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): **December 20, 2019**

Osmotica Pharmaceuticals plc
(Exact name of registrant as specified in its charter)

Ireland	**001-38709**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

400 Crossing Boulevard Bridgewater, NJ	**08807**
(Address of principal executive offices)	(Zip Code)

(Registrant's telephone number, including area code): (908) 809-1300

Not Applicable
(Former name or former address, if changed since last report)

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:

☐ 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(s)	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 in the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 filed by Osmotica Pharmaceuticals plc (the "Company"), in connection with the issuance of the unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2019 and 2018, the Company determined that a revision was required to correct misstatements associated with the tax treatment of certain intercompany transactions at the time of the business combination between Osmotica Holdings Limited and subsidiaries and Vertical/Trigen Holdings LLC, which occurred on February 3, 2016. Additionally, revisions were necessary to correct misstatements related to uncertain tax provisions and prepaid taxes and certain other previously identified immaterial misstatements.

To correct this misstatement, the Company retrospectively adjusted its consolidated financial statements for the fiscal year ended December 31, 2016, which adjustments also resulted in further adjustments in its consolidated financial statements for the years ended December 31, 2018 and 2017. The Company is attaching to this Current Report on Form 8-K as Exhibit 99.1 the Company's retrospectively adjusted Management's Discussion and Analysis of Financial Condition and Results of Operations and audited consolidated financial statements for the fiscal years ended December 31, 2018 and 2017, as well as the related notes, together with the report of the Company's independent registered public accounting firm thereon.

Except for the retrospective adjustments referred to above, this Current Report on Form 8-K, and the disclosures contained herein, do not reflect events occurring subsequent to the filing of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 that was filed with the Securities and Exchange Commission (the "SEC") on March 28, 2019, and do not modify or update the disclosures therein in any way, other than described above and set forth in Exhibit 99.1 attached hereto. For information on developments regarding the Company since the filing of its Annual Report on Form 10-K for the fiscal year ended December 31, 2018, please refer to the Company's reports filed with the SEC since then, including the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
23.1	Consent of BDO USA, LLP
99.1	Management's Discussion and Analysis of Financial Condition and Results of Operations and Audited Financial Statements as of and for the years ended December 31, 2018 and 2017 and Report of the Company's Independent Registered Public Accounting Firm
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

OSMOTICA PHARMACEUTICALS PLC

Date: December 20, 2019

By: /s/ Andrew Einhorn
Andrew Einhorn
Chief Financial Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Osmotica Pharmaceuticals plc
Dublin, Ireland

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-228045) of Osmotica Pharmaceuticals plc, of our report dated March 27, 2019 (except for Note 1, as to which the date is December 20, 2019), relating to the consolidated financial statements, which appears in this Form 8-K.

/s/ BDO USA, LLP
Woodbridge, New Jersey

December 20, 2019

Exhibit 99.1

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. In 2017, we generated total revenues across our existing portfolio of promoted specialty neurology and women's health products, as well as our non-promoted products, which are primarily complex formulations of generic drugs. In 2018 we received regulatory approval from the U.S. Food and Drug Administration, or the FDA, for M-72 (methylphenidate hydrochloride extended-release tablets, 72 mg) for the treatment of attention deficit hyperactivity disorder, or ADHD in patients aged 13 to 65, as well as Osmolex ER (amantadine extended-release tablets) for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions, which are involuntary muscle movements caused by certain medications, in adults. We launched M-72 in the second quarter of 2018 and launched Osmolex ER in January 2019. In addition, we have a late-stage development pipeline highlighted by two new drug application or NDAs, candidates in Phase III clinical trials: Ontinua ER (arbaclofen extended-release tablets) for muscle spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid. Many of our products use our proprietary osmotic-release drug delivery system, Osmodex, which we believe offers advantages over alternative extended-release, or ER, technologies.

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

We are focused on progressing our pipeline, which is highlighted by two Phase III candidates under clinical development — arbaclofen ER and RVL-1201. We developed arbaclofen ER using our proprietary Osmodex drug delivery system and believe this formulation will provide an efficacious and safe treatment for spasticity in multiple sclerosis patients. We recently received topline data from our second Phase III clinical trial of arbaclofen in multiple sclerosis patients with spasticity. The initial review of the preliminary topline data indicates that both doses of arbaclofen demonstrated superiority to placebo in one of the two co-primary endpoints. In addition, there were numerous signals of efficacy and the safety profile was in line with previously reported results. Based on the efficacy and safety exhibited for arbaclofen, the Company remains encouraged and plans to proceed with its clinical and regulatory strategy to submit an NDA. At this time, however, it is unclear whether or not the Company will be required to conduct an additional clinical trial which may delay our submission past 2019. If we are required to conduct any such additional clinical trial, our development costs may increase, our regulatory approval process could be denied or delayed and we may not be able to commercialize and commence sales of arbaclofen ER in the time frame currently contemplated, if at all.

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

Financial Operations Overview

Recent Transactions

RevitaLid Acquisition

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

Segment Information

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

Components of Results of Operations

Revenues

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

Net product sales—Our revenues consist primarily of product sales of our promoted products, principally M-72, Lorzone, Divigel and the OB Complete family of prescription prenatal dietary supplements, and our non-promoted products, principally methylphenidate ER and venlafaxine ER, or VERT. We ship product to a customer pursuant to a purchase order, which in certain cases is pursuant to a master agreement with that customer, and we invoice the customer

upon shipment. For these sales we recognize revenue when control has transferred to the customer, which is typically on delivery to the customer. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which includes estimated chargebacks, commercial rebates, discounts and allowances at the time revenues are recognized.

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

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

Selling, General and Administrative Expenses

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

Research and Development

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

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in our consolidated financial statements as prepaid expenses or accrued expenses as applicable.

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

Financial Operations Overview

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

	Year Ended December 31,		
	2018	2017	% Change
Net product sales	$ 261,398	$ 237,671	10 %
Royalty revenue	1,959	6,449	(70)%
Licensing and contract revenue	344	1,629	(79)%
Total Revenue	263,701	245,749	7 %
Cost of goods sold (inclusive of amortization of intangibles)	140,082	127,636	10 %
Gross profit	123,619	118,113	5 %
Gross profit percentage	47 %	48 %	
Selling, general and administrative expenses	74,243	56,955	30 %
Research and development expenses	43,693	40,240	9 %
Impairment of intangibles and fixed assets	17,903	72,986	(75)%
Impairments of goodwill	86,318	—	NM
Total operating expenses	222,157	170,181	31 %
Interest expense and amortization of debt discount	20,790	29,052	(28)%
Other non-operating (income) expenses, net	(664)	4,522	(115)%
Total other non-operating expenses, net	20,126	33,574	(40)%
Loss before income taxes	(118,664)	(85,642)	(39)%
Income tax benefit	8,983	44,391	(80)%
Net loss	$ (109,681)	$ (41,251)	166 %

NM – Not meaningful

Revenue

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

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

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

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

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

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

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

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

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

Cost of Goods Sold and Gross Profit Percentage

The following table presents a breakdown of total cost of goods sold for the years ended December 31, 2018 and 2017 (dollars in thousands):

	Year Ended December 31,		
	2018	2017	% Change
Amortization of intangible assets	$ 77,096	$ 43,781	76 %
Depreciation expense	2,626	1,978	33 %
Royalty expense	11,949	31,386	(62)%
Other cost of goods sold	48,411	50,491	(4)%
Total cost of goods sold	$ 140,082	$ 127,636	10 %

Cost of goods sold increased $12.4 million in the year ended December 31, 2018 to $140.1 million as compared to $127.6 million in the year ended December 31, 2017. The increase was primarily driven by a $33.3 million increase in amortization of intangible assets, largely attributable to a full year of amortization for methylphenidate ER following its approval and launch in the third quarter of 2017. The increase in depreciation expense is largely attributable to a full year of depreciation related to an expansion project for our manufacturing facility in Marietta, Georgia which was completed during the second quarter of 2017. Royalty expense decreased by $19.4 million primarily reflecting the termination in the second quarter of 2017 of the distribution and marketing arrangement with the ANDA holder for a portfolio of products, including aripiprazole, for which we paid a significant royalty rate on our net sales. The $2.1 million decrease in other cost of goods sold is mostly due to lower API costs for methylphenidate ER during 2018.

Gross profit percentage was 47% for the year ended December 31, 2018 as compared to 48% for the year ended December 31, 2017. Excluding amortization and depreciation, our gross profit percentage increased to 77% for the year

ended December 31, 2018 as compared with 67% for the year ended December 31, 2017, primarily as a result of the termination in the second quarter of 2017 of the distribution and marketing relationship with the ANDA holder for a portfolio of products, including aripiprazole, for which we paid a significant royalty rate on net sales.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $17.3 million in the year ended December 31, 2018 to $74.2 million as compared to $57.0 million in the year ended December 31, 2017. The increase in our selling, general and administrative expenses reflects additions to salesforce headcount and marketing costs associated with the launches of M-72 and Osmolex ER, together with costs we incurred related to our initial public offering and severance expenses due to restructuring of our sales force.

Research and Development Expenses

Research and development expenses increased by $3.5 million in the year ended December 31, 2018 to $43.7 million as compared to $40.2 million in the year ended December 31, 2017. The increase was largely attributable to clinical trial costs of arbaclofen ER and RVL-1201, each of which are in Phase III clinical trials, together with additional headcount. Partially offsetting this increase, research and development expenses for the year ended December 31, 2017 included approximately $16.4 million related to the acquisition of RevitaLid, Inc., owner of the rights to RVL-1201. The purchase of RevitaLid was accounted for as an acquisition of in-process R&D with no alternative future use and expensed at the time of acquisition.

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

	Year Ended December 31,		
	2018	2017	% Change
Osmolex ER	$ 1,732	$ 3,235	(46)%
Arbaclofen ER	19,679	5,976	229 %
RVL 1201	7,225	16,372	(56)%
Other	15,057	14,657	3 %
Total	$ 43,693	$ 40,240	9 %

Impairment of Intangible Assets and Goodwill

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

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

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

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

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

Impairment of Fixed Assets

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

Interest Expense and Amortization of Debt Discount

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

Other Non-operating (Income) Expenses, net

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

Income Tax Benefit

	Year Ended December 31,	
	2018	2017
	(dollars in thousands)	
Income tax benefit	$ 8,983	$ 44,392
Effective tax rate	7.6 %	51.8 %

Income tax benefit decreased by $35.4 million in the year ended December 31, 2018 to $9.0 million as compared to $44.4 million in the year ended December 31, 2017.

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

Liquidity and Capital Resources

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

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

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

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

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

On October 22, 2018, we completed our IPO, in which we issued and allotted 7,647,500 ordinary shares at a public offering price of $7.00 per share. The number of shares issued in the IPO reflected the exercise in full of the underwriters' option to purchase 997,500 additional ordinary shares. In addition, we issued and allotted 2,014,285 ordinary shares at the public offering price in a private placement to certain existing shareholders. The aggregate net proceeds of the IPO and the private placement were approximately $58.1 million after deducting underwriting discounts and commissions and offering expenses. Shortly after the IPO, we prepaid $50 million of our Term A loan and Term B loan.

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

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

The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as other factors, such as successful development and launching of new products and strategic product or business acquisitions. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds or force us to reduce our expenses, either of which could have a material adverse effect on our business.

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

Cash Flows

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

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

Net cash provided by operating activities

Cash flows from operating activities are primarily driven by earnings from operations (excluding the impact of non-cash items), the timing of cash receipts and disbursements related to accounts receivable and accounts payable and the timing of inventory transactions and changes in other working capital amounts. Net cash provided by operating activities was $37.6 million and $57.8 million for the years ended December 31, 2018 and 2017, respectively.

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

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

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

Net cash used in investing activities

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

Net cash provided by (used in) financing activities

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

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

Contractual Obligations

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

	Payments due by period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations[1]	271,360	—	271,360	—	—
Interest expense[2]	70,028	17,632	52,396	—	—
Capital lease obligations[3]	257	119	138	—	—
Operating lease obligations[4]	5,803	1,998	3,314	491	—
Purchase obligations[5]	4,000	4,000	—	—	—
Royalty obligations[6]	8,646	1,375	3,188	3,000	1,083
Insurance premium financing obligations[7]	1,774	1,774	—	—	—
Total	361,868	26,898	330,396	3,491	1,083

(1) Represents the remaining principal amount under our senior secured credit facilities, which is due on December 21, 2022.

(2) These amounts represent future cash interest payments related to our existing debt obligations based on variable interest rates specified in the senior secured credit facilities. Payments related to variable debt are based on applicable rates at December 31, 2018 plus the specified margin in the senior secured credit facilities for each period presented. As of December 31, 2018, the interest rate was 6.09% for Term A Loan and 6.59% for Term B Loan.

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

(4) Includes minimum cash payments related to our leased offices and warehouse facilities under non-cancelable leases in New Jersey, Florida, North Carolina, as well as in Argentina and Hungary.

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

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

(7) Includes obligations to make minimum insurance premium financing payments

Our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. As of December 31, 2018, our liability for unrecognized tax benefits was $1.5 million (excluding interest and penalties). We do not anticipate that the amount of our liability for unrecognized tax benefits will significantly change in the next 12 months.

Critical Accounting Estimates

The significant accounting policies and basis of presentation are described in Note 2,*Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere herein.

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

In order to understand our consolidated financial statements, it is important to understand our critical accounting estimates. We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make

assumptions about matters that were highly uncertain at the time the accounting estimate was made and (ii) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition, results of operations or cash flows. We believe the following accounting policies and estimates to be critical:

Revenue Recognition

Upon adoption of Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (ASC Topic 606) on January 1, 2018, we recognize revenue as described below. The implementation of the new revenue recognition standard did not have a material impact on our consolidated financial statements. The information presented for the periods prior to January 1, 2018 has not been restated and is reported under ASC Topic 605.

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

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

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

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

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

Freight—We record amounts billed to customers for shipping and handling as revenue, and record shipping and handling expenses related to product sales as cost of goods sold. We account for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. When shipping and

handling costs are incurred after a customer obtains control of the products, we also have elected to account for these as costs to fulfill the promise and not as a separate performance obligation.

Sales Deductions

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

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

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

Where available, we have relied on information received from our wholesaler customers about the quantities of inventory held, including the information received pursuant to days of sales outstanding, which we have not independently verified. For other customers, we have estimated inventory held based on buying patterns. In addition, we have evaluated market conditions for products primarily through the analysis of wholesaler and other third party sell-through, as well as internally-generated information, to assess factors that could impact expected product demand at December 31, 2018 and December 31, 2017. We believe that the estimated level of inventory held by our customers is within a reasonable range as compared to both: (i) historical amounts and (ii) expected demand for the products that represent majority of the volume at December 31, 2018 and December 31, 2017.

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

The following table presents the activity and ending balances for our product sales provisions for the years ended December 31, 2018 and 2017 (in thousands):

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

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

Chargebacks—We enter into contractual agreements with certain third parties such as retailers, hospitals and group-purchasing organizations, or GPOs, to sell certain products at predetermined prices. Most of the parties have elected to have these contracts administered through wholesalers that buy the product from us and subsequently sell it to these third parties. When a wholesaler sells products to one of these third parties that are subject to a contractual price

agreement, the difference between the price paid to us by the wholesaler and the price under the specific contract is charged back to us by the wholesaler. Utilizing this information, we estimate a chargeback percentage for each product and record an allowance for chargebacks as a reduction to gross sales when we record our sale of the products. We reduce the chargeback allowance when a chargeback request from a wholesaler is processed. Our provision for chargebacks is fully reserved for at the time when sales revenues are recognized.

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

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

Chargebacks were $365.0 million and $202.4 million, or 38.5% and 31.3% as a percentage of gross product sales, for the years ended December 31, 2018 and 2017, respectively. Chargebacks as a percentage of gross product sales increased in 2018 as compared with 2017, primarily due to a change in product mix and pricing. We expect that chargebacks will continue to significantly impact our reported net product sales.

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

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

We ensure that commercial rebates are reasonable through review of contractual obligations, review of historical trends and evaluation of recent activity. Furthermore, other events that could materially alter commercial rebates include: changes in product pricing as a result of competitive market dynamics or negotiations with customers, changes in demand for specific products due to external factors such as competitor supply position or consumer preferences,

customer shifts in buying patterns from direct to indirect through wholesalers, which could either individually or in aggregate increase or decrease the commercial rebates depending on the direction and velocity of the change(s).

Commercial rebates were $257.9 million and $134.5 million, or 27.2% and 20.8% as a percentage of gross product sales, for the years ended December 31, 2018 and 2017, respectively. Commercial rebates as a percentage of gross product sales increased in 2018 as compared to 2017 primarily due to the change in product mix and customer contracts. We expect that commercial rebates will continue to significantly impact our reported net sales.

Government Program Rebates—Federal law requires that a pharmaceutical distributor, as a condition of having federal funds being made available to the states for the manufacturer's drugs under Medicaid and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the distributor's covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement. CMS is responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are also due on the utilization of Medicaid managed care organizations, or MMCOs. We also pay rebates to MCOs for the reimbursement of a portion of the sales price of prescriptions filled that are covered by the respective plans. The liability for Medicaid, Medicare and other government program rebates is settled in cash and is estimated based on historical and current rebate redemption and utilization rates contractually submitted by each state's program administrator and assumptions regarding future government program utilization for each product sold, and accordingly recorded as a reduction of product sales. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. In addition to the estimates mentioned above, our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, our estimates could differ from actual experience.

Government program rebates were $18.6 million and $26.0 million, or 2.0% and 4.0% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively.

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

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

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

provision for returns. Some of the factors that may be an indication that an increase in inventory levels will be temporary include:

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

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

- declining sales trends based on prescription demand;
- recent regulatory approvals to shorten the shelf life of our products, which could result in a period of higher returns;
- slow moving or obsolete product still in the distribution channel;
- introduction of new product(s) or generic competition;
- increasing price competition from generic competitors; and
- changes to the National Drug Codes, or NDCs, of our products, which could result in a period of higher returns related to product with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

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

Product returns were $20.5 million and $26.3 million, or 2.2% and 4.1% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively. Product returns as a percentage of gross product sales decreased in 2018 as compared to 2017 primarily due to the launch of methylphenidate ER in September, 2017, and product recalls which were not present in 2018. Product returns as a percentage of gross product sales are not expected to change materially for 2019.

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

Advertising and promotions as a percentage of gross product sales did not change materially during the periods presented. Promotions and co-pay discount cards are included in advertising and promotions, which were $4.9 million and $4.4 million, or 0.5% and 0.7% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively.

Discounts and allowances were $20.2 million and $15.4 million, or 2.1% and 2.4% as a percentage of gross product sales, during the years ended December 31, 2018 and 2017, respectively. Discounts and allowances as a percentage of gross product sales did not change materially during the periods presented and are not expected to change materially for the remainder of 2018.

Valuation of long-lived assets

As of December 31, 2018, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is $437.9 million.

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

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

Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations. Our reviews of long-lived assets during the two years ended December 31, 2018 and 2017 resulted in certain impairment charges. These charges relate to both finite and indefinite-lived intangible assets, which are described in Note 7, *Goodwill and Other Intangible Assets,* to our consolidated financial statements.

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

We recorded impairment charges of $10.3 million and $15.9 million, regarding definite-lived intangible assets for the years ended December 31, 2018 and 2017, respectively.

Goodwill and indefinite-lived intangible assets

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

Goodwill Impairment Assessment—We are organized in one reporting unit and evaluate goodwill for our company as a whole. Under the authoritative guidance issued by the Financial Accounting Standards Board, or FASB, we have the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. As further described in Note 2, *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere herein, effective January 1,

2017, we early adopted Accounting Standards Update (ASU) No. 2017-04 *"Intangibles — Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment"* (ASU 2017-04). Subsequent to adoption, we perform our goodwill impairment tests by comparing the fair value and carrying amount of our reporting unit. Any goodwill impairment charges we recognize for our reporting unit are equal to the lesser of (i) the total goodwill allocated to that reporting unit and (ii) the amount by which that reporting unit's carrying amount exceeds its fair value.

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

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of the future results of our operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which we operate, demand for the products and competitor actions. Estimated future cash flows are discounted to present value using a market participant, weighted average cost of capital. The financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any. The discount rates applied to the estimated cash flows for our October 1, 2018 and 2017 annual goodwill impairment test were 14% and 9.0%, respectively, depending on the overall risk associated with the particular asset and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

Based on the quantitative goodwill impairment assessment performed, we determined that there was no impairment of goodwill as of October 1, 2018 and for the year ended December 31, 2017. An increase of 50 basis points to our assumed discount rate used in our goodwill assessment would not have materially changed the results of our analyses.

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

IPR&D Intangible Asset Impairment Assessment—IPR&D, which are indefinite-lived intangible assets representing the value assigned to acquired Research and Development, or R&D, projects that principally represent rights to develop and sell a product that we have acquired which has not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. The fair value of our indefinite-lived intangible assets is determined using an income approach that utilizes a discounted cash flow model and requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. The discount rates applied to the estimated cash flows for our October 1, 2018 and 2017 indefinite-lived intangible asset impairment test were 14% and 9.0%, respectively. The major risks and uncertainties associated with the timely and successful completion of the

IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D product, the assets are reduced to zero. Upon approval of the products in development for sale and placement into service, the associated IPR&D intangible assets are transferred to Product Rights amortizing intangible assets. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated.

If the fair value of the IPR&D is less than its carrying amount, an impairment loss is recognized for the difference. Based on results of the impairment assessment performed, we recognized impairment charges to IPR&D of $7.6 million and $56.6 million for the years ended December 31, 2018 and 2017, respectively. The 2018 impairment charge reflects our decision to cease development activities on a generic asset thereby reducing its fair value to zero.

Income Taxes

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

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

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

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

existing tax laws or regulations, changes in estimates of prior years' items, changes in the international organization, likelihood of settlement, and changes in overall levels of income before taxes.

As of December 31, 2018 and 2017, the Company has a federal net operating loss carryover of $3.3 million and $4.4 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of approximately $22.4 million and $80.1 million, respectively which will begin to expire in 2022. At December 31, 2018 and 2017, the Company had total tax credit carryovers of approximately $4.6 million and $9.1 million, respectively, primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers are expected to be fully realized prior to their expiration, beginning in 2036.

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

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

Share-based compensation

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

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

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

In addition, prior to the IPO the Company adopted the 2018 Equity Incentive Plan, or the 2018 Plan effective upon the IPO. During 2018, the Company granted Time Based Options vesting in a single installment on the fourth anniversary of the Company's IPO, generally subject to the employee's continued employment on the vesting date.

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

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

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

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

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

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

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

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

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

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

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

During the year end December 31, 2018 we recognized $1.9 million of stock compensation expense.

Recently Issued Accounting Standards

For a discussion of recent accounting pronouncements, please see Note 2,*Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere herein.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Osmotica Pharmaceuticals plc
Dublin, Ireland

Opinion on the Consolidated Financial Statements

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

Change in Accounting Method Related to Revenue

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

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

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

Woodbridge, New Jersey
March 27, 2019 (except for Note 1, as to which the date is December 20, 2019)

OSMOTICA PHARMACEUTICALS PLC
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 70,834,496	$ 34,743,152
Trade accounts receivable, net	56,423,866	37,637,957
Inventories, net	24,383,021	16,946,870
Prepaid expenses and other current assets	20,722,358	25,271,568
Total current assets	172,363,741	114,599,547
Property, plant and equipment, net	31,263,432	31,410,133
Intangibles, net	490,389,723	585,388,710
Goodwill	100,854,816	187,172,816
Other non-current assets	751,927	942,419
Total assets	$ 795,623,639	$ 919,513,625
Liabilities and Shareholders' Equity/Partners' Capital		
Current liabilities:		
Trade accounts payable	$ 24,869,593	$ 36,069,936
Accrued liabilities	87,236,940	81,926,390
Current portion of long-term debt, net of deferred financing costs	1,774,199	6,655,604
Current portion of obligation under capital leases	119,344	24,245
Total current liabilities	114,000,076	124,676,175
Long-term debt, net of non-current deferred financing costs	266,802,911	313,949,581
Long-term portion of obligation under capital leases	137,949	57,059
Income taxes payable - long term portion	2,540,780	2,328,854
Deferred taxes	28,294,483	43,807,921
Other long-term liabilities	—	1,047,477
Total liabilities	411,776,199	485,867,067
Commitments and contingencies (See Note 14)		
Shareholders' equity/partners' capital:		
Ordinary shares ($0.01 nominal value 400,000,000 shares authorized, 52,518,924 shares issued and outstanding)	525,189	—
Preferred shares ($0.01 nominal value 40,000,000 shares authorized, no shares issued and outstanding)	—	—
Euro deferred shares (€1.00 nominal value 25,000 shares authorized, no shares issued and outstanding)	—	—
Additional paid in capital	487,287,971	—
Accumulated deficit	(102,119,537)	—
Partners' capital	—	434,279,704
Accumulated other comprehensive loss	(1,846,183)	(633,146)
Total shareholders' equity/partners' capital	383,847,440	433,646,558
Total liabilities and shareholders' equity/partners' capital	$ 795,623,639	$ 919,513,625

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2018	**2017**
Net product sales	$ 261,398,205	$ 237,671,178
Royalty revenue	1,958,571	6,449,095
Licensing and contract revenue	344,573	1,628,759
Total revenues	263,701,349	245,749,032
Cost of goods sold (inclusive of amortization of intangibles)	140,082,250	127,636,390
Gross profit	123,619,099	118,112,642
Selling, general and administrative expenses	74,242,509	56,954,513
Research and development expenses	43,693,242	40,240,107
Impairment of intangibles and fixed assets	17,903,208	72,986,303
Impairment of goodwill	86,318,000	—
Total operating expenses	222,156,959	170,180,923
Operating loss	(98,537,860)	(52,068,281)
Interest expense and amortization of debt discount	20,790,714	29,052,363
Other non-operating (income) loss, net	(664,391)	4,521,898
Total other non-operating expense, net	20,126,323	33,574,261
Loss before income taxes	(118,664,183)	(85,642,542)
Income tax benefit	8,983,442	44,391,726
Net loss	$ (109,680,741)	$ (41,250,816)
Other comprehensive loss, net		
Change in foreign currency translation adjustments	(1,213,036)	(907,927)
Comprehensive loss	$ (110,893,777)	$ (42,158,743)
Loss per share attributable to shareholders		
Basic	$ (2.42)	$ (0.96)
Diluted	$ (2.42)	$ (0.96)
Weighted average shares basic and diluted		
Basic and Diluted	45,276,278	42,855,722

See accompanying notes to consolidated financial statements.

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

	Ordinary shares		Additional	Accumulated	Partners'	Accumulated other comprehensive	
	Shares	Amount	paid in capital	deficit	capital	loss	Total
Balance at December 31, 2016	$ —	—	$ —	$ —	$ 475,402,520	$ 274,781	$ 475,677,301
Net loss	—	—	—	—	(41,250,816)	—	(41,250,816)
Change in foreign currency translation	—	—	—	—	—	(907,927)	(907,927)
Partners' contributions	—	—	—	—	128,000	—	128,000
Balance at December 31, 2017	—	$ —	$ —	$ —	$ 434,279,704	$ (633,146)	$ 433,646,558
Cumulative effect of change in accounting standard (See Note 2)	—	—	—	—	1,047,477	—	1,047,477
Net loss	—	—	—	—	(7,561,204)	—	(7,561,204)
Change in foreign currency translation	—	—	—	—	—	(1,169,244)	(1,169,244)
Share compensation	—	—	—	—	1,248,023	—	1,248,023
Partners' distributions	—	—	—	—	(2,026)	—	(2,026)
Balance at October 17, 2018	—	$ —	$ —	$ —	$ 429,011,974	$ (1,802,390)	$ 427,209,584
Effect of reorganization	42,857,139	428,571	428,583,403	—	(429,011,974)	—	—
Issuance of ordinary shares in initial public offering and private placement, net of offering costs	9,661,785	96,618	57,987,245	—	—	—	58,083,863
Share compensation	—	—	717,323	—	—	—	717,323
Net loss	—	—	—	(102,119,537)	—	—	(102,119,537)
Change in foreign currency translation	—	—	—	—	—	(43,793)	(43,793)
Balance at December 31, 2018	52,518,924	$ 525,189	$ 487,287,971	$ (102,119,537)	$ —	$ (1,846,183)	$ 383,847,440

See accompanying notes to consolidated financial statements.

OSMOTICA PHARMACEUTICALS PLC
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (109,680,741)	$ (41,250,816)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	81,572,591	46,450,146
Share compensation	1,965,346	—
Impairment of intangibles and fixed assets	17,903,208	72,986,303
Impairment of goodwill	86,318,000	
Deferred income tax benefit	(15,513,439)	(47,945,473)
Loss on sale of fixed assets	93,652	—
Bad debt provision	(1,771,487)	832,388
Non-cash interest expense and amortization of deferred financing and loan origination fees	1,651,536	7,506,359
Write off of deferred financing fees in connection with prepayment	875,576	4,981,624
Expensed IPR&D	—	16,372,476
Change in fair value of contingent consideration	—	182,396
Payment for contingent consideration	—	(1,991,288)
Payment of In-kind interest	—	(9,321,500)
Change in operating assets and liabilities:		
Trade accounts receivable, net	(17,040,991)	5,268,883
Inventories, net	(7,436,151)	2,892,119
Prepaid expenses and other current assets	4,549,210	(15,162,955)
Other non-current assets	—	1,512,082
Trade accounts payable	(11,325,623)	588,238
Accrued and other current liabilities	5,397,643	13,936,076
Net cash provided by operating activities	37,558,330	57,837,058
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	10,000	—
Payment for asset acquisition	—	(12,500,000)
Purchase of property, plant and equipment	(4,143,723)	(6,895,332)
Net cash used in investing activities	(4,133,723)	(19,395,332)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	(2,026)	—
Contributions from Partners	—	128,000
Payments on capital lease obligations	(111,554)	(113,842)
Proceeds from issuances of debt	—	327,500,000
Debt financing costs	—	(3,563,499)
Proceeds from insurance financing loan	2,744,852	—
Repayment of insurance financing loan	(970,653)	—
Proceeds from initial public offering and private placement, net of issuance costs	58,083,863	—
Debt repayment	(56,140,063)	(338,756,329)
Payment for contingent consideration	—	(8,508,712)
Net cash provided by (used in) financing activities	3,604,419	(23,314,382)
Net change in cash and cash equivalents	37,029,026	15,127,344
Effect on cash of changes in exchange rate	(937,682)	57,237
Cash and cash equivalents, beginning of period	34,743,152	19,558,571
Cash and cash equivalents, end of period	$ 70,834,496	$ 34,743,152
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 19,618,614	$ 25,272,842
Income taxes paid	$ 2,637,560	$ 17,592,965
Purchase of fixed assets by entering into capital lease	$ 287,542	$ —

See accompanying notes to consolidated financial statements.

Note 1. Organization and Nature of Operations

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

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

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

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

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

Correction of Immaterial Errors

In connection with the preparation of the Company's unaudited condensed consolidated financial statements as of and for the period ended September 30, 2019 and 2018 for inclusion in the Company's Quarterly Report on Form 10-Q, the Company determined that a revision was required to correct misstatements associated with the tax treatment of certain

intercompany transactions at the time of the business combination between Osmotica Holdings Limited and subsidiaries and Vertical/Trigen Holdings LLC which occurred on February 3, 2016. Additionally, revisions were necessary to correct misstatements related to uncertain tax provisions and prepaid taxes and certain other previously identified immaterial misstatements.

The Company assessed the materiality of the misstatements both quantitatively and qualitatively and determined the correction of these errors were immaterial to all prior consolidated financial statements taken as a whole and, therefore, amending previously filed financial statements to correct the errors was not required. However, correcting the cumulative effect of the errors in the Company's period ended September 30, 2019 would materially misstate the operating results of the period ended September 30, 2019. Accordingly, the Company has reflected the corrections in the results for prior periods as described below. The Company will also revise such information in future filings to reflect the correction of the errors.

The impacts of the corrections have been reflected throughout the consolidated financial statements, including the applicable notes, as appropriate. The correction had no impact on the previously reported amounts of consolidated cash flows from operating, investing or financing activities. The errors were identified as a result of improved processes, controls and personnel that were put in place during 2018 and continuing through 2019.

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

	Year ended December 31, 2018		
	As reported	Net adjustments	As corrected
Prepaid expense and other current assets	$ 20,743,685	$ (21,327)	$ 20,722,358
Total assets	795,644,966	(21,327)	795,623,639
Income taxes payable-current portion	393,552	(393,552)	—
Income taxes payable-long term portion	1,803,512	737,268	2,540,780
Deferred taxes	26,237,841	2,056,642	28,294,483
Total liabilites	409,375,841	2,400,358	411,776,199
Additional paid in capital	489,949,791	(2,661,820)	487,287,971
Accumulated deficit	(102,359,672)	240,135	(102,119,537)
Shareholders' equity	386,269,125	(2,421,685)	383,847,440
Total liabilities and shareholders' equity	795,644,966	(21,327)	795,623,639
Income tax benefit	9,267,917	(284,475)	8,983,442
Net loss	(109,396,266)	(284,475)	(109,680,741)
Comprehensive loss	(110,609,302)	(284,475)	(110,893,777)
Loss per share	(2.42)	—	(2.42)
Weighted average shares basic and diluted	45,276,278	—	45,276,278

	Year ended December 31, 2017		
	As reported	Net adjustments	As corrected
Prepaid expense and other current assets	$ 25,498,092	$ (226,524)	$ 25,271,568
Total assets	919,740,149	(226,524)	919,513,625
Income taxes payable-long term portion	1,334,645	994,209	2,328,854
Deferred taxes	42,891,444	916,477	43,807,921
Total liabilites	483,956,381	1,910,686	485,867,067
Partners' capital	436,416,914	(2,137,210)	434,279,704
Total Partners' capital	435,783,768	(2,137,210)	433,646,558
Total liabilities and partners' capital	919,740,149	(226,524)	919,513,625
Income tax benefit	44,500,731	(109,005)	44,391,726
Net loss	(41,141,811)	(109,005)	(41,250,816)
Comprehensive loss	(42,049,738)	(109,005)	(42,158,743)
Loss per share	(0.96)	—	(0.96)
Weighted average shares basic and diluted	42,855,722	—	42,855,722

In each of the tables above, for periods prior to December 31, 2018 weighted averages shares – basic and dilutive have been converted to their ordinary share equivalents by using an exchange ratio of 42.84 (rounded down to the nearest whole share), which was the ratio the common units were converted to ordinary shares of Osmotica Pharmaceuticals plc immediately prior to the Company's initial public offering in October 2018. *See Note 1, Organization and Nature of Operations.*

Other Reclassification Errors

In connection with the preparation of the Company's unaudited condensed consolidated financial statements as of and for the period ended September 30, 2019 and 2018 for inclusion in the Company's Quarterly Report on Form 10-Q, the Company made certain reclassifications to cost of goods sold from research and development expenses which were concluded by the Company to be immaterial. For the years ended December 31, 2018 and 2017, we have reclassified $5,068,252 and $2,447,955, respectively, to cost of goods sold from research and development expenses to conform to the current year presentation in the unaudited condensed consolidated financial statements for the period ended September 30, 2019 and 2018.

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

Significant Accounting Policies

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

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

Use of Estimates—The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases it estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Foreign Currency Translation—The financial position and results of operations of the Company's non-U.S. subsidiaries are generally determined using U.S. Dollars as the functional currency, except our subsidiary in Argentina which uses

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

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

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

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

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

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

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

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

Inventories—Inventories are stated at the lower of cost or net realizable value at approximate costs determined on the first-in first-out basis. The Company maintains an allowance for excess and obsolete inventory as well as inventory where the cost is in excess of its net realizable value ("NRV") based on management's assessments. The Company capitalizes inventory costs associated with its products prior to regulatory approval when, based on management judgement, future commercialization is considered probable and future economic benefit is expected to be realized. As of December 31, 2018 and 2017, there were no capitalized inventory costs associated with products that had not yet achieved regulatory approval. The Company assesses the regulatory approval process and where the product stands in relation to that approval process including any known constraints or impediments to approval. The Company also considers the shelf life of the product in relation to the product timeline for approval. Sample inventory utilized for promoting the Company's products are expensed and included in cost of goods sold when the sample units are purchased or manufactured.

Property, Plant and Equipment—Property, plant and equipment is stated at cost, less accumulated depreciation. Maintenance and repairs are charged to expense when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized and depreciated over the remaining useful lives of the assets. The cost and

accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings. Depreciation is provided using the straight-line method in amounts considered to be sufficient to amortize the cost of the assets to operations over their estimated useful lives or lease terms, as follows:

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

Long-Lived Assets, Including Definite-Lived Intangible Assets—Intangible assets are stated at cost less accumulated amortization. Amortization is generally recorded on a straight-line basis or based on the expected pattern of cash flows over estimated useful lives ranging from 3 to 20 years. The Company periodically reviews the estimated useful lives of intangible assets and makes adjustments when events indicate that a shorter life is appropriate.

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

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

The Company recorded impairment charges of $10,303,208 and $15,894,843, in regard to definite-lived intangible assets for the years ended December 31, 2018 and 2017, respectively (see Note 8).

Goodwill and Indefinite Lived Intangible Assets—Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company is organized in one reporting unit and evaluates the goodwill for the Company as a whole. Goodwill is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. Under the authoritative guidance issued by the Financial Accounting Standards Board (the "FASB"), the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying value, then no impairment is recognized. If the carrying value recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations. There was no impairment of goodwill for the year ended December 31, 2017. For the year ended December 31, 2018 it was determined that the carrying value of goodwill exceeded its fair value. Accordingly, the Company recognized a goodwill impairment charge of $86,318,000 for the year ended December 31, 2018 (see Note 8).

In-Process Research and Development ("IPR&D") intangible assets represent the value assigned to acquired Research & Development ("R&D") projects that principally represent rights to develop and sell a product that the Company has acquired which have not yet been completed or approved. These assets are subject to impairment testing until completion or abandonment of each project. Impairment testing requires the development of significant estimates and assumptions involving the determination of estimated net cash flows for each year for each project or product (including net revenues, cost of sales, R&D costs, selling and marketing costs and other costs which may be allocated), the appropriate discount rate to select in order to measure the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, the potential regulatory and commercial success risks, and competitive trends impacting each asset and related cash flow stream as well as other factors. The major risks and uncertainties associated with the timely and successful completion of the IPR&D projects include legal risk, market risk and regulatory risk. If applicable, upon abandonment of the IPR&D product, the assets are reduced to zero. IPR&D is assessed for impairment on an annual basis as of October 1st of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. If the fair value of the IPR&D is less than its carrying amount, an impairment is recognized for the difference. The Company recognized impairment charges to IPR&D of $7,600,000 and $56,625,436 for the years ended December 31, 2018 and 2017, respectively (see Note 8).

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

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

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

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

Licensing and Contract Revenue—The Company has arrangements with commercial partners that allow for the purchase of product from the Company by the commercial partners for purposes of sub-distribution. The Company recognizes revenue from an arrangement when control of such product is transferred to the commercial partner, which is typically upon delivery. In these situations, the performance obligation is satisfied when product is delivered to the Company's commercial partner. Licensing revenue is recognized in the period in which the product subject to the sublicensing arrangement is sold by the Company to its commercial partner. Sales deductions, such as returns on product sales,

government program rebates, price adjustments, and prompt pay discounts in regard to licensing revenue is generally the responsibility of the Company's commercial partners and not recorded by the Company.

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

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

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

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

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

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

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

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

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

Government Program Rebates—Federal law requires that a pharmaceutical distributor, as a condition of having federal funds being made available to the States for the manufacturer's drugs under Medicaid and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the distributor's covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement. The Centers for Medicare and Medicaid Services ("CMS") are responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are also due on the utilization of Medicaid managed care organizations ("MMCOs").

The Company also pays rebates to managed care organizations ("MCOs") for the reimbursement of a portion of the sales price of prescriptions filled that are covered by the respective plans. The liability for Medicaid, Medicare, and other government program rebates is settled in cash and is estimated at the time when sales revenues are recognized based on historical and current rebate redemption and utilization rates contractually submitted by each state's program

administrator and assumptions regarding future government program utilization for each product sold; and accordingly recorded as a reduction of product sales.

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

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

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

In-Process Research and Development—In-process research and development represent the fair value assigned to incomplete research projects that the Company acquires through business combinations or developed internally which, at that time, have not reached technological feasibility. Intangible assets associated with IPR&D projects are not amortized until regulatory approval is obtained and product is launched, subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated. During the years ended December 31, 2018 and 2017, $0 and $264,100,000 of IPR&D was transferred to Product Rights as the products in development are approved for sale and placed into service (see Note 8). Such amounts will be amortized over their respectful estimated useful lives of 7 and 10 years. At that time an evaluation of fair value was performed immediately prior to such transfer.

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

Advertising—Advertising expense consists primarily of print media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the years ended December 31, 2018 and 2017 amounted to $6,193,610 and $2,650,540, respectively.

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

Income Taxes—Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it

determines will not be realizable in the future.

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

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

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

Segment Reporting—The Company operates in one business segment which focuses on developing and commercializing pharmaceutical products that target markets with underserved patient populations. The Company's business offerings have similar economic and other characteristics, including the nature of products, manufacturing and acquiring processes, types of customers, distribution methods and regulatory environment. The chief operating decision maker ("CODM") reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions. The consolidated financial statements reflect the financial results of the Company's one reportable operating segment. The Company has no significant revenues or tangible assets outside of the United States.

Recently Adopted Accounting Standards

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

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

In August 2016, the FASB issued ASU 2016-15,*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components

of these cash receipts and payments among operating, investing and financing activities. The Company adopted this standard on January 1, 2018 and adoption did not have a material impact on the consolidated financial statements.

In October of 2016, the FASB issued ASU 2016-16,*Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*, ASU 2016-16 requires recognition of the current and deferred income tax effects of an intra-entity asset transfer, other than inventory, when the transfer occurs, as opposed to current GAAP, which requires companies to defer the income tax effects of intra-entity asset transfers until the asset has been sold to an outside party. The income tax effects of intra-entity inventory transfers will continue to be deferred until the inventory is sold. The standard is required to be adopted on a modified retrospective basis with a cumulative-effect adjustment recorded to retained earnings as of the beginning of the period of adoption. The Company adopted this standard on January 1, 2018. Subsequent to the issuance of the condensed consolidated financial statements as of and for the six months ended June 30, 2018, the Company determined that a revision was required to correct for the adoption of this accounting standard resulting in an increase to Partners' capital and decrease to Other long-term liabilities in the amount of $1,047,477. These adjustments were not considered to be material to the Company's condensed consolidated financial statements.

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

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

Recent Accounting Standards

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

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

Note 3. Other Strategic Investments

RevitaLid Asset Acquisition

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

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

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

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

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

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

Note 4. Revenues

The Company's performance obligations are to provide its pharmaceutical products based upon purchase orders from distributors. The performance obligation is satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. The Company invoices its customers after the products have been delivered and invoice payments are generally due within 60 days of invoice date.

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

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

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of products to the customer under the terms of a contract, the Company records a contract liability. The Company classifies contract liabilities as deferred revenue. The Company had no deferred revenue as of December 31, 2018 and 2017. Upon adoption of ASC Topic 606, the Company did not have any contract assets or liabilities. The Company has elected to apply the exemption under paragraph 606-10-50-14(a) related to remaining performance obligations as all open purchase orders are expected to be satisfied with a period of one year from the date of the purchase order.

Contract assets primarily relate to rights to consideration for goods or services transferred to the customer when the right is conditional on something other than the passage of time. Contract assets are transferred to accounts receivable when the rights become unconditional. The Company had no contract assets as of December 31, 2018. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs.*

Note 5. Accounts Receivable, Sales and Allowances

The nature of the Company's business inherently involves, in the ordinary course, significant amounts and substantial volumes of transactions and estimates relating to allowances for product returns, chargebacks, rebates, doubtful accounts and discounts given to customers. This is typical of the pharmaceutical industry and not necessarily specific to the Company. Depending on the product, the end-user customer, the specific terms of national supply contracts and the particular arrangements with the Company's wholesale customers, certain rebates, chargebacks and other credits are deducted from the Company's accounts receivable. The process of claiming these deductions depends on wholesalers reporting to the Company the amount of deductions that were earned under the terms of the respective agreement with the end-user customer (which in turn depends on the specific end-user customer, each having its own pricing arrangement, which entitles it to a particular deduction). This process can lead to partial payments against outstanding invoices as the wholesalers take the claimed deductions at the time of payment.

Accounts receivable result primarily from sales of pharmaceutical products, amounts due under revenue sharing, license and royalty arrangements, which inherently involves, in the ordinary course of business, estimates relating to allowances for product returns, chargebacks, rebates, doubtful accounts and discounts given to customers. Credit is extended based on the customer's financial condition, and, generally, collateral is not required. The Company ages its accounts receivable using the corresponding sale date of the transaction and considers accounts past due based on terms agreed upon in the transaction, which is generally 30 to 60 days for branded and generic sales, depending on the customer and the products purchased.

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

Trade accounts receivable, net consists of the following:

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

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

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

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

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

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

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

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

Provisions and utilizations of provisions activity in the current period which relate to the prior period revenues are not provided because to do so would be impracticable. The Company's current systems and processes do not capture the chargeback and rebate settlements by the period in which the original sales transaction was recorded. Chargeback, rebate claims and certain other gross to net items are not submitted by customers with sufficient details to link the accrual recorded at the point of sale with the settlement of the accrual. As a result, the Company is unable to reasonably determine the dollar amount of the change in estimate in its gross to net reporting reflected in its results of operations for each period presented, and, those changes could be significant. However, the Company uses a combination of factors and applications to estimate the dollar amount of reserves for chargebacks and rebates at each month end. The Company regularly monitors the reserves based on an analysis of the Company's product sales and most recent claims, wholesaler inventory, current pricing, and anticipated future pricing changes. If amounts are different from the estimate due to changes from estimated rates, accrual rate adjustments are considered prospectively when determining provisions in accordance with authoritative U.S. GAAP.

Note 6. Inventories

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

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

The Company maintains an allowance for excess and obsolete inventory, as well as inventory where its cost is in excess of its net realizable value. The activity in the allowance for excess and obsolete inventory account for the years ended December 31, 2018 and 2017, was as follows:

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

Note 7. Property, Plant and Equipment, Net

Property, plant and equipment consist of the following:

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

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

Note 8. Goodwill and Other Intangible Assets

The Company tests goodwill and indefinite-lived intangible assets for impairment annually as of October 1st, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. As further described below, in December 2018, changes in events and circumstances made it more likely than not goodwill had been impaired. As a result we recognized a goodwill impairment charge of $86,318,000. The following table sets forth the carrying value of goodwill as of December 31, 2018 and 2017, respectively.

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

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

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

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

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

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

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

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

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

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

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

As part of the Company's goodwill and intangible asset impairment assessments and when IPR&D assets are put into service, the Company estimates the fair values of the reporting unit and intangible assets using an income approach that utilizes a discounted cash flow model, or, where appropriate, a market approach. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amounts, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rates applied to the estimated cash flows for the Company's October 1, 2018 and 2017 annual goodwill and indefinite-lived intangible assets impairment test ranged from 14.0% to 9.0%, respectively, depending on the overall risk associated with the particular assets and other market factors. The Company believes the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments, if any, are recorded to Impairment of intangible assets in the Consolidated Statements of Operations and Comprehensive Loss.

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

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

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

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

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

Note 9. Accrued Liabilities

Accrued liabilities consist of the following:

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

In the ordinary course of business, the Company enters into contractual agreements with wholesalers pursuant to which the wholesalers distribute sales of Company products to customers and provide sales data to the Company. In return the wholesalers charge the Company a fee for services and other customary rebates and chargebacks based on distribution sales of Company products through the wholesalers and downstream customers.

Note 10. Financing Arrangements

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

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

Term Loan

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a $160,000,000 Term Loan (the "Term Loan") pursuant to a Credit Agreement dated February 3, 2016 (the "Term Loan Agreement") between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent. The Term Loan is secured by certain assets of the Company, excluding certain intangibles and foreign property.

The Term Loan Agreement required quarterly principal repayments equal to 0.625% of the initial aggregate Term Loan amount beginning on the last day of the first full fiscal quarter following the closing of the Term Loan Agreement, with final payment of the remaining principal balance due at maturity six years from the date of closing of the Term Loan Agreement. At the Company's election, interest accrues on a Prime Rate/Federal Funds Effective Rate ("ABR Loan") or a LIBOR ("LIBOR Loan") rate, plus a margin of 4.00% for ABR Loan, and 5.00% for LIBOR Loan. As of December 31, 2016, this rate was 6.00%.

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

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

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

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

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

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

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

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

For Term B Loan, interest accrues with respect to any ABR Loan, 3.25% per annum, and with respect to any LIBOR Rate Loan, 4.25% per annum. As of December 31, 2018 and 2017, the interest rates were 6.09% and 5.25% for Term A Loan and 6.59% and 5.75% for Term B Loan, respectively.

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

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

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

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

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

The Company incurred debt issuance costs associated with the Third Amendment. Pursuant to ASC 835-30-35-2, with respect to a note for which the imputation of interest is required, the difference between the present value and the face amount shall be treated as a discount or premium and amortized as interest expense or income over the life of the note in such a way as to result in a constant rate of interest when applied to the amount outstanding at the beginning of any given period. As such, in accordance with ASC 835-30-35-2, the Company deferred and amortized the debt issuance costs amortized over the length of the Term Loan using the effective interest method. The balance of the debt issuance costs as of the date of the partial prepayment made on October 31, 2018 was $5,627,508.

As a result of the partial extinguishment, the Company has elected, as an accounting policy in accordance with ASC 470-50-40-2, to write off a proportionate amount of the unamortized fees at the time that the financing was partially settled in accordance with the terms of the Third Amendment. The unamortized debt issuance costs are allocated between the remaining original loan balance and the portion of the loan paid down on a pro-rata basis. At the time of repayment, the Company wrote off $875,576 in debt issuance costs and recorded the expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

Revolving Facility

Concurrent with the closing of the Company's acquisition of Osmotica Holdings Corp Limited, the Company entered into a Revolving Facility in an aggregate amount of $30,000,000 (the "Revolving Facility") pursuant to a Credit

Agreement dated February 3, 2016 between the Company as borrower, certain other lenders and CIT Bank, N.A. ("CIT Bank") acting as administrative agent, as discussed above. The Company incurred closing costs associated with the Revolving Facility in the amount of $1,075,187, which were deferred and amortized over the length of the Revolving Facility on a straight-line basis.

On December 21, 2017, the Company amended the Revolving Facility (the "Amended Revolving Facility"). Pursuant to the Amended Revolving Facility, CIT Bank and certain other lenders agreed to increase the revolving credit commitments up to $50,000,000. The Company accounted for the Amended Revolving Facility as a modification of debt in accordance with ASC 470-50, Debt — Modifications and Extinguishments and ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line of Credit Arrangements. Lender fees incurred in the amount of $437,500 were deferred and are amortized over the length of the Amended Revolving Facility on a straight-line basis.

The total amount available under the Revolving Facility includes a Swingline Loan and Letter of Credit subfacility, respectively, in an aggregate principal amount at any time outstanding not to exceed the lesser of (x) in the case of each of the Swingline Loan and Letter of Credit, $5,000,000 and (y) the total revolving commitment, based on certain terms and conditions of the Credit Agreement.

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

Total Leverage Ratio	LIBOR Rate Margin	ABR Margin
Category 1	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		

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

Subordinated Note

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

Promissory Notes

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

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

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

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

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

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

Note 11. Concentrations and Credit Risk

For the years ended December 31, 2018 and 2017, a significant portion of the Company's gross product sales reported were through three customers, and a significant portion of the Company's accounts receivable as of December 31, 2018 and 2017 were due from these customers as well. The following table sets forth the percentage of the Company's gross sales and accounts receivable attributable to these customers for the periods indicated:

	Gross Product Sales	
	Year Ended December 31,	
	2018	2017
Amerisource Bergen	7 %	23 %
Cardinal Health	55 %	37 %
McKesson	34 %	32 %
Combined Total	96 %	92 %

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

Purchasing

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

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

The Company purchases various API of finished products at contractual minimum levels through agreements with third parties. Individually, none of these agreements are material to the Company, therefore, the Company does not believe at this time that any of the purchase obligations represent levels above the normal course of business.

Sales by Product

For the years ended December 31, 2018 and 2017, one product accounted for 66% and 15%, respectively, of the Company's total gross product sales.

Royalty Sales

The following tables set forth the percentage of the revenues and accounts receivable recognized in connection with Company's royalty contracts for the years ended December 31, 2018 and 2017, respectively:

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

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

Note 12. Incentive Plans

Osmotica Pharmaceuticals plc 2018 Equity Incentive Plan

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

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

Effective February 3, 2016, Osmotica Holdings S.C.Sp. adopted the 2016 Equity Incentive Plan (the "2016 Plan") which allows for the issuance of up to 75,000 Units in Osmotica Holdings S.C.Sp. Options to purchase common units granted under the 2016 Plan vest and become exercisable in whole or in part, in accordance with vesting conditions set by the

Company's board of directors. Each option award had a maximum term of ten years from the date of grant. The option awards granted under the 2016 Plan were made up of two components: Time Awards and Performance Awards. The Time Awards vested 25% annually from original grant date, subject to continuous employment on each vesting date. The vesting of the Performance awards was subject to performance criteria, requiring the majority investors in the Company to receive (on a cumulative basis) aggregate net proceeds exceeding certain return on investment targets. The Time Awards and Performance Awards contained a sales restriction in the form of a liquidity event and subsequent disposal of common units by the Major Limited Partners (as defined in the 2016 Plan) before the employee was able to sell vested and exercised common units and were required to remain employed to avoid Company's call option on such common units at a lower of cost or fair market value.

Amended and Restated Osmotica Pharmaceuticals plc. 2016 Equity Incentive Plan

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

Share-based Compensation

The estimated fair value of the options is expensed over the requisite service period, which is generally the vesting period on a graded vesting basis. The compensation cost that has been charged against income for those incentive plans was $1,965,346 for the year ended December 31, 2018, $1.2 million of which related to share based compensation incurred prior to the IPO related to the fiscal year 2018. The total income tax benefit recognized in the statement of operations and comprehensive loss for share-based compensation arrangements was $439,318 for the year ended December 31, 2018. The conversion of the Performance Awards issued under the 2016 Plan to Time Awards upon IPO under the Amended 2016 Plan was accounted for as a modification where the fair value of such awards determined on a modification date, or the IPO date is being recognized over their remaining vesting period.

Share-Based Award Activity

A summary of option activity granted under the 2016 Plan and the Amended 2016 Plan as of December 31, 2018, and changes during the year then ended is presented below:

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

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

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

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

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

As of December 31, 2018, there was $5,062,986 of total unrecognized compensation cost related to nonvested options granted under the Incentive Plans. That cost is expected to be recognized over a weighted-average period of 9.8 years.

The fair value of option awards is estimated using the Black-Scholes option-pricing model. Exercise price of each award is generally not less than the per share fair value in effect as of that award date. The determination of fair value using the Black-Scholes model is affected by the Company's share fair value as well as assumptions regarding a number of complex and subjective variables, including expected price volatility, risk-free interest rate and projected employee share

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

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

The Company estimates its expected volatility by using a combination of historical share price volatilities of similar companies within our industry. The risk-free interest rate assumption is based on observed interest rates for the appropriate term of the Company's options on a grant date. The expected option term assumption is estimated using the simplified method and is based on the mid-point between vest date and the remaining contractual term of the option, since the Company does not have sufficient exercise history to estimate expected term of its historical option awards.

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

Note 13. Earnings (Loss) per Ordinary Share

Basic net income (loss) per ordinary share is computed by dividing net income (loss) by the weighted-average number of shares of ordinary shares outstanding during the period. Diluted net income per ordinary shares is computed by dividing net income by the weighted average number of shares of ordinary shares and potentially dilutive outstanding shares of ordinary shares during the period to reflect the potential dilution that could occur from ordinary shares issuable through contingent share arrangements, share options and warrants.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares and units outstanding as they would have been anti-dilutive at December 31, 2018 and 2017:

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

Note 14. Commitments and Contingencies

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

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

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

Capital Leases

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

Contingent Milestone Payments

The Company has entered into strategic business agreements for the development and marketing of finished dosage form pharmaceutical products with various pharmaceutical development companies. Each strategic business agreement includes a future payment schedule for contingent milestone payments and in certain strategic business agreements, minimum royalty payments. The Company will be responsible for contingent milestone payments and minimum royalty payments to these strategic business partners based upon the occurrence of future events. Each strategic business agreement defines the triggering event of its future payment schedule, such as meeting product development progress timelines, successful product testing and validation, successful clinical studies, and various U.S. Food and Drug Administration and other regulatory approvals.

Royalty Obligations

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

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

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

Supply Agreement Obligations

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

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

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

Defined Contribution Plan

Vertical/Trigen and Legacy Osmotica both had a defined contribution plan under Section 401(k) of the Internal Revenue Code ("IRC") as of December 31, 2016 pursuant to the Merger (the "Contribution Plans"). The employees of the respective Companies are eligible to participate in the Contribution Plans. Participants may contribute amounts through payroll deductions not to exceed IRC limitations. For the year ended December 31, 2016, the Vertical/Trigen Plan provided for nonelective employer contributions equal to 3% of basic compensation. The separate Contribution Plans were merged into one plan effective January 1, 2017. Effective January 1, 2017, the plan provides for employer matching contributions equal to 100% of each employee's elective deferrals up to 3% of base salary, plus 50% of each employee's elective deferrals between 3% and 5% of base salary. For the years ended December 31, 2018 and 2017, the Company recognized expenses related to its contributions under the Plan of $1,076,677 and $896,632, respectively.

Legal Proceedings

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

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

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

On February 16, 2018, the Company received FDA approval for its amantadine extended release tablets under the trade name Osmolex ER. On that same date the Company filed in the Federal District Court for the District of Delaware a Complaint for Declaratory Judgment of Noninfringement of certain patents owned by Adamas Pharmaceuticals, Inc. (Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals, LLC vs. Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC). Adamas was served with the Complaint on February 21, 2018. Adamas filed an answer on April 13, 2018 denying the allegations in the Complaint. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees.

Note 15. Income Taxes

Osmotica Pharmaceuticals plc (formerly known as Lilydale Limited and Osmotica Pharmaceuticals Limited) is an Irish public limited company. Osmotica Holdings S.C.Sp. acquired Osmotica Pharmaceuticals plc on April 30, 2018 for the purpose of facilitating an offering of ordinary shares in an initial public offering. On October 22, 2018, Osmotica Pharmaceuticals plc completed its initial public offering (the "IPO"). Immediately prior to the IPO and prior to the commencement of trading of Osmotica Pharmaceuticals plc's ordinary shares on the Nasdaq Global Select Market, Osmotica Holdings S.C.Sp. undertook a series of restructuring transactions that resulted in Osmotica Pharmaceuticals plc being the direct parent of Osmotica Holdings S.C.Sp. Osmotica Holdings S.C.Sp. is a Luxembourg special limited partnership, formed on January 28, 2016. Osmotica Holdings US LLC, a subsidiary of Osmotica Holdings S.C.Sp. entered into a fifty-fifty partnership (the "Merger"), effective February 3, 2016, pursuant to a definitive agreement between Vertical/Trigen Holdings, LLC ("Vertical/Trigen") and members, and Osmotica Holdings Corp Limited and Subsidiaries. Osmotica Holdings S.C.Sp. and several other holding companies and partnerships were formed as a result of the Merger. Vertical/Trigen Holdings, LLC became a wholly-owned subsidiary of certain U.S. corporations that are directly or indirectly owned by Osmotica Holdings U.S. LLC. These subsidiaries are included in the consolidated financial statements and are designated as C Corp filers for U.S. tax purposes. As such, the activity of Vertical/Trigen Holdings, LLC is subject to federal income tax at the level of its U.S. corporate parents beginning in 2016. In addition, the Company's foreign entities are subject to income tax in various foreign jurisdictions.

The Company follows the Income Taxes topic of ASC 740, which prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, as well as guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The loss before income taxes and the related tax benefit are as follows:

	December 31, 2018	December 31, 2017
Loss before income taxes		
U.S. operations	$ (52,758,931)	$ (41,276,187)
Non-U.S. operations	(65,905,252)	(44,366,355)
Total loss before income taxes	(118,664,183)	(85,642,542)
Current provision		
Federal	2,902,886	1,746,085
State	1,537,683	212,416
Foreign	2,089,428	1,595,246
Total current tax expenses	6,529,997	3,553,747
Deferred (benefit) provision		
Federal	(7,828,116)	(41,477,737)
State	(4,005,413)	(3,282,520)
Foreign	(3,679,910)	(3,185,216)
Total deferred tax benefit	(15,513,439)	(47,945,473)
Total benefit for income taxes	$ (8,983,442)	$ (44,391,726)

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

	December 31, 2018	December 31, 2017
Federal tax at 34% statutory rate	21.00 %	34.00 %
State and local income taxes, net of federal benefit	1.68 %	2.37 %
Differences in tax effects on foreign income	(10.08)%	(14.79)%
Federal tax credits	4.54 %	8.69 %
Uncertain tax positions — interest & penalties	0.13 %	(0.24)%
Enacted change in statutory rates	0.00 %	22.24 %
Change in valuation allowance	0.00 %	0.00 %
Permanent adjustments	(8.46)%	0.09 %
Other	(1.24)%	(0.53)%
Effective tax rate	7.57 %	51.83 %

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

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

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial statement purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at December 31, 2018 and 2017 respectively are as follows:

	December 31, 2018	December 31, 2017
Deferred tax assets:		
Accounts receivable	$ 44,241	$ 495,373
Accrued expenses	12,640,052	11,259,586
Inventory	490,574	341,539
Investment in partnership	9,536,754	7,730,044
Net operating losses	2,819,515	4,799,901
Tax credits	4,616,722	9,091,441
Share compensation	439,318	—
Other	1,229,509	1,932,521
Less: valuation allowance	(298,219)	(137,061)
Deferred tax liabilities:		
Prepaid expenses	(828,216)	(9,200,249)
Property plant & equipment	(3,002,215)	(2,827,186)
Intangible assets	(55,982,518)	(67,293,830)
Total deferred income taxes	$ (28,294,483)	$ (43,807,921)

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

Included in the deferred tax balances above is a net deferred tax liability of $30,289,469 and $44,655,585 respectively for 2018 and 2017 related to the assets and liabilities in Vertical/Trigen Holdings, LLC, which is a partnership for Federal income tax purposes. The Company owns in aggregate 100% of Vertical/Trigen Holdings, LLC and the assets and liabilities of this entity are included in the consolidated financial statements of the Company.

As of December 31, 2018 and 2017, the Company had a federal net operating loss carryover of $3.3 million and $4.4 million, respectively and net operating loss carryovers in certain foreign tax jurisdictions of approximately $22.4 million and $80.1 million, respectively which will begin to expire in 2022. At December 31, 2018 and 2017, the Company had total tax credit carryovers of approximately $4.6 million and $9.1 million primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers begin to expire in 2036. The Company assesses the realizability of the deferred tax assets at each balance sheet date based on actual and forecasted operating results in order to determine the proper amount, if any, required for a valuation allowance. As of December 31, 2018 and 2017, the Company maintains valuation allowances on deferred tax assets applicable to entities in foreign jurisdictions for which separate income tax returns are filed, where realization of the related deferred tax assets from future profitable operations is not reasonably assured. In 2018, the valuation allowance increased by $1.8 million due to incremental net operating losses applicable to entities in foreign jurisdictions.

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

The Company files income tax returns in U.S. federal, state and certain international jurisdictions. For federal and certain state income tax purposes, the Company's 2014 through 2017 tax years remain open for examination by the tax authorities under the normal statute of limitations. For certain international income tax purposes, the Company's 2010 through 2017 tax years remain open for examination by the tax authorities under the normal statute of limitations.

No provision is made for foreign withholding or income taxes associated with the cumulative undistributed earnings of the foreign subsidiaries. The cumulative undistributed earnings, if any, are expected to be reinvested in working capital and other business needs indefinitely. Any future foreign withholding or income taxes associated with the undistributed earnings are not anticipated to be material.

A reconciliation was completed of the beginning and ending amounts of unrecognized tax benefits, excluding accrued interest, for December 31, 2018 and 2017. It is not anticipated that the amount of unrecognized tax benefits will materially change in the next 12 months. If recognized, the total amount of unrecognized benefits of $2.2 million would have no impact on the effective tax rate.

Note 16. Related Parties

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

On August 22, 2018, the Company entered into a Master Service Agreement with United Biosource, LLC or UBC, an Avista portfolio company, for prescription processing and patient access services. In November 2018, the Company and UBC entered into a Statement of Work for services valued at approximately $2.4 million.

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