and payable, the person from whom it is due and payable shall pay interest on the amount unpaid from the day it became due until it is paid at the rate fixed by the terms of allotment of the Share or in the notice of the call or, if no rate is fixed, at the appropriate rate (as defined by the Companies Act), but the Board may waive payment of the interest wholly or in part.

50. An amount payable in respect of a Share on allotment or at any fixed date, whether in respect of nominal value or by way of premium, shall be deemed to be a call and, if it is not paid, the provisions of these Articles shall apply as if that amount had become due and payable by virtue of a call.

51. Subject to the terms of allotment, the Board may make arrangements on the issue of Shares for a difference between the holders in the amounts and times of payment of calls on their Shares.

52. The Directors may, if they think fit, receive from any Member willing to advance the same all or any part of the monies uncalled and unpaid upon any Shares held by him or her, and upon all or any of the monies so advanced may pay (until the same would, but for such advance, become payable) interest at such rate as may be agreed upon between the Directors and the Member paying such sum in advance.

FORFEITURE

53. If a Member fails to pay any call or instalment of a call on the day appointed for payment thereof, the Directors, at any time thereafter during such times as any part of the call or instalment remains unpaid, may serve a notice on him or her requiring payment of so much of the call or instalment as is unpaid together with any interest which may have accrued.

54. The notice shall state a further day (not earlier than the expiration of fourteen (14) clear days from the date of service of the notice) on or before which the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time appointed, the Shares in respect of which the call was made will be liable to be forfeited.

55. If the requirements of any such notice as aforesaid are not complied with, then at any time thereafter before the payment required by the notice has been made, any Shares in respect of which the notice has been given may be forfeited by a resolution of the Directors to that effect. The forfeiture shall include all dividends or other monies payable in respect of the forfeited Shares and not paid before forfeiture. The Board may accept a surrender of any Share liable to be forfeited hereunder.

56. On the trial or hearing of any action for the recovery of any money due for any call, it shall be sufficient to prove that the name of the Member sued is entered in the Register as the holder, or one of the holders, of the Shares in respect of which such debt accrued, that the resolution making the call is duly recorded

in the minute book and that notice of such call was duly given to the Member sued, in pursuance of these Articles, and it shall not be necessary to prove the appointment of the Directors who made such call nor any other matters whatsoever, but the proof of the matters aforesaid shall be conclusive evidence of the debt.

57. A forfeited Share may be sold or otherwise disposed of on such terms and in such manner as the Directors think fit and, at any time before a sale or disposition, the forfeiture may be cancelled on such terms as the Directors think fit. Where for the purposes of its disposal, such a Share is to be transferred to any person, the Board may authorise some person to execute an instrument of transfer of the Share to that person. The Company may receive the consideration, if any, given for the Share on any sale or disposition thereof and may execute a transfer of the Share in favour of the person to whom the Share is sold or disposed of and thereupon he or she shall be registered as the holder of the Share and shall not be bound to see to the application of the purchase money, if any, nor shall his or her title to the Share be affected by any irregularity or invalidity in the proceedings in reference to the forfeiture, sale or disposal of the Share.

58. A person whose Shares have been forfeited shall cease to be a Member in respect of the forfeited Shares, but nevertheless shall remain liable to pay to the Company all monies which, at the date of forfeiture, were payable by him or her to the Company in respect of the Shares, without any deduction or allowance for the value of the Shares at the time of forfeiture but his or her liability shall cease if and when the Company shall have received payment in full of all such monies in respect of the Shares.

59. A statement in writing that the maker of the statement is a Director or the Secretary of the Company, and that a Share in the Company has been duly forfeited on the date stated in the statement, shall be conclusive evidence of the facts therein stated as against all persons claiming to be entitled to the Share.

60. The provisions of these Articles as to forfeiture shall apply in the case of non-payment of any sum which, by the terms of issue of a Share, becomes payable at a fixed time, whether on account of the nominal value of the Share or by way of premium, as if the same had been payable by virtue of a call duly made and notified.

61. The Directors may accept the surrender of any Share which the Directors have resolved to have been forfeited upon such terms and conditions as may be agreed and, subject to any such terms and conditions, a surrendered Share shall be treated as if it has been forfeited.

NON-RECOGNITION OF TRUSTS

62. The Company shall not be obligated to recognise any person as holding any Share upon any trust (except as is otherwise provided in these Articles or to the extent required by law) and the Company shall not be bound by or be compelled in any way to recognise (even when having notice thereof) any equitable, contingent, future, or partial interest in any Share, or any interest in any fractional part of a Share, or (except only as is otherwise provided by these Articles or the Companies Act) any other rights in respect of any Share except an absolute right to the entirety thereof in the registered holder. This shall not preclude the Company from requiring the Members or a transferee of Shares to furnish the Company with information as to the beneficial ownership of any Share when such information is reasonably required by the Company.

TRANSMISSION OF SHARES

63. If a Member dies, the survivor or survivors where the deceased was a joint holder, and the legal personal representatives of the deceased where he or she was a sole holder or the only survivor of joint holders, shall be the only persons recognised by the Company as having any title to his or her interest in the Shares; but nothing herein contained shall release the estate of any deceased holder from any liability in respect of any Share which had been jointly held by him or her solely or jointly with other persons.

64. A person becoming entitled to a Share in consequence of the death, bankruptcy, liquidation or insolvency of a Member, or otherwise becoming entitled to a Share by operation of any law, directive or regulation (whether of Ireland, the European Union, or any other jurisdiction) may elect, upon such evidence of title being produced as the Directors or the Secretary (or such other person as may be nominated by the Secretary for this purpose) may reasonably require at any time and from time to time, and subject as further provided in this Article, either to become the holder of the Share or to have some person nominated by him or her registered as the transferee of such Share. If he or she elects to become the holder of the Share, he or she shall give notice to the Company to that effect and, where the Directors or the Secretary (or such other person as may be nominated by the Secretary for this purpose) are satisfied with the evidence of title produced to them, they may register such person as the holder of the Share, subject to the other provisions of these Articles and of the Companies Act. If he or she elects to have another person registered as the transferee of the relevant Share, he or she shall execute an instrument of transfer of the Share to that person. All of these Articles relating to the transfer of Shares shall apply to the notice or instrument of transfer as if it were an instrument of transfer executed by the relevant Member and the event giving rise to the entitlement of the relevant person to the Shares had not occurred.

65. A person becoming entitled to a Share by transmission shall have the rights to which he or she would be entitled if he or she were the holder of the Share (including the right to receive and give a valid discharge for any dividends, distributions or other moneys payable on or in respect of the Share), except that, before being registered as the holder of the Share, he or she shall not be entitled in respect of it to receive notices of, or to attend or vote at, any meeting of the Company or at any separate meeting of holders of any class of Shares in the Company. The Directors or the Secretary (or such other person as may be nominated by the Secretary for this purpose), at any time, may give notice requiring any such person to elect either to be registered himself or herself as the holder of the Share or to transfer the Share and, if the notice is not complied with within ninety (90) days, the Directors or the Secretary (or such other person as may be nominated by the Secretary for this purpose) thereupon may withhold payment of all dividends, bonuses or other monies payable in respect of the Share until the requirements of the notice have been complied with.

AMENDMENT OF MEMORANDUM OF ASSOCIATION;
CHANGE OF LOCATION OF REGISTERED OFFICE; AND
ALTERATION OF CAPITAL

66. The Company may by Ordinary Resolution (or as otherwise provided in these Articles, or determined by the Board, or otherwise permitted under applicable law):

66.1. divide its share capital into several classes and attach to them respectively any preferential, deferred, qualified or special rights, privileges or conditions;

66.2. increase the authorised share capital by such sum to be divided into Shares of any nominal value;

66.3. consolidate and divide all or any of the Shares into Shares of a larger nominal value than the existing Shares;

66.4. subdivide the Shares, or any of them, into Shares of a smaller nominal value, so however, that in the sub-division the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in the case of the Share from which the reduced Share is derived (and so that the Board may determine that, as between the holders of the Shares resulting from such sub-division, one or more of the Shares may have, as compared with the others, any such preferred, deferred or other rights or be subject to any such restrictions as the Company has power to attach to unissued or new Shares);

66.5. cancel any Shares which have not been taken or agreed to be taken by any person and diminish the amount of the Company's share capital by the amount of the Shares so cancelled;

66.6. increase the nominal value of any of the Shares by the addition to them of any undenominated capital;

66.7. reduce the nominal value of any of the Shares by the deduction from them of any part of that value, subject to the crediting of the amount of the deduction to undenominated capital, other than the share premium account;

66.8. convert any undenominated capital into Shares for allotment as bonus shares to holders of existing Shares; and/or

66.9. subject to applicable law, change the currency denomination of its share capital.

67. Subject to the provisions of the Companies Act and to paragraph 6 of the Memorandum, the Company may:

67.1. by Special Resolution (or as otherwise required or permitted by applicable law and/or paragraph 6 of the Memorandum) change its name, alter or add to the Memorandum with respect to any objects, powers or other matters specified therein or alter or add to these Articles;

67.2. by Special Resolution (or as otherwise required or permitted by these Articles and applicable law (including, without limitation, section 83 of the Companies Act)) reduce its issued share capital and any capital redemption reserve fund, share premium account or undenominated capital account. In relation to such reductions, the Company may by Special Resolution (or as otherwise required or permitted by these Articles and applicable law) determine the terms upon which the reduction is to be effected, including in the case of a reduction of part only of any class of Shares, those Shares to be affected; and

67.3. by resolution of the Directors, change the location of its registered office.

68. Where any difficulty arises in regard to any alteration or reorganisation of the share capital of the Company, the Board may settle the same as they think expedient and in particular, may arrange to sell any Shares representing fractions for the best price reasonably obtainable to any person and distribute the proceeds of sale in due proportion among those Members, and the Board may authorise any person to execute an instrument of transfer of the Shares to, or in accordance with the directions of, the purchaser. The transferee shall not be bound to see to the application of the purchase money nor shall his or her title to the Shares be affected by any irregularity in or invalidity of the proceedings in reference to the sale.

CLOSING REGISTER OF MEMBERS OR FIXING RECORD DATE

69. For the purpose of determining Members entitled to notice of or to vote at any meeting of Members or any adjournment thereof, or Members entitled to receive payment of any dividend, or in order to make a determination of Members for any other proper purpose, the Board may provide, subject to the requirements of section 174 of the Companies Act, that the Register of Members shall be closed for transfers at such times and for such periods, not exceeding in the whole thirty (30) days in each year, as it may determine. If the Register of Members shall be so closed for the purpose of determining Members entitled to notice of, or to vote at, a meeting of Members, such Register of Members shall be so closed for at least five (5) days immediately preceding such meeting and the record date for such determination shall be the date of the closure of the Register of Members.

70. In lieu of, or apart from, closing the Register of Members, the Board may fix in advance a date as the record date (a) for any such determination of Members entitled to notice of or to vote at a meeting of the Members, which record date shall not be more than sixty (60) days before the date of such meeting, and (b) for the purpose of determining the Members entitled to receive payment of any dividend or other distribution, or in order to make a determination of Members for any other proper purpose, which record

date shall not be more than sixty (60) days prior to the date of payment of such dividend or other distribution or the taking of any action to which such determination of Members is relevant.

71. If the Register of Members is not so closed and no record date is fixed for the determination of Members entitled to notice of or to vote at a meeting of Members, the date immediately preceding the date on which notice of the meeting is deemed given under these Articles shall be the record date for such determination of Members. Where a determination of Members entitled to vote at any meeting of Members has been made as provided in these Articles, such determination shall apply to any adjournment thereof; provided, however, that the Directors may fix a new record date of the adjourned meeting, if they think fit.

GENERAL MEETINGS

72. The Board shall convene and the Company shall hold annual general meetings in accordance with the requirements of the Companies Act.

73. The Board may, whenever it thinks fit, and shall, on the requisition in writing of Members holding such number of Shares as is prescribed by, and made in accordance with the Companies Act, convene a general meeting in the manner required by the Companies Act. All general meetings other than annual general meetings shall be called extraordinary general meetings. Where any provision of the Companies Act confers rights on the members of a company to convene a general meeting without first directing the board of directors to convene a general meeting and expresses such rights to apply save where a company's articles of association or constitution provides otherwise, such rights shall not apply to the Members of the Company.

74. The Company shall in each year hold a general meeting as its annual general meeting in addition to any other meeting in that year, and shall specify the meeting as such in the notice calling it. Not more than fifteen (15) months shall elapse between the date of one annual general meeting of the Company and that of the next. Each general meeting shall be held at such time and place as designated by the Board and as specified in the notice of meeting. Subject to section 176 of the Companies Act, all general meetings may be held outside of Ireland.

75. The Board may authorise the Secretary to postpone or cancel any general meeting called in accordance with the provisions of these Articles (other than a meeting requisitioned by the Members in accordance with the Companies Act or the postponement or cancellation of which would be contrary to the Companies Act, law or a Court order pursuant to the Companies Act) if the Board considers that, for any reason, it is impractical or unreasonable to hold the general meeting, provided that notice of postponement or cancellation is given to each Member before the time for such meeting. Fresh notice of the date, time and place for any postponed meeting shall be given to each Member in accordance with the provisions of these Articles.

NOTICE OF GENERAL MEETINGS

76. Subject to the provisions of the Companies Act allowing a general meeting to be called by shorter notice, an annual general meeting, and an extraordinary general meeting called for the passing of a Special Resolution, shall be called on at least twenty-one (21) clear days' notice and all other extraordinary general meetings shall be called on at least fourteen (14) clear days' notice. Such notice shall state the date, time, place of the meeting and the general nature of the business to be considered. Every notice shall specify such other details as are required by applicable law or the relevant code, rules and regulations applicable to the listing of the Shares on any Exchange.

77. A general meeting of the Company shall, whether or not the notice specified in Article 76 has been given and whether or not the provisions of the Articles regarding general meetings have been complied with, be deemed to have been duly convened if applicable law so permits and it is so agreed by the Auditors and by all the Members entitled to attend and vote thereat or by their proxies.

78. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a Special Resolution shall specify the intention to propose a resolution as a Special Resolution. Notice of every general meeting shall be given in any manner permitted by these Articles to all Members.

79. There shall appear with reasonable prominence in every notice of general meeting of the Company a statement that a Member entitled to attend and vote is entitled to appoint one or more proxies to attend and vote instead of him or her and that a proxy need not be a Member of the Company.

80. The accidental omission to give notice of a general meeting to, or the non-receipt of notice of a meeting by, any person entitled to receive notice shall not invalidate the proceedings of that meeting.

81. In cases where instruments of proxy are sent out with notices, the accidental omission to send such instrument of proxy to, or the non-receipt of such instrument of proxy by, any person entitled to receive notice shall not invalidate the notice or any resolution passed or any proceeding at any such meeting. A Member present, either in person or by proxy, at any general meeting of the Company or of the holders of any class of Shares in the Company will be deemed to have received notice of that meeting and, where required, of the purpose for which it was called.

PROCEEDINGS AT GENERAL MEETINGS

82. The business of annual general meetings shall include:

82.1. the consideration of the Company's statutory financial statements and the report of the Directors and the report of the Auditors on those statements and that report;

82.2. the review by the Members of the Company's affairs;

82.3. the appointment or re-appointment of the Auditors;

82.4. the authorisation of the Directors to approve the remuneration of the Auditors; and

82.5. the election and re-election of Directors.

83. No business shall be transacted at any general meeting unless a quorum is present. One or more Members present in person or by proxy (whether or not such Member actually exercises his voting rights in whole, in part or at all at the relevant general meeting) holding not less than a majority of the issued and outstanding Shares of the Company entitled to vote at the meeting in question shall be a quorum.

84. If within 15 minutes (or such longer time not exceeding one hour as the Chairperson of the meeting may decide to wait) after the time appointed for the holding of the meeting a quorum is not present, or if during the meeting a quorum ceases to be present, the meeting (i) if convened on the requisition of Members, shall be dissolved; and (ii) in any other case, shall stand adjourned to the same day in the next week or to such other day and at such other time and place as the Chairperson (or, in default, the Board) may, subject to the provisions of the Companies Act, determine. If at such adjourned meeting a quorum is not present within 15 minutes after the time appointed for holding it the adjourned meeting shall be dissolved.

85. If the Board wishes to make this facility available to Members for any or all general meetings of the Company, a Member may participate in any general meeting of the Company by means of a telephone, video, electronic or similar communication equipment by way of which all persons participating in such meeting can communicate with each other simultaneously and instantaneously and such participation shall be deemed to constitute presence in person at the meeting.

86. Each Director and the Auditors shall be entitled to attend and speak at any general meeting of the Company.

87. The Chairperson, or in his absence, some other Director nominated by the Directors shall preside at every general meeting of the Company, but if at any meeting neither the Chairperson, nor such other Director, is present within fifteen minutes after the time appointed for the holding of the meeting, or if none of them are willing to act as Chairperson, the Directors present shall choose some Director present to be Chairperson, or if no Director is present, or if all the Directors present decline to take the chair, the Members present shall choose some Member present to be Chairperson.

88. The Chairperson of the meeting may, and shall if so directed by the meeting (upon the passage of an Ordinary Resolution), adjourn the meeting from time to time and from place to place, but no business shall be transacted at any adjourned meeting other than the business left unfinished, or which might have been transacted, at the meeting from which the adjournment took place. When a general meeting is adjourned for thirty (30) days or more, notice of the adjourned meeting shall be given as in the case of an original meeting; save as aforesaid it shall not be necessary to give any notice of an adjournment or of the business to be transacted at an adjourned general meeting. Without prejudice to any other power of adjournment which the Chairperson of the meeting may have under these Articles, at common law or otherwise, the Chairperson may, without the consent of the meeting, adjourn the meeting from time to time (or indefinitely) and from place to place if he or she decides that it is necessary or appropriate to do so in order to: (a) secure the proper and orderly conduct of the meeting; (b) give all persons entitled to do so an opportunity of attending the meeting; (c) give all persons entitled to do so a reasonable opportunity of speaking and voting at the meeting; or (d) ensure that the business of the meeting is properly concluded or disposed of, including (without limitation) for the purpose of determining the result of a poll.

89.

89.1. Subject to the Companies Act, a resolution may only be put to a vote at a general meeting of the Company or of any class of Members if:

(a) it is specified in the notice of meeting;

(b) it is proposed by or at the direction of the Board;

(c) it is proposed at the direction of a court of competent jurisdiction;

(d) it is proposed pursuant to, and in accordance with, the procedures and requirements of Article 90 or 155;

(e) it is proposed on the requisition in writing of such number of Members as is prescribed by, and is made in accordance with, section 178(3) of the Companies Act;

(f) the Chairperson of the meeting decides that the resolution may properly be regarded as within the scope of the meeting; or

(g) it has not been withdrawn by the Chairperson in accordance with Article 89.2.

89.2. The Chairperson of the meeting may, at his sole discretion, withdraw any resolution to be put to a vote at a general meeting of the Company or of any class of Members and such withdrawal shall not invalidate the proceedings of such meeting and shall be without prejudice to any other resolutions to be put to a vote at such general meeting of the Company or any class of Members.

89.3. No amendment may be made to a resolution, at or before the time when it is put to a vote, unless the Chairperson of the meeting decides that the amendment or the amended resolution may properly be put to a vote at that meeting.

89.4. If the Chairperson of the meeting rules a resolution or an amendment to a resolution admissible or out of order (as the case may be), the proceedings of the meeting or on the resolution in

question shall not be invalidated by any error in his or her ruling. Any ruling by the Chairperson of the meeting in relation to a resolution or an amendment to a resolution shall be final and conclusive.

90.

90.1. For business to be properly requested by a Member to be brought before a general meeting, (other than nominations of directors, which may only be made in accordance with Article 155.1) the Member must:

(a) be a Member of the Company at the time of the giving of the notice for such general meeting;

(b) be entitled to vote at such meeting; and

(c) have given timely and proper notice in writing to the Secretary in accordance with this Article 90.

90.2. To be timely for an annual general meeting, a Member's notice to the Secretary must be delivered to or mailed and received at the registered office of the Company: (i) with respect to the first annual general meeting of the Company as a public limited company, not later than the 10th day following the day on which public announcement of the date of such annual general meeting is first made by the Company; and (ii) with respect to all other annual general meetings, not less than ninety (90) days nor (except for shareholder proposals subject to Rule14a-8(e)(3) of the Exchange Act) more than one hundred and twenty (120) days prior to the first anniversary of the date of the notice convening the preceding year's annual general meeting; provided, however, that if the date of the annual general meeting is changed by more than thirty (30) days from the first anniversary date of the preceding year's annual general meeting, the Member's notice must be so received not earlier than one hundred and twenty (120) days prior to such annual general meeting and not later than the close of business on the later of (x) the 90th day prior to such annual general meeting or (y) the 10th day following the day on which a public announcement of the date of the annual general meeting is first made. In no event shall the adjournment or postponement of any annual general meeting, or the public announcement of such an adjournment or postponement, commence a new time period (or extend any time period) for the giving of a Member's notice to the Secretary pursuant to this Article 90.2.

90.3. To be timely for a general meeting (other than an annual general meeting), a Member's notice to the Secretary must be delivered to or mailed and received at the registered office of the Company not less than ninety (90) days nor (except for shareholder proposals subject to Rule14a-8(e)(3) of the Exchange Act) more than one hundred and twenty (120) days prior to the date of such meeting or, if the first public announcement of the date of such meeting is less than 100 days prior to the date of such meeting, the 10th day following the date on which public announcement is first made of the date of the general meeting. In no event shall the adjournment or postponement of any general meeting, or the public announcement of such an adjournment or postponement, commence a new time period (or extend any time period) for the giving of a Member's notice to the Secretary pursuant to this Article 90.3.

90.4. To be in proper written form, a Member's notice shall set forth as of the date of the notice and as to the Member giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a Proponent and collectively, the Proponents) as to each matter such Member proposes to bring before the meeting:

(a) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting;

(b) the name and address, in the case of a Member as it appears on the Register of Members, of each Proponent;

(c) date(s) upon which each Proponent acquired such Shares;

(d) the class, series and number of Shares which are beneficially owned by each Proponent and their respective affiliates or associates or others acting in concert therewith;

(e) any option, warrant, convertible security, share appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of Shares or with a value of each Proponent;

(f) any proxy, contract, arrangement, understanding, or relationship pursuant to which each Proponent has a right to vote any class or series of Shares;

(g) any rights to dividends on the Shares beneficially owned by each Proponent that are separated or separable from the underlying Shares;

(h) any proportionate interest in the Shares held, directly or indirectly, by a general or limited partnership in which each Proponent is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(i) any performance-related fees (other than an asset-based fee) that each Proponent is entitled to based on any increase or decrease in the value of the Shares, including without limitation any such interests held by members of each Proponent's immediate family sharing the same household

(j) any significant equity interests, derivative or short interests in any principal competitor of the Company held by each Proponent;

(k) any direct or indirect interest of each Proponent in any contract with the Company, any affiliate of the Company or any principal competitor of the Company (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement);

(l) any agreement, arrangement, understanding, relationship or otherwise, including any repurchase or similar so-called "stock borrowing" agreement or arrangement, involving each Proponent, directly or indirectly, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of any class or series of the Shares by, manage the risk of share price changes for, or increase or decrease the voting power of, each Proponent with respect to any class or series of the Shares, or which provides, directly or indirectly, the opportunity to profit or share in any profit derived from any decrease in the price or value of any class or series of the Shares;

(m) any material interest of each Proponent, or of any other person on whose behalf such business is raised, in such business;

(n) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to such nomination or proposal between or among each Proponent and any of its affiliates or associates, and any others (including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing;

(o) a representation that each Proponent is holders of record or beneficial owners, as the case may be, of Shares entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice (with respect to a notice under Article 155) or to propose the business that is specified in the notice (with respect to a notice under Article 90);

(p) a representation as to whether each Proponent intends to deliver a proxy statement and form of proxy to holders of a sufficient number of holders of the Company's voting shares to elect such nominee or nominees (with respect to a notice under Article 155) or to carry such proposal (with respect to a notice under Article 90);

(q) to the extent known by any Proponent, the name and address of any other Member supporting the proposal on the date of such Member's notice;

(r) a description of all Derivative Transactions by each Proponent during the previous twelve (12) month period, including the date of the transactions and the class, series and number of securities involved in, and the material economic terms of, such Derivative Transactions; and

(s) any other information relating to each Proponent that would be required to be disclosed in a proxy statement and form of proxy or other filings required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to Regulation 14A of the Exchange Act.

90.5. The Chairperson shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting and in accordance with the provisions of this Article and, if he should so determine, he shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

91. Except where a greater majority is required by the Companies Act or where these Articles provide otherwise, any question proposed for a decision of the Members at any general meeting of the Company or a decision of any class of Members at a separate meeting of any class of Shares shall be decided by an Ordinary Resolution.

92. At any general meeting, a resolution put to the vote of the meeting shall be decided on a poll. The Board or the Chairperson may determine the manner in which the poll is to be taken and the manner in which the votes are to be counted.

93. A poll demanded on the election of the Chairperson or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken at such time as the Chairperson of the meeting directs, and any business other than that on which a poll has been demanded may be proceeded with pending the taking of the poll.

94. No notice need be given of a poll not taken immediately. The result of the poll shall be deemed to be the resolution of the general meeting at which the poll was demanded. On a poll, a Member entitled to more than one vote need not use all his or her votes or cast all the votes he or she uses in the same way.

95. If authorised by the Board, any vote taken by written ballot may be satisfied by a ballot submitted by electronic and/or telephonic transmission, provided that any such electronic or telephonic submission must either set forth or be submitted with information from which it can be determined that the electronic or telephonic submission has been authorised by the Member or proxy.

96. The Board may adopt such rules, regulations and procedures for the conduct of any meeting of the Members as it deems appropriate. Except to the extent inconsistent with any applicable rules, regulations or procedures adopted by the Board, the Chairperson of any meeting may adopt such rules, regulations

and procedures for the meeting, and take such actions with respect to the conduct of the meeting, as the Chairperson of the meeting deems appropriate. The rules, regulations and procedures adopted may include, without limitation, ones that (i) establish an agenda or order of business, (ii) are intended to maintain order and safety at the meeting, (iii) contain limitations on attendance at or participation in the meeting to Members of record of the Company, their duly authorised proxies or such other persons as the Chairperson of the meeting shall determine, (iv) contain restrictions on entry to the meeting after the time fixed for its commencement and (v) limit the time allotted to Member questions or comments.

VOTES OF MEMBERS

97. Subject to any rights or restrictions for the time being attached to any class or classes of Shares, every Member present in person or by proxy shall have one vote for each Share registered in his or her name in the Register of Members.

98. In the case of joint holders of record the vote of the senior holder who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holders, and for this purpose seniority shall be determined by the order in which the names stand in the Register of Members.

99. A Member of unsound mind, a Member who has made an enduring power of attorney, or in respect of whom an order has been made by any court, having jurisdiction in cases of unsound mind, may vote by his or her committee, donee of an enduring power of attorney, receiver, guardian or other person appointed by the foregoing court, and any such committee, donee of an enduring power of attorney, receiver, guardian or other persons appointed by the foregoing court may vote by proxy.

100. No Member shall be entitled to vote at any general meeting unless he or she is registered as a Member on the record date for such meeting.

101. No objection shall be raised to the qualification of any voter except at the general meeting or adjourned general meeting at which the vote objected to is given or tendered and every vote not disallowed at such general meeting shall be valid for all purposes. Any such objection made in due time shall be referred to the Chairperson of the general meeting whose decision shall be final and conclusive.

102. Unless the Board decides otherwise, no Member shall be entitled to be present or vote at any meeting either personally or by proxy until such Member has paid all calls due and payable on every Share held by him or her whether alone or jointly with any other person together with interest and expenses (if any) to the Company.

103. Resolutions in writing signed by all of the Members may be validly passed only prior to the completion of the initial public offering of the Company's ordinary shares on the Nasdaq Stock Exchange. For the avoidance of doubt, upon completion of the initial public offering of the Company's ordinary shares on the Nasdaq Stock Exchange, any resolution or action required or permitted to be passed or taken by the Members may be effected only at a duly convened annual or extraordinary general meeting of Members and may not be effected by any resolution or consent in writing by such Members.

PROXIES AND CORPORATE REPRESENTATIVES

104. Votes may be given either personally or by proxy. A Member may appoint more than one proxy or the same proxy under one or more instruments to attend and vote at a meeting and may appoint a proxy to vote both in favour of and against the same resolution in such proportion as specified in the instrument appointing the proxy.

105.

105.1. Every Member entitled to attend and vote at a general meeting may appoint a proxy to attend, speak and vote on his or her behalf and may appoint more than one proxy to attend, speak and

vote at the same meeting. The appointment of a proxy or corporate representative shall be in such form and may be accepted by the Company at such place and at such time as may be specified in the notice convening the meeting or in any other information sent to the Members by or on behalf of the Board in relation to the meeting, subject to applicable requirements of the United States Securities and Exchange Commission and any Exchange on which the Shares are listed.

105.2. Without limiting the foregoing, the Board or the Secretary may from time to time permit appointments of a proxy to be made by means of an electronic or internet communication or facility and may in a similar manner permit supplements to, or amendments or revocations of, any such electronic or internet communication or facility to be made. For the avoidance of doubt, such appointments of proxy made by electronic or internet communications (as permitted by the Board or the Secretary) will be deemed to be deposited at the place specified for such purpose once received by the Company. The Board or the Secretary may in addition prescribe the method of determining the time at which any such electronic or internet communication or facility is to be treated as deposited at the place specified for such purpose. The Board may treat any such electronic or internet communication or facility which purports to be or is expressed to be sent on behalf of a Member as sufficient evidence of the authority of the person sending that instruction to send it on behalf of that Member.

106. Any body corporate which is a Member of the Company may authorise such person or persons as it thinks fit to act as its representative at any meeting of the Company or of any class of Members of the Company and the person or persons so authorised shall be entitled to exercise the same powers on behalf of the body corporate which he or she represents as that body corporate could exercise if it were an individual Member of the Company. The Company may require evidence from the body corporate of the due authorisation of such person or persons to act as the representative of the relevant body corporate.

107. An appointment of proxy relating to more than one meeting (including any adjournment thereof) having once been received by the Company for the purposes of any meeting shall not require to be delivered, deposited or received again by the Company for the purposes of any subsequent meeting to which it relates.

108. Receipt by the Company of an appointment of proxy in respect of a meeting shall not preclude a Member from attending and voting at the meeting or at any adjournment thereof which attendance and voting will automatically cancel any proxy previously submitted.

109. An appointment of proxy shall be valid, unless the contrary is stated therein, for any adjournment of the meeting as well as for the meeting to which it relates.

110. A vote given in accordance with the terms of an appointment of proxy or a resolution authorising a representative to act on behalf of a body corporate shall be valid notwithstanding the death or insanity of the principal, or the revocation of the appointment of proxy or of the authority under which the proxy was appointed or of the resolution authorising the representative to act or transfer of the Share in respect of which the proxy was appointed or the authorisation of the representative to act was given, provided that no notice in writing (whether in electronic form or otherwise) of such death, insanity, revocation or transfer shall have been received by the Company at the registered office before the commencement of the meeting or adjourned meeting at which the appointment of proxy is used or at which the representative acts.

111. The Board may send, at the expense of the Company and subject to applicable law (including the rules and regulations of the United States Securities and Exchange Commission), by post, electronic mail or otherwise, to the Members forms for the appointment of a proxy (with or without stamped envelopes for their return) for use at any general meeting or at any class meeting, either in blank or nominating any one or more of the Directors or any other persons in the alternative.

DIRECTORS

112. The number of Directors on the Board shall be not less than three (3) nor more than fifteen (15). The authorised number of Directors (within such fixed maximum and fixed minimum numbers) shall be determined solely by the Board and, for the avoidance of doubt, shall not require approval or ratification by the Company in general meeting.

113. The remuneration to be paid to the Directors shall be such remuneration as the Directors in their sole discretion shall determine. The Directors shall also be entitled to be paid their travelling, hotel and other expenses properly incurred by them in going to, attending and returning from meetings of the Directors, or any committee of the Directors, or general meetings of the Company, or otherwise in connection with the business of the Company, or to receive a fixed allowance in respect thereof as may be determined by the Board from time to time, or a combination partly of one such method and partly the other. The amount, rate or basis of the remuneration or expenses to be paid to the Directors shall not require approval or ratification by the Company in general meeting. A Director is expressly permitted (for the purposes of section 228(1)(d) of the Companies Act) to use the Company's property pursuant to or in connection with: the exercise or performance of his duties, functions and powers as Director or employee; the terms of any contract of service or employment or letter of appointment; and, or in the alternative, any other usage authorised by the Directors (or a person authorised by the Directors) from time to time; and including in each case for a Director's own benefit or for the benefit of another person.

114. The Board may approve additional remuneration to any Director undertaking any special work or services for, or undertaking any special mission on behalf of, the Company other than his or her ordinary routine work as a Director. Any fees paid to a Director who is also counsel or solicitor to the Company, or otherwise serves it in a professional capacity, shall be in addition to his or her remuneration as a Director.

115. The salary or remuneration of a Director appointed to hold employment or executive office may be a fixed sum of money, or wholly or in part governed by business done or profits made, or as otherwise decided by the Board (including, for the avoidance of doubt, by the Board acting through a duly authorised Board committee), and may be in addition to or instead of a fee payable to such Director for his or her services as Director pursuant to these Articles.

116. Members of special or standing committees may be allowed like compensation for service on any such committees or for attending committee meetings, or both.

DIRECTORS' AND OFFICERS' INTERESTS

117. A Director or an officer of the Company who is in any way, whether directly or indirectly, interested in a contract, transaction or arrangement or proposed contract, transaction or arrangement with the Company shall, in accordance with section 231 of the Companies Act, declare the nature of his or her interest at the first opportunity either (a) at a meeting of the Board at which the question of entering into the contract, transaction or arrangement is first taken into consideration, if the Director or officer of the Company knows this interest then exists, or in any other case, at the first meeting of the Board after learning that he or she is or has become so interested or (b) by providing a general notice to the Directors declaring that he or she is a Director or an officer of, or has an interest in, a person and is to be regarded as interested in any transaction or arrangement made with that person, and after giving such general notice it shall not be necessary to give special notice relating to any particular transaction.

118. A Director may hold any other office or place of profit with the Company (other than the office of its Auditors) in conjunction with his or her office of Director for such period and on such terms as to remuneration and otherwise as the Board may determine.

119. Nothing in section 228(1)(e) of the Companies Act shall restrict a Director from entering into any commitment which has been approved by the Board or has been approved pursuant to such authority as may be delegated by the Board in accordance with these Articles. It shall be the duty of each Director to

obtain the prior approval of the Board, before entering into any commitment permitted by sections 228(1)(e)(ii) and 228(2) of the Companies Act.

120. A Director may act by himself or herself or by his or her firm in a professional capacity for the Company (other than as its Auditors) and he or she or his or her firm shall be entitled to remuneration for professional services as if he or she were not a Director.

121. A Director may be or become a director, managing director, joint managing director, deputy managing director, executive director, manager or other officer or member of any other entity or otherwise interested in any entity promoted by the Company or in which the Company may be interested as member or otherwise, and no such Director shall be accountable to the Company for any remuneration or other benefits received by him or her as a Director, managing director, joint managing director, deputy managing director, executive director, manager or other officer or member of such other entity; provided that he or she has declared the nature of his or her position with, or interest in, such entity to the Board in accordance with Article 117 and this has been approved by a majority of the disinterested Directors, notwithstanding the fact that the disinterested Directors may represent less than a quorum.

122. Nothing in section 228(1)(d) or section 228(1)(f) of the Companies Act shall restrict a Director from engaging directly or indirectly in the same or similar business activities or lines of business as the Company or any of its subsidiaries. To the fullest extent permitted by applicable law, the Company renounces any interest or expectancy of the Company and its subsidiaries in, or in being offered an opportunity to participate in, business opportunities that may from time to time be presented to Directors other than in their role as directors of the Company, even if the opportunity is one that the Company or its subsidiaries might reasonably be expected to have pursued or had the ability or desire to pursue if granted the opportunity to do so. The Directors shall have no duty to communicate or offer such business opportunity to the Company and, to the fullest extent permitted by applicable law, shall not be deemed to have breached any fiduciary or other duty solely by reason of the fact that such Director pursues or acquires such business opportunity, directs such business opportunity to another person or fails to present such business opportunity, or information regarding such business opportunity, to the Company or any of its subsidiaries. A business opportunity shall not be deemed to be an opportunity of the Company if it is an opportunity that the Company is not financially able or contractually permitted or legally able to undertake, or that is, by its nature, not in line with the Company's business or is of no advantage to it or is one in which the Company has no interest or reasonable prospect.

123. No person shall be disqualified from the office of Director or from being an officer of the Company or prevented by such office from contracting with the Company, either as vendor, purchaser or otherwise, nor shall any such contract or any contract or transaction entered into by or on behalf of the Company in which any Director or officer of the Company shall be in any way interested be or be liable to be avoided, nor shall any Director or officer of the Company so contracting or being so interested be liable to account to the Company for any profit realised by any such contract or transaction by reason of such Director or officer of the Company holding office or of the fiduciary relation thereby established; provided that:

123.1. he or she has declared the nature of his or her interest in such contract or transaction to the Board in accordance with Article 117; and

123.2. the contract or transaction is approved by a majority of the disinterested Directors, notwithstanding the fact that the disinterested Directors may represent less than a quorum.

124. A Director may be counted in determining the presence of a quorum at a meeting of the Board which authorises or approves the contract, transaction or arrangement in which he or she is interested and he or she shall be at liberty to vote in respect of any contract, transaction or arrangement in which he or she is interested, provided that the nature of the interest of any Director in any such contract or transaction shall be disclosed by him or her in accordance with Article 117, at or prior to its consideration and any vote thereon.

125. For the purposes of Article 117:

125.1. a general notice given to the Directors that a Director is to be regarded as having an interest of the nature and extent specified in the notice in any transaction or arrangement in which a specified person or class of persons is interested shall be deemed to be a disclosure that the Director has an interest in any such transaction of the nature and extent so specified;

125.2. an interest of which a Director has no knowledge and of which it is unreasonable to expect him or her to have knowledge shall not be treated as an interest of his or hers; and

125.3. a copy of every declaration made and notice given under Article 117 shall be entered within three (3) days after the making or giving thereof in a book kept for this purpose. Such book shall be open for inspection without charge by any Director, Secretary, the Auditors or Member of the Company at the registered office and shall be produced at every general meeting of the Company and at any meeting of the Directors if any Director so requests in sufficient time to enable the book to be available at the meeting.

POWERS AND DUTIES OF DIRECTORS

126. The business of the Company shall be managed by the Directors, who may pay all expenses incurred in promoting and registering the Company and may exercise all such powers of the Company as are not, by the Companies Act or by these Articles, required to be exercised by the Company in general meeting, subject, nevertheless, to any of these Articles and to the provisions of the Companies Act. No resolution made by the Company in general meeting shall invalidate any prior act of the Directors that would have been valid if that resolution had not been made.

127. The Board shall have the power to appoint and remove officers and executives on such terms as the Board sees fit and to give such titles and delegate such responsibilities to those officers and executives as it sees fit.

128. The Company may exercise the powers conferred by section 44 of the Companies Act with regard to having an official seal for use abroad and such powers shall be vested in the Directors.

129. Unless otherwise ordered by the Board, the chief executive officer shall have the authority to exercise the voting powers conferred by shares of any other company held or owned by the Company in such manner in all respects as he or she thinks fit and in particular they may exercise their voting powers in favour of any resolution appointing the Directors or any of them as director or officers of such other company or providing for the payment of remuneration or pensions to the directors or officers of such other company. The Board may from time to time confer like powers upon any other person or persons.

130. All cheques, promissory notes, drafts, bills of exchange and other negotiable instruments and all receipts for money paid to the Company shall be signed, drawn, accepted, endorsed or otherwise executed, as the case may be, by such person or persons and in such manner as the Directors shall from time to time by resolution determine.

131. The Directors may from time to time authorise such person or persons as they see fit to perform all acts, including, without prejudice to the foregoing, to effect a transfer of any shares, bonds, or other evidences of indebtedness or obligations, subscription rights, warrants, and other securities in another company in which the Company holds an interest and to issue the necessary powers of attorney for the same; and each such person is authorised on behalf of the Company to vote such securities, to appoint proxies with respect thereto, and to execute consents, waivers and releases with respect thereto, or to cause any such action to be taken.

132. The Board may exercise all powers of the Company to borrow money and to mortgage or charge its undertaking, property and uncalled capital or any part thereof and to issue debentures, debenture stock, mortgages, bonds or such other securities whether outright or as security for any debt, liability or obligation of the Company or of any third party.

133. The Directors may procure the establishment and maintenance of or participate in, or contribute to, any non-contributory or contributory pension or superannuation fund, scheme or arrangement or life assurance scheme or arrangement for the benefit of, and pay, provide for or procure the grant of donations, gratuities, pensions, allowances, benefits or emoluments to any persons (including Directors or officers) who are or shall have been at any time in the employment or service of the Company or of any company which is or was a subsidiary or holding company of the Company or of any predecessor in business of the Company or any such subsidiary or holding company and the wives, husbands, widows, widowers, families, relatives or dependants of any such persons. The Directors may also procure the establishment and subsidy of or subscription to and support of any institutions, associations, clubs, funds or trusts calculated to be for the benefit of any such persons as aforesaid or otherwise to advance the interests and well-being of the Company or of any such other company as aforesaid or its Members, and payments for or towards the issuance of any such persons as aforesaid and subscriptions or guarantees of money for charitable or benevolent objects or for any exhibition or for any public, general or useful object; provided that any Director shall be entitled to retain any benefit received by him or her under this Article 133, subject only, where the Companies Act requires, to disclosure to the Members and the approval of the Company in general meeting.

134. The Board may from time to time provide for the management of the affairs of the Company in such manner as it shall think fit and the specific delegation provisions contained in the Articles shall not limit the general powers conferred by these Articles.

MINUTES

135. The Board shall cause minutes to be made in books kept for the purpose of all (i) appointments of officers and committees made by the Board; and (ii) resolutions and proceedings at meetings of (a) the Company or of the holders of any class of Shares and (b) the Board and of committees of the Board, including in each case the names of the Directors and others present at each meeting. Any such minutes, if signed by the Chairperson of the meeting at which the proceedings were held or by the Chairperson of the next succeeding meeting or the Secretary, shall be prima facie evidence of the matters stated in them.

DELEGATION OF THE BOARD'S POWERS

136. The Board may delegate any of its powers (with power to sub-delegate) to any committee consisting of one or more Directors and/or (if thought fit) one or more other persons. The Board may also delegate to any Director, officer or member of the management of the Company or any of its subsidiaries such of its powers as it considers desirable to be exercised by him or her. The Board may also designate one or more persons as alternate members of any committee, who may replace any absent or disqualified member at any meeting of any such committee. Any such delegation may be made subject to any conditions the Board may impose, and either collaterally with or to the exclusion of its own powers, and may be revoked or altered. Subject to any such conditions, the proceedings of a committee shall be governed by the Articles regulating the proceedings of Directors, so far as they are capable of applying. Each committee shall keep regular minutes and report to the Board when required. Unless otherwise determined by the Board, the quorum necessary for the transaction of any business at any committee meeting shall be a majority of the members of such committee. Where a provision of the Articles refers to the exercise of a power, authority or discretion by the Board and that power, authority or discretion has been delegated by the Board to a committee, the provision shall be construed as permitting the exercise of the power, authority or discretion by the committee.

137. The Board may, by power of attorney or otherwise, appoint any person to be the agent of the Company on such conditions as the Board may determine, provided that the delegation is not to the exclusion of its own powers and may be revoked by the Board at any time.

138. The Board may, by power of attorney or otherwise, appoint any company, firm, person or body of persons, whether nominated directly or indirectly by the Board, to be the attorney or authorised signatory of the Company for such purpose and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Board under these Articles) and for such period and subject to such conditions

as they may think fit, and any such powers of attorney or other appointment may contain such provisions for the protection and convenience of persons dealing with any such attorneys or authorised signatories as the Board may think fit and may also authorise any such attorney or authorised signatory to delegate all or any of the powers, authorities and discretions vested in him or her.

CHAIRPERSON AND EXECUTIVE OFFICERS

139. The Board may elect any Director as Chairperson of the Board and determine the period for which he or she is to hold office.

140. In addition to the Chairperson, the Directors and the Secretary, the Company may appoint such other officers, including executive officers, as the Board may from time to time determine and, without limitation to the foregoing, the Board may appoint any person (whether or not a Director) to fill the following positions: chief executive officer, chief financial officer, general counsel, president, treasurer and controller. Any person may hold more than one of the foregoing positions.

141. Any person elected or appointed pursuant to Articles 139 and 140 shall hold his or her office or other position for such period and on such terms as the Board may determine and the Board may revoke or vary any such election or appointment at any time by resolution of the Board. Any such revocation or variation shall be without prejudice to any claim for damages that such person may have against the Company or the Company may have against such person for any breach of any contract of service between him or her and the Company which may be involved in such revocation or variation. If any such office or other position becomes vacant for any reason, the vacancy may be filled by the Board.

142. Except as provided in the Companies Act or these Articles, the powers and duties of any person elected or appointed to any office or executive or official position pursuant to Articles 139 and 140 shall be such as are determined from time to time by the Board.

143. Any officer may resign at any time by giving written notice to the Company. The resignation is effective without acceptance when the notice is given to the Company, unless a later effective date is specified in the notice.

144. The use of the word "officer", "director" (save where the relevant person is a Director for the purposes of these Articles) (or similar words) in the title of any executive or other position shall not be deemed to imply that the person holding such executive or other position is an "officer" or "director" of the Company within the meaning of the Companies Act.

PROCEEDINGS OF DIRECTORS

145. Except as otherwise provided by these Articles, the Directors shall meet together for the despatch of business, convening, adjourning and otherwise regulating their meetings and procedures as they think fit. Questions arising at any meeting shall be decided by a majority of votes of the Directors present at a meeting at which there is a quorum. Each Director shall have one vote.

146. Regular meetings of the Board may be held at such times and places as may be provided for in resolutions adopted by the Board. No additional notice of a regularly scheduled meeting of the Board shall be required.

147. A Director may, and the Secretary on the requisition of a Director shall, at any time summon a meeting of the Directors by at least 24 hours' notice (or, if notice is mailed, at least four calendar days' notice) in writing to every Director, unless notice is waived by all the Directors either at, before or after the meeting is held and, provided further, if notice is given in person, by telephone, cable, telex, telecopy or email, the same shall be deemed to have been given on the day it is delivered to the Directors or transmitting organisation, as the case may be. The accidental omission to give notice of a meeting of the Directors to, or the non-receipt of notice of a meeting by, any person entitled to receive notice shall not invalidate the proceedings of that meeting. The presence of a Director at a meeting of the Directors shall be deemed

to be a waiver of any failure to give due notice of such meeting unless such Director states that he or she is not waiving any such failure promptly following the calling to order of such meeting. Notice of a Board meeting shall be deemed to be duly given to a Director if it is given to such Director personally or by word of mouth or sent in writing to his or her last known address or any other address given to the Company by such Director for such purpose or given by electronic communications to an address for the time being notified to the Company by the Director. In this Article "address," in relation to documents in electronic form, includes any number or address used for the supply of documents in electronic form.

148. The quorum necessary for the transaction of the business of the Board shall be a majority of the Directors in office. If a quorum shall not be present at any meeting of the Board, the Directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

149. The continuing Directors may act notwithstanding any vacancy in their body, but if and so long as their number is reduced below the number fixed by or pursuant to these Articles as the minimum number of Directors, the continuing Directors or Director may act for the purpose of increasing the number of Directors to that number, or of summoning a general meeting of the Company, but for no other purpose. If there is/are no Director or Directors able or willing to act, any two Members may summon a general meeting for the purpose of appointing Directors. Any Director so appointed shall hold office (subject to these Articles) only until the dissolution of the annual general meeting next following such appointment unless such Director is re-elected during such meeting.

150. If no Chairperson is elected, or if at any meeting the Chairperson is not present within five (5) minutes after the time appointed for holding the same, the Directors present may choose one of their number to be the Chairperson of the meeting or proceed without a Chairperson of the meeting.

151. All acts done by any meeting of the Directors or of a committee of Directors shall, notwithstanding that it be afterwards discovered that there was some defect in the appointment of any Director, or that they or any of them were disqualified, be as valid as if every such person had been duly appointed and qualified to be a Director.

152. Members of the Board or of any committee thereof may participate in a meeting of the Board or of such committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and participation in a meeting pursuant to this provision shall constitute presence in person at such meeting. Unless otherwise determined by the Directors, the meeting shall be deemed to be held at the place where the telephone call or similar communication was initiated.

153. A resolution or other document in writing (in electronic form or otherwise), signed (whether by electronic signature, advanced electronic signature or otherwise as approved by the Directors) by all the Directors entitled to receive notice of a meeting of Directors or of a committee of Directors, and to vote on the relevant resolution or matter, shall be as valid and effectual as if it had been passed at a meeting of Directors or (as the case may be) a committee of Directors duly convened and held and may consist of several documents in the like form each signed by one or more Directors, and such resolution or other document or documents when duly signed may be delivered or transmitted (unless the Directors shall otherwise determine either generally or in any specific case) by facsimile transmission, electronic mail or some other similar means of transmitting the content of documents.

RESIGNATION AND DISQUALIFICATION OF DIRECTORS

154. The office of a Director shall be vacated ipso facto:

154.1. on the death of a Director;

154.2. if he or she resigns his or her office, on the date on which notice of his or her resignation is delivered to the registered office or tendered at a meeting of the Board or on such later date as may be specified in such notice;

154.3. if he or she ceases to be a Director by virtue of any provision of the Companies Act, is removed from office pursuant to these Articles or the Companies Act or becomes prohibited by law from being a Director;

154.4. if he or she becomes bankrupt, has an interim receiving order made against him or her, makes any arrangement or compounds with his or her creditors generally or applies to the court for an interim order in connection with a voluntary arrangement under any legislation relating to insolvency;

154.5. if the health of the Director is such that, in the opinion of a majority of the other Directors, he or she can no longer be reasonably regarded as possessing adequate decision making capacity;

154.6. in the case of a Director who holds executive office, his or her appointment to such office is terminated or expires and the Board resolves that such Director's office be vacated;

154.7. if he or she is absent, without permission of the Board, from Board meetings for six consecutive months and the Board resolves that his or her office be vacated; or

154.8. if the Director is requested to resign in writing by not less than a majority of the other Directors provided always that this Article 154.8 shall only apply if neither of the Sponsor Holders holds 10% or more of the entire issued share capital of the Company.

155. A resolution of the Board declaring a Director to have vacated office pursuant to this Article shall be conclusive as to the fact and grounds of vacation stated in the resolution.

APPOINTMENT, ROTATION AND NOMINATION OF DIRECTORS

156.

156.1. No person shall be appointed a Director unless nominated in accordance with the provisions of this Article 156. Nominations of persons for election to the Board at a general meeting may be made:

(a) by or at the direction of the Board or a committee thereof;

(b) with respect to election at a general meeting, by any Member who holds Shares carrying the general right to vote at general meetings of the Company, who is a Member at the time of the giving of the required notice of the relevant general meeting provided for in these Articles and at the time of the relevant general meeting, and who has given timely and proper notice in writing to the Secretary in accordance with Article 156.2 and 156.3;

(c) with respect to election at an extraordinary general meeting requisitioned in accordance with section 178(3) of the Companies Act, by a Member or Members who hold Shares carrying the general right to vote at general meetings of the Company and who make such nomination in the written requisition of the extraordinary general meeting in accordance with these Articles, including Article 156.3, and the provisions of the Companies Act relating to nominations of Directors and the proper bringing of special business before an extraordinary general meeting,

(sub-clauses (b) and (c) being the exclusive means for a Member to make nominations of persons for election to the Board).

156.2. For nominations of persons for election as Directors at a general meeting to be timely, a Member's notice must comply with the requirements of Article 90.2 or 90.3 (as applicable).

156.3. To be in proper written form, a Member's notice for nomination(s) of person(s) for election pursuant to Article 156.1(b), or in the case of nomination(s) of person(s) for election pursuant to Article 156.1(c), a Member's written requisition of the extraordinary general meeting, must, in addition to any other applicable requirements, set forth:

(d) as to each person whom the Member proposes to nominate for election or re−election as a Director, all information relating to such person that is required to be disclosed in solicitations for proxies for election of directors, or is otherwise required, in each case pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); and

(e) as to the Member giving the notice and each Proponent, the information required in Article 90.4.

156.4. The Chairperson of the meeting shall determine whether a nomination was made in accordance with the procedures prescribed by these Articles, and if he or she should determine that such nomination was not made in accordance with such procedures, he or she shall declare to the meeting that the nomination was defective and such defective nomination shall be disregarded. Any such ruling by the Chairperson of the meeting shall be final and conclusive.

156.5. The Company may require any proposed nominee to furnish such other information as it may reasonably require, including the completion of any questionnaires, to determine the eligibility of such proposed nominee to serve as a Director and the impact that such service would have on the ability of the Company to satisfy the requirements of laws, rules, regulations and listing standards applicable to the Company or its Directors.

157. At every annual general meeting of the Company, all of the Directors shall retire from office unless re-elected in accordance with Article 156.5. A Director retiring at a meeting shall retain office until the close of that meeting (including any adjournment thereof). Each Director shall be eligible to stand for re-election at an annual general meeting.

158. Directors will be elected by way of Ordinary Resolution of the Company in general meeting, provided that if the number of Director nominees exceeds the number of Directors (as determined by the Board) to be elected at such meeting (a "contested election"), each of those nominees shall be voted upon as a separate resolution and the Directors shall be elected by a plurality of the votes of the Shares present in person or represented by proxy at any such meeting and entitled to vote on the election of Directors. For the purposes of this Article 158, "elected by a plurality" means the election of those Director nominees, equal in number to the number of positions to be filled at the relevant general meeting (as determined by the Board), that received the highest number of votes in the contested election. Cumulative voting is prohibited in the election of Directors.

159. Notwithstanding any other provision of these Articles, the Directors may appoint a person who is willing to act to be a Director, either to fill a casual vacancy or as an additional Director, provided that the appointment does not cause the number of Directors to exceed the number prescribed by the Board in accordance with Article 112. A casual vacancy shall include, without limitation, a vacancy that results from the death, resignation, retirement, disqualification or removal of a Director.

160. The Company may, by Ordinary Resolution, of which notice has been given in accordance with section 146 of the Companies Act, remove any Director before the expiration of his or her period of office notwithstanding anything in these Articles or in any agreement between the Company and such Director. Such removal shall be without prejudice to any claim such Director may have for damages for breach of any contract of service between him or her and the Company.

SECRETARY

161. The Board shall appoint the Secretary and may appoint one or more persons to be a joint, deputy or Assistant Secretary at such remuneration (if any) and on such terms as the Board sees fit and any person so appointed may be removed by the Board at any time.

162. The duties of the Secretary shall be those prescribed by the Companies Act, together with such other duties as shall from time to time be prescribed by the Board, and in any case, shall include the making and keeping of records of the votes, doings and proceedings of all meetings of the Members and the Board of the Company, and committees, and the authentication of records of the Company.

163. A provision of the Companies Act or these Articles requiring or authorising a thing to be done by or to a Director and the Secretary shall not be satisfied by its being done by or to the same person acting both as Director and as, or in the place of, the Secretary.

SEAL

164. The Company may, if the Board so determines, have a Seal (including any official seals kept pursuant to the Companies Act) which shall only be used by the authority of the Board or by a duly authorised committee of the Board and every instrument to which the Seal has been affixed shall be signed by any person who shall be either a Director or the Secretary or some other person authorised by the Board, either generally or specifically, for that purpose.

165. The Company may have for use in any place or places outside Ireland a duplicate Seal or Seals, each of which shall be a duplicate of the Seal of the Company, except, in the case of a seal for use in sealing documents creating or evidencing securities issued by the Company, for the addition on its face of the word "Securities" and, if the Board so determines, with the addition on its face of the name of every place where it is to be used.

DIVIDENDS, DISTRIBUTIONS AND RESERVES

166. The Company in general meeting may by Ordinary Resolution declare dividends, but no dividends shall exceed the amount recommended by the Board. Subject to the Companies Act, the Board may, from time to time, pay such interim dividends as appear to it to be justified by the profits of the Company available for distribution. The Board may direct that any dividend declared by the Company in general meeting or by the Board in accordance with these Articles, may be paid wholly or partly by the distribution of specific assets and in particular of paid up shares, debentures or debenture stocks of any other company or in any one or more of such ways. Where any difficulty arises in regard to such distribution, the Board may settle the same as they think expedient, and in particular may issue fractional certificates or ignore fractions, fix the value for distribution of such specific assets or any part thereof and may determine that cash payments shall be made to any Members upon the footing of the value so fixed, in order to adjust the rights of all the parties, and may vest any such specific assets in trustees as may seem expedient to the Board.

167. Subject to the Companies Act, the Board may from time to time declare dividends (including interim dividends) and distributions on Shares outstanding and authorise payment of the same out of the funds of the Company lawfully available therefore and in any currency chosen at its discretion.

168. The Board may, before recommending or declaring any dividends or distributions, set aside such sums as it thinks proper as a reserve or reserves which shall, as directed by the Board, be applicable for any purpose of the Company and pending such application may, as directed by the Board, be employed in the business of the Company or be invested in such investments as the Directors may lawfully determine. The Directors may also, without placing the same to reserve, carry forward any profits which they may think it prudent not to dividend or distribute.

169. No dividend, interim dividend or distribution shall be paid otherwise than in accordance with the provisions of section 117 of the Companies Act.

170. Subject to the rights of persons, if any, entitled to Shares with special rights as to dividends or distributions, if dividends or distributions are to be declared on a class of Shares, they shall be declared and paid according to the amounts paid or credited as paid on the Shares of such class outstanding on the record date for such dividend or distribution as determined in accordance with these Articles.

171. The Directors may deduct from any dividend payable to any Member all sums of money (if any) immediately payable by him or her to the Company in relation to his or her Shares.

172. Any dividend, distribution, interest or other monies payable in cash in respect of Shares may be paid by cheque or warrant sent through the post, or sent by any electronic or other means of payment, directed to the registered address of the holder or, in the case of joint holders, to the holder who is first named on the Register of Members or to such person and to such address as such holder or joint holders may in writing direct. Every such cheque or warrant, electronic or other payment shall be made payable to the order of the person to whom it is sent and payment of the cheque or warrant shall be a good discharge to the Company. Any one of two or more joint holders may give effectual receipts for any dividends, bonuses, or other monies payable in respect of the Share held by them as joint holders. Any such dividend or other distribution may also be paid by any other method (including payment in a currency other than US$, electronic funds transfer, direct debit, bank transfer or by means of a relevant system) which the Directors consider appropriate and any Member who elects for such method of payment shall be deemed to have accepted all of the risks inherent therein. The debiting of the Company's account in respect of the relevant amount shall be evidence of good discharge of the Company's obligations in respect of any payment made by any such methods.

173. No dividend or distribution shall bear interest against the Company.

174. All unclaimed dividends or other monies payable by the Company in respect of a Share may be invested or otherwise made use of by the Board for the benefit of the Company until claimed. If the Directors so resolve, subject to applicable law, any dividend which has remained unclaimed for twelve (12) years from the date of its declaration shall be forfeited and cease to remain owing by the Company. The payment by the Directors of any unclaimed dividend or other monies payable in respect of a Share into a separate account shall not constitute the Company a trustee in respect thereof.

175. If, in respect of a dividend or other amount payable in respect of a Share (i) a cheque, warrant or money order is returned undelivered or left uncashed or (ii) a transfer made by or through a bank transfer system and/or other funds transfer system(s) fails or is not accepted, on two consecutive occasions, or one occasion and reasonable enquiries have failed to establish another address or account of the person entitled to the payment, the Company shall not be obliged to send or transfer a dividend or other amount payable in respect of such Share to such person until he or she notifies the Company of an address or account to be used for such purpose.

CAPITALISATION

176. Without prejudice to any powers conferred on the Directors as aforesaid, and subject to the Board's authority to issue and allot Shares under Article 7, the Board may:

176.1. resolve to capitalise an amount standing to the credit of reserves (including, without limitation, a share premium account, undenominated capital account, capital redemption reserve and profit and loss account), whether or not available for distribution;

176.2. appropriate the sum resolved to be capitalised to the Members in proportion to the nominal amount of Shares held by them respectively and apply that sum on their behalf in or towards paying up in full unissued Shares or debentures of a nominal amount equal to that sum, and allot the Shares or debentures, credited as fully paid, to the Members (or as the Board may direct) in

those proportions, or partly in one way and partly in the other, but the share premium account, undenominated capital account, capital redemption reserve and profits that are not available for distribution may, for the purposes of this Article 176, only be applied in paying up unissued Shares to be allotted to Members credited as fully paid;

176.3. make any arrangements it thinks fit to resolve a difficulty arising in the distribution of a capitalised reserve, including that where Shares or debentures become distributable in fractions, the Board may deal with the fractions as it thinks fit;

176.4. authorise a person to enter (on behalf of all the Members concerned) into an agreement with the Company providing for the allotment to the Members respectively, credited as fully paid, of Shares or debentures to which they may be entitled on the capitalisation and any such agreement made under this authority being effective and binding on all those Members; and

176.5. generally do all acts and things required to give effect to the resolution of the Board.

177. Any such capitalisation will not require approval or ratification by the Members of the Company.

ACCOUNTS

178. The Board shall, in accordance with Chapter 2 of Part 6 of the Companies Act, cause to be kept adequate accounting records, whether in the form of documents, electronic form or otherwise, that:

178.1. correctly record and explain the transactions of the Company;

178.2. will at any time enable the financial position of the Company to be determined with reasonable accuracy;

178.3. will enable the Board to ensure that any financial statements of the Company comply with the requirements of the Companies Act and any directors' report, required to be prepared under the Acts, comply with the requirements of the Companies Act and, where applicable, Article 4 of the IAS Regulation;

178.4. will record all sums of money received and expended by the Company and the matters in respect of which the receipt or expenditure takes place, all sales and purchases of goods by the Company and the assets and liabilities of the Company; and

178.5. will enable the financial statements of the Company to be readily and properly audited.

179. Accounting records shall be kept on a continuous and consistent basis and entries therein shall be made in a timely manner and be consistent from year to year. The Company may send by post, electronic mail or any other means of electronic communication a summary financial statement to its Members or persons nominated by any Member. The Company may meet, but shall be under no obligation to meet, any request from any of its Members to be sent additional copies of its full report and accounts or summary financial statement or other communications with its Members.

180. The accounting records shall be kept at the registered office of the Company or, subject to the provisions of the Companies Act, at such other place as the Directors think fit and shall be open at all reasonable times to the inspection of the Directors.

181. Accounting records shall not be deemed to be kept as required by Articles 178 to 180 if there are not kept such accounting records as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions.

182. In accordance with the provisions of the Companies Act, the Board may from time to time cause to be prepared and to be laid before the Company in general meeting profit and loss accounts, balance sheets, group accounts (if any) and such other reports and accounts as may be required by law.

183. A copy of every balance sheet (including every document required by law to be annexed thereto) which is to be laid before the annual general meeting of the Company together with a copy of the Directors' report and Auditors' report shall be sent by post, electronic mail or any other means of communication (electronic or otherwise), not less than twenty-one (21) clear days before the date of the annual general meeting, to every person entitled under the provisions of the Companies Act to receive them; provided that in the case of those documents sent by electronic mail or any other means of electronic communication, such documents shall be sent with the consent of the recipient, to the address of the recipient notified to the Company by the recipient for such purposes.

AUDIT

184. Auditors shall be appointed and their duties regulated in accordance with Part 6, Chapter 18 of the Companies Act or any statutory amendment thereof, any other applicable law and such requirements not inconsistent with the Companies Act as the Board may from time to time determine.

NOTICES

185. Any notice to be given, served, sent or delivered pursuant to these Articles shall be in writing (whether in electronic form or otherwise).

185.1. A notice or document to be given, served, sent or delivered in pursuance of these Articles, and the annual report of the Company, may be given to, served on or delivered to any Director, Member or committee member by the Company:

(a) by handing same to their authorised agent;

(b) by delivering same to their registered address;

(c) by sending same by the post in a pre-paid cover addressed to their registered address; or

(d) by sending, with the consent of the Director, Member or committee member to the extent required by law, same by means of electronic mail or other means of electronic communication approved by the Directors or the Secretary (or such other person as may be nominated by the Secretary for this purpose), to the address of the Director, Member or committee member notified to the Company by the Director, Member or committee member for such purpose (or if not so notified, then to the address of the Director, Member or committee member last known to the Company). A notice or document may be sent by electronic means to the fullest extent permitted by the Companies Act.

185.2. For the purposes of these Articles and the Companies Act, a document, including the Company's financial statements and the directors' and auditor's reports thereon, shall be deemed to have been sent to a Director, Member or committee member if a notice is given, served, sent or delivered to the Director, Member or committee member and the notice specifies the website or hotlink or other electronic link at or through which the Director, Member or committee member may obtain a copy of the relevant document.

185.3. Where a notice or document is given, served or delivered pursuant to sub-paragraph 184.1(a) or 184.1(b) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the time the same was handed to the Director, Member or committee member or his or her authorised agent, or left at his or her registered address (as the case may be).

185.4. Where a notice or document is given, served or delivered pursuant to sub-paragraph 184.1(c) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the expiration of twenty-four (24) hours after the cover containing it was posted. In proving service or delivery it shall be sufficient to prove that such cover was properly addressed, stamped and posted.

185.5. Where a notice or document is given, served or delivered pursuant to sub-paragraph 184.1(d) of this Article, the giving, service or delivery thereof shall be deemed to have been effected at the expiration of forty-eight (48) hours after despatch.

185.6. Every legal personal representative, committee, receiver, curator bonis or other legal curator, assignee in bankruptcy, examiner or liquidator of a Member shall be bound by a notice given as aforesaid if sent to the last registered address of such Member, or, in the event of notice given or delivered pursuant to sub-paragraph 184.1 (d), if sent to the address notified to the Company by the Member for such purpose notwithstanding that the Company may have notice of the death, lunacy, bankruptcy, liquidation or disability of such Member.

185.7. Notwithstanding anything contained in this Article to the contrary, the Company shall not be obliged to take account of or make any investigations as to the existence of any suspension or curtailment of postal services within or in relation to all or any part of any jurisdiction.

185.8. Any requirement in these Articles for the consent of a Member in regard to the receipt by such Member of electronic mail or other means of electronic communications approved by the Directors, including the receipt of the Company's annual report, statutory financial statements and the Directors' and auditor's reports thereon, shall be deemed to have been satisfied where the Company has written to the Member informing him or her of its intention to use electronic communications for such purposes and the Member has not, within four (4) weeks of the issue of such notice, served an objection in writing on the Company to such proposal. Where a Member has given, or is deemed to have given, his/her consent to the receipt by such Member of electronic mail or other means of electronic communications approved by the Directors, she/he may revoke such consent at any time by requesting the Company to communicate with him or her in documented form; provided, however, that such revocation shall not take effect until five (5) days after written notice of the revocation is received by the Company. No such consent shall be necessary, and to the extent it is necessary, such consent shall be deemed to have been given, if electronic communications are permitted to be used under the rules and regulations of the United States Securities and Exchange Commission or any Exchange on which the Shares or other securities of the Company are listed.

185.9. Without prejudice to the provisions of sub-paragraphs 185.1 (a) and 185.1(b) of this Article, if at any time by reason of the suspension or curtailment of postal services in any territory, the Company is unable effectively to convene a general meeting by notices sent through the post, a general meeting may be convened by a public announcement (as defined below) and such notice shall be deemed to have been duly served on all Members entitled thereto at noon (New York time) on the day on which the said public announcement is made. In any such case the Company shall put a full copy of the notice of the general meeting on its website. A "public announcement" shall mean disclosure in a press release reported by a financial news service or in a document publicly filed by the Company with the United States Securities and Exchange Commission pursuant to sections 13, 14 or 15(d) of the Exchange Act and the rules and regulations promulgated thereunder.

186. Notice may be given by the Company to the joint holders of a Share by giving the notice to the joint holder whose name stands first in the Register in respect of the Share and notice so given shall be sufficient notice to all the joint holders.

187.

187.1. Every person who becomes entitled to a Share shall, before his or her name is entered in the Register in respect of the Share, be bound by any notice in respect of that Share which has been duly given to a person from whom he or she derives his or her title.

187.2. A notice may be given by the Company to the persons entitled to a Share in consequence of the death or bankruptcy of a Member by sending or delivering it, in any manner authorised by these Articles for the giving of notice to a Member, addressed to them at the address, if any, supplied by them for that purpose. Until such an address has been supplied, a notice may be given in any manner in which it might have been given if the death or bankruptcy had not occurred.

188. The signature (whether electronic signature, an advanced electronic signature or otherwise) to any notice to be given by the Company may be written (in electronic form or otherwise) or printed.

189. A Member present, either in person or by proxy, at any meeting of the Company or the holders of any class of Shares in the Company shall be deemed to have received notice of the meeting and, where requisite, of the purposes for which it was called.

UNTRACED HOLDERS

190.

190.1. Subject to applicable law, the Company shall be entitled to sell, at the best price reasonably obtainable, any Share or stock of a Member or any Share or stock to which a person is entitled by transmission if and provided that:

(a) for a period of twelve (12) years (not less than three (3) dividends having been declared and paid) no cheque or warrant sent by the Company through the post in a prepaid letter addressed to the Member or to the person entitled by transmission to the Share or stock at his or her address on the Register or other than the last known address given by the Member or the person entitled by transmission to which cheques and warrants are to be sent has been cashed and no communication has been received by the Company from the Member or the person entitled by transmission; and

(b) at the expiration of the said period of twelve (12) years, the Company has given notice by advertisement in a leading newspaper circulating in the area in which the address referred to in paragraph (a) of this Article is located of its intention to sell such Share or stock; and

(c) the Company has not during the further period of three (3) months after the date of the advertisement and prior to the exercise of the power of sale received any communication from the Member or person entitled by transmission.

190.2. To give effect to any such sale, the Company may appoint any person to execute as transferor an instrument of transfer of such Share or stock and such instrument of transfer shall be as effective as if it had been executed by the Member or person entitled by transmission to such Share or stock. The Company shall account to the Member or other person entitled to such Share or stock for the net proceeds of such sale by carrying all monies in respect thereof to a separate account which shall be a permanent debt of the Company and the Company shall be deemed to be a debtor and not a trustee in respect thereof for such Member or other person. Monies carried to such separate account may either be employed in the business of the Company or invested in such investments (other than shares of the Company or its holding company if any) as the Directors may from time to time think fit.

190.3. To the extent necessary in order to comply with any laws or regulations to which the Company is subject in relation to escheatment, abandonment of property or other similar or analogous laws or regulations ("**Applicable Escheatment Laws**"), the Company may deal with any Share of any

Member and any unclaimed cash payments relating to such Share in any manner which it sees fit, including transferring or selling such Share and transferring to third parties any unclaimed cash payments relating to such Share.

190.4. The Company may only exercise the powers granted to it in paragraph 190.1 above in circumstances where it has complied with, or procured compliance with, the required procedures (as set out in the Applicable Escheatment Laws) with respect to attempting to identify and locate the relevant member of the Company.

190.5. Any stock transfer form to be executed by the Company in order to sell or transfer a Share pursuant to Article 190.1 may be executed in accordance with Article 28.1.

DESTRUCTION OF DOCUMENTS

191. Subject to applicable law, the Company may destroy:

191.1. any dividend mandate or any variation or cancellation thereof or any notification of change of name or address, at any time after the expiry of two (2) years from the date such mandate variation, cancellation or notification was recorded by the Company;

191.2. any instrument of transfer of Shares which has been registered, at any time after the expiry of six (6) years from the date of registration; and

191.3. any other document on the basis of which any entry in the Register was made, at any time after the expiry of six (6) years from the date an entry in the Register was first made in respect of it,

and it shall be presumed conclusively in favour of the Company that every share certificate (if any) so destroyed was a valid certificate duly and properly sealed and that every instrument of transfer so destroyed was a valid and effective instrument duly and properly registered and that every other document destroyed hereunder was a valid and effective document in accordance with the recorded particulars thereof in the books or records of the Company provided always that:

(a) the foregoing provisions of this Article shall apply only to the destruction of a document in good faith and without express notice to the Company (by a Member or a court) that the preservation of such document was relevant to a claim;

(b) nothing contained in this Article shall be construed as imposing upon the Company any liability in respect of the destruction of any such document earlier than as aforesaid or in any case where the conditions of proviso (a) above are not fulfilled; and

(c) references in this Article to the destruction of any document include references to its disposal in any manner.

WINDING UP

192. If the Company shall be wound up and the assets available for distribution among the Members as such shall be insufficient to repay the whole of the paid up or credited as paid up share capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the Members in proportion to the capital paid up or credited as paid up at the commencement of the winding up on the Shares held by them respectively. If in a winding up the assets available for distribution among the Members shall be more than sufficient to repay the whole of the share capital paid up or credited as paid up at the commencement of the winding up, the excess shall be distributed among the Members in proportion to the capital at the commencement of the winding up paid up or credited as paid up on the said Shares held by them respectively. Notwithstanding the foregoing, this Article shall not affect the rights of the Members holding Shares issued upon special terms and conditions.

192.1. In case of a sale by the liquidator under section 601 of the Companies Act, the liquidator may by the contract of sale agree so as to bind all the Members, for the allotment to the Members directly, of the proceeds of sale in proportion to their respective interests in the Company and may further, by the contract, limit a time at the expiration of which obligations or Shares not accepted or required to be sold shall be deemed to have been irrevocably refused and be at the disposal of the Company, but so that nothing herein contained shall be taken to diminish, prejudice or affect the rights of dissenting Members conferred by the said section.

192.2. The power of sale of the liquidator shall include a power to sell wholly or partially for debentures, debenture stock, or other obligations of another company, either then already constituted or about to be constituted for the purpose of carrying out the sale.

193. If the Company is wound up, the liquidator, with the sanction of a Special Resolution and any other sanction required by the Companies Act, may divide amongst the Members in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not), and, for such purpose, may value any assets and determine how the division shall be carried out as between the Members or different classes of Members. The liquidator, with the like sanction, may vest the whole or any part of such assets in trustees upon such trusts for the benefit of the contributories as, with the like sanction, he or she determines, but so that no Member shall be compelled to accept any assets upon which there is a liability.

INDEMNITY

194.

194.1. Subject to the provisions of, and so far as may be permitted by, the Companies Act, every Director and Secretary shall be entitled to be indemnified by the Company against all costs, charges, losses, expenses and liabilities incurred by him or her in the execution and discharge of his or her duties or in relation thereto, or in his or her capacity as an officer, including any liability incurred by him in defending any proceedings, civil or criminal, which relate to anything done or omitted or alleged to have been done or omitted by him as a director, officer or employee of the Company and in which judgement is given in his or her favour (or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on his or her part) or in which he or she is acquitted or in connection with any application under any statute for relief from liability in respect of any such act or omission in which relief is granted to him by the Court.

194.2. As far as permissible under the Companies Act, the Company shall indemnify any current or former Official (excluding any Director or Secretary in respect only of their role as Director or Secretary of the Company) against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the Enterprise in respect of which the Official serves or has served as an Official, to which he or she was, is or is threatened to be, made a party by reason of the fact that he or she is or was such an Official, provided always that the indemnity contained in this Article 194.2 shall not extend to any matter which would render it void pursuant to the Companies Act.

194.3. In the case of any threatened, pending or completed action, suit or proceeding by or in the right of an Enterprise in respect of which a current or former Official serves or has served, the Company shall indemnify, to the fullest extent permitted by the Companies Act, each person indicated in Article 194.2 against expenses, including attorneys' fees actually and reasonably incurred in connection with the defence or the settlement thereof, except no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for fraud or dishonesty in the performance of his or her duty to the relevant Enterprise unless and only to the extent that the Court or the court in which such action or suit was brought shall determine upon application that despite the adjudication of liability, but in view

of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the Court shall deem proper.

194.4. As far as permissible under the Companies Act, expenses, including attorneys' fees, incurred in defending any action, suit or proceeding referred to in this Article shall be paid by the Company in advance of the final disposition of such action, suit or proceeding upon receipt of a written affirmation by or on behalf of the Director, Secretary, Official or other indemnitee of a good faith belief that the criteria for indemnification have been satisfied and a written undertaking to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Company as authorised by these Articles.

194.5. It being the policy of the Company that indemnification of the persons specified in this Article shall be made to the fullest extent permitted by law, the indemnification provided by this Article shall not be deemed exclusive (a) of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the Memorandum, Articles, any agreement, any insurance purchased by the Company, any vote of Members or disinterested Directors, or pursuant to the direction (however embodied) of any court of competent jurisdiction, or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office, (b) of the power of any Enterprise to indemnify any Official, to the same extent and in the same situations and subject to the same determinations as are hereinabove set forth with respect to a Director, Secretary or Official or (c) of any amendments or replacements of the Companies Act which permit for greater indemnification of the persons specified in this Article and any such amendment or replacement of the Companies Act shall hereby be incorporated into these Articles. As used in this Article 194.5, references to the "Company" include all constituent companies in a consolidation or merger in which the Company or any predecessor to the Company by consolidation or merger was involved. The indemnification provided by this Article shall continue as to a person who has ceased to be a Director, executive, officer or trustee and shall inure to the benefit of the heirs, executors, and administrators of such a person.

194.6. The Directors shall have power to purchase and maintain for any Director, the Secretary or other officers or employees of the Company insurance against any such liability as referred to in section 235 of the Companies Act and such insurance in respect of Officials as the Directors deem to be appropriate.

194.7. The Company may additionally indemnify any employee or agent of the Company or any director, executive, officer, employee or agent of any of its subsidiaries to the fullest extent permitted by law.

FINANCIAL YEAR

195. The financial year of the Company shall be as prescribed by the Board from time to time.

SHAREHOLDER RIGHTS PLAN

196. The Board is hereby expressly authorised to adopt any shareholder rights plan, or similar plan, agreement or arrangement pursuant to which, under circumstances provided therein, some or all Members will have rights to acquire Shares or interests in Shares, upon such terms and conditions as the Board deems expedient and in the best interests of the Company.

BUSINESS COMBINATION

197.

197.1. The Company may not engage in any business combination, or vote, consent, or otherwise act to authorise a subsidiary of the Company to engage in any business combination, with, with respect to, proposed by or on behalf of, or pursuant to any written or oral agreement,

arrangement, relationship, understanding, or otherwise with, any interested Member of the Company or any affiliate or associate of the interested Member for a period of three (3) years following the date that the Member became an interested Member unless:

(a) prior to the date that the Member became an interested Member, the business combination was approved by a committee of the Board formed in accordance with Article 197.3; or

(b) at or following the date that the Member became an interested Member, the business combination is approved by a committee of the Board formed in accordance with Article 197.3 and is authorized by a Special Resolution of the Members. In determining whether the Special Resolution has been adopted by the general meeting, votes cast with respect to Shares of interested Members and their affiliates and associates shall not be taken into account.

197.2. If a good faith definitive proposal regarding a business combination is made in writing to the Board, a committee of the Board formed in accordance with Article 197.3 shall consider and take action on the proposal and respond in writing within thirty (30) days after receipt of the proposal by the Company, setting forth its decision regarding the proposal.

197.3. When a business combination is proposed pursuant to this Article 197, the Board shall promptly form a committee composed solely of one or more disinterested Directors. The committee shall take action on the proposal by the affirmative vote of a majority of committee members. No larger proportion or number of votes shall be required. Notwithstanding anything in these Articles to the contrary, subject to applicable law, the committee shall not be subject to any direction or control by the Board with respect to the committee's consideration of, or any action concerning, a business combination pursuant to this Article 197. If the Board has no disinterested Directors, the Board shall select three or more disinterested persons to be committee members. Committee members shall act in accordance with the standard of conduct applicable to the Directors and shall be indemnified in accordance with Article 194. For purposes of this Article 197.3, a Director or person is "disinterested" if the Director or person is neither an officer nor an employee, nor has been an officer or employee within five (5) years preceding the formation of the committee pursuant to this Article 197.3, of the Company or of a related company.

197.4. This Article 197 may only be amended in accordance with paragraph 6 of the Memorandum. In determining whether the relevant resolution has been approved by the requisite majority, votes cast with respect to Shares of interested Members and their affiliates and associates shall not be taken into account. Notwithstanding any such amendment, unless determined otherwise by the Board, this Article 197 (as its stands prior to any such amendment) shall apply to any business combination of the Company with an interested Member who became an interested Member before the effective date of the amendment of this Article 197.

197.5. As used in this Article 197 only, the term:

(i) "affiliate" means a person that directly or indirectly controls, is controlled by, or is under common control with, a specified person;

(ii) "associate", when used to indicate a relationship with any person, means any of the following:

(a) any company of which the person is an officer or partner or is, directly or indirectly, the beneficial owner of fifteen percent (15%) or more of any class or series of shares entitled to vote or other equity interest;

(b) any trust or estate in which the person has a substantial beneficial interest or as to which the person serves as trustee or executor or in a similar fiduciary capacity; or

(c) any relative or spouse of the person, or any relative of the spouse, residing in the home of the person;

(iii) "beneficial owner", when used with respect to shares or other securities, includes, but is not limited to, any person who, directly or indirectly through any written or oral agreement, arrangement, relationship, understanding, or otherwise, has or shares the power to vote, or direct the voting of, the shares or securities or has or shares the power to dispose of, or direct the disposition of, the shares or securities, except that:

(a) a person shall not be deemed the beneficial owner of shares or securities tendered pursuant to a tender or exchange offer made by the person or any of the person's affiliates or associates until the tendered shares or securities are accepted for purchase or exchange; and

(b) a person shall not be deemed the beneficial owner of shares or securities with respect to which the person has the power to vote or direct the voting arising solely from a revocable proxy given in response to a proxy solicitation required to be made and made in accordance with the applicable rules and regulations under the Exchange Act and is not then reportable under that act on a Schedule 13D or comparable report, or, if the company is not subject to the rules and regulations under the Exchange Act, would have been required to be made and would not have been reportable if the company had been subject to the rules and regulations;

(iv) "beneficial ownership" includes, but is not limited to, the right to acquire shares or securities through the exercise of options, warrants, or rights, or the conversion of convertible securities, or otherwise. The shares or securities subject to the options, warrants, rights, or conversion privileges held by a person shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares or securities of the class or series owned by the person, but shall not be deemed to be outstanding for the purpose of computing the percentage of the class or series owned by any other person. A person shall be deemed the beneficial owner of shares and securities beneficially owned by any relative or spouse of the person or any relative of the spouse, residing in the home of the person, any trust or estate in which the person owns fifteen percent (15%) or more of the total beneficial interest or serves as trustee or executor or in a similar fiduciary capacity, any company in which the person owns fifteen percent (15%) or more of the equity, and any affiliate of the person.

When two or more persons act or agree to act as a partnership, limited partnership, syndicate, or other group for the purposes of acquiring, owning, or voting shares or other securities of a company, all members of the partnership, syndicate, or other group are deemed to constitute a "person" and to have acquired beneficial ownership, as of the date they first so act or agree to act together, of all shares or securities of the company beneficially owned by the person;

(v) "business combination" means any of the following:

(a) any merger, acquisition, scheme of arrangement or amalgamation of the Company or any subsidiary of the Company with (1) the interested Member or (2) any other company (whether or not itself an interested Member of the Company) that is, or after the merger would be, an affiliate or associate of the interested Member, but excluding (x) the merger of a wholly owned subsidiary of the Company into the Company, (y) the merger of two or more wholly owned subsidiaries of the Company, or (z) the merger of a company, other than an interested Member or an affiliate or associate of an interested Member, with a wholly owned subsidiary of the Company pursuant to

which the surviving company, immediately after the merger, becomes a wholly owned subsidiary of the Company;

(b) any exchange of Shares or other securities of the Company or any subsidiary of the Company or money, or other property, for shares, other securities, money, or property of (1) the interested Member or (2) any other company (whether or not itself an interested Member of the Company) that is, or after the exchange would be, an affiliate or associate of the interested Member, but excluding the exchange of shares of a company, other than an interested Member or an affiliate or associate of an interested Member, pursuant to which the company, immediately after the exchange, becomes a wholly owned subsidiary of the Company;

(c) any sale, lease, exchange, mortgage, pledge, transfer, or other disposition (in a single transaction or a series of transactions), other than sales of goods or services in the ordinary course of business, to or with the interested Member or any affiliate or associate of the interested Member, other than to or with the Company or a wholly owned subsidiary of the Company, of assets of the Company or any subsidiary of the

Company (1) having an aggregate market value equal to ten percent (10%) or more of the aggregate market value of all the assets, determined on a consolidated basis, of the Company, (2) having an aggregate market value equal to ten percent (10%) or more of the aggregate market value of all the outstanding Shares of the Company, or (3) representing ten percent (10%) or more of the earning power or net income, determined on a consolidated basis, of the Company, except a cash dividend or distribution paid or made pro rata to all Members of the Company;

(d) the issuance or transfer by the Company or any subsidiary of the Company (in a single transaction or a series of transactions) of any shares of, or other ownership interests in, the Company or any subsidiary of the Company that have an aggregate market value equal to five percent (5%) or more of the aggregate market value of all the outstanding Shares of the Company to the interested Member or any affiliate or associate of the interested Member, except pursuant to the exercise of warrants or rights to purchase shares offered, or a dividend or distribution paid or made, pro rata to all Members of the Company other than for the purpose, directly or indirectly, of facilitating or effecting a subsequent transaction that would have been a business combination if the dividend or distribution had not been made;

(e) the adoption of any plan or proposal for the liquidation or dissolution of the Company, or any reincorporation of the Company in another jurisdiction, proposed by or on behalf of, or pursuant to any written or oral agreement, arrangement, relationship, understanding, or otherwise with, the interested Member or any affiliate or associate of the interested Member;

(f) any reclassification of securities (including, without limitation, any bonus shares or share split, reverse share split, or other distribution of shares in respect of shares), recapitalisation of the Company, merger of the Company with any subsidiary of the Company, exchange of Shares of the Company with any subsidiary of the Company, or other transaction (whether or not with or into or otherwise involving the interested Member), proposed by or on behalf of, or pursuant to any written or oral agreement, arrangement, relationship, understanding, or otherwise with, the interested Member or any affiliate or associate of the interested Member, that has the effect, directly or indirectly, of increasing the proportionate share of the outstanding shares of any class or series of shares entitled to vote, or securities that are exchangeable for, convertible into, or carry a right to acquire shares entitled to vote, of the Company or any subsidiary of the Company that is, directly or indirectly, owned by the interested Member or any affiliate or associate of the interested Member, except as a result of immaterial changes due to fractional share adjustments; or

(g) any receipt by the interested Member or any affiliate or associate of the interested Member of the benefit, directly or indirectly (except proportionately as a Member of the Company), of any loans, advances, guarantees, pledges, or other financial assistance, or any tax credits or other tax advantages provided by or through the Company or any subsidiary of the Company;

(vi) "company" means a corporation, limited liability company, partnership, limited partnership, joint venture, association, business trust, estate, trust, enterprise, and any other legal or commercial entity;

(vii) "control", including the terms "controlling", "controlled by", and "under common control with", means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise. A person's beneficial ownership of fifteen percent (15%) or more of the voting power of a company's outstanding shares entitled to vote in the election of directors creates a presumption that the person has control of the company. Notwithstanding the foregoing, a person is not considered to have control of a company if the person holds voting power, in good faith, as an agent, bank, broker, nominee, custodian, or trustee for one or more beneficial owners who do not individually or as a group have control of the company;

(viii) "governing body" means the body of a company selected by its owners that has the ultimate power to determine the company's policies and control its activities; and

(ix) "interested Member" means any person (including for this purpose any persons acting in concert with that person (as that term is defined in the Takeover Rules issued pursuant to the Irish Takeover Panel Act 1997)) that is (1) the beneficial owner, directly or indirectly, of fifteen percent (15%) or more of the voting power of the outstanding Shares entitled to vote of the Company or (2) an affiliate or associate of the Company that, at any time within the three (3) year period immediately before the date on which it is sought to be determined whether such person is an interested Member, was the beneficial owner, directly or indirectly, of fifteen percent (15%) or more of the voting power of the then outstanding Shares entitled to vote of the Company.

If a person who has not been a beneficial owner of fifteen percent (15%) or more of the voting power of the outstanding Shares entitled to vote of the Company immediately prior to an acquisition of Shares by, or recapitalisation of, the Company or similar action shall become a beneficial owner of fifteen percent (15%) or more of the voting power solely as a result of the share acquisition, recapitalisation, or similar action, the person shall not be deemed to be the beneficial owner of fifteen percent (15%) or more of the voting power for purposes of (1) or (2) above, unless:

(a) the share acquisition, recapitalisation, conversion, or similar action was proposed by or on behalf of, or pursuant to any agreement, arrangement, relationship, understanding, or otherwise (whether or not in writing) with, the person or any affiliate or associate of the person; or

(b) the person thereafter acquires beneficial ownership, directly or indirectly, of outstanding Shares entitled to vote of the Company and, immediately after the acquisition, is the beneficial owner, directly or indirectly, of fifteen percent (15%) or more of the voting power of the outstanding Shares entitled to vote of the Company.

(x) an "interested Member" does not include:

(a) the Company or any of its subsidiaries;

(b) either of the Sponsor Holders;

(c) a savings, employee stock ownership, or other employee benefit plan of the Company or its subsidiary, or a fiduciary of the plan when acting in a fiduciary capacity pursuant to the plan; or

(d) a licensed broker/dealer or licensed underwriter who (1) purchases Shares of the Company solely for purposes of resale to the public and (2) is not acting in concert with an interested Member.

Shares beneficially owned by a plan described in clause (b) or by a fiduciary of a plan described in clause (b), pursuant to the plan, are not deemed to be beneficially owned by a person who is a fiduciary of the plan;

(xi) "market value", when used in reference to shares or other property of any company, means the following:

(a) in the case of shares, the average closing sale price of a share during the thirty (30) trading days immediately preceding the date in question:

(1) on the composite tape for Nasdaq Stock Market listed shares; or

(2) if the shares are not quoted on the composite tape or not listed on the Nasdaq Stock Market, on the principal United States securities exchange registered under Exchange Act on which the shares are listed; or

(3) if the shares are not listed on any such exchange, on any system then in use.

If no quotation under clauses (1) through (3) is available, then the market value is the fair market value on the date in question of the shares as determined in good faith by the governing body of the company.

(b) in the case of property other than cash or shares, the fair market value of the property on the date in question as determined in good faith by the governing body of the company.

(xii) “parent” of a specified company means a company that directly, or indirectly through related companies, owns more than fifty percent (50%) of the voting power of the shares or other ownership interests entitled to vote for directors or other members of the governing body of the specified company;

(xiii) “person” includes a natural person and a company;

(xiv) “related company” of a specified company means:

(a) a parent or subsidiary of the specified company;

(b) another subsidiary of a parent of the specified company;

(c) a limited liability company owning, directly or indirectly, more than fifty percent (50%) of the voting power of the shares entitled to vote for directors of the specified company;

(d) a limited liability company having more than fifty percent (50%) of the voting power of its membership interests entitled to vote for members of its governing body owned directly or indirectly by the specified company;

(e) a limited liability company having more than fifty percent (50%) of the voting power of its membership interests entitled to vote for members of its governing body owned directly or indirectly either (1) by a parent of the specified company or (2) a limited liability company owning, directly or indirectly, more than fifty percent (50%) of the voting power of the shares entitled to vote for directors of the specified company; or

(f) a company having more than fifty percent (50%) of the voting power of its shares entitled to vote for directors owned directly or indirectly by a limited liability company owning, directly or indirectly, more than fifty percent (50%) of the voting power of the shares entitled to vote for directors of the specified company;

(xv) "security" means a note, stock, treasury stock, security future, bond, debenture, evidence of indebtedness, certificate of interest or participation in a profit-sharing agreement, collateral trust certificate, preorganization certificate or subscription, transferable share, investment contract, voting trust certificate, certificate of deposit for a security, fractional undivided interest in oil, gas, or other mineral rights, put, call, straddle, option, or privilege on a security, certificate of deposit, or group or index of securities, including an interest therein or based on the value thereof, put, call, straddle, option, or privilege entered into on a national securities exchange relating to foreign currency, or, in general, an interest or instrument commonly known as a "security"; or a certificate of interest or participation in, temporary or interim certificate for, receipt for, guarantee of, or warrant or right to subscribe to or purchase, any of the foregoing. The term:

(a) includes both a certificated and an uncertificated security;

(b) does not include an insurance or endowment policy or annuity contract under which an insurance company promises to pay a fixed or variable sum of money either in a lump sum or periodically for life or other specified period;

(c) does not include an interest in a contributory or non-contributory pension or welfare plan subject to the United States Employee Retirement Income Security Act of 1974, as amended;

(d) includes as an "investment contract," among other contracts, an interest in a limited partnership and a limited liability company and an investment in a viatical settlement or similar agreement; and

(e) does not include any equity interest of a closely held corporation or other entity with not more than thirty-five (35) holders of the equity interest of such entity offered or sold pursuant to a transaction in which one hundred percent (100%) of the equity interest of such entity is sold as a means to effect the sale of the business of the entity if the transaction has been negotiated on behalf of all purchasers and if all purchasers have access to inside information regarding the entity before consummating the transaction; and

(xvi) "subsidiary" of a specified company means a company having more than fifty percent (50%) of the voting power of its shares or other ownership interests entitled to vote for directors or other members of the governing body of the company owned directly, or indirectly through related companies, by the specified company.

EXCLUSIVE JURISDICTION

198.

198.1. Save in the case of any actions brought by, or on behalf of, or against, the Company relating to US securities law, unless the Board or one of its duly authorised committees approves the selection of an alternate forum, the courts of Ireland shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any Director, officer or other employee of the Company to the Company or the Members, (iii) any action asserting a claim against the Company arising pursuant to any provision of Irish law or this Constitution and (iv) any action to interpret, apply, enforce or determine the validity of this Constitution (each an "**Irish Proceeding**").

198.2. If any action the subject matter of an Irish Proceeding is filed in a court outside the jurisdiction of Ireland (a "**Foreign Action**"), in the name of any person or entity (a "**Claiming Party**") without the prior approval of the Board or one of its duly authorised committees in the manner described above in Article 198.1, such Claiming Party shall be deemed to have consented to (i) the jurisdiction of the courts of Ireland in connection with any action brought by the Company in any such courts to enforce Article 198.1 above (an "**Enforcement Action**") and (ii) having service of process made upon such Claiming Party in any such Enforcement Action by service upon such Claiming Party's counsel in the Foreign Action as agent for such Claiming Party.

198.3. Any person or entity purchasing or otherwise acquiring any interest in Share(s) of the Company shall be deemed to have notice of and consented to the provisions of this Article 198 and waived any argument relating to the inconvenience of the forums referenced above in connection with any Irish Proceeding.

We, the corporate body whose name and address is subscribed, wish to be formed into a company in pursuance of this memorandum of association, and we agree to take the number of shares in the capital of the Company set opposite our respective names.

Name, Address and Description of the Subscriber	Number of shares taken by the Subscriber

For and on behalf of

Dated

Witness to the above signature:

Name:

Address:

Occupation:

Exhibit 4.1

Execution Version

SHAREHOLDERS AGREEMENT

DATED AS OF

OCTOBER 17, 2018

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 1 LLC

ORBIT CO-INVEST II LLC

ORBIT CO-INVEST III LLC

AND

THE MANAGEMENT SHAREHOLDERS IDENTIFIED HEREIN

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THIS SHAREHOLDERS AGREEMENT (this "***Agreement***"), dated as of October 17, 2018, is entered into by and among Osmotica Pharmaceuticals plc, a public limited company incorporated under the laws of Ireland with registration number 607944 and registered office at 25-28 North Wall Quay, Dublin 1, Ireland (together with its successors, the "***Company***"), ACP Holdco (Offshore), L.P., a Bermuda exempted limited partnership (" ***ACP Offshore***"), ACP III AIV, L.P., a Bermuda exempted limited partnership (the " ***VCOC***", and together with ACP Offshore, the "***Avista Shareholder***"), Altchem Limited (the "***Altchem Shareholder***"), and each of Altchem, on the one hand, and the Avista Shareholder, collectively, on the other hand, a " ***Sponsor***"), Orbit Co-Invest A-I LLC, a Delaware LLC ("***Orbit A-1***"), Orbit Co-Invest I LLC, a Delaware LLC ("***Orbit 1***") and Orbit Co-Invest III, LLC ("***Orbit 3***", and together with Orbit A-1 and Orbit 1, the "***Co-Invest Vehicles***"), the shareholders listed on Annex A hereto as Management Shareholders, and the Persons who on becoming shareholders of the Company execute and deliver a Joinder Agreement, substantially as set forth on **Annex A** hereto (a "***Joinder Agreement***") (each of the foregoing a "***Shareholder***" and collectively, the "***Shareholders***").

WHEREAS, the Company was formed pursuant to the Irish Companies Act 2014 on July 13, 2017;

WHEREAS, in connection with the contemplated initial public offering (the *"**Offering**")* of the Company's Ordinary Shares (as defined below), the board of directors of the Company (the "***Board***") has approved this Agreement at a meeting of the Board on August 14, 2018;

WHEREAS, this Agreement shall be effective upon the consummation of the IPO (as defined below) (the "***Effective Time***")*;*

WHEREAS, Schedule A hereto sets forth the names of and the number of Equity Securities owned by each Shareholder as of the date hereof, and the Company shall update Schedule A from time to time to reflect any issuances or Transfers of Equity Securities;

WHEREAS, the parties believe that it is in the best interests of the Company and the Shareholders to set forth herein their agreements on certain matters relating to the governance of the Company and the rights and obligations of the Shareholders; and

NOW, THEREFORE, in consideration of the promises and mutual agreements contained herein and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Section 1.01. **Definitions**.

(a) The following terms, as used herein, have the following meanings:

"***Affiliate***" means, with respect to any Person, any other Person who, directly or indirectly, Controls such first Person or is Controlled by said Person or is under common Control with said

Person; provided, that no Shareholder shall be deemed an Affiliate of any other Shareholder solely by reason of an investment in, or holding Equity Securities of, the Company.

"***Altchem Co-Invest Vehicles***" means Orbit A-I LLC (to the extent that it remains Controlled by the Altchem Shareholder or one of its Controlled Affiliates) or any other co-investment vehicle controlled by the Altchem Shareholder or one of its Controlled Affiliates and that holds Equity Securities from and after the Effective Date, collectively referred to as "Altchem Co-Invest Vehicles"; provided, that the Altchem Shareholder and its Permitted Transferees shall in no event be deemed to be an Altchem Co-Invest Vehicle.

"***Avista Co-Invest Vehicle***" means any of Orbit 1, Orbit 3 and any other co-investment vehicle controlled by the Avista Shareholder or one of its controlled Affiliates and that holds Equity Securities from or after the Effective Date, collectively referred to as "Avista Co-Invest Vehicles"; provided, that the Avista Shareholder and their Permitted Transferees shall in no event be deemed to be an Avista Co-Invest Vehicle.

"***Business***" means, from time to time, the marketing, distribution, manufacturing or sale of branded and generic pharmaceutical products of the Company and/or of Subsidiaries of the Company at such time or which products have been presented to the Board or board of directors of the Subsidiaries of the Company for future marketing, distribution, manufacturing or sale at prior to such time; provided, that "Business" includes any business that develops or commercializes osmotic-based drug delivery technology in the United States or Canada.

"***Business Day***" means any day except a Saturday, Sunday or other day on which commercial banks in New York City, New York and Dublin, Ireland are authorized or required by applicable law to close.

"***Company Competitor***" means (a) any Person that is reasonably determined by the Board to be a competitor of the Company or any of its Subsidiaries in any material respect and (b) any Affiliate of any such Person specified in clause (a). For purposes hereof, without limiting the foregoing, any Person with, or whose Affiliate has, substantial operations in the Business shall be presumed to be a Company Competitor unless the Board otherwise determines; provided, however, that for purposes of this Agreement, no private equity fund, including the Sponsors (or any of their respective Affiliates), shall be deemed a Company Competitor solely due to its direct or indirect investment in a portfolio company of such Person where such portfolio company would be deemed a Company Competitor.

"***Constitution***" means the constitution of the Company, as the same may be amended from time to time, a copy of which is attached as Exhibit B hereto, as the same may be amended from time to time as permitted hereunder.

"***Control***," "***Controlled***" and "***Controlling***" mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"***Equity Securities***" means, without duplication, (i) the Ordinary Shares, and (ii) any other securities convertible into or exchangeable or exercisable for, or options, warrants or other rights to acquire, Ordinary Shares, or any other equity or equity-linked security issued by the Company.

*"**Exchange Act**"* means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"***Family Member***" means, with respect to any Person who is an individual, any spouse (or partner by civil union or registered domestic partnership), lineal descendants (including adoptive relationships), or siblings.

"***FINRA***" means the Financial Industry Regulatory Authority, Inc.

*"**Governmental Authority***" means any federal, state, local or foreign governmental authority, department, commission, board, bureau, agency, court, instrumentality or judicial or regulatory body or entity.

"***Incentive Plan***" means the Company's 2018 Equity Incentive Plan, as the same may be amended, modified or supplemented.

"***IPO***" means the initial Public Offering registered on Form S-1 (or any successor form under the Securities Act).

*"**Management Affiliated Entity***" means, as to any Management Person, (i) any vehicle or entity (excluding a Co-Invest Vehicle) that holds Equity Securities on behalf or for the direct or indirect benefit of such Management Person or their Permitted Transferee, and (ii) any Shareholder that would be or qualify as a Permitted Transferee of such Person if such Person was a Shareholder.

"***Management Person***" means any current or former employee, officer, director or consultant of the Company or any of its Subsidiaries that holds Equity Securities of the Company, either directly or indirectly through a Management Affiliated Entity or a Co-Invest Vehicle.

*"**Management Shareholders**"* means (a) the shareholders listed on Annex A hereto and (b) any Shareholder in its capacity as (i) a Management Person, (ii) a Management Affiliated Entity, or (iii) any Permitted Transferee of (i) or (ii).

"***Option***" means an option to purchase Ordinary Shares granted pursuant to the Incentive Plan.

"***Ordinary Shares***" means the ordinary shares of $0.01 each in the capital of the Company, with such rights and preferences as set forth in the Constitution.

*"**Permitted Transferee***" means, (a) with respect to any Management Person, (i) any executor, administrator or testamentary trustee of such Management Person's estate if such Management Person dies, (ii) any Family Member receiving Equity Securities of such Management Person by will, intestacy laws or the laws of descent or survivorship, (iii) any trustee of a trust (including an *inter vivos* trust) of which there are no principal beneficiaries other than such Management Person or one or more Family Members of such Management Person or (iv) any investment vehicle which is 100% wholly owned by a Management Person, one or more Family Members of such Management Person, or a trust described in clause (iii) above, (b) with respect to any Management Affiliated Entity, the employee, officer, director or consultant of the Company or any of its Subsidiaries that qualifies such Shareholder as a Management Affiliated

Entity, (c) with respect to the Altchem Shareholder or its Permitted Transferees, (i) as to any individual owner of the Altchem Shareholder or such Permitted Transferee, the Persons described in clause (a)(i) through (iv) of this definition, *mutatis mutandis*; provided, that, any such Permitted Transferee of the Altchem Shareholder pursuant to this subsection (i) shall hold Equity Securities in the Company indirectly through the Altchem Shareholder or through a vehicle Controlled by the Altchem Shareholder; and (ii) any Affiliate of the Altchem Shareholder or such Permitted Transferees, (d) with respect to the Avista Shareholder or its Permitted Transferees, an investment fund that is a parallel fund (but not a successor fund) or alternative investment vehicle of the Avista Shareholder with the same or Affiliated general partner as the Avista Shareholder or a direct or indirect wholly-owned Subsidiary of the Avista Shareholder or such parallel fund or alternate investment vehicle, (e) with respect to the Avista Co-Invest Vehicles, the Avista Shareholder, its Permitted Transferees and any other Avista Co-Invest Vehicle, (f) with respect to the members of the Avista Co-Invest Vehicles, (i) any Affiliate of such member other than a Company Competitor; (ii) the Avista Shareholder; and (iii) any current or prospective limited partners of the Avista Shareholder or of other investment funds managed by the Avista Shareholder or any of its Affiliates; provided, that, any such Permitted Transferee of the members of the Avista Co-Invest Vehicles pursuant to this clause (f) shall hold Equity Securities in the Company indirectly through the Avista Shareholder or through a vehicle Controlled by the Avista Shareholder (except in the case that the Avista Shareholder is the Permitted Transferee, in which case it shall be permitted to hold Equity Securities in the Company directly), and (g) with respect to the Altchem Co- Invest Vehicle, the Altchem Shareholder and its Permitted Transferees and any other Altchem Co-Invest Vehicle; provided, however, that no "portfolio company" (as such term is customarily used among institutional investors) of the Avista Shareholder or any entity Controlled by any portfolio company of the Avista Shareholder shall constitute a Permitted Transferee of the Avista Shareholder, an Avista Co-Invest Vehicle, or the members of an Avista Co-Invest Vehicle; provided, further, however, that in no event shall (A) the Company or any of its Subsidiaries, or (B) any Company Competitor (whether or not an Affiliate of the transferring Shareholder), constitute a "Permitted Transferee".

"***Person***" means any individual, corporation, limited liability company, partnership, association, trust or other entity or organization, including a Governmental Authority and, where the context so permits, the legal representatives, successors in interest and permitted assigns of such Person.

"***Proceeding***" means an investigation, action, suit, arbitration or other proceeding, whether civil or criminal.

"***Proportion***" means the percentage derived by dividing the amount of Ordinary Shares to be transferred by any Sponsor or its Affiliates, by the total amount of Ordinary Shares held by all of the Sponsors and their Affiliates before such proposed Transfer.

"***Public Offering***" means an underwritten public offering of Ordinary Shares pursuant to an effective registration statement under the Securities Act, other than pursuant to a registration statement on Form S-4 or Form S-8 or any similar or successor form.

*"**Registrable Securities***" means at any time, any equity securities (other than non-participating, non-convertible preferred share) of the Company held by any other Shareholders;

provided, that Registrable Securities shall not include any shares (i) the sale of which has been registered pursuant to the Securities Act and which shares have been sold pursuant to such registration, (ii) which have been sold or are eligible to be sold or distributed pursuant to Rule 144 or Rule 145 without limitation, (iii) which have been registered for resale pursuant to an effective Registration Statement on a Form S-8 (or any successor or similar form), or (iv) which represent less than 1% of the outstanding Ordinary Shares of the Company.

*"**Registration Expenses**"* means any and all expenses incident to the performance of or compliance with any registration or marketing of securities, including all (i) registration and filing fees, and all other fees and expenses payable in connection with the listing of securities on any securities exchange or automated interdealer quotation system, (ii) fees and expenses of compliance with any securities or "blue sky" laws (including reasonable fees and disbursements of counsel in connection with "blue sky" qualifications of the securities registered), (iii) expenses in connection with the preparation, printing, mailing and delivery of any Registration Statements, prospectuses and other documents in connection therewith and any amendments or supplements thereto, (iv) security engraving and printing expenses, (v) internal expenses of the Company (including all salaries and expenses of its officers and employees performing legal or accounting duties), (vi) fees and disbursements of counsel for the Company and customary fees and expenses for independent certified public accountants retained by the Company (including the expenses relating to any comfort letters or costs associated with the delivery by independent certified public accountants of any comfort letters to be provided pursuant to Section 4.05(h) hereof), (vii) fees and expenses of any special experts retained by the Company in connection with such registration, (viii) fees and out-of-pocket expenses of one counsel for each of the Sponsors (including the reasonable fees and expenses of one counsel collectively for the Avista Co-Invest Vehicles and one counsel for the Altchem Co-Invest Vehicle), and any other "local" counsel required to render legal opinions on behalf of any such Sponsor, (ix) fees and expenses in connection with any review of the underwriting arrangements or other terms of the offering, and all fees and expenses of any "qualified independent underwriter" required to participate in any offering, including reasonable fees and expenses of any counsel thereto, (x) fees and disbursements of underwriters customarily paid by issuers or sellers of securities, but excluding any underwriting fees, discounts and commissions attributable to the sale of Registrable Securities, (xi) costs of printing and producing underwriting agreements, any "blue sky" or legal investment memoranda and any selling agreements and other documents in connection with the offering, sale or delivery of the Registrable Securities, (xii) transfer agents' and registrars' fees and expenses and the fees and expenses of any other agent or trustee appointed in connection with such offering, (xiii) expenses relating to any analyst or investor presentations or any "road shows" undertaken in connection with the registration, marketing or selling of the Registrable Securities, (xiv) fees and expenses payable in connection with any ratings of the Registrable Securities, including expenses relating to any presentations to rating agencies, and (xv) all other reasonable costs and expenses incurred by the Company or its officers in connection with their compliance with Section 4.01 and Section 4.12 hereof.

"**Registration Statement**" shall mean any registration statement of the Company, under the Securities Act which permits the public offering of any of the Registrable Securities pursuant to the provisions of this Agreement, including the prospectus, amendments and supplements to such registration statement, including post-effective amendments, all exhibits and all material incorporated by reference or deemed to be incorporated by reference in such registration statement.

*"**Requisite Consent**"* means the prior written consent of each of the Sponsors, for so long as such Sponsor holds at least ten (10%) of the shares of Ordinary Shares then outstanding.

"***Rule 144***" means Rule 144 (or any successor provision) under the Securities Act.

*"**Rule 145**"* means Rule 145 (or any successor provision) under the Securities Act.

*"**SEC**"* means the Securities and Exchange Commission.

*"**Securities Act**"* means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

*"**Subsidiary**"* means, with respect to any specified Person, any other Person in which such specified Person, directly or indirectly through one or more Affiliates or otherwise, beneficially owns at least fifty percent (50%) of the ownership interest (determined by equity or economic interests) in, or the voting control of, such other Person.

*"**Transfer**"* means, with respect to any Equity Securities, (i) when used as a verb, to sell, assign, dispose of, exchange, pledge, encumber, hypothecate or otherwise transfer such Equity Securities or any participation or interest therein, whether directly or indirectly, or agree or commit to do any of the foregoing, and (ii) when used as a noun, a direct or indirect sale, assignment, disposition, exchange, pledge, encumbrance, hypothecation, or other transfer of such Equity Securities or any participation or interest therein or any agreement or commitment to do any of the foregoing.

(b) Each of the following terms is defined in the Section set forth opposite such term:

TERM	SECTION
Agreement	Preamble
Altchem Shareholder	Preamble
Altchem Designees	Section 2.01(a)
Altchem DIK	Section 3.01(b)
Avista	Preamble
Avista Designees	Section 2.01(a)
Avista DIK	Section 3.01(a)
Avista Shareholder	Preamble
Board	Recitals
Company	Preamble
Confidential Information	Section 6.01
Confidentiality Affiliates	Section 6.01
Coordination Committee	Section 3.02(a)
Damages	Section 4.06
Demand Maximum Offering Size	Section 4.01(d)
Demand Registration	Section 4.01(a)
Determination Time	Section 3.03(a)
Effective Time	Recitals
Indemnified Party	Section 4.08

TERM	SECTION
Indemnifying Party	Section 4.08
Indemnity Obligations	Section 2.05
Inspectors	Section 4.05(g)
IPO Lock-Up Period	Section 4.04(a)
Joinder Agreement	Preamble
LuxCo	Section 5.02
Offering	Recitals
Piggyback Maximum Offering Size	Section 4.02(b)
Piggyback Registration	Section 4.02(a)
Records	Section 4.05(g)
Registering Shareholders	Section 4.01(a)(i)
Relative Ownership Percentage	Section 3.03(a)
Requesting Shareholders	Section 4.01(a)
Shelf Registration	Section 4.03(a)
Shelf Request	Section 4.03(a)
Shareholder	Preamble
Shareholders	Preamble
Sponsor Designees	Section 2.01(a)(ii)
Sponsor Parties	Section 2.05
Sponsors	Preamble
Underwritten Shelf Take-down	Section 4.03(b)
Unrestricted Securities	Section 3.03(a)
Unwinding Event	Section 3.04(b)
Withdrawing Holders	Section 4.04(c)

(c) Other Definitional and Interpretive Matters. Unless otherwise expressly provided, for purposes of this Agreement, the following rules of interpretation shall apply:

Calculation of Time. When calculating the period before which, within which or after which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded. If the last day of such period is a non- Business Day, the period in question shall end on the next succeeding Business Day.

Dollars. Any reference in this Agreement to "$" means U.S. dollars.

Annexes/Exhibits/Schedules. The Annexes, Exhibits and Schedules to this Agreement are hereby incorporated and made a part hereof and are an integral part of this Agreement. Any capitalized terms used in any Annex, Exhibit or Schedule but not otherwise defined therein shall be defined as set forth in this Agreement.

Gender and Number. Any reference in this Agreement to gender shall include all genders, and words imparting the singular number only shall include the plural and vice versa.

Headings. The provision of a Table of Contents, the division of this Agreement into Articles, Sections and other subdivisions and the insertion of headings are for convenience of

reference only and shall not affect or be utilized in construing or interpreting this Agreement. All references in this Agreement to any "Article" or "Section" are to the corresponding Article or Section of this Agreement unless otherwise specified.

Herein. The words such as *"herein"* "*hereinafter"* *hereof"* and "*hereunder*" refer to this Agreement as a whole and not merely to a subdivision in which such words appear unless the context otherwise requires.

Other. The words "*include*" "*includes*" and "*including*" when used herein shall be deemed in each case to be followed by the words "*without limitation.*" The phrases "*provided to*" "*furnished to*" and phrases of similar import when used herein, unless the context otherwise requires, shall mean that a true, correct and complete copy of the information or material referred to has been provided to the party to whom such information or material is to be provided. The word "*extent*" in the phrase "*to the extent*" means the degree to which a subject or other thing extends, and such phrase does not mean simply "*if.*"

ARTICLE 2

CORPORATE GOVERNANCE

Section 2.01. **Composition of the Board**.

(a) Subject to the applicable law, the Avista Shareholder, shall have the right to nominate two directors to the Board of the Company (the *"**Avista Designees**").*

(b) Subject to the applicable law, the Altchem Shareholder shall have the right to nominate two directors for appointment to the Board of the Company (the *"**Altchem Designees**"* and, together with the Avista Designees, the *"**Sponsor Designees**").*

(c) (i) In the event that any Sponsor (and its Affiliates) ceases to beneficially own Ordinary Shares that equal at least twenty percent (20%) of the Ordinary Shares then outstanding, such Sponsor shall no longer have the right to nominate for appointment two Sponsor Designees and shall have the right to nominate for appointment only one Sponsor Designee, and (ii) in the event that any Sponsor (and its Affiliates) cease to beneficially own Ordinary Shares that equal at least ten percent (10%) of the Ordinary Shares then outstanding, such Sponsor shall no longer have the right to nominate any Sponsor Designees.

(d) The Company shall use all reasonable efforts to facilitate the appointment of the Sponsor Designees pursuant to this Section 2.01 to be elected as members of the Board, and to permit the Sponsors to remove, replace or change their Sponsor Designees from time to time and fill vacancies created by reason of death, removal or resignation of such Sponsor Designees, including by calling a general or special meeting of shareholders of the Company for the purpose of voting on any appointment, removal, replacement or change.

(e) Until such time as any of the Sponsors (together with its Affiliates) individually ceases beneficially to own Ordinary Shares that equal at least ten percent (10%) of the Ordinary Shares then outstanding, each Sponsor and each Co-Invest Vehicle shall, at any time it is then entitled to vote for the election of directors to the Board, vote all of its Equity Securities

that are entitled to vote or execute proxies or written consents, as the case may be, and take all other necessary action (including causing the Company to call a special meeting of Shareholders) in order to ensure that the composition of the Board is as set forth in this Section 2.01.

(f) The Company shall reimburse each Sponsor Designee for all reasonable out-of-pocket expenses incurred in connection with the attendance by such Sponsor Designee at meetings of the Board or any committee thereof, including, without limitation, travel, lodging and meal expenses.

Section 2.02. **Additional Provisions**.

(a) Subject to the confidentiality obligations of Shareholders pursuant to Section 6.01 of this Agreement and to the fiduciary duties of each of the Sponsor Designees, the Company agrees and acknowledges that the Sponsor Designees may share confidential, non-public information about the Company with the Sponsors.

(b) (i) The Company covenants and agrees to, until such time as such Sponsor ceases to beneficially own Ordinary Shares that equal less than ten percent (10%) of the outstanding Ordinary Shares, (i) deliver to each of the Sponsors with reasonable promptness, such information and data, including, but not limited to, any information necessary to assist each of the Sponsors in preserving its qualification as a "venture capital operating company" as defined in the regulations promulgated under the Employment Retirement Income Security Act of 1974 by the United States Department of Labor, with respect of the Company and each of its subsidiaries from time to time may be reasonably requested by such Sponsor and (ii) cause its and its Subsidiaries' officers, directors, employees, auditors and other agents to (a) afford the officers, employees, auditors and other agents of such Sponsor, during normal business hours and upon reasonable notice, reasonable access and consultation rights at all reasonable times to its officers, employees, auditors, legal counsel, properties, offices, plants and other facilities and to all books and records, and (b) afford such Sponsor the opportunity to discuss the Company's affairs, finances and accounts with the Company's officers from time to time as each such Sponsor may reasonably request.

(c) At the Effective Time, the limited partnership agreement of LuxCo, as in effect immediately prior to the Effective Time, shall be amended and restated to reflect a wholly-owned subsidiary of the Company and substantially in the form attached hereto as **Exhibit C**.

Section 2.03. **Exculpation**.

(a) Without limiting the scope or application of Section 2.04 and to the full extent permitted by applicable law, no Indemnified Party (as defined below) shall be liable, in damages or otherwise, to the Company, the Shareholders or any of their Affiliates for any act or omission performed or omitted by any of them in good faith (including any act or omission performed or omitted by any of them in reliance upon and in accordance with the opinion or advice of experts, including of legal counsel as to matters of law, of accountants as to matters of accounting, or of investment bankers or appraisers as to matters of valuation), except with respect to (i) any act taken by such Indemnified Party purporting to bind the Company that such Indemnified Party did not reasonably believe to have been taken in accordance with this

Agreement (or authorized by the Board), or (ii) any act or omission with respect to which such Indemnified Party was grossly negligent or engaged in intentional misconduct.

(b) The provisions of this Agreement, to the extent that they restrict, modify or eliminate the duties and liabilities of an Indemnified Party otherwise existing at law or in equity, are agreed by the parties hereto to replace such other duties and liabilities of such Indemnified Party, to the maximum extent permitted by applicable law.

Section 2.04. **Indemnification**.

(a) To the fullest extent permitted by applicable law, the Company shall and does hereby agree to indemnify and hold harmless and pay all judgments and claims against (i) each director of the Company and (ii) each officer of the Company, and their respective Affiliates, officers, directors, employees, shareholders, partners, managers and members (each, an "***Indemnified Party***"), each of which shall be a third-party beneficiary of this Agreement solely for purposes of this Section 2.04 and Section 2.05), from and against any loss or damage incurred by such Indemnified Party, for any act or omission taken or suffered by such Indemnified Party in good faith (including any act or omission taken or suffered by any of them in reliance upon and in accordance with the opinion or advice of experts, including of legal counsel as to matters of law, of accountants as to matters of accounting, or of investment bankers or appraisers as to matters of valuation) in connection with the Board or the Company's business, including costs and reasonable attorneys' fees and any amount expended in the settlement of any claims or loss or damage, except with respect to (i) any act taken by such Indemnified Party purporting to bind the Company that has not been authorized pursuant to this Agreement or (ii) any act or omission with respect to which such Indemnified Party was grossly negligent or engaged in intentional misconduct.

(b) The satisfaction of any indemnification obligation pursuant to Section 2.04(a) shall be from and limited to Company assets (including insurance and any agreements pursuant to which the Company, the Board and their respective officers or employees are entitled to indemnification) and no Shareholder, in such capacity, shall be subject to personal liability therefor.

(c) Expenses reasonably incurred by an Indemnified Party in defense or settlement of any claim that may be subject to a right of indemnification hereunder shall be advanced by the Company prior to the final disposition thereof upon receipt of an undertaking by or on behalf of such Indemnified Party to repay such amount to the extent that it shall be determined upon final adjudication after all possible appeals have been exhausted that such Indemnified Party is not entitled to be indemnified hereunder.

(d) The Company may purchase and maintain insurance, on behalf of all Indemnified Parties and other Persons against any liability which may be asserted against, or expense which may be incurred by, any such Person in connection with the Company's activities, whether or not the Company would have the power to indemnify such Person against such liabilities under the provisions of this Agreement.

(e) Promptly after receipt by an Indemnified Party of notice of the commencement of any Proceeding, such Indemnified Party shall, if a claim for indemnification in

respect thereof is to be made against the Company, give written notice to the Company of the commencement of such Proceeding; provided, however, that the failure of any Indemnified Party to give notice as provided herein shall not relieve the Company of its obligations under this Section 2.04, except to the extent that the Company is actually prejudiced by such failure to give notice. In case any such Proceeding is brought against an Indemnified Party (other than a derivative suit in right of the Company or the Board), the Company will be entitled to participate in and to assume the defense thereof to the extent that the Company may wish, with counsel reasonably satisfactory to such Indemnified Party. After notice from the Company to such Indemnified Party of the Company's election to assume the defense of such Proceeding, the Company will not be liable for expenses subsequently incurred by such Indemnified Party in connection with the defense thereof. The Company will not consent to entry of any judgment or enter into any settlement of such Proceeding that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party a release from all liability in respect of such Proceeding and the related claim.

(f) The right to indemnification and the advancement of expenses conferred in this Section 2.04 shall not be exclusive of any other right which any Person may have or hereafter acquire under any statute, agreement, bylaw, vote of the Board or otherwise. The rights conferred upon any Indemnified Party in Section 2.03 and Section 2.04 shall be contract rights that vest upon the occurrence or alleged occurrence of any act or omission giving rise to any Proceeding or threatened Proceeding and such rights shall continue as to any Indemnified Party who has ceased to be a director or officer and shall inure to the benefit of such Indemnified Party's heirs, executors and administrators. Any amendment, alteration or repeal of Section 2.03 and Section 2.04 that adversely affects any right of any Indemnified Party or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any Proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

Section 2.05. **Primary Obligation**. With respect to any Indemnified Party who is employed, retained or otherwise associated with, or appointed or nominated by, the Board, any Sponsor or any of their respective Affiliates and who acts or serves as a director, officer, manager, fiduciary, employee, consultant, advisor or agent of, for or to the Board, the Company or any of its Subsidiaries, the Company or its Subsidiaries shall be primarily liable for all indemnification, reimbursements, advancements or similar payments (the "***Indemnity Obligations***") afforded to such Indemnified Party acting in such capacity or capacities on behalf or at the request of the Board, the Company or any of their respective Subsidiaries, in such capacity, whether the Indemnity Obligations are created by law, organizational or constituent documents, contract (including this Agreement) or otherwise. Notwithstanding the fact that such Sponsors or any of its Affiliates, other than the Company (such Persons, together with its and their heirs, successors and assigns, the "***Sponsor Parties***"), may have concurrent liability to an Indemnified Party with respect to the Indemnity Obligations, the Company hereby agrees that in no event shall the Company or any of their respective Subsidiaries have any right or claim against any of the Sponsor Parties for contribution or have rights of subrogation against any Sponsor Parties through an Indemnified Party for any payment made by the Company or any of its Subsidiaries with respect to any Indemnity Obligation. In addition, the Company hereby agrees that in the event that any Sponsor Parties pay or advance to an Indemnified Party any amount with respect to an Indemnity

Obligation, the Company will, or will cause its Subsidiaries to, as applicable, promptly reimburse such Sponsor Parties for such payment or advance upon request.

ARTICLE 3

TRANSFERS AND RESTRICTIONS ON TRANSFER

Section 3.01. **Co-Invest Vehicle Participation; Aggregation of Interests**.

(a) Notwithstanding anything in this Agreement to the contrary, in connection with any Transfer of Equity Securities by the Avista Shareholder or its Permitted Transferees (including under Section 4.01, Section 4.02 or Section 4.03), such Transfers shall (and the Avista Shareholder shall cause such Transfer to) include a number of Equity Securities held by each of the Avista Co-Invest Vehicles equal to Avista's Proportion multiplied by the number of Equity Securities held by such Avista Co-Invest Vehicle as of immediately prior to such Transfer, and any and all references to Transfers by the Avista Shareholder or Sponsor (as such term relates to or refers to the Avista Shareholder) shall be deemed to refer to both the Avista Shareholder and the Avista Co-Invest Vehicles; provided, that this Section 3.01(a) shall not apply to Transfers by the Avista Shareholder to its Permitted Transferees or a "distribution-in-kind" made by an Avista Shareholder or its partners or members (an "***Avista DIK***").

(b) Notwithstanding anything in this Agreement to the contrary, in connection with any Transfer of Equity Securities by the Altchem Shareholder or its Permitted Transferees (including under Section 4.01, Section 4.02 or Section 4.03), such Transfers shall (and the Altchem Shareholder shall cause such Transfer to) include a number of Equity Securities held by each of the Altchem Co-Invest Vehicles equal to Altchem's Proportion multiplied by the number of Equity Securities held by such Altchem Co-Invest Vehicle as of immediately prior to such Transfer, and any and all references to Transfers by the Altchem Shareholder or Sponsor (as such term relates to or refers to the Altchem Shareholder) shall be deemed to refer to both the Altchem Shareholder and the Altchem Co-Invest Vehicles; provided, that this Section 3.01(b) shall not apply to Transfers by the Altchem Shareholder to its Permitted Transferees or a "distribution-in-kind" made by an Altchem Shareholder or its partners or members (an "***Altchem DIK***").

(c) All Equity Securities held by a Shareholder and its Permitted Transferees shall be aggregated together for purposes of determining the availability of any rights under this Agreement (and for the avoidance of doubt, Permitted Transferees will be subject to the restrictions and obligations under this Agreement, and the applicable Shareholder shall (without limiting any liability a Permitted Transferee may have) be responsible for its Permitted Transferees' compliance therewith). In addition, other than for purposes of Section 3.01, (i) Equity Securities held by the Avista Co-Invest Vehicles shall be attributed or aggregated together for purposes of determining the rights and obligations of the Avista Shareholders and any such Equity Securities held by the Avista Co-Invest Vehicles shall be included in the numerator or denominator for purposes of determining the rights or obligations of the Avista Shareholder, and (ii) Equity Securities held by the Altchem Co-Invest Vehicles shall be attributed or aggregated together for purposes of determining the rights and obligations of the Altchem Shareholder and any such Equity Securities held by the Altchem Co-Invest Vehicles shall be included in the numerator or denominator for purposes of determining the rights or obligations of the Altchem Shareholder.

Section 3.02. **General Restrictions on Transfer**.

(a) Each Shareholder understands and agrees that the Equity Securities held by it have not been registered under the Securities Act and are restricted securities under the Securities Act. No Shareholder shall Transfer any Equity Securities (or solicit any offers in respect of any Transfer of any Equity Securities), except in compliance with the Securities Act, any other applicable securities or "blue sky" laws and any restrictions on Transfer contained in this Agreement or any other provisions set forth in any other agreements or instruments pursuant to which such Equity Securities were issued.

(b) Following the IPO, the Sponsors shall create a coordination committee (the *"**Coordination Committee***"), which shall not be a committee of the Board, and will maintain such committee until the earlier of (i) the first anniversary of the IPO or (ii) until such time as the Sponsors have consummated a first registered secondary sale after the IPO of any of their respective Registrable Securities. During the one (1) year period following the IPO, the Coordination Committee shall facilitate coordination of dispositions by the Sponsors of any Equity Securities held by the Sponsors, and any Sponsor wishing to Transfer any Equity Securities during such period shall consult with and obtain the approval of the Coordination Committee prior to taking such action or entering into any definitive agreement with respect to such action; provided, however, that the foregoing shall not apply to an Avista DIK or an Altchem DIK. Each Sponsor shall be permitted to designate one representative (who may, but need not, be a director of the Company) to participate on the Coordination Committee, and shall be permitted to remove and replace such designee from time to time. The procedures governing the conduct of the Coordination Committee shall be established from time to time by consent of the Sponsors; provided, that such procedures shall not discriminate against any particular designee or designees in any material way. For the avoidance of doubt, for the purposes of this Section 3.02(b), references to Sponsors shall include their respective Permitted Transferees.

Section 3.03. **Restrictions on Transfer by Management Shareholders**. Notwithstanding anything in this Agreement to the contrary:

(a) Following the IPO, until such time as the Sponsors have Transferred at least 50% of the Equity Securities owned by the Sponsors immediately prior to the IPO, no Management Shareholder shall Transfer any Equity Securities (other than to Permitted Transferees pursuant to Section 3.04 or with the Requisite Consent) to the extent that such Transfer would result in the Relative Ownership Percentage (as defined below) of such Management Shareholder immediately following the effective time of such Transfer (the "***Determination Time***") being less than the Relative Ownership Percentage of the Sponsors immediately following the Determination Time. For purposes of this Section 3.03(a), "***Relative Ownership Percentage***" means:

> with respect to a Management Shareholder, a fraction (expressed as a percentage), (A) the numerator of which is the number of Equity Securities other than unvested options to purchase Ordinary Shares ("***Unrestricted Securities***") owned by such Management Shareholder immediately following the Determination Time, and (B) the denominator of which is the sum of (x) the number of Unrestricted Securities owned by such Management Shareholder immediately following the IPO and (y) the number of Equity Securities owned by such Management Shareholder that were not Unrestricted

Securities immediately following the IPO but that have subsequently become Unrestricted Securities; and

with respect to the Sponsors and each of their respective Co-Invest Vehicles, a fraction (expressed as a percentage), (A) the numerator of which is the aggregate number of Equity Securities owned by the Sponsors and the Co-Invest Vehicles immediately following the Determination Time and (B) the denominator of which is the aggregate number of Equity Securities owned by the Sponsors and the Co-Invest Vehicles immediately following the IPO.

(b) Any attempt by a Management Shareholder to Transfer any Equity Securities not in compliance with this Section 3.03 shall be null and void and have no force or effect, and the Company shall not, and shall cause any transfer agent not to, give any effect in the Company's share records to such attempted Transfer. The parties hereto acknowledge that the transfer restrictions contained herein are reasonable and in the best interests of the Company.

Section 3.04. **Management Permitted Transferees**.

(a) Subject to Section 3.01, any Management Shareholder may at any time Transfer any or all of its Equity Securities to a Permitted Transferee without the consent of any Person and without compliance with Section 3.03, so long as such Permitted Transferee shall have agreed in writing to be bound by the terms of this Agreement by executing a Joinder Agreement. Such Management Shareholder must give prior written notice to the Company of any proposed Transfer to a Permitted Transferee, including the identity of such proposed Permitted Transferee and such other documentation reasonably requested by the Company, to ensure compliance with the terms of this Agreement.

(b) If, while a Permitted Transferee holds any Equity Securities, a Permitted Transferee ceases to qualify as a Permitted Transferee in relation to the initial transferring Management Shareholder from whom or which such Permitted Transferee or any previous Permitted Transferee of such initial transferring Management Shareholder received such shares (an *"**Unwinding Event**"),* then:

(i) The relevant initial transferor Management Shareholder shall forthwith notify the other Shareholders and the Company of the pending occurrence of such Unwinding Event; and

(ii) immediately following such Unwinding Event, without limiting any other rights or remedies, such initial transferor Management Shareholder shall take all actions necessary to effect a Transfer of all the Equity Securities held by the relevant Affiliate either back to such Management Shareholder or, pursuant to this Section 3.04, to another Person that qualifies as an Affiliate of such initial transferring Management Shareholder.

ARTICLE 4

REGISTRATION RIGHTS

Section 4.01. **Demand Registration**.

(a) At any time after the six month anniversary of the consummation by the Company of the IPO, if the Company shall receive a written request from either or both Sponsors holding outstanding Registrable Securities for itself and its respective Co-Invest Vehicles (such requesting Persons, the *"**Requesting Shareholders**")* that the Company effect the registration under the Securities Act of all or any portion of such Requesting Shareholders' Registrable Securities, and specifying the intended method of disposition thereof, then the Company shall promptly give notice of such requested registration (each such request shall be referred to herein as a "***Demand Registration***") at least ten (10) days prior to the anticipated filing date of the Registration Statement relating to such Demand Registration to the other Sponsor, if applicable, and any other Shareholder that holds Registrable Securities, and thereupon shall use its reasonable best efforts to effect, as expeditiously as possible, the registration under the Securities Act of:

(i) all Registrable Securities for which the Requesting Shareholders have requested registration under this Section 4.01, and

(ii) subject to the restrictions set forth in Section 4.01(d), all other Registrable Securities that any other Shareholders that hold Registrable Securities (all such Shareholders, together with the Requesting Shareholders, the *"**Registering Shareholders**")* have requested the Company to register by request received by the Company within five (5) Business Days after any non-initiating Sponsor received the Company's notice of the Demand Registration, or any other Shareholder pursuant to and in accordance with Section 4.02, all to the extent necessary to permit the disposition (in accordance with the intended methods thereof as aforesaid) of the Registrable Securities so to be registered; provided that no Person may participate in any Registration Statement pursuant to this Section 4.01(a) unless such Person agrees to sell their Registrable Securities to the underwriters selected as provided in Section 4.05(f) on the same terms and conditions as apply to the Requesting Shareholders; provided, further, that no such Registering Shareholders shall be required to make any representations or warranties, or provide any indemnity, in connection with any such registration other than representations and warranties (or indemnities with respect thereto) as to (i) such Person's ownership of his, her or its Registrable Securities to be transferred free and clear of all liens, claims, and encumbrances, (ii) such Person's power and authority to effect such transfer, and (iii) such matters pertaining to compliance with securities laws by such Registering Shareholders as may be reasonably requested; provided, further, that the obligation of such Person to indemnify pursuant to any such underwriting arrangements shall be several, not joint and several, among such Persons selling Registrable Securities, and the liability of each such Person will be in proportion thereto; provided, further, that such liability will be limited to the net proceeds received by such Person from the sale of his, her or its Registrable Securities pursuant to such registration; provided, further, that, notwithstanding anything to the contrary herein, the number of Registrable Securities that a Shareholder may request to include in a Demand Registration (including pursuant to Section 4.02) cannot exceed the number of Registrable Securities, determined by multiplying the aggregate number of Registrable Securities held by such Shareholder by a fraction, the numerator of which is the number of Registrable Securities that the Requesting Shareholder proposes to sell in such Demand Registration and the denominator of which is the total number of Registrable Securities held by such Requesting Shareholder prior to such Demand Registration, and provided, further, that the Company shall not be obligated to effect a Demand Registration unless the aggregate gross proceeds expected to be received from the sale of the Registrable Securities requested to be included by all Registering Shareholders in such Demand Registration are at least $25,000,000.

(b) At any time prior to the effective date of the Registration Statement relating to such registration, a majority of the Requesting Shareholders (measured by the number of Registrable Securities proposed to be sold by all Requesting Shareholders and not by the number of Requesting Shareholders) may revoke such request without liability to any of the other Registering Shareholders, by providing a notice to the Company revoking such request. The decision as to whether to consummate and as to the terms of any Demand Registration shall be made by a majority of the Requesting Shareholders (measured by the number of Registrable Securities proposed to be sold by all Requesting Shareholders and not by the number of Requesting Shareholders) in their sole and absolute discretion.

(c) The Company shall be liable for and pay all Registration Expenses in connection with each Demand Registration, regardless of whether such Registration is effected; provided that holders of Registrable Securities shall pay all underwriting discounts, selling commissions and share transfer taxes applicable to the sale of their respective Registrable Securities, but fees and disbursements of their respective counsel shall be borne and paid by the Company as a Registration Expense.

(d) If a Demand Registration involves a Public Offering and the managing underwriter advises the Company and the Requesting Shareholders that, in its view, the number of Registrable Securities that the Registering Shareholders and the Company propose to include in such registration exceeds the largest number of Registrable Securities that can be sold without having an adverse effect on such offering, including the price at which such Registrable Securities can be sold (the *"**Demand Maximum Offering Size**"),* the Company shall include in such registration, in the priority listed below, up to the Demand Maximum Offering Size:

(i) first, all Registrable Securities requested to be registered by the Registering Shareholders (the Registrable Securities in this clause (i) allocated, if necessary for the offering not to exceed the Demand Maximum Offering Size, pro rata among the Requesting Shareholders and the other holders of Registrable Securities on the basis of the relative number of Registrable Securities so requested to be included in such registration by each); and

(ii) second, all Registrable Securities proposed to be registered by the Company.

(e) The Company may defer the filing (but not the preparation) of a Registration Statement, or suspend the continued use of a Registration Statement, required by Section 4.01 for a period of up to sixty (60) days after the request to file a Registration Statement if at the time the Company receives the request to register Registrable Securities, the Company or any of its Subsidiaries are engaged in confidential negotiations or other confidential business activities, disclosure of which would be required in such Registration Statement (but would not be required if such Registration Statement were not filed), and the Board determines in good faith, after consultation with external legal counsel, that such disclosure would have a material adverse effect on the Company or its business or on the Company's ability to effect a proposed material acquisition, disposition, financing, reorganization, recapitalization or similar transaction. A deferral of the filing of a Registration Statement, or the suspension of the continued use of a Registration Statement, pursuant to this Section 4.01(e), shall be promptly lifted, and the requested Registration Statement shall be filed as expeditiously as possible, in the case of a deferral, if the

negotiations or other activities are disclosed or terminated. In order to defer the filing of a Registration Statement, or suspend the continued use of a Registration Statement, pursuant to this Section 4.01(e), the Company shall promptly (but in any event within five (5) days), upon determining to seek such deferral or suspension, deliver to each Requesting Shareholder a certificate signed by Board stating that the Company is deferring such filing, or suspending the continued use of a Registration Statement, pursuant to this Section 4.01(e) and a general statement of the reason for such deferral or suspension, as the case may be, and an approximation of the anticipated delay. The Company may defer the filing, or suspend the continued use of, a particular Registration Statement pursuant to this Section 4.01(e) no more than twice in any twelve month period; provided, that there must be an interim period of at least sixty (60) days between the end of one deferral or suspension period and the beginning of a subsequent deferral or suspension period. In the event the Company exercises its rights under this Section 4.01(e), the Company shall, within ten (10) days following receipt by the holders of Registrable Securities of the notice of deferral or suspension, as the case may be, update the deferred or suspended Registration Statement as may be necessary to permit the holders of Registrable Securities to resume use thereof in connection with the offer and sale of their Registrable Securities in accordance with applicable law.

Section 4.02. **Piggyback Registration**.

(a) If the Company proposes to register any Equity Securities under the Securities Act (whether for itself or otherwise in connection with a sale of securities by another Person (including a Demand Registration by a Sponsor), but other than (i) in connection with a Shelf Registration and any resale of Registrable Securities by a Sponsor pursuant to a Shelf Registration, which shall be governed by the terms of Section 4.03, (ii) a registration on a Form S-4 in connection with a direct or indirect acquisition by the Company of another Person, (iii) a registration on a Form S-8, or (iv) the IPO (unless the Sponsors are participating therein as selling equityholders), the Company shall at each such time give prompt written notice at least ten (10) days prior to the anticipated filing date of the Registration Statement relating to such registration to each Shareholder holding Registrable Securities hereunder, which notice shall set forth such Shareholder's rights under this Section 4.02 and shall offer such Shareholder the opportunity to include in such Registration Statement all or any portion of the Registrable Securities held by such Shareholder (a "***Piggyback Registration***"), subject to the restrictions set forth herein, including the second to last proviso in Section 4.01(a)(ii) above. Upon the request of any such Shareholder made within ten (10) days after the receipt of notice from the Company (which request shall specify the number of Registrable Securities intended to be registered by such Shareholder), the Company shall use its reasonable best efforts to effect the registration under the Securities Act of all Registrable Securities that the Company has been so requested to register by all such Shareholders (subject to the last proviso of Section 4.01(a)(ii) above) with rights to require registration of Registrable Securities hereunder, to the extent required to permit the disposition of the Registrable Securities so to be registered; provided, that if such registration involves a Public Offering, all such Shareholders requesting to be included in the Company's registration must sell their Registrable Securities to the underwriters selected as provided in Section 4.05(f) on the same terms and conditions as apply to the Company or any other selling equityholders; provided, however, that no such Person shall be required to make any representations or warranties, or provide any indemnity, in connection with any such registration other than representations and warranties (or indemnities with respect thereto) as to (i) such Person's ownership of his, her or its Registrable

Securities to be transferred free and clear of all liens, claims, and encumbrances, (i) such Person's power and authority to effect such transfer, and (ii) such matters pertaining to compliance with securities laws by such Person as may be reasonably requested; provided, further, that the obligation of such Person to indemnify pursuant to any such underwriting arrangements shall be several, not joint and several, among such Persons selling Registrable Securities, and the liability of each such Person will be in proportion thereto, and provided, further, that such liability will be limited to, the net proceeds received by such Person from the sale of his, her or its Registrable Securities pursuant to such registration. If, at any time after giving notice of its intention to register any Registrable Securities pursuant to this Section 4.02(a) and prior to the effective date of the Registration Statement filed in connection with such registration, the Company or the initiating holders, as applicable, shall decide for any reason and in its sole and absolute discretion not to register such securities, the Company shall give notice to all such Shareholders and, thereupon, shall be relieved of its obligation to register any Registrable Securities in connection with such registration. No registration effected under this Section 4.02 shall relieve the Company of its obligations to effect a Demand Registration to the extent required by Section 4.01. The Company shall be liable for and pay all Registration Expenses in connection with each Piggyback Registration, regardless of whether such registration is effected.

(b) If a Piggyback Registration involves a Public Offering (other than any Demand Registration, in which case the provisions with respect to priority of inclusion in such offering set forth in Section 4.01(d) shall apply) and the managing underwriter advises the Company that, in its view, the number of Registrable Securities that the Company and all selling equityholders propose to include in such registration exceeds the largest number of Registrable Securities that can be sold without having an adverse effect on such offering, including the price at which such Registrable Securities can be sold (the "***Piggyback Maximum Offering Size***"*),* the Company shall include in such registration, in the following priority, up to the Piggyback Maximum Offering Size:

(i) first, such number of Registrable Securities proposed to be registered for the account of the Company, if any, as would not cause the offering to exceed the Piggyback Maximum Offering Size; and

(ii) second, all Registrable Securities requested to be included in such registration by any Shareholders pursuant to this Section 4.02 (the Registrable Securities in this clause (ii) allocated, if necessary for the offering not to exceed the Piggyback Maximum Offering Size, pro rata among such Shareholders based on their relative number of Registrable Securities requested to be included in the Piggyback Registration).

Section 4.03. **Shelf Registration**.

(a) At any time after the 12 month anniversary of the consummation by the Company of the IPO, upon receipt of a written request (the *"**Shelf Request***") from either or both Sponsors (for themselves and their respective Co-Invest Vehicles) that the Company file a "shelf" Registration Statement pursuant to Rule 415 under the Securities Act (the *"**Shelf Registration**")* on Form S-3 (or any successor form to Form S-3, or any similar short-form registration statement), covering the resale of Registrable Securities, the reasonably anticipated gross proceeds from all resales covered thereunder of which would exceed $25,000,000, the Company shall (i) within five

(5) days of the receipt by the Company of such notice, give written notice of such proposed registration to any non-requesting Sponsor, and (ii) use its reasonable best efforts, consistent with the terms of this Agreement, to cause the Shelf Registration to be filed with the SEC as soon as practicable (but in no event later than thirty (30) days following its receipt of the Shelf Request) and to include all Registrable Securities held by such requesting Sponsor to be registered on such form for the offering together with all or such portion of the Registrable Securities of any non-requesting Sponsor joining in such request as are specified in a written request received by the Company within ten (10) days after receipt of such written notice from the Company and (iii) use its reasonable best efforts, consistent with the terms of this Agreement, to cause such Shelf Registration to be declared effective by the SEC as soon as possible. As soon as reasonably practicable after the IPO, the Company will use its reasonable best efforts, consistent with the terms of this Agreement, to qualify for and remain eligible to use Form S-3 registration or a similar short-form registration. The provisions of Section 4.05 shall be applicable to each sale of Registrable Securities from a Shelf Registration initiated under this Section 4.03 and any subsequent resale of Registrable Securities pursuant thereto; provided, that the gross proceeds from such sales equal at least $25,000,000.

(b) In connection with any proposed firmly underwritten resale of Registrable Securities, including by underwritten "block trade", which is not pursuant to a Demand Registration under Section 4.01 and with respect to which such Shelf Registration is expressly being utilized to effect such resale (an *"**Underwritten Shelf Take-down**"*) pursuant to a Shelf Registration, each Sponsor agrees, in an effort to conduct any such Underwritten Shelf Take-Down in the most efficient and organized manner, to coordinate with the other Sponsor participating in such Shelf Take-Down prior to initiating any sales efforts and cooperate with such other Sponsor as to the terms of such Underwritten Shelf Take-Down, including the aggregate amount of securities to be sold and the number of Registrable Securities to be sold by each participating Sponsor. In furtherance of the foregoing, the Company shall give prompt notice to the non-initiating Sponsor (if such Sponsor's Registrable Securities are included in the Shelf Registration) of the receipt of a request from the initiating Sponsor (whose Registrable Securities are included in the Shelf Registration) of a proposed Underwritten Shelf Take-Down under and pursuant to the Shelf Registration and, notwithstanding anything to the contrary contained herein, will provide such non-initiating Sponsor a period of two (2) Business Days to participate in such Underwritten Shelf Take-Down, subject to the terms negotiated by and applicable to the initiating Sponsor and subject to "cutback" limitations set forth in Section 4.01(d) as if the subject Underwritten Shelf Take-Down was being effected pursuant to a Demand Registration. All such Sponsors electing to be included in an Underwritten Shelf Take-down must sell their Registrable Securities to the underwriters selected as provided in Section 4.05(f) on the same terms and conditions as apply to any other selling equityholders; provided, however, that no such Person shall be required to make any representations or warranties, or provide any indemnity, in connection with any such registration other than representations and warranties (or indemnities with respect thereto) as to (i) such Person's ownership of his, her or its Registrable Securities to be transferred free and clear of all liens, claims, and encumbrances, (ii) such Person's power and authority to effect such transfer, and (iii) such matters pertaining to compliance with securities laws by such Person as may be reasonably requested; provided, further, however, that the obligation of such Person to indemnify pursuant to any such underwriting arrangements shall be several, not joint and several, among such Persons selling Registrable Securities, and the liability of each such Person will be in proportion

thereto, and provided, further, that such liability will be limited to the net proceeds received by such Person from the sale of his, her or its Registrable Securities pursuant to such registration.

(c) The Company shall be liable for and pay all Registration Expenses in connection with each Shelf Registration, regardless of whether such Shelf Registration is effected, and any Underwritten Shelf Take-Down; provided, that holders of Registrable Securities shall each pay their *pro rata* portion of all underwriting discounts, selling commissions, and share transfer taxes applicable to the sale of Registrable Securities, but fees and disbursements of their respective counsel shall be borne and paid by the Company as a Registration Expense.

(d) Notwithstanding anything to the contrary contained herein, no Management Shareholder will be entitled to participate with respect to any shelf registration effected pursuant to this Section 4.03 or with respect to any resales of securities pursuant to any shelf registration. For the avoidance of doubt, this Section 4.03(d) shall not apply to any Management Shareholder to the extent of any such Person's interests held in a Co-Invest Vehicle.

Section 4.04. **Lock-Up Agreements**.

(a) In connection with each underwritten Public Offering, including any Underwitten Shelf Take-down, and if reasonably requested by the applicable managing underwriter, each of the Company and the Shareholders agree not to effect any public sale or private offer or distribution (other than a distribution-in-kind pro rata to all shareholders, limited partners or members, as the case may be, of such Shareholder) of any Registrable Securities during the ten (10) days prior to the consummation of such Public Offering and during such time period after the consummation of such Public Offering, not to exceed ninety (90) days (one-hundred and eighty (180) days in the case of the IPO (the "***IPO Lock-Up Period***")) as may be requested by the managing underwriter; provided, that such lock-up agreements are also required from all directors and executive officers and from all Shareholders who hold at least five percent (5%) of the Registrable Securities; provided, further, that each such director, executive officer or Shareholder referenced in the foregoing proviso, shall enter into such lock-up agreements if so required. Notwithstanding the foregoing, this Section 4.04 shall not apply to any sale by a Shareholder or a director or officer of a Shareholder of Equity Securities acquired in open market transactions or block purchases by such Shareholder or its Affiliates subsequent to the IPO or with respect to any Rule 10b5-1 sale program approved by the Board for the benefit of any director or officer of the Company. Any discretionary waiver or reduction of the requirements under the foregoing provisions made by the Company or the applicable lead managing underwriters shall apply to each Shareholder on a pro rata basis.

(b) Notwithstanding anything herein to the contrary, if the Company shall, at any time, register under the Securities Act an offering and sale of Registrable Securities held by the Shareholders for sale to the public pursuant to an underwritten Public Offering, the Company shall not, without the prior written consent of the lead underwriters for such offering, effect any public sale or distribution of securities similar to those being registered, or any securities convertible into or exercisable or exchangeable for such securities, for such period as shall be determined by the lead underwriters and that is for the same period and on substantially similar terms as agreed to by the Sponsors.

(c) At any time following the IPO, either Sponsor that, together with its Affiliates, holds less than five percent (5%) of the then outstanding vested Equity Securities may elect (on behalf of itself and its Affiliates (collectively, the "***Withdrawing Holders***"), by written notice to the Company, to withdraw from the provisions of this ARTICLE 4 and as a result of such withdrawal, such Withdrawing Holders shall no longer be entitled to the rights, nor be subject to the obligations, of Section 4.01 through Section 4.12 and the Equity Securities held by the Withdrawing Holders shall conclusively be deemed thereafter not to be "Registrable Securities" under this Agreement. No withdrawal pursuant to this Section 4.04(c) shall release or limit any Withdrawing Holder from its indemnification and contribution rights and obligations, if any, pursuant to Section 4.06, Section 4.07,Section 4.08 and Section 4.09 herein.

Section 4.05. **Registration Procedures**. Whenever any Shareholders request that any Registrable Securities be registered pursuant to Section 4.01, Section 4.02 or Section 4.03 hereof, subject to the provisions of such Sections, the Company shall use its reasonable best efforts to effect the registration and the sale of such Registrable Securities in accordance with the intended method of disposition thereof as quickly as practicable, and, in connection with any such request:

(a) The Company shall, as expeditiously as possible, and, if the Company is not qualified for the use of Form S-3, no later than thirty (30) days from the date of receipt by the Company of the written request, prepare and file with the SEC a Registration Statement on any form for which the Company then qualifies and the managing underwriter, if any, and the holders of a majority of the Registrable Securities to be registered thereunder shall deem appropriate and which form shall be available for the sale of the Registrable Securities to be registered thereunder in accordance with the intended method of distribution thereof, and use its reasonable best efforts to cause such filed Registration Statement to become and remain effective for a period of not less than one-hundred and eighty (180) days or in the case of a Shelf Registration, not less than two years (or such shorter period in which all of the Registrable Securities of the Registering Shareholders included in such registration statement shall have actually been sold thereunder); provided, however, that such one-hundred and eighty (180) day period or two year period, as applicable, shall be extended for a period of time equal to the period any Shareholder refrains from selling any securities included in such registration at the request of an underwriter and in the case of any Shelf Registration, subject to compliance with applicable SEC rules, such two year period shall be extended, if necessary, to keep the Registration Statement effective until all such Registrable Securities are sold.

(b) Prior to filing a Registration Statement or prospectus or any amendment or supplement thereto, the Company shall furnish to each participating Shareholder and each underwriter, if any, of the Registrable Securities covered by such Registration Statement copies of such Registration Statement as proposed to be filed, and thereafter the Company shall furnish to such Shareholder and underwriter, if any, such number of copies of such Registration Statement, each amendment and supplement thereto (in each case including all exhibits thereto and documents incorporated by reference therein), the prospectus included in such registration statement (including each preliminary prospectus and any summary prospectus) and any other prospectus filed under Rule 424 or Rule 430A under the Securities Act and such other documents as such Shareholder or underwriter may reasonably request in order to facilitate the disposition of the Registrable Securities owned by such Shareholder.

(c) After the filing of the Registration Statement, the Company shall (i) promptly notify each Shareholder holding Registrable Equity Securities covered by such Registration Statement of the time when such Registration Statement has been declared effective or a supplement or amendment to any prospectus forming a part of such Registration Statement has been filed, (ii) cause the related prospectus to be supplemented by any required prospectus supplement, and, as so supplemented, to be filed pursuant to Rule 424 under the Securities Act and shall incorporate such information as the managing underwriter or underwriters and each of the Sponsors agree should be included therein relating to the plan of distribution; provided, that in the event the Registrable Securities being sold for either of the Sponsors are less than 50% of the Registrable Securities of the other Sponsor, then the agreement of the Sponsor who holds such lesser amount of Registrable Securities being sold, shall not be required under this Section 4.05(c), (ii) comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement during the applicable period in accordance with the intended methods of disposition by the Registering Shareholders thereof set forth in such Registration Statement or supplement to such prospectus and (iii) promptly notify each Registering Shareholder holding Registrable Securities covered by such Registration Statement of any stop order issued or threatened by the SEC or any state securities commission and take all reasonable actions required to prevent the entry of such stop order or to remove it if entered.

(d) The Company shall use its reasonable best efforts to (i) register or qualify the Registrable Securities covered by such Registration Statement under such other securities or "blue sky" laws of such jurisdictions in the United States as any Registering Shareholder holding such Registrable Securities reasonably (in light of such Shareholder's intended plan of distribution) requests and (ii) cause such Registrable Securities to be registered with or approved by such other governmental agencies or authorities as may be necessary by virtue of the business and operations of the Company and do any and all other acts and things that may be reasonably necessary or advisable to enable such Shareholder to consummate the disposition of the Registrable Securities owned by such Registering Shareholder; provided that the Company shall not be required to (A) qualify generally to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 4.05(d), (B) subject itself to taxation in any such jurisdiction or (C) consent to general service of process in any such jurisdiction.

(e) The Company shall immediately notify each Registering Shareholder holding such Registrable Securities covered by such Registration Statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the occurrence of an event requiring the preparation of a supplement or amendment to such prospectus so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and promptly prepare and make available to each such Registering Shareholder and file with the SEC any such supplement or amendment.

(f) Except for a Demand Registration and Underwritten Shelf Take-down, the Board shall have the right to select the underwriter or underwriters in connection with any Public Offering. In connection with the offering of Registrable Securities pursuant to a Demand Registration or Underwritten Shelf Take-down, the holders of a majority of the Registrable

Securities to be registered in a Demand Registration or Underwritten Shelf Take-down shall select the underwriter or underwriters. In connection with any Public Offering, the Company shall enter into customary agreements (including an underwriting agreement in customary form, provided that the scope of the indemnity contained in such underwriting agreement on the part of the selling Shareholders is not more extensive than the indemnity described in Section 4.07 hereof), provided that such agreements are consistent with this Agreement, and take all such other actions as are reasonably required in order to expedite or facilitate the disposition of such Registrable Securities in any such Public Offering, including the engagement of a "qualified independent underwriter" in connection with the qualification of the underwriting arrangements with FINRA. The Company shall make such representations and warranties to the holders of Registrable Securities being registered, and the underwriters or agents, if any, in form, substance and scope as are customarily made by issuers in secondary underwritten public offerings and take any other actions as the Sponsors, or the managing underwriter or underwriters, if any, reasonably request in order to expedite or facilitate the registration and disposition of such Registrable Securities. Each Shareholder participating in such underwriting shall also enter into such agreement, provided that the terms of any such agreement are consistent with this Agreement.

(g) Upon execution of confidentiality agreements in form and substance reasonably satisfactory to the Company, the Company shall make available for inspection by any Registering Shareholder and any underwriter participating in any disposition pursuant to a Registration Statement being filed by the Company pursuant to this Section 4.05 and any attorney, accountant or other professional retained by any such Registering Shareholder or underwriter (collectively, the "***Inspectors***"), all financial and other records, pertinent corporate documents and properties of the Company (collectively, the *"**Records**")* as shall be reasonably necessary or desirable to enable them to exercise their due diligence responsibility, and cause the Company's officers, directors and employees to supply all information reasonably requested by any Inspectors in connection with such Registration Statement. Records that the Company determines, in good faith, to be confidential and that it notifies the Inspectors are confidential shall not be disclosed by the Inspectors unless (i) the disclosure of such Records is necessary to avoid or correct a misstatement or omission in such Registration Statement or (ii) the release of such Records is ordered pursuant to a subpoena or other order from a court of competent jurisdiction or is otherwise required by law. Each Shareholder agrees that at the time that such Shareholder is a Registering Shareholder, information obtained by it as a result of such inspections shall be deemed confidential and shall not be used by it or its Affiliates as the basis for any market transactions in Equity Securities unless and until such information is made generally available to the public, and further agrees that, upon learning that disclosure of such Records is sought in a court of competent jurisdiction, it shall give notice to the Company and allow the Company, at its expense, to undertake appropriate action to prevent disclosure of the Records deemed confidential.

(h) The Company shall cause to be furnished to each Registering Shareholders and to each such underwriter, if any, a signed counterpart, addressed to such Registering Shareholder or underwriter, of (i) an opinion or opinions of counsel to the Company and (ii) a comfort letter or comfort letters from the Company's independent public accountants, each in customary form and covering such matters of the kind customarily covered by opinions or comfort letters, as the case may be, as a majority of such Shareholders or the managing underwriter therefor reasonably requests.

(i) The Company shall otherwise use its reasonable best efforts to comply with all applicable rules and regulations of the SEC, and make available to its security holders, as soon as reasonably practicable, an earnings statement or such other document that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 thereunder. The Company shall cooperate with each seller of Registrable Securities and each underwriter, if any, participating in the disposition of such Registrable Securities and their respective counsel in connection with any filings to be made with FINRA.

(j) The Company may require each such Registering Shareholder, by written notice given to each such Registering Shareholder not less than ten (10) days prior to the filing date of such Registration Statement, to promptly, and in any event within seven (7) days after receipt of such notice, furnish in writing to the Company such information regarding the distribution of the Registrable Securities as the Company may from time to time reasonably request and such other information as may be legally required in connection with such registration. Each holder of Registrable Securities agrees to furnish such information to the Company and cooperate with the Company as reasonably necessary to enable the Company to comply with the provisions of this Agreement.

(k) Each Shareholder agrees that at the time that such Shareholder is a Registering Shareholder, upon receipt of any written notice from the Company of the occurrence of any event requiring the preparation of a supplement or amendment of a prospectus relating to the Registrable Securities covered by a registration statement that is required to be delivered under the Securities Act so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein or to make the statements therein not misleading, such Shareholder shall forthwith discontinue disposition of Registrable Securities pursuant to the registration statement covering such Registrable Securities until such Shareholder's receipt of the copies of a supplemented or amended prospectus, and, if so directed by the Company, such Shareholder shall deliver to the Company all copies, other than any permanent file copies then in such Shareholder's possession, of the most recent prospectus covering such Registrable Securities at the time of receipt of such notice. If the Company shall give such notice, the Company shall extend the period during which such Registration Statement shall be maintained effective (including the period referred to in Section 4.05(a)) by the number of days during the period from and including the date of the giving of notice pursuant to Section 4.05(e) to the date when the Company shall make available to such Shareholder a prospectus supplemented or amended to conform with the requirements of Section 4.05(e).

(l) The Company shall use its reasonable best efforts to list all Registrable Securities covered by such Registration Statement on any securities exchange or quotation system on which any of the Registrable Securities are then listed or traded and if none of the Registrable Securities are so listed, on any securities exchange or quotation system on which similar securities issued by the Company are then listed, and if no such similar securities are listed, on any national securities exchange.

(m) The Company shall have appropriate officers of the Company (i) prepare and make presentations at any "road shows" and before analysts and rating agencies, as the case may be, (ii) take other reasonable actions to obtain ratings for any Registrable Securities and (iii)

otherwise use their reasonable best efforts to cooperate as requested by the underwriters in the offering, marketing or selling of the Registrable Securities.

Section 4.06. **Indemnification by the Company**. The Company shall indemnify and hold harmless each Shareholder, its officers, directors, employees, managers, members, partners and agents, and each Person, if any, who controls any such Persons within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, damages, liabilities and expenses (including reasonable expenses of investigation and reasonable attorneys' fees and expenses) ("***Damages***") caused by or relating to any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement or prospectus relating to the Registrable Securities (as amended or supplemented if the Company shall have furnished any amendments or supplements thereto) or any preliminary or free writing prospectus, or caused by or relating to any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or caused by or related to any violation or alleged violation of the Securities Act or Exchange Act, except insofar as such Damages are caused by or related to any such untrue statement or omission or alleged untrue statement or omission so made in reliance upon and in conformity with information furnished in writing to the Company by such Shareholder or on such Shareholder's behalf expressly for use therein, provided that, with respect to any untrue statement or omission or alleged untrue statement or omission made in any preliminary prospectus, or in any prospectus, as the case may be, the indemnity agreement contained in this paragraph shall not apply to the extent that any Damages result from the fact that a current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) was not sent or given to the Person asserting any such Damages at or prior to the written confirmation of the sale of the Registrable Securities concerned to such Person if it is determined that the Company has provided such prospectus to such Shareholder and it was the responsibility of such Shareholder to provide such Person with a current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) and such current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) would have cured the defect giving rise to such Damages.

Section 4.07. **Indemnification by the Participating Shareholders**. Each Shareholder, at the time that such Shareholder is a Registering Shareholder holding Registrable Securities included in any Registration Statement agrees, severally but not jointly, to indemnify and hold harmless from and against all Damages the Company, its officers, directors and agents and each Person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act (i) with respect to information furnished in writing to the Company by such Shareholder or on such Shareholder's behalf expressly for use in any Registration Statement or prospectus relating to the Registrable Securities, or any amendment or supplement thereto, or any preliminary prospectus or (ii) to the extent that any Damages result from the fact that a current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) was not sent or given to the Person asserting any such Damages at or prior to the written confirmation of the sale of the Registrable Securities concerned to such Person if it is determined that it was the responsibility of such Shareholder to provide such Person with a current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) and such current copy of the prospectus (or such amended or supplemented prospectus, as the case may be) was available to such Shareholder and would have cured the defect giving rise to such Damages. As a condition to including Registrable Securities in any Registration Statement filed

in accordance with Section 4.01 through Section 4.12, the Company may require that it shall have received an undertaking reasonably satisfactory to it from any underwriter to indemnify and hold it harmless to the extent customarily provided by underwriters with respect to similar securities. No Shareholder shall be liable under this Section 4.06 for any Damages in excess of the net proceeds realized by such Shareholder in the sale of Registrable Securities of such Shareholder to which such Damages relate.

Section 4.08. **Conduct of Indemnification Proceedings**. If any proceeding (including any governmental investigation) shall be instituted involving any Indemnified Party in respect of which indemnity may be sought pursuant to Section 4.01 through Section 4.12, such Indemnified Party shall promptly notify the Person against whom such indemnity may be sought (the *"**Indemnifying Party**")* in writing and the Indemnifying Party shall assume the defense thereof, including the employment of counsel reasonably satisfactory to such Indemnified Party, and shall assume the payment of all fees and expenses, provided that the failure of any Indemnified Party so to notify the Indemnifying Party shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that the Indemnifying Party is materially prejudiced by such failure to notify. In any such proceeding, any Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (ii) in the reasonable judgment of such Indemnified Party, representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that, in connection with any proceeding or related proceedings in the same jurisdiction, the Indemnifying Party shall not be liable for the reasonable fees and expenses of more than one separate firm of attorneys (in addition to any local counsel) at any time for all such Indemnified Parties, and that all such fees and expenses shall be reimbursed as they are incurred. In the case of any such separate firm for the Indemnified Parties, such firm shall be designated in writing by the Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, which consent shall not be unreasonably withheld, but if settled with such consent, or if there be a final judgment for the plaintiff, the Indemnifying Party shall indemnify and hold harmless such Indemnified Parties from and against any Damages (to the extent stated above) by reason of such settlement or judgment. Without the prior written consent of the Indemnified Party, no Indemnifying Party shall effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Party is or could have been a party and indemnity could have been sought hereunder by such Indemnified Party, unless such settlement includes an unconditional release of such Indemnified Party from all liability arising out of such proceeding.

Section 4.09. **Contribution**.

(a) If the indemnification provided for in Section 4.06 to Section 4.08 is unavailable to the Indemnified Parties or insufficient in respect of any Damages (other than by reason of the exceptions provided herein), then each such Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Damages, as between the Company on the one hand and each such Shareholder on the other, in such proportion as is appropriate to reflect the relative fault of the Company and of each such Shareholder in connection with such statements or omissions, as well as any other relevant equitable considerations. The relative fault of the Company on the one

hand and of each such Shareholder on the other shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by such party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

(b) The Company and the Shareholders agree that it would not be just and equitable if contribution pursuant to this Section 4.09 were determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in the immediately preceding paragraph. The amount paid or payable by an Indemnified Party as a result of the Damages referred to in the immediately preceding paragraph shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such Indemnified Party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 4.09, no Shareholder shall be required to contribute any amount in excess of the amount by which the net proceeds realized by such Shareholder in the sale of Registrable Securities of such Shareholder to which such Damages relate exceeds the amount of any Damages that such Shareholder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. Subject to the foregoing and as among the Shareholders, each Shareholder's obligation to contribute pursuant to this Section 4.09 is several in the proportion that the proceeds of the offering received by such Shareholder bears to the total proceeds of the offering received by all such Registering Shareholders and not joint.

Section 4.10. **Cooperation by the Company**. With a view to making available to the Shareholders the benefits of certain rules and regulations of the SEC that may at any time permit the sale of securities to the public without registration, the Company agrees to use its reasonable best efforts to:

(a) make and keep public information available, as those terms are defined in Rule 144, at all times after the effective date that the Company becomes subject to the reporting requirements of the Securities Act or the Exchange Act;

(b) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements);

(c) furnish to any Shareholder, so long as such Shareholder owns any Registrable Securities, upon request by such Shareholder, (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144 (at any time after ninety (90) days after the effective date of the first registration statement filed by the Company for a Public Offering), and of the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements) or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after it so qualifies), (ii) a copy of the most recent annual or quarterly report of the Company and (iii) such other reports and documents of the Company and other information in the possession of or reasonably obtainable by the Company as a Shareholder

may reasonably request in availing itself of any rule or regulation of the SEC allowing a Shareholder to sell any such securities without registration; and

(d) upon the reasonable request of any Shareholder, and subject always to the fiduciary duties of the directors to the Company and to applicable law, instruct the transfer agent in writing that it shall rely on the written legal opinion of such Shareholder's counsel, and that the transfer agent shall act in accordance with the reasonable written instructions of such Shareholder's counsel, with respect to any transfer of Equity Securities.

Section 4.11. **Restriction on Company Grants of Subsequent Registration Rights**. So long as any Sponsor holds any Registrable Securities in respect of which registration rights provided for in Section 4.01 of this Agreement remain in effect, the Company will not, directly or indirectly, without the Requisite Consent, grant to any Person or agree to otherwise become obligated in respect of (i) the rights of registration in the nature or substantially in the nature of those set forth in Section 4.01 of this Agreement that would have priority over or parity with the Registrable Securities with respect to the inclusion of such securities in any registration or (ii) demand registration rights exercisable prior to such time as the Sponsors can first exercise their rights under Section 4.01.

Section 4.12. **Assignment of Registration Rights**. Following the IPO, the registration rights granted pursuant to Section 4.01 through Section 4.11 shall not be assignable, except to a Permitted Transferee.

ARTICLE 5

ACCOUNTING AND TAX MATTERS

Section 5.01. **Books and Records; Financial Reports**. At all times during the existence of the Company, the Company shall maintain, at its registered office, books of account for the Company. Subject to reasonable confidentiality restrictions and other reasonable standards, in each case established by the Board, and subject at all times to the fiduciary duties of the directors and officers of the Company and to applicable law, the Company shall, and shall cause its and its Subsidiaries' officers, directors, employees, auditors and other agents to, for as long as any Sponsor's Relative Ownership Percentage is at least ten percent (10%), (a) afford the officers, employees, auditors and other agents of such Sponsor, during normal business hours and upon reasonable written notice to the Company, reasonable access and consultation rights at all reasonable times to the officers, auditors, legal counsel of the Company and its Subsidiaries, employees, properties, offices, plants and other facilities of the Company's Subsidiaries, and to all books and records of the Company and its Subsidiaries, and (b) afford such Sponsor the opportunity to discuss the Company's and its Subsidiaries' affairs, finances and accounts with the officers of the Company and its Subsidiaries from time to time as each such Sponsor may reasonably request and such officers shall give due consideration to any advice or views provided by such Sponsor.

Section 5.02. **Tax Returns**. The Board, at the expense of the Company, shall cause Osmotica Holdings S.C.SP., a special limited partnership (société en commandite spéciale) pursuant to the Luxembourg law dated 10 August 1915 on commercial companies (art. 22-1 et

seq., as amended from time to time) ("***LuxCo***") to endeavor to cause the preparation and timely filing (including extensions) of all tax returns for any period prior to the Effective Time. Each Shareholder shall furnish to the Company all pertinent information in its possession that is necessary to enable LuxCo's tax returns to be prepared and filed.

Section 5.03. **Accounting Methods; Elections**. The Board shall cause LuxCo to determine the accounting methods and conventions to be used in the preparation of LuxCo's tax returns and shall cause LuxCo to make any and all elections under the tax laws of the United States and any other relevant jurisdictions as to the treatment of items of income, gain, loss, deduction and credit of LuxCo, or any other method or procedure related to the preparation of LuxCo's tax returns, in each case, for any period prior to the Effective Time; provided, however, that the Company shall elect to be classified as an association taxable as a corporation pursuant to United States Treasury Regulations Section 301.7701-3(a) for United States federal and applicable state and local income tax purposes, and none of the Board, the Shareholders or LuxCo shall take any action inconsistent therewith.

Section 5.04. **United States Federal Income Tax Classification**. The Shareholders intend, and the Company shall cause LuxCo, not to take any position inconsistent with, treating LuxCo as an association taxable as a corporation for United States federal, state and local income and franchise tax purposes for any period prior to the Effective Time.

ARTICLE 6

CERTAIN COVENANTS AND AGREEMENTS

Section 6.01. **Confidentiality**.

(a) Each Shareholder agrees that it shall (and shall cause its Affiliates, and its and their officers, directors, employees, partners, legal counsel, accountants, tax advisors, agents and representatives (collectively, the "***Confidentiality Affiliates***") to) (i) hold confidential and not disclose (other than by a Shareholder to its Confidentiality Affiliates having a reasonable need to know in connection with the permitted purposes hereunder), without the prior approval of the Board, all confidential or proprietary written, recorded or oral information or data (including research, developmental, engineering, manufacturing, technical, marketing, sales, financial, operating, performance, cost, business and process information or data, know how and computer programming and other software techniques) provided or developed by the Company and any of its Subsidiaries, another Shareholder or its Confidentiality Affiliates in connection herewith or with the Business, whether such confidentiality or proprietary status is indicated orally or in writing or in a context in which any of the Company and any of its Subsidiaries or the disclosing Shareholder or any of their Confidentiality Affiliates reasonably communicated, or the receiving Shareholder or its Confidentiality Affiliates should reasonably have understood, that the information should be treated as confidential, whether or not the specific words "confidential" or "proprietary" are used ("***Confidential Information***") and (ii) use such Confidential Information only for the purposes of performing its obligations hereunder to which it is a party and carrying on the business of the Company and monitoring its investment in the Company; provided, however, that Shareholders may disclose any such Confidential Information on a confidential basis to (x) current and prospective lenders in connection with a loan or prospective loan to the Company,

after such lender has entered into a non-disclosure agreement reasonably acceptable to the Board, (y) and, in connection with a Transfer of Equity Securities in the Company permitted under this Agreement, to prospective purchasers of such Equity Securities, after such prospective purchaser has entered into a non-disclosure agreement reasonably acceptable to the Board, as well as to such prospective purchaser's legal counsel, auditors, agents and representatives, and (z) to the Sponsor's respective Co-Invest Vehicles and to the members of such Co-Invest Vehicles; provided, further, that any Person to which a Sponsor discloses Confidential Information pursuant to clause (z) shall be deemed a Confidentiality Affiliate of such Sponsor. Notwithstanding the foregoing, the Avista Shareholder may disclose any such Confidential Information on a confidential basis to limited partners or prospective limited partners or investors of the Avista Shareholder or its Confidentiality Affiliates (including any prospective investors in one of its Co-Invest Vehicles), subject to such limited partners or prospective limited partners or investors having an obligation or having agreed to, maintain the confidentiality of any such Confidential Information; provided, however, that the Avista Shareholder shall not (and shall cause its Confidentiality Affiliates and its limited partners or prospective limited partners or investors of such Shareholder or its Confidentiality Affiliates not to) disclose any Confidential Information to any Person that is a Company Competitor. Each Shareholder agrees that it shall be responsible and liable for any breach of this Section 6.01 by its Confidentiality Affiliates and its limited partners or prospective limited partners or investors of such Shareholder or its Confidentiality Affiliates (as if such Confidentiality Affiliates, limited partners or prospective limited partners or investors were parties to and bound by the provisions of this Section 6.01 by which such Shareholder is bound), and that, subject to the fiduciary duties of the directors of the Company, either Sponsor may direct the Company in its enforcement of such obligations without the need for any consent or approval of the other Sponsor or the Board where the breach or alleged breach involves the other Sponsor or its Confidentiality Affiliates.

(b) The obligations contained in Section 6.01 shall not apply, or shall cease to apply, to Confidential Information if or when, and to the extent that, such Confidential Information (i) was, or becomes through no breach of the receiving Shareholder's obligations hereunder, known to the public, (ii) becomes known to the receiving Shareholderr or its Confidentiality Affiliates from other sources under circumstances not involving any breach of any confidentiality obligation between such source and the disclosing Shareholder's or discloser's Confidentiality Affiliates or a third party, (iii) is independently developed by the receiving Shareholder or its Confidentiality Affiliates, or (iv) is required to be disclosed by law, governmental regulation or applicable legal process; provided, that to the extent permitted by law, such Shareholder shall notify the Company promptly of such request or requirement so that the Company may seek an appropriate protective order or other appropriate relief (it being understood that either Sponsor may direct the Company in such efforts of such obligations without the need for any consent or approval of the other Sponsor or the Board where the other Sponsor or one of its Confidentiality Affiliates is the disclosing party); provided, further, that in the absence of a protective order or other appropriate relief, such Shareholder shall use commercially reasonable efforts to obtain an order or other assurance that confidential treatment will be accorded to such portion of the information required to be disclosed as the Company shall designate.

Section 6.02. **Directors' and Officers' Insurance**. The Company shall purchase, within a reasonable period following the date of this Agreement, and maintain for such periods as the Board shall in good faith determine, at its expense, insurance in an amount determined in good faith by the Board to be appropriate, on behalf of any person who after the date of this Agreement

is or was a director, manager or officer of the Company or any Subsidiary, or is or was serving at the request of the Board, the Company or any Subsidiary as a director, manager, officer, or agent of another limited company, corporation, partnership, joint venture, trust or other enterprise, including any direct or indirect subsidiary of the Company, against any expense, liability or loss asserted against such Person and incurred by such Person in any such capacity, or arising out of such Person's status as such, subject to customary exclusions. The provisions of this Section 6.02 shall survive any termination of this Agreement.

Section 6.03. **No Exclusive Duty to Company**. In recognition that the Sponsors and their respective Permitted Transferees currently have, and will or may in the future have or will consider acquiring, investments in numerous companies with respect to which the Sponsors (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their respective Permitted Transferees may serve as an advisor, a director or in some other capacity, and in recognition that the Sponsors (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their respective Permitted Transferees may have a myriad of duties to various investors and partners, and in anticipation that the Company, on the one hand, and a Sponsor (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and its Permitted Transferees on the other hand, may engage in the same or similar activities or lines of business and have an interest in the same areas of corporate opportunities, and in recognition of the benefits to be derived by the Company hereunder and in recognition of the difficulties which may confront the Sponsors and their respective Permitted Transferees in determining the full scope of its duties in any particular situation, subject to and to the fullest extent permitted by applicable law, the provisions of this Section 6.03 are set forth to regulate, define and guide the conduct of certain affairs of the Company as they may involve the Sponsors and their respective Permitted Transferees. Subject to and to the full extent permitted by law, and notwithstanding any other provision of this Agreement or in any agreement contemplated herein or applicable provision of law or equity or otherwise, except as a Sponsor may otherwise agree in writing after the date hereof:

(a) the Sponsors (or their one or more Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their respective Permitted Transferees will have the right:

(i) to directly or indirectly engage in any business (including any business activities or lines of business that are the same as or similar to those pursued by, or competitive with, the Sponsors or any of its Subsidiaries) or invest, own or deal in equity securities of any other Person so engaged in any business;

(ii) to directly or indirectly do business with any client or customer of the Sponsors or any of its Subsidiaries;

(iii) to take any other action that a Sponsor (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and its Permitted Transferees believe in good faith is necessary or appropriate to fulfill their obligations as described in the first sentence of this Section 6.03; and

(iv) not to present potential transactions, matters or business opportunities to the Company or any of its Subsidiaries, and to pursue, directly or indirectly, any such opportunity for itself, and to direct any such opportunity to another Person.

(b) the Sponsors (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their respective Permitted Transferees will have no duty (contractual or otherwise) to communicate or present any corporate opportunities to the Company or any of its Subsidiaries or to refrain from any actions specified in Section 6.03(a), and the Company, on their own behalf and on behalf of their respective Affiliates, hereby renounces and waives any right to require the Sponsors (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their Permitted Transferees to act in a manner inconsistent with the provisions of this Section 6.03.

(c) the Sponsors (or their Affiliates, associated investment funds, portfolio companies or employees, as applicable) and their respective Permitted Transferees shall not be liable to the Company or any of its Subsidiaries for breach of any duty (contractual or otherwise) by reason of any activities or omissions of the types referred to in this Section 6.03 or by reason of its or their participation therein.

ARTICLE 7

MISCELLANEOUS

Section 7.01. **Binding Effect; Assignability; Benefit**.

(a) This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, successors, legal representatives and permitted assigns. Any Shareholder that ceases to beneficially own any Equity Securities shall cease to be bound by the terms hereof (other than as expressly set forth herein or with respect to Section 6.01 or ARTICLE 7).

(b) Other than as expressly set forth herein, neither this Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assignable by any party hereto pursuant to any Transfer of Equity Securities or otherwise.

(c) Except for Section 4.06, Section 4.08, Section 4.09, Section 4.09, Section 6.02, Section 6.03, Section 7.04,Section 7.05,Section 7.06 and Section 7.07, nothing in this Agreement, expressed or implied, is intended to confer on any Person other than the parties hereto, and their respective heirs, successors, legal representatives and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Section 7.02. **Notices**.

(a) In the event a notice or other document is required to be sent hereunder to the Company, the Board, or any Shareholder or legal representative of a Shareholder, such notice or other document shall be made in writing by hand-delivery, registered or certified first-class

mail, facsimile, email, or air courier guaranteeing overnight delivery to such party at the following addresses (or at such other address as shall be given in writing by any party to the others):

(i) in the case of the Company:

Osmotica Pharmaceuticals plc
25 – 28 North Wall Quay
Dublin 1
Ireland
Attention: Chris Klein
Facsimile No.: 908-809-1301

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: Craig Marcus
Email: Craig.Marcus@ropesgray.com

(ii) in the case of the Board:

Board of Directors of Osmotica Pharmaceuticals plc
25 – 28 North Wall Quay
Dublin 1
Ireland
Attention: Chris Klein
Facsimile No.: 908-809-1301

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: Craig Marcus
Email: Craig.Marcus@ropesgray.com

(iii) if to any Shareholder, to the address, e-mail address or facsimile set forth on the books of the Company or any other address or facsimile number as a party may hereafter specify for such purpose to the Company.

(b) The Company, the Board, or any Shareholder or their respective legal representatives may effect a change of address for purposes of this Agreement by giving notice of such change to the Company, and the Company shall, upon the request of any such Person, notify the other parties hereto of such change in the manner provided herein. Until such notice of change of address is properly given, the addresses set forth herein shall be effective for all purposes.

(c) All notices given in accordance with this Section 7.02 shall be deemed to have been duly given: when delivered by hand, if personally delivered; five business days after being deposited in the mail, postage prepaid, if mailed; when sent, if sent via email; when transmission confirmation is received, if sent by facsimile; and on the next business day, if timely delivered to an air courier guaranteeing overnight delivery.

Section 7.03. **Waiver; Amendment; Termination**.

(a) No provision of this Agreement may be waived, amended or otherwise modified except by an instrument in writing executed by (i) the Company and (ii) with the Requisite Consent; provided, however, that any waiver, amendment or modification that adversely affects Management Shareholders disproportionately as compared to the Sponsors (taking into account and considering the rights of Management Shareholders prior to such amendment or modification), shall require the prior written consent of the holders of a majority of the Ordinary Shares then held by the Management Shareholders; provided, further, that any waiver, amendment or modification that materially and adversely affects a Shareholder disproportionately as compared to all other Shareholders, shall require the prior written consent of a majority-in-interest of such Shareholders so adversely affected; provided, further, that no update of any Schedule hereto shall be deemed to constitute an amendment to this Agreement.

(b) This Agreement shall terminate at such time that there are no Registrable Securities, except for the provisions of Section 4.06,Section 4.06 Section 4.08, Section 4.08 and Section 4.09 and all of this ARTICLE 7.

Section 7.04. **Non-Recourse**. Notwithstanding anything that may be expressed or implied in this Agreement, the Company and each Shareholder covenant, agree and acknowledge that no recourse under this Agreement or any documents or instruments delivered in connection with this Agreement in respect of each Shareholder's obligations under this Agreement or any documents or instruments delivered in connection with this Agreement shall be had against any current or future director, officer, employee, general or limited partner or member or equity holder of any Shareholder or of any Affiliate or assignee thereof (in their capacity as such and not, as the case may be, in their capacity as a director or officer of the Company), whether by the enforcement of any assessment or by any legal or equitable proceeding, or by virtue of any statute, regulation or other applicable law, it being expressly agreed and acknowledged that no personal liability whatsoever shall attach to, be imposed on or otherwise be incurred by any current or future officer, agent or employee of any Shareholder or any current or future member or equity holder of any Shareholder or any current or future director, officer, employee, partner or member or equity holder of any Shareholder or of any Affiliate or assignee thereof (in their capacity as such and not, as the case may be, in their capacity as a director or officer of the Company), as such for any obligation of any Shareholder under this Agreement or any documents or instruments delivered in connection with this Agreement for any claim based on, in respect of or by reason of such obligations or their creation.

Section 7.05. **Governing Law; Venue**. All issues and questions concerning the construction, validity, interpretation and enforceability of this Agreement and the exhibits and schedules hereto, and their negotiation, execution, performance or nonperformance, interpretation, termination, construction and all matters based upon, arising out of or related to any of the

foregoing, whether arising in law or equity, shall be governed by, and construed in accordance with, the laws of the New York, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York. Any legal action or proceeding with respect this Agreement shall be brought in the courts of the United States District Court for the Southern District of New York or any other competent court of the State of New York, and, by execution and delivery of this Agreement, each party hereby irrevocably accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of such courts. Each party irrevocably waives any objection which it may now or hereafter have to the laying of venue of the aforesaid actions or proceedings arising out of or in connection with this Agreement in the courts referred to in this paragraph and hereby further irrevocably waives and agrees not to plead or claim in any such court that any such action or proceeding brought in any such court has been brought in an inconvenient forum. Each party agrees that service of process upon such party in any action shall be effective if notice is given in accordance with Section 7.02.

Section 7.06. **WAIVER OF JURY TRIAL**. EACH OF THE SHAREHOLDERS HEREBY IRREVOCABLY WAIVES ALL RIGHT OF TRIAL BY JURY IN ANY LEGAL ACTION OR PROCEEDING (INCLUDING COUNTERCLAIMS) RELATING TO OR ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ANY OF THE TRANSACTIONS OR RELATIONSHIPS HEREBY CONTEMPLATED OR OTHERWISE IN CONNECTION WITH THE ENFORCEMENT OF ANY RIGHTS OR OBLIGATIONS HEREUNDER.

Section 7.07. **Specific Enforcement; Cumulative Remedies**. The parties hereto acknowledge that money damages may not be an adequate remedy for violations of this Agreement and that any party, in addition to any other rights and remedies which the parties may have hereunder or at law or in equity, may, in his or its sole discretion, apply to a court of competent jurisdiction for specific performance or injunction or such other relief as such court may deem just and proper in order to enforce this Agreement or prevent any violation hereof and, to the extent permitted by applicable law, each party waives any objection to the imposition of such relief. All rights, powers and remedies provided under this Agreement or otherwise available in respect hereof at law or in equity shall be cumulative and not alternative, and the exercise or beginning of the exercise of any thereof by any party shall not preclude the simultaneous or later exercise of any other such rights, powers or remedies by such party.

Section 7.08. **Entire Agreement**. This Agreement, together with all agreements referenced to herein and any schedules, exhibits and other documents referred to herein or therein constitute the entire agreement and understanding among the parties hereto in respect of the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements, agreements and understandings, both oral and written, whether in term sheets, presentations or otherwise among the parties hereto, or between any of them, with respect to the subject matter hereof and thereof.

Section 7.09. **Severability**.

(a) If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the

remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated. Upon such a determination, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner so that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

(b) To the extent the terms of the Constitution or any other constitutive documents of the Company are contradictory to, or inconsistent with, the terms of this Agreement, the terms of this Agreement shall, to the extent permitted by law, supersede such conflicting or inconsistent terms. All terms of the Constitution and any other constitutive documents not contradictory to, or inconsistent with, the terms of this Agreement shall remain in full force and effect.

Section 7.10. **Counterparts; Effectiveness**. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

OSMOTICA PHARMACEUTICALS PLC

By: /s/ Christopher Klein
Name: Christopher Klein
Title: Secretary

ALTCHEM LIMITED

By: /s/ Georgia Kafkalia
Name: Georgia Kafkalia
Title: Director

ACP HOLDCO (OFFSHORE), L.P.
By: ACP III AIV GP, Ltd.
Its: General Partner

By: /s/ Ben Silbert
Name: Ben Silbert
Title: Director

ACP III AIV, L.P.
By: ACP III AIV GP, Ltd.
Its: General Partner

By: /s/ Ben Silbert
Name: Ben Silbert
Title: Director

ORBIT CO-INVEST I, LLC

By: Avista Capital Partners III GP, L.P.
Its: Manager

By: /s/ Ben Silbert
Name: Ben Silbert
Title: Authorized Representative

ORBIT CO-INVEST III, LLC

By: Avista Capital Partners III GP, L.P.
Its: Manager

By: /s/ Ben Silbert
Name: Ben Silbert
Title: Authorized Representative

ORBIT CO-INVEST A-I LLC

By: Altchem Limited
Its: Manager

By: /s/ Georgia Kafkalia
Name: Georgia Kafkalia
Title: Director

/s/ Jarret Miller

Jarret Miller

HARPUA, L.L.C

By: /s/ Andrew Einhorn
Name: Andrew Einhorn
Title: Manager

/s/ Brian Markison

Brian Markison

/s/ JD Schaub

JD Schaub

ALASKA TRUST COMPANY, AS TRUSTEE OF THE STEVEN SQUASHIC 2013 NON-GRANTOR ALASKA TRUST DATED SEPTEMBER 11, 2013

By: /s/ Brandon Cintula

Name: Brandon Cintula

Title: Senior Vice President & Senior Trust Officer

PREMIER TRUST, INC., AS TRUSTEE OF THE KEVIN HUDY 2013 NON-GRANTOR NEVADA TRUST DATED SEPTEMBER 18, 2013

By: /s/ Brian Simmons
Name: Brian Simmons
Title: Trust Officer

/s/ Christopher Klein

Christopher Klein

/s/ David Purdy

David Purdy

/s/ Rich Buecheler

Rich Buecheler

Annex A

Management Shareholders

1. Brian Markison
2. JD Schaub
3. Alaska Trust Company, as Trustee of the Steven Squashic 2013 Non-Grantor Alaska Trust dated September 11, 2013
4. Premier Trust, Inc., as Trustee of the Kevin Hudy 2013 Non-Grantor Nevada Trust dated September 18, 2013
5. Christopher Klein
6. David Purdy
7. Rich Buecheler
8. Jarret Miller
9. Harpua, L.L.C

Exhibit 21.1

Osmotica Pharmaceuticals plc

Subsidiary	State or Other Jurisdiction of Organization
Osmotica Holdings S.C.Sp.	Luxembourg
Osmotica Holdings US LLC	Delaware
Osmotica Holdings Corp LTD	Cyprus
Osmotica Kereskedelmi es Szolgaltato Kft	Hungary
Osmotica Pharmaceutical Corp.	Delaware
RevitaLid, Inc.	Delaware
Osmotica Argentina, S.A.	Argentina
Orbit Blocker I LLC	Delaware
Orbit Blocker II LLC	Delaware
Valkyrie Group Holdings, Inc.	Delaware
Vertical/Trigen Holdings, LLC(1)	Delaware
Osmotica Pharmaceutical US, LLC	Delaware
Vertical/Trigen Midco, LLC	Delaware
Vertical/Trigen Opco, LLC	Delaware
Trigen Laboratories, LLC	Delaware
Vertical Pharmaceuticals, LLC	Delaware

(1) Vertical/Trigen Holdings, LLC is jointly-owned by Orbit Blocker I, LLC, Orbit Blocker II, LLC, Valkyrie Group Holdings, Inc. and Osmotica Pharmaceutical Corp.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Osmotica Pharmaceuticals plc
Dublin, Ireland

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-228045) of Osmotica Pharmaceuticals plc, of our report dated March 27, 2019, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP
Woodbridge, New Jersey

March 27, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Markison, certify that:

1. I have reviewed this annual report on Form 10-K of Osmotica Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2019

/s/ Brian Markison
Name: Brian Markison
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Einhorn, certify that:

1. I have reviewed this annual report on Form 10-K of Osmotica Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2019

/s/ Andrew Einhorn
Name: Andrew Einhorn
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Osmotica Pharmaceuticals plc (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Markison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2019

/s/ Brian Markison
Brian Markison
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Osmotica Pharmaceuticals plc (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Einhorn, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2019

/s/ Andrew Einhorn
Andrew Einhorn
Chief Financial Officer
(Principal Financial Officer)