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

FORM 8-K

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

Date of Report (Date of earliest event reported): September 8, 2021

Osmotica Pharmaceuticals plc
(Exact Name of Registrant as Specified in Charter)

Ireland	**001-38709**	**Not Applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Crossing Boulevard **Bridgewater, NJ** **(Address of Principal Executive Offices)**	**08807** **(Zip Code)**

Registrant's Telephone Number, Including Area Code (908) 809-1300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Ordinary Shares	**OSMT**	**Nasdaq Global Select Market**

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

Emerging growth company ☒

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

Item 8.01 Other Events.

As previously disclosed, on August 27, 2021, the Company and certain of its wholly owned subsidiaries completed the divestiture of the Company's legacy products business (the "Legacy Business"). The divestiture was consummated through the sale of the equity interests of certain of the Company's indirect subsidiaries and other assets comprising the Legacy Business to Acella Holdings, LLC.

Osmotica Pharmaceuticals plc (the "Company") is filing this Current Report on Form 8-K to recast its consolidated financial statements in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 that was previously filed with the Securities and Exchange Commission (the "SEC") on March 30, 2021 (the "2020 Annual Report") to reflect the presentation of the Legacy Business as discontinued operations and to update and supersede the risk factors and management's discussion and analysis of financial condition and results of operations included in the 2020 Annual Report.

We have revised the following items of the 2020 Annual Report (collectively, the "Revised Sections") to reflect the retrospective revisions described above:

- Exhibit 99.1: Part I, Item 1A. Risk Factors;
- Exhibit 99.2: Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; and
- Exhibit 99.3: Part II, Item 8. Financial Statements and Supplementary Data.

This report does not reflect events occurring after the March 30, 2021 filing date of the 2020 Annual Report and does not modify or update disclosures therein except to reflect the Legacy Business as discontinued operations and to reflect the Company's ability to continue as a going concern. For developments since the filing of the 2020 Annual Report, refer to the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021 and its Current Reports on Form 8-K filed subsequent to the 2020 Annual Report.

Information contained in Exhibits 99.1, 99.2 and 99.3 should be read in conjunction with and as a supplement to information contained in the 2020 Annual Report. For information on events occurring since the filing of the 2020 Annual Report, please refer to the Company's subsequent filings with the SEC.

Item 9.01 Financial Statements and Exhibits.

(b)

The information set forth in Item 8.01 of this Current Report is incorporated herein by reference in its entirety.

(d)

Exhibit Number	Description of Document
23.1	Consent of Ernst & Young LLP
99.1	Part I, Item 1A. Risk Factors
99.2	Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Part II, Item 8. Financial Statements and Supplementary Data
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OSMOTICA PHARMACEUTICALS PLC

Date: September 8, 2021

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-236193), and
(2) Registration Statement (Form S-8 No. 333-228045);

of our report dated March 30, 2021 (except for Note 3, as to which the date is September 8, 2021, and except for the effects of discontinued operations described in Note 4 to the consolidated financial statements, as to which the date is September 8, 2021), with respect to the consolidated financial statements of Osmotica Pharmaceuticals plc included in this Current Report on Form 8-K.

/s/Ernst & Young LLP

Iselin, New Jersey
September 8, 2021

RISK FACTORS

This Current Report on Form 8-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 Current Report on Form 8-K, including our consolidated financial statements and the related notes appearing elsewhere in this Current Report on Form 8-K. We have presented the below risks as "Risks related to our business," "Risks related to the development and commercialization of products," "Risks related to our intellectual property rights," "Risks related to our industry," "Risks related to our indebtedness," "Risks related to our ordinary shares," "Risks related to being an Irish corporation listing ordinary shares," "Risks related to taxation" and "General risk factors." If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially and adversely affect our business, prospects, operating results or financial condition.

Risks related to our business

Due to our dependence on Upneeq, our business would be materially adversely affected if this product does not perform as well as expected.

On June 24, 2021, we and certain of our wholly-owned subsidiaries entered into a purchase and sale agreement with Acella Holdings, LLC, or Acella, and Alora Pharmaceuticals, LLC, an affiliate of Acella, pursuant to which we agreed to divest our legacy products business to Acella through the sale of the equity interests of certain of our indirect subsidiaries and other assets. Following the closing of this transaction and the divestiture of our legacy assets, we retained the RVL Pharmaceuticals business focused on eye care and medical aesthetics, led by Upneeq.

Going forward, any material adverse developments, including an inability of our sales force to effectively market and sell Upneeq, new competition from generic or other brand products, pricing pressures or supply shortages with respect to the sale, distribution or use of Upneeq, or our failure to successfully introduce Upneeq into the medical aesthetics market, could have a material adverse effect on our revenues and gross profit.

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

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

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

- the efficacy and potential advantages of Upneeq compared to alternative treatments, including surgery;
- the price at which we offer Upneeq;
- the clinical indication for which Upneeq is approved;
- the willingness of the target patient population to try new therapies and of clinicians to prescribe these therapies;
- the effectiveness of our marketing and distribution support, and our available resources to support adequate marketing efforts; and
- the timing of market introduction of competitive products.

Our assessment of the potential market opportunity for Upneeq is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, some of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their

information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The potential market opportunity for the treatment of acquired blepharoptosis, or droopy eye lid, is difficult to estimate precisely. The results from our physician and patient surveys may be less reflective of the acquired blepharoptosis population as a whole than a survey conducted with a larger sample size. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size or otherwise fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for Upneeq may be smaller than we expect, and as a result our product revenue may be less than expected. The uncertainty with respect to the future progression of the COVID-19 pandemic and its long-term effects may also adversely impact the accuracy of such estimates and our potential market opportunity for Upneeq. Upneeq is only available through our pharmacy, RVL Pharmacy, and is a cash-only product not covered by any private or government insurance. We control the price for Upneeq which is consistent for all patients. Although we believe this cash-only model with consistent pricing is a benefit to patients, the price or distribution model may not be accepted by clinicians or patients and may negatively impact filled prescriptions and sales of Upneeq.

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

We face a number of additional risks in developing or maintaining internal sales and marketing capabilities, including:

- not being able to attract talented and qualified personnel to build an effective marketing or sales force capability, or not being able to attract personnel with sufficient experience in selling and marketing to the physicians in eye care and medical aesthetics;
- the cost of establishing a marketing and sales force capability may not be justified in light of the total revenues generated from our product; and
- our direct sales and marketing efforts for Upneeq 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 product will be limited and this could have a material adverse effect on our business, financial position and results of operations.

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

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

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

- our inability to recruit, train and retain adequate numbers of effective eye care and medical aesthetics sales and marketing personnel;
- the inability of sales personnel to obtain access to clinicians, including as a result of limitation on office visits as a result of COVID-19 or other health concerns, or persuade adequate numbers of clinicians to prescribe Upneeq; and

- unforeseen costs and expenses associated with maintaining and expanding an independent sales, marketing and pharmacy organization.

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

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

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

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

Our ability to continue our operations requires that we raise additional capital and our operations could be curtailed or discontinued if we are unable to obtain the additional funding as or when needed.

The divestiture of the Legacy Business resulted in the loss of substantially all of our revenue generating assets, and our business plan is focused on the launch of Upneeq, which will diminish our cash flows in at least the near term, in particular cash inflows from product sale. We will require additional capital to repay the remaining portion of our term loans, fund our operating needs, including the commercialization of Upneeq and other activities. Accordingly, we expect to incur significant expenditures and increasing operating losses in the future. These conditions give rise to substantial doubt as to our ability to operate as a going concern as our current sources of liquidity will not be sufficient to meet our obligations through the end of the year. Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets. We are exploring

options to raise additional funding and may seek to raise additional capital through sales of our common stock, including through equity sales agreements with broker/dealers or other public or private equity financings, through new debt facilities, including convertible debt or through a sale of a portion or all rights to any of our assets. We cannot provide assurance that we will receive cash proceeds from any of these potential sources or to the extent cash proceeds are received, that such proceeds would be sufficient to support our current operating plan or allow to continue as a going concern. Additional funds may not be available when we need them on terms that are acceptable to us or at all and the terms of any such financings may impose operating restrictions on us that limit or restrict our ability to operate our business, which could adversely affect our ability to pursue the commercialization of Upneeq and other activities on our intended timeline or at all.

We may incur operating losses in the future.

Our net loss was $27.3 million for the six months ended June 30, 2021. Our operating results may fluctuate significantly from quarter to quarter and year to year.

We devote significant amounts of financial resources to the marketing, sale and commercialization of Upneeq, and support of our research and development of our clinical and preclinical programs. We expect to incur significant expenses in the future. These expenses include those related to ongoing activities, as we:

- add personnel to support our marketing, commercialization and sales of Upneeq and continue clinical and preclinical product development efforts;
- launch new products into the marketplace;
- conduct clinical trials and seek regulatory approval for arbaclofen ER and additional indications for Upneeq;
- continue development of our pipeline product candidates;
- continue our efforts for identifying 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 business may be adversely affected by the ongoing coronavirus outbreak.

The economic impact of the spread of COVID-19, which has caused a broad impact globally, such as restrictions on travel, access, gatherings and stay at home orders put into place by businesses and governments, may adversely affect us. In particular, we launched our commercial activities for Upneeq and began engaging with eye care providers to promote Upneeq in September 2020, and since that time have expanded our field sales force. In some instances our sales force has encountered challenges engaging with eye care providers during this on-going pandemic. Although many areas of the United States have re-opened, or begun to re-open, access to offices and other commercial facilities, there continue to be areas where restrictions remain in place or may be reinstated as a result of concerns about the spread of the Delta variant, which may have the potential to affect our ability to conduct our business and the ability of patients to visit their eye care providers. Additionally, new variants, including the Delta variant, which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future, and our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted.

In addition, the disruptions caused by the COVID-19 pandemic could divert healthcare resources away from, or materially delay the FDA approval with respect to, our clinical trials and product candidates, including arbaclofen ER. It is unknown how long these disruptions could continue. Other known and unknown factors caused by COVID-19 could also materially delay our clinical trials that may be required for these or other product candidates, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and/or approval of our product candidates.

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

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

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

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

Our branded pharmaceutical expenditures, including those for Upneeq, may not result in commercially successful products.

Commercializing branded products is more costly than generic products. We have historically made significant investments in the development, launch and commercialization of branded products and, following the divestiture of our legacy business, expect to continue to do so, particularly with respect to Upneeq. These investments have led to increased infrastructure costs. We cannot be certain that these business expenditures will result in the successful commercialization of Upneeq or any additional branded products or will improve the long-term profitability of our business. Our branded product will confront competitive pressures from generic pharmaceutical companies that may seek to introduce generic versions of our branded product. 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 product. While we have endeavored (with our relevant development and manufacturing partners, as applicable) to protect our branded assets by distributing to patients exclusively through our own pharmacy, 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 Upneeq and any additional branded products we may launch will be based largely on the successful commercialization of our existing product, 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 product. In addition, we cannot be certain that our branded product expenditures will result in commercially successful launches of these products or will improve the long-term profitability of our branded products. Any future

commercialization efforts that do not meet expectations could result in a write-down of assets related to the relevant products.

We may face competition, including from other drug manufacturers and compounding pharmacies, 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 drug manufacturers' products in direct competition with our product;
- introduction of authorized generic products in direct competition with our product, 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;
- compounding pharmacies which may offer products in direct competition with our product;
- the willingness of our customers to switch among products;
- 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); and
- product appearance and labeling.

Currently our commercial product, Upneeq, is the only FDA approved pharmaceutical agent to treat blepharoptosis in adults. That may change in the future and we may face competition from other pharmaceutical and biopharmaceutical, companies developing similar products and technologies. Our competitors may 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 product 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 product uncompetitive or obsolete.

We may 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. 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.

Our product Upneeq is a reference listed drug. After the regulatory exclusivity period expires for Upneeq in 2023, manufacturers may gain approval of generic versions of Upneeq through the submission of Abbreviated New Drug Applications, or 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. Ordinarily a generic drug developer will obtain samples of a reference listed drug on the open market. However, in cases where a reference listed drug is not available because of, for example, limited distribution, a generic company may request samples of the reference listed drug from the NDA holder under the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act established a process that requires brand-name companies to provide generic companies with needed samples if the product is not generally available. The CREATES Act imposes substantial penalties if a branded company does not follow timing or other requirements set out in the law or otherwise acts in bad faith with respect to the sample request. As of June 30, 2021, we have received two requests for samples of Upneeq from generic companies pursuant to the CREATES Act. We have provided samples in response to each request.

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 Upneeq could negatively impact our future total revenues, profitability and cash flows.

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

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

We depend to a large extent on third-party suppliers and distributors for the raw materials for our product, particularly the chemical compounds comprising the API used in our product, 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 Nephron Pharmaceuticals Corporation is our only supplier of Upneeq.

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

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

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 Upneeq and any other products we may develop 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. 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 product or customers and those of an acquired entity that may create conflicts in relationships or other commitments detrimental to the integrated businesses;
- difficulties in obtaining approval from governmental authorities such as the Federal Trade Commission, or FTC;
- our inability to achieve expected total revenues and gross profit for any products we may acquire;
- possible contingent liability that includes, among others, known or unknown environmental, patent or product liability claims;
- the diversion of management’s attention from other business concerns; and
- risks and challenges of entering or operating in markets in which we have limited or no prior experience, including the unanticipated effects of export controls, exchange rate fluctuations, foreign legal and regulatory requirements, and political and economic conditions.

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

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

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

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

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

Risks related to the development and commercialization of products

If we are unable to successfully develop or commercialize new products, or to do so on a timely or cost-effective basis, or to extend life cycles of our existing product, 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 challenges to our branded product 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 or that we may seek to develop 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 Investigational New Drug Application, or IND, or completing clinical trials, our expenses could increase.

NDAs are subject to uncertainties, high costs and lengthy time frames associated with research and development of such products and the inherent unproven market acceptance of such products. For example, in December 2020 we received a complete response letter, or CRL, from the FDA in connection with our NDA for arbaclofen ER for the treatment of multiple sclerosis patients with spasticity. A CRL indicates that FDA will not approve an NDA or ANDA in its present form due to certain deficiencies. In the CRL, FDA recommended that we conduct a new study in order to provide substantial evidence of efficacy of arbaclofen. On March 4, 2021, we participated in a meeting with the FDA during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a Special Protocol Assessment, or SPA, to the FDA proposing an additional clinical study for arbaclofen ER. The FDA will review the SPA and notify us whether or not it agrees with our proposed study design. The FDA's review, as well as any subsequent clinical testing, has delayed and may prevent the commercial launch of arbaclofen ER and increase our operating expenses, including the expenses associated with any additional clinical trials for arbaclofen ER, which could have a material adverse effect on our business, financial position and results of operations. If we are unable to develop and commercialize branded products successfully or are delayed in our attempts to do so, we may have to rely primarily on revenue from Upneeq to support research and development efforts.

If any of our product candidates, 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.

We expend resources on research and development primarily to enable us to manufacture and market FDA-approved products in accordance with FDA regulations. 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 NDA, the FDA may request that we conduct additional clinical trials for an NDA. For example, in December 2020 we received a CRL from the FDA in connection with our NDA for arbaclofen ER. In the CRL FDA indicated we would need to conduct a new study in order to provide substantial evidence of efficacy of arbaclofen given that the primary endpoint for Study OS440-3004, change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, was not met and the co-primary endpoint, results from the clinical global impression of change on Day 84, did not support a treatment benefit. On March 4, 2021, we participated in a meeting with the FDA during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a Special Protocol Assessment, or SPA, to the FDA proposing an additional clinical study for arbaclofen ER. The FDA will review the SPA and notify us of whether it agrees with our proposed study design. Any additional clinical studies required for arbaclofen ER as a result of our discussions with the FDA regarding the CRL may result in substantial additional research and development costs.

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

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

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

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

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

The testing required for the regulatory approval and maintenance 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, contract research organizations, or 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 good clinical practices, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites.

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

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

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

Although we have received Orphan Drug Designation for arbaclofen, we may not obtain or maintain the benefits associated with Orphan Drug Designation, including market exclusivity for arbaclofen.

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

Although we have received Orphan Drug Designation for arbaclofen for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, we may not receive the full set of benefits potentially associated with Orphan Drug Designation. The FDA has previously approved baclofen, a racemic mixture comprised of an R- and an S-isomer, for the treatment of intractable muscle spasticity in multiple sclerosis patients. If the FDA determines that our product, arbaclofen, which is the R-isomer of baclofen, contains the same active ingredient and is indicated for the same use as the approved product, we could be precluded from obtaining orphan drug exclusivity for our product unless we are able to demonstrate that our product is clinically superior to the approved product, which could potentially require a head-to-head study. Moreover, even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to

patient care. A competitor also may receive approval of different products for the same indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Additionally, orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

Treatment with our product or product candidates may produce undesirable side effects or adverse reactions or events. Although certain of our 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 product or product candidates is generally known, our 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 product or product candidates, or other potentially harmful characteristics. For example, the active ingredient in Upneeq, oxymetazoline hydrochloride, is available in certain over the counter nasal products, and was available in certain over the counter ophthalmic products, at concentrations lower than that in Upneeq. Such characteristics could cause us, our institutional review boards, or IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

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

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

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

If our product or product candidates do not produce the effects intended our business may suffer. For example, in July 2020, we received regulatory approval from the FDA for Upneeq, the first approved non-surgical treatment for acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 with an in-person sales effort focused on ophthalmologists and optometrists. Despite these efforts, Upneeq may not produce sufficient treatment such that patients or eye care specialists deem it an effective treatment for acquired blepharoptosis. Upneeq and any products we may develop in the future may not have the effect intended if they are not taken in accordance with applicable instructions. Even when used as directed, there can be no assurance that Upneeq or any products we may develop in the future will not experience an actual or perceived lack of efficacy or increase in side effects.

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

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

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

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

Moreover, clinical data are often susceptible to varying interpretations, and many companies that have believed their drug candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their drug candidate. Furthermore, results from our clinical trials may not meet the level of statistical significance or otherwise provide the level of evidence or safety and efficacy required by the FDA or other regulatory authorities for approval of a drug candidate. Finally, clinical trials are expensive and require significant operational resources to implement and maintain.

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

Risks related to our intellectual property rights

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

Our success depends on our ability to protect and defend the intellectual property rights associated with Upneeq and any products we may develop in the future. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that may be confused with, Upneeq or any products we may develop in the future, and our generic competitors may obtain regulatory approval to make and distribute generic versions of Upneeq or any future 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 Upneeq or any products we may develop in the future 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 Upneeq or any products we may develop in the future.

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

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

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

We also rely particularly on trade secrets, unpatented know-how and proprietary expertise and continuing innovation to develop and maintain our competitive position. We generally enter into confidentiality agreements with licensees, suppliers, employees, consultants and other parties. 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 product 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 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. Litigation often involves significant expense and can delay or prevent introduction or sale of our 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 product, 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. Third parties, including our competitors, may allege that our product violates their patent rights, which would expose us to the same risks. A license may not be available from the patent holder on commercially reasonable terms, or at all. If available, we may choose to take a license under a third party's patent rights to resolve a dispute, even in the absence of a finding by a court that a patent is valid, enforceable and infringed.

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

Litigation concerning intellectual property rights in the pharmaceutical industry is commonplace and can be protracted and expensive. 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. The threat of intellectual property 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 new products, or result in the loss of our intellectual property rights, which could have a material adverse effect on our business, financial condition, prospects and results of operations. For more information on our material pending litigation, see "Legal Proceedings."

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

We are a party to certain licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements, for example our License Agreement with VOOM, LLC pursuant to which we have license rights to certain patents covering Upneeq, 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 product 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 product 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 product.

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 product 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 product, 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.

Risks related to our industry

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

Currently RVL Pharmaceuticals, Inc. does not participate in any federal healthcare programs. Upneeq is a cash-pay only product not covered by any public or private health insurance plans that is dispensed exclusively through RVL Pharmacy. However, this may change for Upneeq in the future, or products we may develop in the future that we commercialize may be covered under public and/or private insurance. There is no assurance 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 product and at what level, we expect that third-party payors will consider factors that include the efficacy, cost effectiveness and safety of our product, as well as the availability of other treatments including other generic prescription drugs and over-the-counter alternatives. Further, in order to obtain and maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we may face mounting pressure to offer discounts or rebates from list prices to increase existing discounts and rebates, to offer discounts and rebates to a greater number of third-party payors or to implement other unfavorable pricing modifications. Obtaining and maintaining favorable reimbursement can be a time consuming and expensive process, and there is no guarantee that we will be able to negotiate or continue to negotiate pricing terms with third-party payors at levels that are profitable to us, or at all. Additionally, any reimbursement granted may not be maintained and any limits on reimbursement available from third-party payors may reduce the demand for, or negatively affect the price of those products, and could significantly harm our business, results of operations, financial condition and cash flows.

In particular, there is no assurance that drug plans participating under the Medicare Part D program will cover our product or that any covered drugs will be reimbursed at amounts that reflect current or historical levels. Medicare Part D is a voluntary program that offers prescription drug coverage through private plans to Medicare beneficiaries (primarily

the elderly over 65 and the disabled) enrolled with the plan. Medicare Part D coverage may vary from plan to plan and the plans may implement formularies and certain utilization management activities (such as tired co-pay structures and prior authorization requirements) as well as negotiate rebates with pharmaceutical manufacturers to manage access and costs. Manufacturers must also provide discounts on Medicare Part D brand name prescription drugs sold to Medicare beneficiaries in the Medicare Part D coverage gap (i.e., the so called “donut hole”), which discount increased from 50% to 70% in 2019.

There is no assurance that Medicaid programs would offer coverage, and adequate reimbursement levels, for pharmaceutical products we may develop in the future. 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 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 products may depend on the extent to which they appear on the preferred drug lists of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. In addition, there is significant fiscal pressure on the Medicaid program, and legislative and regulatory action to lower the pharmaceutical costs of the program is possible. Any such legislative action could materially adversely affect our anticipated total revenues and results of operations.

In addition, third-party payors are increasingly challenging pricing of pharmaceutical products, and imposing controls to manage costs. Adverse determination of audits resulting from such challenges could result in the imposition of significant financial penalties, which could have a material adverse impact on our results of operations and financial condition.

The trend toward managed healthcare in the United States and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. The ACA was signed into law in March 2010. 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.

Executive, legislative and judicial action subsequent to the enactment of the ACA has sought to repeal, modify or delay implementation of the ACA. Tax reform legislation enacted in 2017 removed the tax penalty applicable to the “individual mandate,” which requires Americans to carry a minimal level of health insurance. Starting in 2019, the tax penalty for not carrying such insurance is zero. Effective January 1, 2019, the point-of-sale discount that pharmaceutical manufacturers who participate in Medicare Part D must provide to Medicare Part D beneficiaries in the coverage gap was increased from 50% to 70%. There have also been judicial challenges to the ACA. For example, in June 2021, the Supreme Court rejected a challenge to the constitutionality of the Affordable Care Act on the grounds that the states and individuals that brought the challenge did not have standing. There may be additional challenges.

Beyond the ACA, there have been ongoing health care reform efforts, including a number of recent actions. Some reform efforts affect pricing or payment for drug products.

For example, President Biden recently issued an Executive Order that included various measures to promote competition in the healthcare industry (e.g., by directing the U.S. Department of Health and Human Services to increase support for generic and biosimilar drugs and to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging). Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Some of these changes have been and may continue to be subject to legal challenge. For example, courts temporarily enjoined a new “most favored nation” payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would limit payment based on international drug price

and the Centers for Medicare & Medicaid Services subsequently indicated that the rule would not be implemented without further rulemaking.

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, future product's commercial success. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2030 (except May 1, 2020 to December 31, 2021) unless additional Congressional action is taken. The Congressional Budget Office has indicated that the American Rescue Plan Act of 2021 will likely trigger a statutory provision that requires that automatic payment cuts be put into place if a statutory action creates a net increase in the deficit and require reductions in Medicare spending. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

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

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

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 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 product. If we, our product, the manufacturing facilities for our product, 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 us, that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. From time to time, we have voluntarily recalled our products and may do so in the future.

Because of the chemical ingredients of pharmaceutical products and the nature of the manufacturing process, the pharmaceutical industry is subject to extensive environmental laws and regulation and the risk of incurring liability for damages and the costs of remedying environmental problems. These requirements include regulation of the handling, manufacture, transportation, storage, use and disposal of materials, including the discharge of hazardous materials and pollutants into the environment. We do not currently own a manufacturing facility and instead use third parties to manufacture for us. Should we acquire a manufacturing facility in the future, it would expose us 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 New Jersey, and overseas in 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. If any legislative or administrative actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted, and if we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product 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 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 current or future 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 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 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 product and product candidates.

If we are found to have improperly promoted our product, we may be subject to restrictions on the sale or marketing of our product 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. Upneeq has been approved by FDA for the treatment of acquired blepharoptosis, or droopy eye lid, in adults. Acquired blepharoptosis may be caused by a variety of factors and may negatively impact the vision and appearance of a patient. Although we cannot legally promote Upneeq for uses inconsistent with its FDA-approved labeling, we cannot control how prescribers choose to use the product. We have policies, procedures, and controls in place to address off-label promotion, but there remains a risk that the FDA or other regulatory agencies could view our promotional practices as improper. If 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. Violation of the FDCA, and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. 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 interactions with third parties in the health care industry, including healthcare professionals, other healthcare providers, third-party payors and patient organizations, are or may be subject to a wide range of healthcare and other regulatory laws and any failure to comply with such laws could expose us to penalties and other sanctions.

Our business operations and interactions with third parties in the healthcare industry, including healthcare professionals, other healthcare providers, third-party payors and patient organizations, are or may be subject to a wide range of healthcare and other regulatory laws These laws constrain the business or financial arrangements through which we conduct our operations, including how we research, market, sell and distribute Upneeq and any products we may develop in the future. In particular, if we market products reimbursed by government healthcare programs and private health plans, that may expose us to significant penalties and sanctions. Healthcare and other regulatory laws applicable to our activities or activities related to any products we may develop in the future may include:

- U.S. federal anti-kickback or similar fraud and abuse laws which prohibit the offer, solicitation, payment or receipt of value in order to generate business reimbursable under government healthcare programs and/or private health plans;
- U.S. federal false claims or fraud laws which prohibit, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid or the defrauding of government healthcare programs and/or private health plans;
- the U.S. federal law HIPAA, as amended, which imposes certain privacy, security and breach reporting obligations, with respect to individually identifiable health information upon covered entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates which perform certain services that involve creating, using, maintaining or transmitting individually identifiable health information;
- the U.S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the so-called federal "Sunshine" or Open Payments law, which requires pharmaceutical and medical device companies to report certain financial interactions with teaching hospitals, physicians and certain non-physician practitioners as well as ownership and investment interests held by physicians and their immediate family members to the federal government for re-disclosure to the public;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws; state laws that require pharmaceutical companies to comply with specific compliance standards; state laws that require pharmaceutical companies to report certain financial interactions with healthcare providers; state laws that require drug manufacturers to file reports relating to pricing sales, shipping and marketing information; 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 have not or do not comply with past, current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties.

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

We are subject to certain risks associated with our operations in non-U.S. jurisdictions, including 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 Criminal Justice (Corruption Offences) Act 2018 renders a company liable for prosecution where any of its officers, managers, employees, agents or subsidiaries are found to be involved in corruption. The only defense is for the company to show that it took all reasonable steps and exercised all due diligence to prevent such corruption from taking place. The legislation also applies to certain international activities. The Irish Money Laundering Acts provide for criminal sanctions for engaging in "money laundering offences," which are offenses committed where a person knows or believes that (or is reckless as to whether or not) the property represents the proceeds of criminal conduct and the party is involved in concealing or disguising the true nature, source, location, disposition, movement or ownership of property, or in converting, transferring, handling, acquiring possession or using the property, or removing the property from, or bringing the property into, Ireland. In addition, the U.K. Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the U.K. Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to our business practices, including the cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase our compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition. As a result of our policy to comply with the FCPA, the Irish Money Laundering Acts, the Irish Criminal Justice (Corruption Offences) Act 2018, the U.K. Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws and regulations.

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

Numerous U.S. states and countries in which we operate, manufacture and sell our product have, or are developing, laws protecting data privacy and the confidentiality of certain personal data, including not only patient health information but also data on employees, customers, contractors and other types of individuals with whom we interact. The global data protection landscape is rapidly evolving, and we expect that there will continue to be new and proposed laws, regulations, and industry standards concerning privacy, data protection and information security, and we cannot yet determine the impact that such future laws, regulations and standards may have on our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. One example of such a law is the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to receive certain details regarding the processing of their data by covered companies, the right to request deletion of their data, and the right to opt out of sales of their data. The CCPA additionally imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities. The CCPA provides for imposition of substantial fines on companies that violate the law and also confers a private right of action on data subjects to seek statutory or actual damages for breaches of their personal information. On November 3, 2020, California voters passed a ballot initiative approving the California Privacy Rights Act (CPRA), which will significantly expand the CCPA to incorporate additional provisions, including a requirement that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA will also expand personal information rights of California residents, including creating a right to opt out of sharing of personal information with third parties for advertising, expanding the lookback period for the right to know about personal information held by businesses, and expanding the right to erasure for information held by third parties. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022. Other states are also enacting comprehensive privacy legislation, including Virginia and Colorado, both of which passed expansive privacy laws in 2021 that take effect in 2023.

In Europe, the EU General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Economic Area (EEA) and substantial fines for breaches of the data protection rules. The GDPR expanded the territorial scope of European data privacy legislation to include not

only entities that are established in the EEA, but also entities that are not established in the EEA but that offer goods or services to individuals located in the EEA or monitor the behavior of individuals located in the EEA. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition. The GDPR also provides for the assessment of fines on entities that violate the regulation of up to 20 million Euros or four percent of annual turnover and provides data subjects a private right of action to seek compensation for damages suffered as a result of violations of the regulation.

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

European data protection law generally prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, unless there are specific frameworks or mechanisms in place, such as the European Commission approved standard contractual clauses, or if very narrow legal exceptions (such as data subject consent) apply. The July 2020 invalidation by the Court of Justice of the European Union of the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S., has led to increased scrutiny on data transfers from the EEA to the U.S. generally and may increase our costs of compliance with data privacy legislation. Our ability to receive data from the EEA could be affected by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as challenges to these mechanisms in the European courts.

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

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

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

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA’s criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA’s requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information that we receive throughout the clinical trial process or in the course of our research collaborations. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach

of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR.

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

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 legacy pharmaceutical products, and could subject us to litigation costs for a period of time

Aggressive enforcement by the DEA or other regulators, unfavorable publicity regarding, for example, the use or misuse of opioid drugs or the limitations of abuse-deterrent formulations, litigation, public inquiries or investigations related to the abuse, sales, marketing, distribution or storage of our legacy products could harm our reputation and result in financial consequences in the form of, for example, litigation costs.

The attorneys general from nearly every state have also either opened an investigation into or filed a lawsuit against pharmaceutical manufacturers and distributors of opioid products. At the state and local level, a number of states, cities, counties, Native American tribes, third party payors, hospitals and other health service providers, schools, individuals and guardians of children diagnosed with neonatal abstinence syndrome have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. Over 2,500 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. The outcome of those bellwether cases will be used to evaluate the settlement and litigation value of the remaining coordinated cases. The legacy business was 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. If similar federal or state lawsuits are filed against the legacy business in the future, we may be subject to litigation costs or negative publicity, which could have a material adverse effect on our business, results of operations and financial condition.

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 our product would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, 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 product. 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.

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 product, 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 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 and the FDA may in the future issue a Warning Letter for violation of post-marketing adverse drug experience reporting requirements. 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 product 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 product 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 product, which do not meet the rigorous manufacturing and testing standards that our product 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

The outstanding indebtedness under our amended credit agreement (the "Credit Agreement") will mature in November 2021. We may not be able to generate sufficient cash to refinance 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 outstanding indebtedness under the Credit Agreement will become due in November 2021. Our ability to refinance our debt obligations 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 expect that our cash flows and capital resources will be insufficient to repay our debt in full or to fund planned capital expenditures and other corporate expenses, and we would face substantial liquidity constraints and could be forced to raise additional capital through sales of our ordinary shares, including through equity sales agreements with broker/dealers or other public or private equity financings, through new debt facilities, including convertible debt or through a sale of a portion or all rights to any of our assets. We may not be able to obtain any such capital on commercially reasonable terms or at all and, even if successful, we may still be unable 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.

Significant delays in our planned capital expenditures, implementing cost savings measures or divestiture of assets may materially and adversely affect our future revenue prospects. In addition, we cannot assure our creditors that we will be able to refinance any of our indebtedness on commercially reasonable terms or at all.

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.

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 facility could foreclose against the assets securing the borrowings; and
- we could be forced into bankruptcy or liquidation.

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

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

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

The terms of Credit Agreement restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.

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

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

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

A breach of the covenants under the Credit Agreement could result in an event of default under the Credit Agreement. Such an event of default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies which could have a material adverse effect on our business, operations and financial results. 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 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 subsidiary, RVL Pharmaceuticals, Inc. As a result, notwithstanding any restrictions on payment of dividends under our existing indebtedness or under Irish law, our ability to pay dividends, if any, will be dependent upon cash dividends and distributions or other transfers from our subsidiaries. Payments to us by our subsidiaries will be contingent upon their respective earnings and subject to any limitations on the ability of such entities to make payments or other distributions to us. The Credit Agreement restricts our subsidiaries from paying dividends and making distributions to its direct or indirect equity holders unless there are available exceptions thereunder. If we are not able to meet such available exceptions that would allow our subsidiaries to pay a dividend or make a distribution to us, and which would then allow us to pay a dividend to you, then we will need to obtain a waiver from the lenders under the senior secured credit facilities.

We may incur significant future indebtedness in the future.

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, and restrictions contained in any future debt agreements, 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. In addition, the restrictions in the Credit Agreement will no longer apply following our repayment of the indebtedness under that agreement. At that time, we will be able to incur new indebtedness without regard to the restrictions in the Credit Agreement, which could result in similar, or more severe, risks as those described above.

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

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

Risks related to our ordinary shares

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public

companies that are not emerging growth companies, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation.

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

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

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

We are currently controlled by Avista and Altchem, who we refer to as our Sponsors. As of June 30, 2021, investment funds affiliated with the Sponsors beneficially owned approximately 64.3% of our outstanding ordinary shares. For as long as the Sponsors own or control at least a majority of our outstanding voting power, they will have the ability to exercise substantial control over all corporate actions requiring shareholder approval, irrespective of how our other shareholders may vote, including over the election and removal of directors, any amendment to our Constitution, the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. Even if their ownership falls below 50%, they will continue to be able to strongly influence or effectively control our decisions so long as they continue to hold a significant portion of our ordinary shares. In addition, each of the Sponsors has a contractual right to nominate two directors for so long as such Sponsor owns at least 20% of our outstanding ordinary shares, and one director for so long as such Sponsor owns less than 20% but more than 10% of our outstanding ordinary shares.

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

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

Because the Sponsors control a majority of the voting power of our outstanding ordinary shares, we are a "controlled company" within the meaning of the corporate governance standards of the Nasdaq Stock Market. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or

another company is a “controlled company” and may elect not to comply with certain corporate governance requirements, including the requirements that, within one year of the date of the listing of our ordinary shares:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our share price has been and may continue to be volatile. Since our initial public offering in October 2018, the closing price of our ordinary shares as reported on the Nasdaq Global Select Market has ranged from a low of $2.34 on June 10, 2019 to a high of $9.20 on October 22, 2018. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could subject the market price of our shares to wide price fluctuations regardless of our operating performance. The trading price of our shares may fluctuate in response to various factors, including:

- market conditions in the broader stock market;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- introduction of new products or services by us or our competitors;
- issuance of new or changed securities analysts' reports or recommendations;
- results of operations that vary from expectations of securities analysts and investors;
- results of operations that vary from those of our competitors;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- strategic actions by us or our competitors;
- announcement by us, our competitors or our vendors of significant contracts or acquisitions;
- sales, or anticipated sales, of large blocks of our shares;
- additions or departures of key personnel;

- regulatory, legal or political developments;
- public response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- litigation and governmental investigations;
- changing economic conditions;
- changes in accounting principles;
- default under agreements governing our indebtedness;
- exchange rate fluctuations; and
- other events or factors, including those from natural disasters, war, acts of terrorism or responses to these events.

These and other factors, many of which are beyond our control, may cause our market price and demand for our shares to fluctuate substantially. Fluctuations in our share price could limit or prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of shares have been volatile, holders of those shares have sometimes instituted securities class action litigation against the company that issued the shares. For example, on April 30, 2019 we were was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*, and on May 10, 2019, a complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints named us, certain of our directors and officers and the underwriters of our initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for our initial public offering of ordinary shares. The parties negotiated a settlement, which called for a payment by the Company of $5.25 million (a portion of which was covered by applicable insurance). The court has scheduled a hearing for November 9, 2021 regarding final approval of the settlement.

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.

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

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

Risks related to being an Irish corporation listing ordinary shares

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

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

There are a number of approaches for acquiring an Irish public limited company, including a court-approved scheme of arrangement under the Irish Companies Act, through a tender offer by a third party, by way of a merger with a company incorporated in the European Economic Area, or EEA, under the EU Cross-Border Mergers Directive (EU) 2017/1132

as implemented in Ireland by the European Communities (Cross-Border Mergers) Regulations 2008 (as amended) and by way of a merger with a company incorporated in Ireland under the Irish Companies Act. Each method requires shareholder approval or acceptance and different thresholds apply.

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

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

- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions that allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before shareholder meetings, including proposed nominations of persons for election to our board of directors;
- the ability of our board of directors to fill vacancies on our board in certain circumstances; and
- imposing particular approval and other requirements in relation to certain business combinations.

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

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

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

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

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

Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities, although we are unable to provide any assurance as to whether the Irish Takeover Panel will overrule this presumption in the future.

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

Our Articles of Association provide that, unless our board of directors or one of its duly authorized committees approves the selection of an alternate forum and to the fullest extent permitted by applicable law, the courts of Ireland shall be the exclusive forum for all actions or proceedings, other than those related to U.S. securities law, but including (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty 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. We have opted out of these preemption rights in our Articles of Association as permitted under Irish law for the maximum period permitted of five years from the date of adoption of the Articles of Association;
- under Irish law, certain matters require the approval of holders of 75% of the votes cast at a general meeting of our shareholders, including amendments to our Articles of Association, which may limit our flexibility to manage our capital structure;
- under Irish law, a bidder seeking to acquire us would need, on a tender offer, to receive shareholder acceptance in respect of 80% of our outstanding shares. If this 80% threshold is not achieved in the offer, under Irish law, the bidder cannot complete a "second step merger" to obtain 100% control of us. Accordingly, tender of 80% of our outstanding shares will likely be a condition in a tender offer to acquire us, not 50% as is more common in tender offers for corporations organized under U.S. law; and
- under Irish law, shareholders may be required to disclose information regarding their equity interests upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on the transfer of the shares, as well as restrictions on voting, dividends and other payments.

Risks related to taxation

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

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

A number of factors may increase our future effective tax rates, including: the jurisdictions in which profits are determined to be earned and taxed (which may vary depending on our taxable presence in such jurisdictions as may be determined by tax authorities in such jurisdictions); the resolution of issues arising from tax audits that may be undertaken by various tax authorities; changes in the valuation of our deferred tax assets and liabilities due to changes in applicable tax legislation; increases in expenses that are not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; changes in available tax credits; changes in share-based compensation; changes in tax laws or the interpretation of such tax laws changes to currently applicable tax treaties,

including those resulting in a loss of treaty benefits; changes in GAAP; and challenges to the transfer pricing policies related to our structure undertaken by various tax authorities. Currently, jurisdictions within the Organization for Economic Co-Operation and Development, or the OECD, are reviewing OECD proposals relating to base erosion and profit shifting. Our effective tax rate could be adversely affected to the extent that countries adopt such OECD proposals.

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

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

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

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

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

We do not believe that we were a PFIC for the 2020 taxable year, and, based upon our current and projected income and assets, and projections as to the value of our assets, we do not anticipate becoming a PFIC for the 2021 taxable year. However, no assurance can be given in this regard because the determination of whether we are a PFIC is made annually after the end of such taxable year and depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) that are subject to change and also may be affected by the application of the PFIC rules, which are subject to differing interpretations. In addition, the value of our assets for purposes of the asset test, including the value of our goodwill, may be determined by reference to the market price of our ordinary shares from time to time. Furthermore, the composition of our income and assets may also be affected by how quickly we spend any cash that is raised in any financing transaction, including this offering and any cash received in the Divestiture and related transactions. our risk of becoming classified as a PFIC may substantially increase. In certain circumstances, and if our ordinary shares are not treated as “publicly traded” within the meaning of applicable U.S. Treasury Regulations, our risk of becoming classified as a PFIC may increase. 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. If we are classified as a PFIC in any taxable year with respect to which a U.S. holder owns ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless the U.S. holder makes a ‘‘deemed sale election.’’ Furthermore, whether or not U.S. holders of our ordinary shares make timely qualified electing fund, or QEF, elections, if we provide the necessary information to U.S. holders to make such elections, or mark-to-market elections may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and any distributions such U.S. holders may receive. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

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

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

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

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

General risk factors

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

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

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

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

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

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

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

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

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

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

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

- our ability to create demand in the marketplace for products we promote;
- the number of new product introductions;
- losses related to inventory write-offs;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- price decreases and associated customer shelf stock adjustments;
- availability of raw materials and finished products from suppliers;
- our ability to manufacture products at our manufacturing facilities;
- the scope and outcome of governmental regulatory actions;
- our dependence on Upneeq for a significant portion of total revenues or income; and
- legal actions asserting intellectual property rights against our product 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 product, the costs to purchase products from third parties and our ability to manufacture our product in a cost-effective manner. If our total revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of total revenues could, therefore, significantly harm our business and operating results.

ITEM 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"in our Annual Report on Form 10-K for the year ended December 31, 2020 that was previously filed with the Securities and Exchange Commission ("SEC") on March 30, 2021. 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 in our Annual Report on Form 10-K filed with the SEC on March 30, 2021. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. As used in this Current Report on Form 8-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 Current Report on Form 8-K.

We are a fully integrated specialty pharmaceutical company focused on the commercialization and development of products that target markets with underserved patient populations. In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrocholoride ophthalmic solution, 0.1%), for the treatment of acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 to a limited number of eye care professionals and expanded our commercialization efforts in 2021 among ophthalmology, optometry and oculoplastic specialties. In 2018, we received regulatory approval from the FDA for Osmolex ER (amantadine extended-release tablets) for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions, which are involuntary muscle movements caused by certain medications, in adults. We completed the launch of Osmolex ER in January 2019. In January 2021, we concluded the sale of Osmolex ER.

On June 24, 2021 we entered into a Purchase and Sale Agreement or PSA, among Acella Holdings, LLC and Alora Pharmaceuticals, LLC, or Alora. Pursuant to the PSA, on August 27, 2021, we closed on the divestiture of the Company's portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility, or the Legacy Business, to certain affiliates of Alora Pharmaceuticals, or Alora, for total consideration of approximately $111 million, subject to certain customary post-closing adjustments, and up to $60 million in contingent milestone payments. We retain the rights to Upneeq and to arbaclofen extended release tablets which is under development for the treatment of spasticity in multiple sclerosis. As a result of the divestiture of the Legacy Business, our business will be primarily focused on the commercialization and development of specialty pharmaceuticals in the ocular and aesthetics therapeutic areas. As a result, in the second quarter of 2021, we presented the Legacy Business as a discontinued operation in our condensed consolidated financial statements. Accordingly, all prior periods have been recast to conform to this presentation. Our audited financial statements for the fiscal years ended December 31, 2020 and 2019 and this Management's Discussion and Analysis of Financial Condition and Results of Operations reflect the results of our Legacy Business as of and through December 31, 2020 as discontinued operations.

The Legacy Business met the criteria within Accounting Standards Codification ("ASC") 205-20, Presentation of Financial Statements to be reported as discontinued operations because the transaction was a strategic shift in business that had a major effect on our operations and financial results. Therefore, we have reported the historical results of the Legacy Business including the results of operations and cash flows as discontinued operations, and related assets and liabilities were retrospectively reclassified as assets and liabilities of discontinued operations for all periods presented herein. Unless otherwise noted, applicable amounts in the prior year have been recast to conform to this discontinued operations presentation. Refer to Note 2, "Summary of Significant Accounting Policies" of our condensed consolidated financial statements included elsewhere in this Current Report on Form 8-K for additional information. Unless otherwise indicated, the following information relates to our continuing operations following the sale of our Legacy Business to Alora. A description of our business prior to the consummation of the transaction is included in Item 1. "Business", in Part I of the Annual Report on Form 10-K for the year ended December 31, 2020 that was previously filed with the SEC on March 30, 2021.

With the divestiture of the Legacy Business, our commercial operations will be conducted by our wholly-owned subsidiary, RVL Pharmaceuticals, Inc. and its subsidiary RVL Pharmacy, LLC, or RVL. RVL operates pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

On July 8, 2020, the FDA approved our NDA for Upneeq for the treatment of acquired blepharoptosis in adults. Upneeq was approved based on three Phase III clinical studies that supported Upneeq's efficacy and safety. Results from Upneeq's first Phase III clinical trial showed that the formulation met its primary efficacy endpoint and was well-tolerated.

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

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

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

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

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

Business Update Regarding COVID-19

The continuing COVID-19 pandemic has presented a substantial public health and economic challenge around the world. In particular, the ongoing COVID-19 pandemic has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and/or could adversely affect our commercialization plans and results. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

We launched our commercial activities for Upneeq and began engaging with eye care providers to promote Upneeq in September 2020 and have since expanded our field sales force. In some instances our sales force has encountered challenges engaging with eye care providers during this on-going pandemic. Although many areas of the United States have re-opened, or begun to re-open, access to offices and other commercial facilities, there continue to be areas where restrictions remain in place, which may have the potential to affect our ability to conduct our business. Additionally, new variants, including the Delta variant, some of which could be resistant to existing vaccines, may lead to new shutdowns or business disruptions in the future, and our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted.

To date, we have been able to continue to supply Upneeq to patients without significant disruptions, and we do not currently anticipate significant interruption in the near term. However, we are continuing to monitor the potential impact of the COVID-19 pandemic on our business and operations, including our sales, expenses, and pharmacy operations. Our third-party contract manufacturing partner for Upneeq has been able to operate its manufacturing facility at or near normal levels. While we currently do not anticipate significant interruptions in our manufacturing supply chain, the COVID-19 pandemic and related mitigation efforts may have a negative impact in the future on our third party suppliers' and contract manufacturing partner's ability to manufacture our products or to have our products reach all markets.

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

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in our annual report on Form 10-K filed with the SEC on March 30, 2021.

Financial Operations Overview

Segment Information

We currently operate in one business segment focused on the commercialization and development of specialty pharmaceutical products that target markets with underserved patient populations. We are not organized by market and are managed and operated as one business. We also do not operate any separate lines of business or separate business entities with respect to our products. A single management team reports to our chief operating decision maker who comprehensively manages our entire business. Accordingly, we do not accumulate discrete financial information with respect to separate product lines and do not have separately reportable segments. See Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Current Report on Form 8-K.

Components of Results of Operations – Continuing Operations

Revenues

As a result of the divestiture, all revenues of the Legacy Business have been reclassified under discontinued operations. Our revenues consist of product sales, royalty revenues and licensing revenue.

Net product sales—Our revenues consist of sales of Upneeq sold through the pharmacy operations of RVL and sales of Osmolex. Osmolex was shipped to customers pursuant to purchase orders, which in certain cases were pursuant to a master agreement with that customer, and we invoiced the customer upon shipment. For these sales we recognized revenue when control transferred to the customer, typically on delivery to that customer. The amount of revenue we recognized is equal to the selling price, adjusted for any variable consideration, which includesd estimated chargebacks, commercial rebates, discounts and allowances at the time revenues are recognized.

RVL ships Upneeq to our customers pursuant to prescriptions which in certain cases are fulfilled by a third party pharmacy partner. All sales are paid for using credit cards for which we are paid prior to shipment. We recognize revenue when control has transferred to the customer, which is typically on delivery to the customer. Accordingly a

portion of revenue is deferred until we have evidence that the product was delivered to the customer. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which largely consists of disputed chargebacks, at the time revenues are recognized.

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

Licensing revenue—We have arrangements with commercial partners that allow for the purchase of Upneeq from us by the commercial partners for the purpose of sub-distribution. Licensing revenue is recognized when the performance obligation identified in the arrangement is completed. Variable considerations, such as returns on Upneeq 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, sales, marketing, finance, accounting, business development, legal and human resource functions. General and administrative expenses also include corporate facility costs, including rent, utilities, insurance, legal fees related to corporate matters, share based compensation and fees for accounting and other consulting services. We expect to continue to incur additional general 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, share based compensation, 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 condensed consolidated financial statements as prepaid expenses or accrued expenses as applicable.

Results of Operations – Continuing Operations

Comparison of Years Ended December 31, 2020 and 2019

Financial Operations Overview

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

	Year Ended December 31,		
	2020	2019	% change
Net product sales	$ 1,942	$ 439	342 %
Royalty revenue	820	763	7 %
Licensing revenue	25,000	—	NW %
Total revenues	27,762	1,202	2,210 %
Cost of goods sold (inclusive of amortization of intangibles)	3,293	3,122	5 %
Gross profit	24,469	(1,920)	(1,374)%
Gross profit percentage	88 %	(160)%	
Selling, general and administrative expenses	72,824	84,728	(14)%
Research and development expenses	13,387	23,380	(43)%
Impairment of intangibles	28,910	17,730	63 %
Total operating expenses	115,121	125,838	(9)%
Operating loss	(90,652)	(127,758)	(29)%
Interest expense and amortization of debt discount	4,095	6,014	(32)%
Other non-operating (gain) loss	48	(995)	(105)%
Total other non-operating expense	4,143	5,019	(17)%
Loss before income taxes	(94,795)	(132,777)	(29)%
Income tax benefit	(5,782)	(26,226)	(78)%
Loss from continuing operations	(89,013)	(106,551)	(16)%
Income (loss) from discontinued operations before income tax expense	10,508	(165,245)	(106)%
Income tax expense (benefit) - discontinued operations	1,084	(895)	(221)%
Income (loss) from discontinued operations, net of tax	9,424	(164,350)	(106)%
Net and other comprehensive loss	$ (79,589)	$ (270,901)	(71)%

Revenue

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

	Year Ended December 31,		
Pharmaceutical Product	2020	2019	% change
Upneeq net product sales	$ 526	$ —	NM %
Osmolex	1,416	439	223 %
Net product sales	1,942	439	342 %
Royalty revenue	820	763	7 %
Licensing revenue	25,000	—	NM %
Total revenues	$ 27,762	$ 1,202	2,210 %

Total revenues increased to $27.8 million for the year ended December 31, 2020, from $1.2 million for the year ended December 31, 2019 primarily due to the receipt of $25 million of licensing revenue from Santen, the commercial launch of Upneeq during the third quarter of 2020 and higher royalty revenues.

Net Product Sales. Net product sales increased by $1.5 million to $1.9 million for the year ended December 31, 2020, as compared to $0.4 million for the year ended December 31, 2019. The $1.5 million increase is driven by a $1.7 million

increase attributable to higher volumes of product sold, offset by $0.2 million of lower realized prices, primarily due to Osmolex. Higher volumes reflect both sales of Upneeq which was launched in September 2020 and higher volumes of Osmolex during 2020.

Royalty Revenue. Royalty revenue increased by $0.1 million for the year ended December 31, 2020, compared to the prior year period, primarily due to higher product sales by license partners during the year.

Licensing Revenue. Licensing revenue increased by $25.0 million in 2020 reflecting the license agreement with Santen, granting the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Under the agreement, the Company received an upfront milestone payment of $25.0 million.

Cost of Goods Sold and Gross Profit Percentage

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

	Year Ended December 31,		
	2020	2019	% change
Amortization of intangible assets	$ —	$ 1,970	(100)%
Depreciation expense	8	—	NM %
Royalty expense	74	42	76 %
Other cost of goods sold	3,211	1,110	189 %
Total cost of goods sold	$ 3,293	$ 3,122	5 %

Total cost of goods sold increased $0.2 million in the year ended December 31, 2020 to $3.3 million as compared to $3.1 million in the year ended December 31, 2019, primarily driven by product and sample costs for Upneeq which was commercially launched during 2020, offset by a decline in amortization expense related to Osmolex which was fully impaired during 2019. Royalty expense increased slightly during 2020 due to higher sales of licensed products.

Gross profit percentage increased to 88% for the year ended December 31, 2020 compared to (160)% for the year ended December 31, 2019. Excluding amortization and depreciation, our gross profit percentage for the year ended December 31, 2020 was 88% as compared to 4% for the year ended December 31, 2019 largely due to licensing revenue from Santen and Upneeq which was commercially launched during 2020.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased approximately $11.9 million in the year ended December 31, 2020 to $72.8 million as compared to $84.7 million in the year ended December 31, 2019. The decrease in our selling, general and administrative expenses reflects salesforce reductions in the third quarter of 2019 and the first quarter of 2020, partially offset by higher marketing expenses associated with the launch of Upneeq and higher general and administrative expenses largely due to costs associated with the Santen license transaction and legal expenses during the year.

Research and Development Expenses

Research and development expenses decreased by approximately $10.0 million in the year ended December 31, 2020 to $13.4 million as compared to $23.4 million in the year ended December 31, 2019. The decrease primarily reflects the completion of the Phase III clinical trials of both arbaclofen ER and RVL-1201 during the first and second quarters of 2019, respectively, and the NDA filing fees for RVL-1201 incurred in the third quarter of 2019.

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

	Year Ended December 31,		
	2020	2019	% change
Arbaclofen ER	$ 3,146	$ 7,430	(58)%
RVL-1201	3,257	7,059	(54)%
Other	6,984	8,891	(21)%
Total	$ 13,387	$ 23,380	(43)%

Impairment of Intangible Assets and Goodwill

There was no impairment of goodwill during the years ended December 31, 2020 and 2019. Impairments of intangible assets for the year-ended December 31, 2020 was $28.9 million consisting of the write-down to fair value for arbaclofen ER, an indefinite-lived In-Process R&D asset, which resulted in an impairment charge of $28.9 million due to a delay in the anticipated launch of the product candidate, if approved.

Impairment of intangible assets was $17.7 million during the year ended December 31, 2019 consisting of the full write-down of Osmolex ER. Osmolex ER was impaired due to underperforming revenue expectations subsequent to the launch of the product.

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by $1.9 million in the year ended December 31, 2020 to $4.1 million as compared to $6.0 million in the year ended December 31, 2019. The decrease in interest expense and amortization of debt discount reflects lower levels of interest rates during 2020.

Other Non-operating (gain) Loss

Other non-operating (gain) expense was $0.1 million and ($1.0) million for the years ended December 31, 2020 and 2019, respectively.

Income Tax Benefit

	Year Ended December 31,	
	2020	2019
	(dollars in thousands)	
Income tax benefit	$ (5,782)	$ (26,226)
Effective tax rate	6.1 %	19.7 %

Income tax benefit decreased by $20.4 million in the year ended December 31, 2020 to $5.8 million as compared to $26.2 million in the year ended December 31, 2019. The decrease in the 2020 income tax benefit was primarily the result of recording a valuation allowance in 2019.

Components of Results of Operations – Discontinued Operations

Revenues

Our revenues from discontinued operations consisted of product sales, royalty revenues and licensing and contract revenue.

Net product sales—Our revenues consisted primarily of product sales of our promoted products, principally Divigel and the OB Complete family of prescription prenatal dietary supplements, M-72, Lorzone, and our non promoted products.

We shipped our products to our customers pursuant to purchase orders, which in certain cases were pursuant to a master agreement with that customer, and we invoiced the customer upon shipment. For these sales we recognized revenue when control was transferred to the customer, which was typically on delivery to the customer. The amount of revenue we recognized was equal to the selling price, adjusted for any variable consideration, which included estimated chargebacks, commercial rebates, discounts and allowances at the time revenues were recognized.

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

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted primarily of personnel expenses, including salaries and benefits for employees in sales, marketing, accounting, legal and human resource functions. General and administrative expenses also included corporate facility costs, including rent, utilities, insurance, legal and other fees related to accounting and other consulting services.

Research and Development

Costs for research and development were charged as incurred and included 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, were 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 were based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and were reflected in our consolidated financial statements as prepaid expenses or accrued expenses as applicable.

Results of Operations – Discontinued Operations

Comparison of Years Ended December 31, 2020 and 2019

Financial Operations Overview

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

	Year Ended December 31,	
	2020	2019
Total revenues	$ 150,122	$ 238,829
Cost of goods sold (exclusive of depreciation and amortization shown separately below)	53,656	55,962
Selling, general and administrative expense	9,137	8,302
Depreciation and amortization	17,531	52,546
Impairment of intangibles	43,273	266,017
Research and development expenses	6,309	8,939
Income (loss) from operations	20,216	(152,937)
Interest expense	10,301	12,197
Other non-operating (gain) loss	(593)	111
Income (loss) from discontinued operations before costs of disposal and provision for income taxes	10,508	(165,245)
Income tax expense (benefit)	1,084	(895)
Income (loss) from discontinued operations before gain on disposal	$ 9,424	$ (164,350)

Revenue

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

	Year Ended December 31,	
	2020	2019
Venlafaxine ER (VERT)	$ 25,576	$ 75,601
Methylphenidate ER	31,699	73,205
Divigel	31,629	26,794
Nitrofurantoin	10,443	5,726
Lorzone	4,058	15,004
OB Complete	6,948	9,851
Other	33,556	28,852
Net product sales	143,909	235,033
Royalty revenue	3,287	2,878
Licensing and contract revenue	2,926	918
Total revenues	$ 150,122	$ 238,829

Total revenues decreased by $88.7 million to $150.1 million for the year ended December 31, 2020, as compared to $238.8 million for the year ended December 31, 2019 primarily due to a decrease in net product sales.

Net Product Sales. Net product sales decreased by $91.1 million to $143.9 million for the year ended December 31, 2020, as compared to $235.0 million for the year ended December 31, 2019. Approximately $52.0 million of this decrease was attributable to lower realized prices, and approximately $39.1 million was due to lower volumes of products sold. Net product sales of methylphenidate ER (including M-72), decreased 57% due to price erosion from generic competitors resulting in significantly lower net selling prices and lower volumes. Product sales from VERT decreased by 66% for the year ended December 31, 2020 due to additional generic competition resulting in lower

volumes and net realized selling prices. During the first quarter of 2020 two competitors launched competing dosage strengths of VERT which negatively affected selling prices and volumes. VERT sales were favorably impacted by $6.4 million, in the aggregate related to product returns during the twelve months ended December 31, 2020 based on actual experience.

Product sales from Lorzone declined 73% for the year ended December 31, 2020, reflecting lower volume due to the launch of generic competitors in late 2019 and 2020, and transition of sales to the Company's authorized generic product during the period. Product sales from Divigel increased by 18%, driven primarily by the launch of a new dosage strength in 2020 together with targeted promotional activities and strong patient access. Product sales from the OB Complete family of prescription prenatal dietary supplements decreased by $2.9 million or 29% during 2020 due to lower volumes sold reflecting a shift of promotional resources to another product. Sales of Nitrofurantoin increased 82% as the 2020 represented the first full year of sales following the product's launch during 2019. Other product sales increased by 16%, largely due to increased pricing and volumes of other non-promoted products sold during the year.

Royalty Revenue. Royalty revenue increased by $0.4 million for the year ended December 31, 2020, compared to the prior year period, primarily due to higher product sales by license partners during the year.

Licensing and Contract Revenue. Licensing and contract revenue increased by $2.0 million in 2020 primarily reflecting higher sales activity among our collaboration partners.

Cost of Goods Sold and Gross Profit Percentage

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

	Year Ended December 31,		
	2020	2019	% change
Amortization of intangible assets	$ 16,046	$ 50,687	(68)%
Depreciation expense	1,484	2,343	(37)%
Royalty expense	9,209	10,155	(9)%
Other costs of goods sold	44,448	45,323	(2)%
Total costs of goods sold	$ 71,187	$ 108,508	(34)%

Total cost of goods sold decreased $37.3 million in the year ended December 31, 2020 to $71.2 million as compared to $108.5 million in the year ended December 31, 2019, primarily driven by a $34.6 million decrease in amortization of intangible assets, due to lower amortization for methylphenidate ER and VERT reflecting impairment charges recognized during the year. Royalty expense decreased by $0.9 million due to decrease in net sales of certain licensed products. There was no material change in depreciation expense or other cost of goods sold.

Gross profit percentage decreased to 53% for the year ended December 31, 2020 compared to 55% for the year ended December 31, 2019. Excluding amortization and depreciation, our gross profit percentage for the year ended December 31, 2020 was 64% as compared to 77% for the year ended December 31, 2019 largely due to higher unit production costs, partially offset by lower inventory reserves and royalty expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $0.8 million in the year ended December 31, 2020 to $9.1 million as compared to $8.3 million in the year ended December 31, 2019. The increase in our selling, general and administrative expenses is driven by higher selling and marketing expenses for Divigel and OB Complete during 2020 following the curtailment of personal promotion.

Research and Development Expenses

Research and development expenses decreased by $2.6 million in the year ended December 31, 2020 to $6.3 million as compared to $8.9 million in the year ended December 31, 2019. The decrease primarily reflects the completion of development programs for several non-promoted products during 2020.

Impairment of Intangible Assets and Goodwill

Impairments of intangible assets for the year-ended December 31, 2020 was $43.3 million primarily consisting of write-downs to fair value for methylphenidate ER, VERT, and Oxybutynin of $19.5 million, $20.2 million, and $3.6 million, respectively. The impairments of methylphenidate ER, VERT and Oxybutynin reflect the competitive generic environment which has continued to erode net realized pricing and volumes of these products. In the fourth quarter of 2020 we recognized an impairment of finite-lived development technology and product rights for VERT of $10.7 million and $9.5 million, respectively due to the approval of a competing product and the anticipated deterioration of pricing and volumes.

Impairment of intangible assets was $266.0 million during the year ended December 31, 2019 primarily consisting of write-downs to fair value of methylphenidate ER, VERT, and Corvite of $128.1 million, $137.7 million, and $0.2 million, respectively. Methylphenidate ER tablets and VERT were impaired due to lower revenues reflecting an increasingly competitive environment which deteriorated pricing and volumes; Corvite was impaired due to the discontinuation of the product. In the third and fourth quarter of 2019, we also recognized an impairment of finite-lived

development technology and product rights for VERT of $73.0 million and $64.7 million, respectively, due to approvals of competing products which deteriorated pricing and volumes.

	Year Ended December 31, 2020	
Asset/Asset Group	**Impairment Charge**	**Reason For Impairment**
Product Rights		
Methylphenidate ER	$ 19,539	Lower revenue due to generic competition.
	19,539	
Developed Technology		
Venlafaxine ER	10,655	Lower revenue due to generic competition.
Oxybutynin	3,618	Lower revenue expectations
	14,273	Lower anticipated revenue due to generic competition.
Distribution Rights		
Venlafaxine ER	9,461	Lower revenue due to generic competition.
Total Impairment Charges for year ended December 31, 2020	$ 43,273	

	Year Ended December 31, 2019	
Asset/Asset Group	**Impairment Charge**	**Reason For Impairment**
Product Rights		
Methylphenidate ER	$ 128,113	Lower revenue due to generic competition.
Corvite	190	Discontinued formulation
	128,303	
Developed Technology		
Venlafaxine ER	72,995	Revenue underperforming expectations due to new generic market entrants.
Distribution Rights		
Venlafaxine ER	64,718	Revenue underperforming expectations due to new generic market entrants.
Total Impairment Charges for year ended December 31, 2019	$ 266,016	

Impairment of Fixed Assets

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

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by $1.9 million in the year ended December 31, 2020 to $10.3 million as compared to $12.2 million in the year ended December 31, 2019. The decrease in borrowing costs reflects lower levels of indebtedness following the prepayment of debt in the third quarter of 2020, and lower interest rates during 2020.

Other Non operating (Gain) Loss, net

Other non-operating (gain) loss was ($0.6) million and $0.1 million for the years ended December 31, 2020 and 2019, respectively.

Income Tax

	Year Ended December 31,	
	2020	2019
	(dollars in thousands)	
Income tax expense (benefit)	$ 1,084	$ (895)
Effective tax rate	11.0 %	0.5 %

Income tax expense increased by $2.0 million in the year ended December 31, 2020 to an income tax expense $1.1 million as compared to an income tax benefit of $0.9 million in the year ended December 31, 2019. The change in the 2020 income tax benefit was the result of income from discontinued operations in 2020.

Liquidity and Capital Resources

Our principal sources of liquidity are cash and cash equivalents on hand. We had cash and cash equivalents of $114.1 million as of December 31, 2020. Our primary uses of cash are to fund operating expenses, product development costs, capital expenditures, and debt service payments.

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

At December 31, 2020, we had $50 million available under the revolver, and there were no outstanding borrowings or outstanding letters of credit under the Revolver.

On January 13, 2020 we completed an equity offering and allotted 6.9 million ordinary shares at a public offering price of $5.00 per share. The number of shares issued in this offering reflected the exercise in full of the underwriters option to purchase 900,000 ordinary shares. The aggregate net proceeds from the follow-on offering were approximately $31.8 million after deducting underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

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

Going Concern

As of December 31, 2020, the Company’s cash and cash equivalents totaled $114.1 million. For the fiscal year ended December 31, 2020 and 2019 the Company incurred net losses of $79.6 million, and $270.9 million, respectively. As of December 31, 2020, the Company had interest bearing debt of $221.4 million. In connection with the divestiture of the Legacy Business (the “Transaction”), the Company entered into an amendment to its credit agreement (the “Credit Agreement Amendment”), which provided for the release of liens on the Legacy Business and (i) reduced the outstanding term loan balance to $30.0 million upon the closing of the Transaction which occurred on August 27, 2021, (ii) terminated the revolving credit facilities, and (iii) shortened the maturity of the $30 million remaining term loans to November 21, 2021. In addition, upon closing of the Transaction, the Company transferred substantially all of its cash to subsidiaries of the Company subject to the lien of the credit agreement. Additionally, the Company agreed to pay fees to the lenders based upon the outstanding principal balance of the term loans upon maturity of the remaining term loans.

As a result of the Transaction, the Company divested substantially all its revenue generating assets and the Company's business plan is focused on the launch of its commercial product, Upneeq, which will diminish the Company's cash flows in at least the near term, in particular cash inflows from product sales. The Company will require additional capital to repay the remaining portion of its term loans, fund its operating needs, including the commercialization of Upneeq and other activities. Accordingly, the Company expects to incur significant expenditures and increasing operating losses in the future. As a result, the Company's current sources of liquidity will not be sufficient to meet its obligations for the 12 months following the date the consolidated financial statements contained in this Current Report on Form 8-K are issued. These conditions give rise to substantial doubt as to the Company's ability to operate as a going concern. The Company's ability to continue as a going concern will require the Company to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

The Company's plans to address these conditions include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or are entirely within our control:

- raise funds through additional sales of our ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings.

- raise capital through new debt facilities, including convertible debt.

- partner or sell a portion or all rights to any of our assets to potentially secure additional non-dilutive funds.

There can be no assurance that the Company will receive cash proceeds from any of these potential resources or, to the extent cash proceeds are received, such proceeds would be sufficient to support the current operating plan for at least the next 12 months from the date the consolidated financial statements contained in this Current Report on Form 8-K are issued. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If the Company raises additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our ordinary shares and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

Our audited consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on the ability to obtain the necessary financing to meet the Company's obligations and repay liabilities arising from the normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that the Company will be able to continue as a going concern. The audited consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	Change
Net cash provided by operating activities	$ 17,590	$ 33,567	$ (15,977)
Net cash used in investing activities	(3,084)	(4,020)	936
Net cash provided by (used in) financing activities	3,682	(4,691)	8,373
Net increase in cash and cash equivalents	$ 18,188	$ 24,856	$ (6,668)

Net cash provided by operating activities

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

Net cash used in investing activities

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

Net cash provided by (used in) financing activities

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

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

The following table presents the significant non-cash items and purchases of property, plant and equipment for the discontinued operations for the Legacy Business that are included in the accompanying consolidated statements of cash flows.

	Year Ended December 31,	
Cash flows from operating activities:	2020	2019
Depreciation and amortization	$ 19,118	$ 53,734
Share compensation	1,008	942
Impairment of intangibles	43,273	266,017
Cash flows from investing activities:		
Purchase of property, plant and equipment	$ (2,304)	$ (3,883)

Contractual Obligations

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

	Payments due by period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations[1]	$ 219,525	$ —	$ 219,525	$ —	$ —
Interest expense[2]	20,915	10,659	10,256	—	—
Capital lease obligations[3]	20	20	—	—	—
Operating lease obligations[4]	2,196	1,288	908	—	—
Total	$ 242,656	$ 11,967	$ 230,689	$ —	$ —

(1) Represents the remaining principal amount under our senior secured credit facilities. Pursuant to the Credit Agreement Amendment, which became effective upon the closing of the sale of the Legacy Business, the principal amount was reduced to $30 million which is due November 21st, 2021. See Note 4 Discontinued Operations.

(2) These amounts represent future cash interest payments related to our existing debt obligations based on variable interest rates specified in the senior secured credit facilities. Payments related to variable debt are based on applicable rates at December 31, 2020 plus the specified margin in the senior secured credit facilities for each period presented. As of December 31, 2020, the interest rate was 4.75% for Term A Loan and 5.25% for Term B Loan. As referenced in Note (1) above, following the closing of the sale of the Legacy Business, the principal amount of long-term debt is due November 21st, 2021.

(3) Includes minimum cash payments related to certain fixed assets, primarily office equipment.

(4) Includes minimum cash payments related to our leased offices under non-cancelable leases in New Jersey and Buenos Aires, Argentina.

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

Critical Accounting Estimates – Continuing Operations

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 Current Report on Form 8-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. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have considered the impact of COVID-19 in the estimates within our financial statements and there may be changes to those estimates in future periods. 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

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

Revenue is recorded at the transaction price, which is the amount of consideration we expect to receive in exchange for transferring products to a customer. We consider the unit of account for each purchase order that contains more than one product. Because all products in a given purchase order are generally delivered at the same time and the method of 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.

	Chargebacks	Commercial Rebates	Government and Managed Care Rebates	Product Returns	Discounts and Allowances	Total
Balance at December 31, 2018	$ —	$ —	$ —	$ —	$ —	$ —
Provision	1,265	46	51	51	12	1,425
Charges processed	—	(39)	(21)	4	(10)	(66)
Balance at December 31, 2019	$ 1,265	$ 7	$ 30	$ 55	$ 2	$ 1,359
Provision	6	56	155	53	14	284
Charges processed	105	(59)	(139)	(20)	(15)	(128)
Balance at December 31, 2020	$ 1,376	$ 4	$ 46	$ 88	$ 1	$ 1,515

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 Revenue— We recognize development and regulatory milestone revenue from milestone events under our license with Santen that have been achieved and the Company is reasonably certain such revenues would not have to be reversed.

Freight—We record amounts billed to customers for shipping and handling as revenue, and record shipping and handling expenses related to product sales as selling, general and administrative expenses. We account for shipping and handling activities related to 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.

Valuation of long-lived assets

As of December 31, 2020, our combined long-lived assets balance, principally property, plant and equipment is $2.4 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.

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. Please see Note 9, *Goodwill and Other Intangible Assets*, to our consolidated financial statements included in the Current Report on Form 8-K for additional information.

Evaluations of the recoverability of an asset are 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 could increase or decreased our estimated discounted future cash flows and the resulting estimated fair values of these assets, causing increases or decreases in the recoverability of assets, potentially resulting asset impairment charges. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted.

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. The assessment of goodwill has been based on the historical goodwill for the continuing and discontinued operations of the business on a combined basis.

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 Current Report on Form 8-K, 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, 2020 and 2019 annual goodwill impairment test were 19.5% and 16.5%, respectively, depending on the overall risk associated with the particular asset and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

Based on the goodwill impairment assessment performed, we determined that there was no impairment of goodwill as of October 1, 2020 and for the year ended December 31, 2020.

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

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

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

Income Taxes

Income taxes are recorded under the asset and liability method of accounting. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and

liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled.

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

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

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

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

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. While we have concluded in the past that some of such undistributed earnings are indefinitely reinvested, facts and circumstances may change in the future. Changes in facts and circumstances may include a change in the estimated capital needs of our subsidiaries, or a change in our corporate liquidity requirements. Such changes could result in our management determining that some or all of such undistributed

earnings are no longer indefinitely reinvested. In that event, we would be required to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely reinvested outside the relevant tax jurisdiction.

Share-based compensation

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

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

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

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

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

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

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

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our ordinary shares, the exercise price, the expected option term, share price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our share-based compensation expense could be materially different in the future.

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

- *Expected Option Term*. Due to the lack of sufficient company-specific historical exercise data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB), Topic 14.D.2, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option.

- *Expected Volatility*. Due to lack of a public market for the trading of our ordinary shares, the expected volatility is based on historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB 14.D.6.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- *Expected Dividends*. The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our ordinary shares.

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

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

During the years ended December 31, 2020 and 2019, we recognized $3.9 million and $4.0 million, respectively, of stock compensation expense.

Recently Issued Accounting Standards

For a discussion of recent accounting pronouncements, please see Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Current Report on Form 8-K.

Exhibit 99.3

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Osmotica Pharmaceuticals plc

Opinion on the Financial Statements

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

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Ernst & Young LLP

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

Iselin, New Jersey
March 30, 2021
except for Note 3, as to which the date is September 8, 2021, and except for the effects of the discontinued operations described in Note 4, as to which the date is September 8, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 114,053	$ 95,865
Trade accounts receivable, net	3,149	794
Inventories, net	1,831	395
Prepaid expenses and other current assets	12,592	8,772
Assets held for sale	41,529	66,804
Total current assets	173,154	172,630
Property, plant and equipment, net	2,391	2,049
Operating lease assets	1,953	3,916
Intangibles, net	35,090	64,000
Goodwill	55,847	55,847
Other non-current assets	373	563
Assets held for sale	102,141	164,250
Total assets	$ 370,949	$ 463,255
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	$ 3,128	$ 1,487
Accrued liabilities	16,951	17,637
Current portion of obligation under finance leases	20	26
Current portion of lease liability	1,199	1,803
Income taxes payable - current portion	2	—
Liabilities held for sale	34,484	54,984
Total current liabilities	55,784	75,937
Long-term debt, net of non-current deferred financing costs	219,525	267,950
Long-term portion of obligation under finance leases	—	20
Long-term portion of lease liability	871	2,293
Deferred taxes	345	1,500
Liabilities held for sale	568	847
Total liabilities	277,093	348,547
Commitments and contingencies (See Note 16)		
Shareholders' equity:		
Ordinary shares ($0.01 nominal value 400,000,000 shares authorized, 62,545,832 and 51,845,742 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively)	625	518
Preferred shares ($0.01 nominal value 40,000,000 shares authorized, no shares issued and outstanding)	—	—
Euro deferred shares (€1.00 nominal value 25,000 shares authorized, no shares issued and outstanding)	—	—
Additional paid in capital	548,070	489,440
Accumulated deficit	(452,610)	(373,021)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	93,856	114,708
Total liabilities and shareholders' equity	$ 370,949	$ 463,255

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Net product sales	$ 1,942	$ 439
Royalty revenue	820	763
Licensing revenue	25,000	—
Total revenues	27,762	1,202
Cost of goods sold	3,293	3,122
Gross profit	24,469	(1,920)
Selling, general and administrative expenses	72,824	84,728
Research and development expenses	13,387	23,380
Impairment of intangibles	28,910	17,730
Total operating expenses	115,121	125,838
Operating loss	(90,652)	(127,758)
Interest expense and amortization of debt discount	4,095	6,014
Other non-operating (gain) loss	48	(995)
Total other non-operating expense	4,143	5,019
Loss before income taxes	(94,795)	(132,777)
Income tax benefit	(5,782)	(26,226)
Loss from continuing operations	(89,013)	(106,551)
Income (loss) from discontinued operations before income tax expense	10,508	(165,245)
Income tax expense (benefit) - discontinued operations	1,084	(895)
Income (loss) from discontinued operations, net of tax	9,424	(164,350)
Net and other comprehensive loss	$ (79,589)	$ (270,901)
Other comprehensive loss, net		
Change in foreign currency translation adjustments	—	(383)
Comprehensive loss	$ (79,589)	$ (271,284)
(Loss) income per share attributable to shareholders:		
Basic and Diluted, continuing operations	$ (1.47)	$ (2.43)
Basic and Diluted, discontinued operations	0.16	(2.75)
Basic and Diluted loss per share	$ (1.31)	$ (5.17)
Weighted average shares basic and diluted:		
Basic and Diluted	60,652,999	52,367,444

See accompanying notes to consolidated financial statements.

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

	Ordinary shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount				
Balance at January 1, 2019	52,518,924	$ 525	$ 487,288	$ (102,120)	$ (1,846)	$ 383,847
Repurchase of ordinary shares	(673,182)	(7)	(2,780)	—	—	(2,787)
Share compensation	—	—	4,932	—	—	4,932
Net loss	—	—	—	(270,901)		(270,901)
Change in foreign currency translation	—	—	—	—	(383)	(383)
Balance at December 31, 2019	51,845,742	518	489,440	(373,021)	(2,229)	114,708
Repurchase of ordinary shares	(1,435,725)	(15)	(8,086)	—	—	(8,101)
Proceeds from issuance of ordinary shares, net of offering costs	11,900,000	119	62,321	—	—	62,440
Payments for taxes relatd to the net share settlement of equity awards	—	—	(749)	—	—	(749)
Share compensation	235,815	3	5,144	—	—	5,147
Net loss	—	—	—	(79,589)	—	(79,589)
Balance at December 31, 2020	62,545,832	$ 625	$ 548,070	$ (452,610)	$ (2,229)	$ 93,856

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Cash Flows from Operating Activities:		
Net loss from continuing operations	$ (89,013)	$ (106,551)
Net income (loss) from discontinued operations	9,424	(164,350)
Net loss	(79,589)	(270,901)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	21,026	57,015
Share compensation	4,925	4,932
Impairment of intangibles	72,183	283,747
Deferred income tax benefit	(1,156)	(26,794)
Loss on sale of fixed and leased assets	287	173
Bad debt provision	6	(164)
Amortization of deferred financing and loan origination fees	1,269	1,337
Write off of deferred financing fees in connection with prepayment	496	—
Change in operating assets and liabilities:		
Trade accounts receivable, net	17,496	12,674
Inventories, net	3,371	3,078
Prepaid expenses and other current assets	(3,209)	9,177
Trade accounts payable	(1,723)	(16,375)
Accrued and other current liabilities	(17,792)	(24,332)
Net cash provided by operating activities	17,590	33,567
Cash Flows from Investing Activities:		
Proceeds from sale of fixed and leased assets	50	17
Payments on disposal of leased assets	(214)	(74)
Purchase of property, plant and equipment	(2,920)	(3,963)
Net cash used in investing activities	(3,084)	(4,020)
Cash flows from Financing Activities:		
Payments on finance lease obligations	(127)	(130)
Proceeds from public offering, net of issuance costs	62,440	—
Proceeds from purchases of stock under ESPP	219	—
Debt repayment	(50,000)	—
Repurchases of ordinary shares	(8,101)	(2,787)
Payments for taxes related to net share settlement of equity awards	(749)	—
Proceeds from insurance financing loan	—	1,314
Repayment of insurance financing loan	—	(3,088)
Net cash provided by (used in) financing activities	3,682	(4,691)
Net change in cash and cash equivalents -continuing operations	18,188	24,856
Effect on cash of changes in exchange rate	—	175
Cash and cash equivalents, beginning of period	95,865	70,834
Cash and cash equivalents, end of period	$ 114,053	$ 95,865
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 14,745	$ 15,181
Cash paid for taxes	$ 2,044	$ 1,290

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, an Irish public limited company (the "Company"), together with its subsidiaries, is a specialty pharmaceutical company focused on the development and commercialization of products that target markets with underserved patient populations. In July 2020, the Company received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrocholoride ophthalmic solution, 0.1%), for the treatment of acquired blepharoptosis, or droopy eyelid, in adults. Upneeq was commercially launched September 2020 to a limited number of eye care professionals with commercialization operations expanded in 2021 among ophthalmology, optometry and oculoplastic specialties.

On June 24, 2021, the Company entered into an agreement for the divestiture of the Company's portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility (the "Legacy Business") to certain affiliates of Alora Pharmaceuticals, or Alora, for total consideration of approximately $111 million subject to certain customary post-closing adjustments, and up to $60 million in contingent milestone payments. The divestiture of the Legacy Business closed on August 27, 2021. Pursuant to the agreement the Company retained the rights to Upneeq and to arbaclofen extended release tablets which is under development for the treatment of spasticity in multiple sclerosis. Following the divestiture of the Legacy Business the primary focus of the Company is on the commercialization and development of specialty pharmaceuticals in the ocular and aesthetics therapeutic areas.

With the divestiture of the Legacy Business the Company's commercial operations will be conducted by its wholly-owned subsidiaries, RVL Pharmaceuticals, Inc. and RVL Pharmacy, LLC, or RVL. RVL operates pharmacy operations dedicated to the processing and fulfillment of prescriptions for Upneeq.

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.

Discontinued Operations— Upon divestiture of a business, the Company classifies such business as a discontinued operation, if the divested business represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. The divestiture of the Legacy Business qualifies as a discontinued operation nd therefore have been presented as such. The results of businesses that have qualified as discontinued operations have been presented as such for all reporting periods. Results of discontinued operations include all revenues and expenses directly derived from such businesses; general corporate overhead is not allocated to discontinued operations.

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. Our subsidiary in Argentina is currently operating in a highly inflationary environment, as a result, we account for translation in accordance with US GAAP.

Foreign currency transaction gains and losses are included in selling, general and administrative expenses in the Company's statements of operations.

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

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

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

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

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

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

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

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

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
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 15 years. The Company periodically reviews the estimated useful lives of intangible assets and makes adjustments when events indicate that a shorter life is appropriate. Following the divestiture of the Legacy Business the Company does not have definite-lived intangible assets.

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 $28.9 million and $17.7 million, in regard to definite-lived and indefinite-lived intangible assets for the years ended December 31, 2020 and 2019, respectively (see Note 9).

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, 2020 and 2019, respectively. (see Note 9).

In-Process Research and Development ("IPR&D") intangible assets represent the value assigned to acquired Research & Development ("R&D") projects that principally represent rights to develop and sell a product that the Company has

acquired which have not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. Impairment testing requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D product, the assets are reduced to zero. IPR&D is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. If the fair value of the IPR&D is less than its carrying amount, an impairment is recognized for the difference. The Company recognized an impairment charge to IPR&D of $28.9 million for the year ended December 31, 2020 and we recognized no impairment charges of IPR&D for the year ended December 31, 2019 (see Note 9).

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 Revenue— We recognize development and regulatory milestone revenue from milestone events under our license agreement that have been achieved and the Company is reasonably certain such revenues would not have to be reversed (see Note 5). 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 licensee 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.

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. There were no purchases of developed products or licenses in the years ended December 31, 2020 or 2019.

In-Process Research and Development—In-process research and development represent the fair value assigned to incomplete research projects that the Company acquires through business combinations or developed internally which, at that time, have not reached technological feasibility. Intangible assets associated with IPR&D projects are not amortized until regulatory approval is obtained and product is launched, subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated. During the years ended December 31, 2020 and 2019, there was $0 million and $19.7 million, respectively, of IPR&D transferred to Product Rights (see Note 9). Such amounts will be amortized over their respectful estimated useful lives. At that time an evaluation of fair value was performed immediately prior to such transfer and no impairments were recognized at that time. Assets are subsequently evaluated for indicators of impairment.

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

Advertising—Advertising expense consists primarily of print media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2020 and 2019 amounted to $6.8 million and $6.9 million, 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*. Share-based compensation expense is measured at the date of grant, based on the fair value of the award. Compensation for share-based awards with vesting conditions other than service are recognized at the time that those conditions will be achieved. Forfeitures are recognized as they are incurred.

Income Taxes—Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are

measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

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

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

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

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

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which introduces a new methodology for accounting for credit losses on financial instruments, including available-for-sale debt securities. The guidance establishes a new "expected loss model" that requires entities to estimate current expected credit losses on financial instruments by using all practical and relevant information. The estimate of credit losses must be based on all relevant information including historical information, current conditions, and reasonable and supportable forecasts that affect the collectability of the amounts. The Company adopted this standard on January 1, 2020, and there was no material impact to the Company's consolidated financial statements. The Company has provided additional disclosures as required by the standard upon adoption. Refer to Note 6 for additional details.

Note 3. Going Concern Evaluation

As of December 31, 2020, the Company's cash and cash equivalents totaled $114.1 million. For the fiscal year ended December 31, 2020 and 2019 the Company incurred net losses of $79.6 million, and $270.9 million, respectively. As of December 31, 2020, the Company had interest bearing debt of $221.4 million. In connection with the divestiture of the Legacy Business (the "Transaction"), the Company entered into an amendment to its credit agreement (the "Credit Agreement Amendment"), which provided for the release of liens on the Legacy Business and (i) reduced the outstanding term loan balance to $30.0 million upon the closing of the Transaction which occurred on August 27, 2021, (ii) terminated the revolving credit facilities, and (iii) shortened the maturity of the $30 million remaining term loans to November 21, 2021. In addition, upon closing of the Transaction, the Company transferred substantially all of its cash to subsidiaries of the Company subject to the lien of the credit agreement. Additionally, the Company agreed to pay fees to the lenders based upon the outstanding principal balance of the term loans upon maturity of the remaining term loans.

As a result of the Transaction, the Company divested substantially all its revenue generating assets and the Company's business plan is focused on the launch of its commercial product, Upneeq, which will diminish the Company's cash flows in at least the near term, in particular cash inflows from product sales. The Company will require additional capital

to repay the remaining portion of its term loans, fund its operating needs, including the commercialization of Upneeq and other activities. Accordingly, the Company expects to incur significant expenditures and increasing operating losses in the future. As a result, the Company's current sources of liquidity will not be sufficient to meet its obligations for the 12 months following the date the consolidated financial statements contained in this Current Report on Form 8-K are issued. These conditions give rise to substantial doubt as to the Company's ability to operate as a going concern. The Company's ability to continue as a going concern will require the Company to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

The Company's plans to address these conditions include pursuing one or more of the following options to secure additional funding, none of which can be guaranteed or are entirely within our control:

- raise funds through additional sales of our ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings.

- raise capital through new debt facilities, including convertible debt.

- partner or sell a portion or all rights to any of our assets to potentially secure additional non-dilutive funds.

There can be no assurance that the Company will receive cash proceeds from any of these potential resources or, to the extent cash proceeds are received, such proceeds would be sufficient to support the current operating plan for at least the next 12 months from the date the consolidated financial statements contained in this Current Report on Form 8-K are issued. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If the Company raises additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our ordinary shares and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

Our audited consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on the ability to obtain the necessary financing to meet the Company's obligations and repay liabilities arising from the normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that the Company will be able to continue as a going concern. The audited consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern.

Note 4. Discontinued Operations

On August 27, 2021, we closed the divestiture of our Legacy Business and received total cash consideration of approximately $111 million, subject to post-closing adjustments, plus up to $60 million in additional contingent milestone payments. In connection with the divestiture, on June 24, 2021 the Company amended the Term Loan Agreement (the "Fifth Amendment to the Term Loan Agreement"). Pursuant to the Fifth Amendment to the Term Loan Agreement, the Term Loan Agreement was amended to, among other things, release of liens on the Legacy Business and (i) reduce the outstanding term loan balance to $30.0 million upon the closing of the divestiture of the Legacy Business, (ii) terminate the revolving credit facilities, and (iii) shorten the maturity of the $30 million remaining term loans to November 21, 2021. Upon the closing of the Legacy business the outstanding term loans were reduced by $186.1 million. Please refer to Note 12 for more information regarding the Company's financing arrangements.

We have determined the divestiture of the Legacy Business represents a strategic shift that will have a major effect on our business and therefore met the criteria for classification as discontinued operations at December 31, 2020. Accordingly, the assets and liabilities associated with the Legacy Business have been classified as held for sale in the accompanying Consolidated Balance Sheets at December 31, 2020 and December 31, 2019. The operations and cash flows of the Legacy Business are presented as discontinued for all periods presented.

Unless otherwise indicated or required by the context, references throughout to "Osmotica," or the "Company", refer to our continuing operations following the sale of the Legacy Business to Alora. A description of our business prior to the consummation of the transaction is included in Item 1. "Business", in Part I of the Annual Report on Form 10-K for the year ended December 31, 2020 that was previously filed with the Securities and Exchange Commission ("SEC") on March 30, 2021. The continuing operations reflect the results of the product Osmolex ER, as discussed in Note 16, the global rights of which were sold in January, 2021; however, as the sale did not qualify for presentation as a discontinued operation, the financial results of Osmolex ER are included within the continuing operations herein.

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

	Year Ended December 31,	
	2020	2019
Total revenues	$ 150,122	$ 238,829
Cost of goods sold (exclusive of depreciation and amortization shown separately below)	53,656	55,962
Selling, general and administrative expense	9,137	8,302
Depreciation and amortization	17,531	52,546
Impairment of intangibles	43,273	266,017
Research and development expenses	6,309	8,939
Income (loss) from operations	20,216	(152,937)
Interest expense	10,301	12,197
Other income, net	(593)	111
Income (loss) from discontinued operations before costs of disposal and provision for income taxes	10,508	(165,245)
Income tax expense (benefit)	1,084	(895)
Income (loss) from discontinued operations before gain on disposal	$ 9,424	$ (164,350)

The following table summarizes the carrying amounts of major classes of assets and liabilities of discontinued operations for each of the periods presented.

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ —	$ —
Accounts receivable, net	23,263	43,120
Inventories	16,103	20,911
Prepaid expenses and other current assets	2,163	2,773
Total current assets of discontinued operations	41,529	66,804
Property, plant and equipment, net	25,663	28,188
Operating lease right-of-use assets	803	1,067
Goodwill	45,008	45,008
Intangible assets, net	30,667	89,987
Total non-current assets of discontinued operations	102,141	164,250
Total assets of discontinued operations	$ 143,670	$ 231,054
Accounts payable	3,640	7,010
Accrued liabilities	30,566	47,614
Current portion of operating lease liabilities	278	360
Total current liabilities of discontinued operations	34,484	54,984
Operating lease liabilities, net of current portion	568	847
Total non-current liabilities of discontinued operations	568	847
Total liabilities of discontinued operations	35,052	55,831
Net assets of discontinued operations	$ 108,618	$ 175,223

The following table presents the significant non-cash items and purchases of property, plant and equipment for the discontinued operations for the Legacy Business that are included in the accompanying consolidated statements of cash flows.

	Year Ended December 31,	
Cash flows from operating activities:	2020	2019
Depreciation and amortization	$ 19,118	$ 53,734
Share compensation	1,008	942
Impairment of intangibles	43,273	266,017
Cash flows from investing activities:		
Purchase of property, plant and equipment	$ (2,304)	$ (3,883)

Note 5. 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 either collects payment in advance from its customers or invoices after the products have been delivered and invoice payments are generally due within 30 – 60 days of invoice date.

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

	Year Ended December 31,	
Pharmaceutical Product	2020	2019
Upneeq net product sales	$ 526	$ —
Osmolex	1,416	439
Net product sales	1,942	439
Royalty revenue	820	763
Licensing revenue	25,000	—
Total revenues	$ 27,762	$ 1,202

On July 28, 2020, the Company entered into a License Agreement with Santen Pharmaceutical Co. Ltd, granting Santen exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as Europe, the Middle East and Africa ("EMEA") countries. Under the agreement the Company is entitled to certain development and regulatory milestone payments. The Company is also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories. During the year ended December 31, 2020, the Company received a $25.0 million milestone payment which was recognized as license revenue in the period as all performance obligations were met.

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 an immaterial amount of deferred revenue as of December 31, 2020 and 2019. The Company has elected to apply the exemption under paragraph 606-10-50-14(a) related to remaining performance obligations as all open purchase orders are expected to be satisfied with a period of one year from the date of the purchase order.

Contract assets primarily relate to rights to consideration for goods or services transferred to the customer when the right is conditional on something other than the passage of time. Contract assets are transferred to accounts receivable when the rights become unconditional. The Company had no contract assets as of December 31, 2020 and 2019, respectively. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs.*

Note 6. Accounts Receivable, Sales and Allowances

Accounts receivable result primarily from sales of pharmaceutical products, amounts due under revenue sharing, license and royalty arrangements.

The Company is exposed to credit losses primarily through sales of its products. Prior to January 1, 2020, accounts receivable were recorded at cost less an allowance for doubtful accounts. Subsequent to January 1, 2020, accounts receivable are recorded at amortized cost less an allowance for expected credit losses that are not expected to be recovered. The Company's expected loss methodology for accounts receivable is developed using historical collection experience, a review of the current status of customer's trade receivables, and current and future market conditions. Due to the short-term nature of such receivables, the estimate of accounts receivable that may not be collected is based on the aging of accounts receivable balances and the financial condition of customers. The Company's monitoring activities include timely account reconciliations, dispute resolution, payment confirmation, consideration of customers' financial condition and macroeconomic conditions. Balances are written-off when determined to be uncollectible. The Company considered the current and expected future economic and market conditions surrounding a novel strain of the coronavirus, referred to as 2019-ncov, COVID-19 coronavirus epidemic, or COVID-19, and determined that the estimate of credit losses was not significantly impacted.

With the exception of the allowance for credit losses, which is reflected as part of selling, general and administrative expense, the provisions for the following customer reserves are reflected as a reduction of revenues in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

Trade accounts receivable, net consists of the following (in thousands):

	December 31, 2020	December 31, 2019
Gross trade accounts receivable:		
Trade accounts receivable	$ 196	$ 262
Royalty accounts receivable	55	45
Other receivable	2,903	496
Less reserves for:		
Commercial rebates	(4)	(7)
Discounts and allowances	(1)	(2)
Total trade accounts receivable, net	$ 3,149	$ 794

For the years ended December 31, 2020 and 2019, the Company recorded the following adjustments to gross product sales (in thousands):

	Year Ended December 31,	
	2020	2019
Gross product sales	$ 2,510	$ 1,242
Less provisions for:		
Chargebacks	(6)	—
Government and managed care rebates	(155)	(51)
Commercial rebates	(56)	(46)
Product returns	(53)	(51)
Discounts and allowances	(14)	(12)
Advertising and promotions	(284)	(643)
Net product sales	$ 1,942	$ 439

For the years ended December 31, 2020 and 2019, the activity in the Company's allowance for customer deductions against trade accounts receivable is as follows (in thousands):

	Commercial Rebates	Discounts and Allowances	Total
Balance at December 31, 2018	$ —	$ —	$ —
Provision	46	12	58
Charges processed	(39)	(10)	(49)
Balance at December 31, 2019	$ 7	$ 2	$ 9
Provision	56	14	70
Charges processed	(59)	(15)	(74)
Balance at December 31, 2020	$ 4	$ 1	$ 5

Note 7. Inventories

The components of inventories, net of allowances, are as follows (in thousands):

	December 31, 2020	December 31, 2019
Finished goods	$ 1,593	$ 119
Work in process	90	-
Raw materials and supplies	148	276
	$ 1,831	$ 395

Note 8. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following (in thousands):

	Year Ended	
	December 31, 2020	December 31, 2019
Leasehold improvements	$ 2,214	$ 2,133
Machinery	1,045	1,306
Furniture, fixtures and equipment	28	49
Computer hardware and software	1,209	347
	4,496	3,835
Accumulated depreciation	(2,131)	(1,787)
	2,365	2,048
Construction in progress	26	1
	$ 2,391	$ 2,049

Depreciation expense was $1.9 million and $1.3 million for the years ended December 31, 2020 and 2019, respectively. There is less than $0.1 million of remaining construction in progress expenditures to substantially complete the projects.

Note 9. 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. The assessment of goodwill has been based on the historical goodwill for the continuing and discontinued operations of the business on a combined basis which was $100.9 million as of December 31, 2020 and 2019. Goodwill is net of accumulated impairment charges of $86.3 million at December 31, 2020 and 2019. The following table sets forth the carrying value of goodwill as of December 31, 2019 and 2020, respectively (in thousands).

	Goodwill
January 1, 2019	$ 55,847
Impairments	—
December 31, 2019	55,847
Impairments	—
December 31, 2020	$ 55,847

The following tables sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of December 31, 2020 and 2019, for those assets that are not already fully amortized (in thousands):

	December 31, 2020				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
IPR&D	$ 64,000	$ —	$ (28,910)	$ 35,090	Indefinite Lived
	$ 64,000	$ —	$ (28,910)	$ 35,090	

	December 31, 2019				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Product Rights	$ 19,700	$ (1,970)	$ (17,730)	$ —	—
IPR&D	$ 64,000	$ —	$ —	$ 64,000	Indefinite Lived
	$ 83,700	$ (1,970)	$ (17,730)	$ 64,000	

Changes in intangible assets during the years ended December 31, 2019 and 2020, were as follows (in thousands):

	Intangible Assets	Total
January 1, 2019	$ 83,700	$ 83,700
Amortization	(1,970)	(1,970)
Impairments	(17,730)	(17,730)
December 31, 2019	64,000	64,000
Amortization	—	—
Impairments	(28,910)	(28,910)
December 31, 2020	$ 35,090	$ 35,090

As part of the Company's goodwill and intangible asset impairment assessments performed on the annual assessment date, when indicators of impairment are identified and when IPR&D assets are put into service, when a qualitative assessment is performed, the Company estimates the fair values of the intangible assets using an income approach that utilizes a discounted cash flow model, or, where appropriate, a market approach. The discounted cash flow models are

dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amounts, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. As of October 1, 2020, the Company performed a qualitative assessment for goodwill and for the IPR&D assets and concluded that the assets were not impaired. The discount rates applied to the estimated cash flows for the Company's 2019 annual goodwill and indefinite-lived intangible assets impairment test was 16.5%, based on the overall risk associated with the particular assets and other market factors. Indefinite-lived intangible assets classified as in-process research and development, or IPRD, are subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development. The POS factor applied to the IPRD asset on a subsequent assessment as of December 31, 2020 was 69.6% and the discount rate was 9.5%. The Company believes the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments, if any, are recorded to Impairment of intangible assets in the Consolidated Statements of Operations and Comprehensive Loss.

Impairments of intangible assets for the year-ended December 31, 2020 was $28.9 million consisting of the write-down to fair value for arbaclofen ER, an indefinite-lived In-Process R&D asset, which resulted in an impairment charge of $28.9 million due to a delay in the anticipated commercialization date of the product, if approved.

During 2019, we recognized an impairment of finite-lived intangible assets of $17.7 million, consisting primarily of the write-off of Osmolex ER. Osmolex ER was impaired due to underperforming revenue expectations subsequent to the launch of the product.

Amortization expense was $0.0 million and $2.0 million for the years ended December 31, 2020 and 2019, respectively and is recorded to Cost of goods sold (inclusive of amortization of intangibles) in the Consolidated Statements of Operations and Comprehensive Loss.

Note 10. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Accrued chargeback	$ 1,376	$ 1,265
Accrued product returns	88	55
Accrued royalties	29	—
Accrued compensation	6,232	7,632
Accrued government and managed care rebates	46	30
Accrued research and development	721	2,630
Accrued expenses and other liabilities	8,455	5,860
Customer coupons	4	165
Total	$ 16,951	$ 17,637

Note 11. Leases

The Company leases office space in Bridgewater, New Jersey for its principal offices under two non-cancelable leases that expire in July 2022 and November 2023 , in addition to office and warehouse space in various domestic and international locations. The Company also leases certain vehicles under operating leases. As of December 31, 2020, the Company's operating leases had remaining lease terms ranging from 0.99 years to 3.00 years.

We assess whether an arrangement is a lease or contains a lease at inception. For arrangements considered leases or that contain a lease that is accounted for separately, we determine the classification and initial measurement of the right-of-

use asset and lease liability at the lease commencement date, which is the date that the underlying asset becomes available for use. The Company has elected to account for non-lease components associated with our leases and lease components as a single lease component.

The Company recognizes a right-of use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments are calculated using either the implicit interest rate in the lease or an incremental borrowing rate.

Our lease assets and liabilities were classified as follows on our Condensed Consolidated Balance Sheet at December 31, 2020 (in thousands):

Leases	Classification	Balance at December 31, 2020	Balance at December 31, 2019
Assets			
Operating	Operating Lease Assets	$ 1,953	$ 3,916
Finance	Property, plant and equipment, net	22	47
Total leased assets		$ 1,975	$ 3,963
Liabilities			
Current			
Operating	Current portion of lease liability	$ 1,199	$ 1,803
Finance	Current portion of obligations under finance leases	20	26
Non-current			
Operating	Long-term portion of lease liability	871	2,293
Finance	Long-term portion of obligations under finance leases	—	20
Total lease liabilities		$ 2,090	$ 4,142

The Company recognizes lease expense on a straight-line basis over the lease term. The components of lease cost are as follows (in thousands):

Lease Cost	Classification	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating lease cost	SG&A expenses	$ 1,471	$ 1,891
	R&D expenses	104	139
	Cost of goods sold	55	—
Finance lease cost			
Amortization of leased assets	Depreciation and amortization	26	26
Interest on lease liabilities	Interest expense	1	1
Total lease cost		$ 1,657	$ 2,057

The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the leases as follows (in thousands):

Years ending December 31	Operating Leases
2021	$ 1,288
2022	647
2023	261
Total lease payments	2,196
Less: interest	126
Present value of lease payments	$ 2,070

The Company has future minimum lease payments required under the finance leases of less than $0.1 million less interest expense of less than $0.1 million for total present value lease payments of less than $0.1 million for the years ended December 31, 2021 through December 31, 2022.

The weighted-average remaining lease term and the weighted-average discount rate of our leases were as follows (in thousands):

Lease Term and Discount Rate	December 31, 2020	December 31, 2019
Weighted average remaining lease term (years)		
Operating leases	1.96	2.55
Finance leases	1.07	1.27
Weighted average discount rate		
Operating leases	5.37 %	5.01 %
Finance leases	1.67 %	1.57 %

Other Information	December 31, 2020	December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ (1,630)	$ (2,030)
Operating cash flows for finance leases	(1)	(1)
Financing cash flows for finance leases	(26)	(26)

For the years ended December 31, 2020 and 2019, the Company recorded $0.2 million and $1.4 million, respectively, of leased assets obtained in exchange for new operating lease liabilities and $0.0 million and less than $0.1 million, respectively, of leased assets obtained in exchange for new finance lease liabilities. During the years ended December 31, 2020 and 2019, the Company disposed of $0.6 million and $0.4 million, respectively, of leased assets.

Note 12. Financing Arrangements

The composition of the Company’s debt and financing obligations are as follows (in thousands):

	December 31, 2020	December 31, 2019
CIT Bank, N.A. Term Loan, net of deferred financing costs of $1.8 million and $3.4 million as of December 31, 2020 and December 31, 2019, respectively	$ 219,525	$ 267,950
Total debt	219,525	267,950
Less: current portion	—	—
Long-term debt	$ 219,525	$ 267,950

Term Loan

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a $160.0 million Term Loan (the "Term Loan") pursuant to a Credit Agreement dated February 3, 2016 (as amended, supplemented or otherwise modified, the "Term Loan Agreement") between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent. The Term Loan is secured by certain assets of the Company, excluding certain intangibles and foreign property.

The Term Loan Agreement required quarterly principal repayments equal to 0.625% of the initial aggregate Term Loan amount beginning on the last day of the first full fiscal quarter following the closing of the Term Loan Agreement, with final payment of the remaining principal balance due at maturity six years from the date of closing of the Term Loan Agreement. At the Company's election, interest accrues on a Prime Rate/Federal Funds Effective Rate ("ABR Loan") or a LIBOR ("LIBOR Loan") rate, plus a margin of 4.00% for ABR Loan, and 5.00% for LIBOR Loan.

On November 10, 2016, the Company amended the Term Loan Agreement (the "First Amendment to the Term Loan Agreement") in conjunction with the reacquisition of venlafaxine distribution rights. Pursuant to the First Amendment to the Term Loan Agreement, CIT Bank and certain other lenders agreed to make available to the Company, an Incremental Term Loan in the aggregate principal amount of $117,500,000, which was added to the Term Loan; there were no other modifications to the Term Loan Agreement.

On April 28, 2017, the Company amended the Term Loan Agreement (the "Second Amendment to the Term Loan Agreement"), in which the due date of the Company's annual financial statements was modified for the first fiscal year after the closing of the Second Amendment to Term Loan Agreement.

On December 21, 2017, the Company amended the Term Loan Agreement (the "Third Amendment to the Term Loan Agreement"). Pursuant to the Third Amendment to the Term Loan Agreement, CIT Bank and certain other lenders agreed to increase the principal amount of the Term Loan to an aggregate principal amount of $327,500,000. Of the aggregate principal amount, $277,500,000 was designated as the Term A Loan and $50,000,000 was designated as the Term B Loan.

On December 11, 2020, the Company amended the Term Loan Agreement (the "Fourth Amendment to the Term Loan Agreement"). Pursuant to the Fourth Amendment to the Term Loan Agreement, the Term Loan Agreement was amended to, among other things, remove a limit on the exercise of the Company’s right to cure a breach of the financial covenant under the Term Loan Agreement and providing that any proceeds received by the company as a result of the exercise of such cure right will be applied to repay term loans under the Term Loan Agreement.

The Term Loan Agreement requires quarterly principal repayments to 0.6925% of the original principal amount of the Term A Loan and in the case of the Term B Loan 0.25% of the original principal amount of the Term B Loan, with final payment of the remaining principal balance due at maturity five years from the date of closing of the Term Loan Agreement.

At the Company's election, for the Term A Loan, interest accrues on a Prime Rate/Federal Funds Effective Rate ("ABR Loan") or a LIBOR ("LIBOR Loan") rate in which the applicable rate per annum set forth below under the caption "ABR Spread" or "LIBOR Rate Spread," based upon the Total Leverage Ratio (as defined in the Term Loan Agreement) as of last day of the most recently ended fiscal quarter is as follows:

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

For Term B Loan, interest accrues with respect to any ABR Loan, 3.25% per annum, and with respect to any LIBOR Rate Loan, 4.25% per annum. As of December 31, 2020 and 2019, the interest rates were 4.75% and 5.79% for Term A Loan and 5.25% and 6.29% for Term B Loan, respectively.

The Term Loan Agreement contains covenants that require the Company to deliver quarterly and annual financial statements along with certain supplementary financial information and schedules and ratios. The Term Loan Agreement also contains covenants that limit the ability of the Company to, among other things: incur additional indebtedness; incur liens; make investments; make payments on indebtedness; dispose of assets; enter into merger transactions; and make distributions. In addition, the Company shall not permit the total leverage ratio to be greater than 4.75:1.00 until March 31, 2020 at which time the total leverage ratio remains constant at a required 4.50:1.00. The total leverage ratio is the ratio, as of any date of determination, of (a) consolidated total debt, net of unrestricted cash and cash equivalents as of such date to (b) consolidated adjusted earnings before income taxes, depreciation and amortization ("Consolidated EBITDA") for the test period then most recently ended for which financial statements have been delivered. Also, the Company will not permit the fixed charge coverage ratio to fall below 1.25:1.0 beginning on March 31, 2018 through the final maturity date. The fixed charge coverage ratio, as of the date of determination, is the ratio of (x) Consolidated EBITDA net of capital expenditures and cash taxes paid to (y) interest payments, scheduled principal payments, restricted payments and management fees paid to related parties. The Company obtained a waiver from CIT Bank in regard to its non-compliance of its covenant to deliver annual financial statements by April 2, 2018. The Company did not incur a waiver fee as a condition to the waiver. The Company was in compliance with all covenants of the Term Loan Agreement as of December 31, 2020 and 2019.

As a result, of payments made in 2018, as of both December 31, 2020 and 2019, there are no remaining scheduled installments of principal due in respect of the Term Loans until the final maturity date.

During the year ended December 31, 2020, the Company prepaid $50.0 million in aggregate of the outstanding principal amount. The prepayments consisted of $42.3 million of Term A Loan outstanding principal and $7.7 million of Term B Loan outstanding principal. As required by the Third Amendment, the prepayments were made on a pro rata basis between the Term A Loan and the Term B Loan. The Company intends to continue to make interest payments accrued on the outstanding remaining balance through the date of maturity.

In accordance with ASC 470, when debt is prepaid within its contractual terms and the terms of the remaining debt are not modified, the prepayment should be treated as a partial extinguishment rather than a modification. This conclusion is reached without regard to consideration of the 10% cash flow test since no change to terms of the original debt instrument was modified in connection with the prepayment. The Third Agreement allows for partial prepayments without creating changes to the terms of Term Loan A or Term Loan B.

The Company incurred debt issuance costs associated with the Third Amendment. Pursuant to ASC 835-30-35-2, with respect to a note for which the imputation of interest is required, the difference between the present value and the face amount shall be treated as a discount or premium and amortized as interest expense or income over the life of the note in such a way as to result in a constant rate of interest when applied to the amount outstanding at the beginning of any given period. As such, in accordance with ASC 835-30-35-2, the Company deferred and amortized the debt issuance costs amortized over the length of the Term Loan using the effective interest method.

As a result of the partial extinguishment, the Company has elected, as an accounting policy in accordance with ASC 470-50-40-2, to write off a proportionate amount of the unamortized fees at the time that the financing was partially settled in accordance with the terms of the Third Amendment. The unamortized debt issuance costs are allocated between the remaining original loan balance and the portion of the loan paid down on a pro-rata basis. The Company wrote off $0.5 million in debt issuance costs relating to the prepayment which occurred during the year ended December 31, 2020, and recorded the expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

Revolving Facility

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a Revolving Facility in an aggregate amount of $30.0 million (the "Revolving Facility") pursuant to a Credit Agreement dated February 3, 2016 between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent, as discussed above. The Company incurred closing costs associated with the Revolving Facility in the amount of $1.1 million, which were deferred and amortized over the length of the Revolving Facility on a straight-line basis.

On December 21, 2017, the Company amended the Revolving Facility (the "Amended Revolving Facility"). Pursuant to the Amended Revolving Facility, CIT Bank and certain other lenders agreed to increase the revolving credit commitments up to $50.0 million. The Company accounted for the Amended Revolving Facility as a modification of debt in accordance with ASC 470-50, Debt — Modifications and Extinguishments and ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line of Credit Arrangements. Lender fees incurred in the amount of $0.4 million were deferred and are amortized over the length of the Amended Revolving Facility on a straight-line basis.

The total amount available under the Revolving Facility includes a Swingline Loan and Letter of Credit subfacility, respectively, in an aggregate principal amount at any time outstanding not to exceed the lesser of (x) in the case of each of the Swingline Loan and Letter of Credit, $5.0 million and (y) the total revolving commitment, based on certain terms and conditions of the Credit Agreement.

The Company will be required to repay the Revolving Facility upon its expiration five years from issuance, subject to permitted extension, and will pay interest on the outstanding balance monthly based, at the Company's election, on an adjusted prime/federal funds rate ("ABR") or an adjusted LIBOR ("LIBOR"), in which the applicable rate per annum set forth below under the caption "ABR Spread" or "LIBOR Rate Spread," based upon the Total Leverage Ratio (as defined in the Credit Agreement) as of last day of the most recently ended fiscal quarter. Additionally, the Company will pay a Commitment Fee based on the average daily unused revolving credit commitment. The LIBOR Rate Margin, the ABR Margin and Commitment Fee are as follows:

Total Leverage Ratio	LIBOR Rate Margin	ABR Margin	Commitment Fee
Category 1 Greater than 2.00 to 1.00	3.75 %	2.75 %	0.50 %
Category 2 Equal to or less than 2.00 to 1.00	3.25 %	2.25 %	0.38 %

At December 31, 2020 and 2019, there were no outstanding borrowings or outstanding letters of credit. Availability under the Revolving Facility as of December 31, 2020, was $50.0 million. The Revolving Facility was reduced to $25 million and fully terminated on August 27, 2021 pursuant to the Fifth Amendment to the Term Loan Agreement.

Note 13. Concentrations and Credit Risk

The Company does not have significant concentrations of credit risk with its customers.

Purchasing

The Company does not have significant purchase agreements with third parties.

Sales by Product

For the years ended December 31, 2020 and 2019, one product accounted for 73% and 100%, respectively, of the Company's total gross product sales.

Royalty Sales

The Company does not have significant concentrations of royalty sales.

Note 14. Shareholders' Equity

Osmotica Pharmaceuticals plc 2018 Equity Incentive Plan

Prior to the IPO, the Company adopted the 2018 Incentive Plan (the "2018 Plan") which became effective upon our IPO and allows for the issuance of up to 4,100,000 ordinary shares of the Company ("Shares") in satisfaction of awards under the 2018 Plan. The 2018 Plan provides for the grant of share options, SARs, restricted and unrestricted share and share units, performance awards, and other awards that are convertible into or otherwise based on the Company's shares to employees and non-employee directors, consultants and advisors to the Company. The Company's compensation committee shall determine the time at which an award vests or becomes exercisable. In connection with the IPO, the Company granted share options under the 2018 Plan that will vest on the fourth anniversary of the grant date, subject to the employee's continued employment through such vesting date.

Osmotica Holdings S.C.Sp. 2016 Equity Incentive Plan

Effective February 3, 2016, Osmotica Holdings S.C.Sp. adopted the 2016 Equity Incentive Plan (the "2016 Plan") which allows for the issuance of up to 75,000 Units in Osmotica Holdings S.C.Sp. Options to purchase common units granted under the 2016 Plan vest and become exercisable in whole or in part, in accordance with vesting conditions set by the Company's board of directors. Each option award had a maximum term of ten years from the date of grant. The option awards granted under the 2016 Plan were made up of two components: Time Awards and Performance Awards. The Time Awards vested 25% annually from original grant date, subject to continuous employment on each vesting date. The vesting of the Performance awards was subject to performance criteria, requiring the majority investors in the Company to receive (on a cumulative basis) aggregate net proceeds exceeding certain return on investment targets. The Time Awards and Performance Awards contained a sales restriction in the form of a liquidity event and subsequent disposal of common units by the Major Limited Partners (as defined in the 2016 Plan) before the employee was able to sell vested and exercised common units and were required to remain employed to avoid Company's call option on such common units at a lower of cost or fair market value.

Amended and Restated Osmotica Pharmaceuticals plc. 2016 Equity Incentive Plan

On August 14, 2018, the board of directors amended and restated the 2016 Plan in connection with the Reorganization. The Amended and Restated 2016 Equity Incentive Plan (the "Amended 2016 Plan") became effective upon our IPO which closed on October 22, 2018. In connection with the Reorganization, options to purchase common units of Osmotica Holdings S.C.Sp. were converted into options to purchase shares of the Company and existing sales restriction was removed. In connection with the IPO, the number of shares issuable pursuant to the Amended 2016 Plan and the corresponding exercise prices of options were adjusted to reflect a stock split initiated prior to the IPO. Additionally, effective upon the IPO, the Amended 2016 Plan modified the terms of Performance Awards previously issued under the 2016 Plan by converting these awards to time based awards vesting in equal annual installments on the first four anniversaries of the IPO, subject to continuous employment. There were 3,015,572 ordinary shares issuable upon exercise of options issued and outstanding as of December 31, 2018 under the Amended 2016 Plan. Prior to the modification date, there was no share based compensation recognized for the Performance Awards due to a performance condition based upon the majority investors in the Company receiving aggregate net proceeds exceeding certain return on investment targets.

Ordinary Share Repurchase Program

In September 2019, the Company's board of directors authorized the repurchase of up to 5,251,892 ordinary shares pursuant to a share repurchase program. Purchases under the ordinary share repurchase program can be made on the open market or in privately negotiated transactions, with the size and timing of these purchases based on a number of factors, including the price of our ordinary shares, our business and market conditions. The Company has retired

ordinary shares acquired under the repurchase program. For the years ended December 31, 2020 and 2019, the Company repurchased 1,435,725 ordinary shares for an aggregate of $8.1 million and 673,182 ordinary shares for an aggregate of $2.8 million, respectively.

2019 Employee Share Purchase Plan

In September 2019, the Company's board of directors adopted and approved, the Employee Share Purchase Plan (the "ESPP"). The ESPP allows each eligible employee who is participating in the plan to purchase shares by authorizing payroll deductions of up to $2,000 per payroll period. Unless the participating employee has previously withdrawn from the offering, accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85 percent of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than $25,000 worth of ordinary shares, valued at the start of the purchase period, under the ESPP in any calendar year. There is no minimum holding period associated with shares purchased pursuant to this plan. An employee's purchase rights terminate immediately upon termination of employment.

The Company accounts for employee stock purchases made under its ESPP using the estimate grant date fair value of accounting in accordance with ASC 718, Stock Compensation. The purchase price discount and the look-back feature cause the ESPP to be compensatory and the Company to recognize compensation expense. The compensation cost is recognized on a straight-line basis over the requisite service period. The Company recognized $113,860 and $31,619 of compensation expense for the years ended December 31, 2020 and 2019, respectively. The Company values ESPP shares using the Black-Scholes model.

As of December 31, 2020 and 2019, there were no unrecognized ordinary share compensation expense related to the ESPP. There were 51,905 ordinary shares issued under the ESPP during the year ended December 31, 2020. There were no ordinary shares issued under the ESPP during the year ended December 31, 2019. On January 4, 2021, the Company issued 39,321 ordinary shares to the employees who participated in the ESPP during the offering period ended December 31, 2020.

Share-based Compensation

The compensation cost that has been charged against income for all incentive plans was $3.9 million for the year ended December 31, 2020 and $4.0 million for the year ended December 31, 2019. The conversion of the Performance Awards issued under the 2016 Plan to Time Awards upon IPO under the Amended 2016 Plan was accounted for as a

modification where the fair value of such awards determined on a modification date, or the IPO date is being recognized over their remaining vesting period.

Share-Based Award Activity

The following tables of share based activity are based on the historical activity of the continuing and discontinuing operaations of the Company on a combined basis. A summary of option activity granted under the 2016 Plan and the Amended 2016 Plan as of December 31, 2020, and changes during the year then ended is presented below:

2016 Equity Incentive Plan	**Number of Shares Time**	**Weighted Average Exercise Price**	**Weighted Average Contractual Term**
Outstanding at January 1, 2019	3,015,572	$ 14.96	7.5 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(55,686)	$ 14.95	
Outstanding at December 31, 2019	2,959,886	$ 14.96	6.4 years
Vested Options at December 31, 2019	1,459,005	$ 14.96	6.4 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(132,786)	$ 15.21	
Outstanding at December 31, 2020	2,827,100	$ 14.95	5.4 years
Vested Options at December 31, 2020	2,099,950	$ 14.95	5.4 years

There were no options granted during 2020 and 2019, respectively, under the 2016 Plan. The intrinsic value of options under the 2016 Plan outstanding at December 31, 2020 and 2019, respectively, was $0. The fair value of options vested under the 2016 Plan during the years ended December 31, 2020 and 2019 were $8,832 and $6,431, respectively.

A summary of option activity granted under the 2018 Plan as of December 31, 2020, and changes during the year then ended is presented below:

2018 Equity Incentive Plan	**Number of Shares Time**	**Weighted Average Exercise Price**	**Weighted Average Contractual Term**
Outstanding at January 1, 2019	178,600	$ 7.00	9.8 years
Granted	—	—	
Exercised	—	—	
Expired / Forfeited	(44,400)	$ 7.00	
Outstanding at December 31, 2019	134,200	$ 7.00	8.7 years
Vested Options at December 31, 2019	—	0	
Granted			
Exercised			
Expired / Forfeited	(37,800)	$ 7.00	
Outstanding at December 31, 2020	96,400	$ 7.00	
Vested Options at December 31, 2020	—	—	7.7 years

There were no options granted during 2020 and 2019, respectively.

The estimated fair value of the options is expensed over the requisite service period, which is generally the vesting period on a graded vesting basis. As of December 31, 2020 and 2019, there was $0.8 million and $2.2 million of total

unrecognized compensation cost related to nonvested options granted under the Incentive Plans. That cost is expected to be recognized over a weighted-average period of 1.3 years and 1.5 years, respectively.

The fair value of option awards is estimated using the Black-Scholes option-pricing model. Exercise price of each award is generally not less than the per share fair value in effect as of that award date. The determination of fair value using the Black-Scholes model is affected by the Company's share fair value as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, risk-free interest rate and projected employee share option exercise behaviors. There were no options granted during 2020 and 2019, respectively.

For all periods prior to the IPO, our Board of Directors has determined the fair value of the common unit underlying our option with assistance from management and based upon information available at the time of grant. Prior to our IPO, given the absence of a public trading market for our common units, estimating the fair value of our common units was based on the actual operational and financial performance, current business conditions and discounted cash flow projections. The estimated fair value of our common units, prior to our IPO was adjusted for lack of marketability and control existing at the grant date.

Restricted and Performance Stock Units

On May 18, 2020 and May 20, 2020, the Company granted performance stock units ("PSUs") under its existing 2018 Incentive Plan (the "2018 Plan") to certain key employees of the Company that gives holders the potential to receive a certain number of earned PSUs at the end of a pre-determined term. Unless earlier terminated, forfeited, relinquished or expired, the earned PSUs will vest in full on the vesting date, subject to the grantee remaining in continuous employment from the date of grant through the vesting date. The vesting date is the third anniversary from the grant date for the PSUs granted on May 18, 2020 and the fifth anniversary from the grant date for the PSUs granted on May 20, 2020. The number of PSUs that become earned PSUs as of the end of the performance period shall be equal to the number of PSUs multiplied by the applicable percentage based on Stock Price Hurdle attainment, as set forth in the PSU Award Agreement and 2018 Plan. The fair value of these market-based awards is estimated on the date of grant using a Monte Carlo simulation model with the following assumptions:

	Years Ended December 31, 2020
Expected volatility	90 %
Risk-free interest rate	.21% - .24 %
Expected dividend yield	— %
Performance period in years	3.00

The Company estimates its expected volatility by using a combination of historical share price volatilites of similar companies within our industry. The risk-free interest rate assumption is based on observed interest rates for the appropriate term of the Company's options on a grant date.

As of December 31, 2020 total compensation cost not yet recognized related to unvested PSUs $3.2 million which is expected to be recognized over a weighted average period of 3.0 years.

The following table summarizes the information as of December 31, 2020 and activity during 2020 related to our PSUs:

	Number of PSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term (Years)
Outstanding at January 1, 2020	—	$ —	—
PSUs granted	825,997	4.99	—
PSUs vested	—	—	—
PSUs forfeited	(36,198)	4.90	—
Outstanding at December 31, 2020	789,799	$ 4.99	3.01

During 2020 and 2019 we granted restricted stock units, or RSUs, covering an equal number of our ordinary shares to employees and certain directors with a weighted average grant date fair value of $4.46 and $7.19, respectively. The fair value of RSUs are determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized ratably over the vesting period of four years for employees and one to three years for directors. As of December 31, 2020 and 2019 total compensation cost not yet recognized related to unvested RSUs was $8.5 million and $8.0 million which is expected to be recognized over a weighted average period of 2.8 years and 3.2 years, respectively.

The following table summarizes the information as of December 31, 2020 and activity during 2020 related to our RSUs:

	Number of RSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term (Years)
Outstanding at January 1, 2019	—	$ —	—
RSUs granted	1,486,020	7.19	—
RSUs vested	—	—	—
RSUs forfeited	(51,787)	7.18	—
Outstanding at December 31, 2019	1,434,233	$ 7.19	3.20
RSUs granted	976,429	4.46	—
RSUs vested	(300,788)	6.73	—
RSUs forfeited	(118,317)	6.07	—
Outstanding at December 31, 2020	1,991,557	$ 5.99	2.11

2020 Equity Offering

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

On July 16, 2020 we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately $30.6 million after deducting offering expenses. Proceeds from the offering will be used for working capital and general corporate purposes.

Note 15. Earnings (Loss) per Ordinary Share

Basic net income (loss) per ordinary share is computed by dividing net income (loss) by the weighted-average number of shares of ordinary shares outstanding during the period. Diluted net income per ordinary shares is computed by dividing net income by the weighted average number of shares of ordinary shares and potentially dilutive outstanding shares of

ordinary shares during the period to reflect the potential dilution that could occur from ordinary shares issuable through contingent share arrangements, share options and warrants.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares and units outstanding as they would have been anti-dilutive at December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Performance and restricted stock units	2,781,356	1,434,233
Options to purchase ordinary shares	2,923,500	3,093,786
Shares to be purchased through employee stock purchase plan	39,321	29,550

Note 16. Commitments and Contingencies

Contingent Milestone Payments

The Company has entered into strategic business agreements for the development and marketing of finished dosage form pharmaceutical products with various pharmaceutical development companies. Each strategic business agreement includes a future payment schedule for contingent milestone payments and in certain strategic business agreements, minimum royalty payments. The aggregate amount of future potential milestone payments payable in connection with such agreement are currently not material to the Company's financial statements. The Company will be responsible for contingent milestone payments and minimum royalty payments to these strategic business partners based upon the occurrence of future events. Each strategic business agreement defines the triggering event of its future payment schedule, such as meeting product development progress timelines, successful product testing and validation, successful clinical studies, and various U.S. Food and Drug Administration and other regulatory approvals. The aggregate amount of future potential milestone payments are currently not material to our financial statements.

Royalty Obligations

The Company does not have agreements with third parties that require the Company to make minimum royalty payments.

Supply Agreement Obligations

The Company is engaged in various supply agreements with third parties which obligate the Company to purchase various API or finished products at contractual minimum levels. None of these agreements are individually in the aggregate material to the Company. Further, the Company does not believe at this time that any of the purchase obligations represent levels above that of normal business demands.

The Company has no enforceable and legally binding purchase obligations as of December 31, 2020.

Defined Contribution Plan

Vertical/Trigen and Legacy Osmotica both had a defined contribution plan under Section 401(k) of the Internal Revenue Code ("IRC") as of December 31, 2016 pursuant to the Merger (the "Contribution Plans"). The employees of the respective companies are eligible to participate in the Contribution Plans. Participants may contribute amounts through payroll deductions not to exceed IRC limitations. For the year ended December 31, 2016, the Vertical/Trigen Plan provided for nonelective employer contributions equal to 3% of basic compensation. The separate Contribution Plans were merged into one plan effective January 1, 2017. Effective January 1, 2017, the plan provides for employer matching contributions equal to 100% of each employee's elective deferrals up to 3% of base salary, plus 50% of each employee's elective deferrals between 3% and 5% of base salary. For the years ended December 31, 2020 and 2019, the Company recognized expenses related to its contributions under the Plan of $0.5 million and $1.3 million, respectively.

Legal Proceedings

The Company is a party in legal proceedings and potential claims arising from time to time in the ordinary course of its business. The amount, if any, of ultimate liability with respect to such matters cannot be determined. Despite the inherent uncertainties of litigation, management of the Company believes that the ultimate disposition of such proceedings and exposures will not have a material adverse impact on the financial condition, results of operations, or cash flows of the Company.

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

Additionally, in connection with the settlement and the sale of the global rights to Osmolex ER, the parties entered into a supply agreement pursuant to which the Company agreed to supply Adamas with amantadine extended release tablets for a six-year term, subject to possible two-year extensions and customary closing conditions.

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

Note 17. 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 from continuing operations are as follows (in thousands):

	December 31, 2020	December 31, 2019
Loss before income taxes		
U.S. operations	$ (75,325)	$ (85,954)
Non-U.S. operations	(19,470)	(46,823)
Total loss before income taxes	(94,795)	(132,777)
Current tax (benefit) provision		
Federal	(4,145)	(16,970)
State	232	(592)
Foreign	80	(2,849)
Total current tax (benefit) expenses	(3,833)	(20,411)
Deferred tax benefit		
Federal	(1,660)	(5,785)
State	(190)	(719)
Foreign	(99)	689
Total deferred tax benefit	(1,949)	(5,815)
Total benefit for income taxes	$ (5,782)	$ (26,226)

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate from continuing operations for the years ended December 31, 2020 and 2019 respectively are as follows:

	December 31, 2020	December 31, 2019
Federal tax at 21% statutory rate	21.00 %	21.00 %
State and local income taxes, net of federal benefit	1.15 %	2.28 %
Differences in tax effects on foreign income	(3.28)%	(4.43)%
Federal tax credits	1.20 %	1.32 %
Uncertain tax positions	0.83 %	0.24 %
NOL carryback rate differential	3.46 %	0.00 %
Tax audit adjustment	(3.26)%	0.00 %
Change in valuation allowance	(13.87)%	(1.39)%
Permanent adjustments	(0.6)%	0.21 %
Other	(0.50)%	0.48 %
Effective tax rate	6.13 %	19.71 %

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) from continuing operations at December 31, 2020 and 2019 respectively are as follows (in thousands):

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Accounts receivable	$ —	$ 31
Accrued expenses	5,921	9,535
Inventory	295	243
Investment in partnership	2,393	8,696
Net operating losses	1,285	2,627
Operating lease liabilities	657	1,121
Tax credits	6,486	3,249
Share compensation	1,816	1,399
Intangible assets	19,082	—
Other	3,327	1,685
Less: valuation allowance	(27,811)	(21,216)
Deferred tax liabilities:		
Prepaid expenses	(658)	(689)
Property plant & equipment	(3,261)	(3,252)
Operating lease assets	(9,254)	(3,814)
Other	(623)	(1,115)
Total deferred income taxes	$ (345)	$ (1,500)

Included in the deferred tax balances above is a net deferred tax asset of $14.9 million and deferred tax liability of $4.6 million, respectively for 2020 and 2019 related to the assets and liabilities in Vertical/Trigen Holdings, LLC, which is a partnership for Federal income tax purposes. The Company owns in aggregate 100% of Vertical/Trigen Holdings, LLC and the assets and liabilities of this entity are included in the consolidated financial statements of the Company.

As of December 31, 2020 and 2019, the Company had a federal and state net operating loss carryover of $29.1 million and $2.2 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of $3.8 million and $9.9 million, respectively which will begin to expire in 2022. At December 31, 2020 and 2019, the Company had total tax credit carryovers of approximately $6.7 million and $4.6 million primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers begin to expire in 2035. The Company assesses the realizability of the deferred tax assets at each balance sheet date based on actual and forecasted operating results in order to determine the proper amount, if any, required for a valuation allowance. As of December 31, 2020 and 2019, the Company maintains valuation allowances on deferred tax assets applicable to entities in the United States and foreign jurisdictions for which separate income tax returns are filed, where realization of the related deferred tax assets from future profitable operations is not reasonably assured. In 2020, the valuation allowance increased by $6.6 million.

The Coronavirus Aid Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020 in the United States. The CARES Act and related notices include several significant provisions, including delaying certain payroll tax payments, mandatory transition tax payments under the Tax Cuts and Jobs Act, and estimated income tax payments that we expect to defer to future periods. The Cares Act provides a five year carryback for losses generated in 2018-2020, The Company incurred losses in the current period that will be carried back to the earliest year, 2015. The loss generated in 2020 will be carried back to a tax year with a higher tax rate providing a benefit of $3.2 million. The impact to the Company’s effective tax rate is 3.8%. The Cares Act made the business interest limitation less restrictive in that it increased the deduction limit for business interest to 50% of adjusted taxable income as well as allowing taxpayers to elect to utilize 2019 adjusted taxable income when computing the limitation in 2020. The Company utilized this clause in the CARES ACT when computing the current period income tax benefit.

The Company files income tax returns in U.S. federal, state and certain international jurisdictions. For federal and certain state income tax purposes, the Company's 2015 through 2018 tax years remain open for examination by the tax

authorities under the normal statute of limitations. For certain international income tax purposes, the Company's 2015 through 2019 tax years remain open for examination by the tax authorities under the normal statute of limitations.

Two of the Company’s subsidiaries, Osmotica Pharmaceutical Corp. and Valkyrie Group Holding Inc., finalized audits by the Internal Revenue Service for tax years 2016 and 2017. The Company agreed to an IRS adjustments and correspondingly recorded tax expense of $1.9 million which includes $1.4 million of income tax $0.5 million of interest and penalty expense.

No provision is made for foreign withholding or income taxes associated with the cumulative undistributed earnings of the foreign subsidiaries. Any future foreign withholding or income taxes associated with the undistributed earnings are not anticipated to be material.

A reconciliation was completed of the beginning and ending amounts of unrecognized tax benefits, excluding accrued interest, for December 31, 2020 and 2019. It is not anticipated that the amount of unrecognized tax benefits will materially change in the next 12 months. If recognized, the total amount of unrecognized benefits of $0.2 million would an immaterial impact on the effective tax rate.

	December 31, 2020	December 31, 2019
Unrecognized tax benefits beginning balance	$ 2,677	$ 2,218
Additions related to current period tax positions	171	459
Releases related to prior period tax positions	(2,677)	—
Unrecognized tax benefits ending balance	$ 171	$ 2,677

The Company classifies interest expense related to unrecognized tax benefits as components of the tax provision for income taxes. Interest and penalties recognized in the consolidated income statement as of December 31, 2020 resulted in an immaterial amount of interest and penalties as of December 31, 2020 and in a decrease of $0.1 million as of December 31, 2019. As of December 31, 2020 and 2019 the Company has recorded accrued interest of an immaterial amount and $0.2 million, respectively. The current year release of unrecognized tax benefits is due to an accounting method change which eliminated the need for an uncertain tax position.

Note 18. Related Parties

On August 22, 2018, the Company entered into a Master Service Agreement with United Biosource, LLC or UBC, an Avista portfolio company, for prescription processing and patient access services. In November 2018, the Company and UBC entered into a Statement of Work for services through the end of 2019 valued at approximately $2.4 million. During 2019, we amended the initial Statement of Work to add approximately $275,000 of additional services for 2019. On January 1, 2020, we entered into an additional Statement of Work for services during 2020 valued at approximately $1.7 million. The Company had accrued $0.2 million of liabilities related to this agreement as of December 31, 2020 and had recognized $1.0 million of related expense for the year ended December 31, 2020. The Company had accrued less than $0.1 million of liabilities related to this agreement as of December 31, 2019 and had recognized $1.9 million of related expense for the year ended December 31, 2019.