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

FORM 10-Q

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

For the quarterly period ended September 30, 2018
OR

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

For the transition period from to
Commission file number 001-38709

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

Ireland	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No X

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer X	Smaller reporting company X Emerging growth company X

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. X

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

There were 52,518,924 ordinary shares ($0.01 nominal value per share) outstanding as of November 7, 2018.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "plan," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives and financial needs. Examples of forward-looking statements include, among others, statements we make regarding: our intentions, beliefs or current expectations concerning, among other things, future operations; future financial performance, trends and events, particularly relating to sales of current products and the development, approval and introduction of new products; FDA and other regulatory applications, approvals and actions; the continuation of historical trends; and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs.

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

- if we are unable to successfully develop or commercialize new products, or do so on a timely or cost effective basis, our operating results will suffer;
- due to our dependence on a limited number of products, our business could be materially adversely affected if one or more of our key products do not perform as well as expected;
- failures of or delays in clinical trials could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales for new products;
- we are, and will continue to be in the future, a party to legal proceedings that could result in adverse outcomes;
- as of September 30, 2018, we had total outstanding debt of approximately $321.9 million (excluding original issue discount or upfront payments), and we had unused commitments of $50.0 million under our senior secured credit facilities. Our substantial debt could adversely affect our liquidity and our ability to raise additional capital to fund operations and could limit our ability to pursue our growth strategy or react to changes in the economy or our industry;
- we face intense competition from both brand and generic companies, which could significantly limit our growth and materially adversely affect our financial results;
- a business interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on could have a material adverse effect on our business;
- our profitability depends on our major customers, and if our relationships with them do not continue as expected, our business, prospects and results of operations could materially suffer;
- if we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell our products;

- our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business;
- our profitability depends on coverage and reimbursement by governmental authorities and other third-party payors and healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels;
- we are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations;
- our products or product candidates may cause adverse side effects that could delay or prevent their regulatory approval, or result in significant negative consequences following regulatory approval;
- manufacturing or quality control problems may damage our reputation, require costly remedial activities or otherwise negatively impact our business; and
- other factors that are described in the "Risk Factors" section of our prospectus relating to our initial public offering that was filed on October 19, 2018.

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

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

OSMOTICA PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 32,202,522	$ 34,743,152
Trade accounts receivable, net	72,718,271	37,637,957
Inventories, net	25,593,897	16,946,870
Prepaid expenses and other current assets	18,802,004	25,814,289
Total current assets	149,316,694	115,142,268
Property, plant and equipment, net	31,301,546	31,410,133
Intangibles, net	521,238,774	585,388,710
Goodwill	152,815,716	152,815,716
Other non-current assets	799,658	942,419
Total assets	$ 855,472,388	$ 885,699,246
Liabilities and Partners' Capital		
Current liabilities:		
Trade accounts payable	$ 27,860,913	$ 36,069,936
Accrued liabilities	81,576,774	81,926,390
Current portion of long-term debt, net of deferred financing costs	6,065,749	6,655,604
Current portion of obligation under capital leases	110,769	24,245
Total current liabilities	115,614,205	124,676,175
Long-term debt, net of non-current deferred financing costs	310,008,919	313,949,581
Long-term portion of obligation under capital leases	148,826	57,059
Income taxes payable	1,072,746	1,334,645
Deferred taxes	13,124,607	25,364,055
Other long-term liabilities	—	1,047,477
Total liabilities	439,969,303	466,428,992
Commitments and contingencies (See Note 11)		
Partners' capital:		
Partners' capital	417,374,758	419,903,400
Accumulated other comprehensive loss	(1,871,673)	(633,146)
Total partners' capital	415,503,085	419,270,254
Total liabilities and partners' capital	$ 855,472,388	$ 885,699,246

See accompanying notes to unaudited condensed consolidated financial statements

OSMOTICA PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net product sales	$ 65,443,818	$ 54,678,197	$ 196,263,666	$ 162,903,437
Royalty revenue	903,260	(1,085,212)	1,655,541	5,121,751
Licensing and contract revenue	(2,233)	148,198	85,392	1,391,566
Total revenues	66,344,845	53,741,183	198,004,599	169,416,754
Cost of goods sold (inclusive of amortization of intangibles)	32,011,554	21,464,233	99,149,685	77,363,924
Gross profit	34,333,291	32,276,950	98,854,914	92,052,830
Selling, general and administrative expenses	17,450,763	13,258,578	51,289,585	41,300,537
Research and development expenses	13,309,602	6,492,183	32,450,682	18,186,905
Impairment of intangible assets	6,173,000	30,747,638	6,173,000	72,447,638
Total operating expenses	36,933,365	50,498,399	89,913,267	131,935,080
Operating (loss) income	(2,600,074)	(18,221,449)	8,941,647	(39,882,250)
Interest expense and amortization of debt discount	5,311,330	7,301,027	15,395,727	21,720,518
Other non-operating income, net	(434,065)	(1,202,727)	(880,664)	(2,484,598)
Total other non-operating expense, net	4,877,265	6,098,300	14,515,063	19,235,920
Loss before income taxes	(7,477,339)	(24,319,749)	(5,573,416)	(59,118,170)
Income tax benefit	2,489,029	12,046,928	1,999,323	16,785,658
Net loss	$ (4,988,310)	$ (12,272,821)	$ (3,574,093)	$ (42,332,512)
Other comprehensive (loss) income, net				
Change in foreign currency translation adjustments	(148,183)	292,850	(1,238,527)	416,968
Comprehensive loss	$ (5,136,493)	$ (11,979,971)	$ (4,812,620)	$ (41,915,544)
Loss per unit attributable to unitholders				
Basic	$ (4.99)	$ (12.27)	$ (3.57)	$ (42.31)
Diluted	$ (4.99)	$ (12.27)	$ (3.57)	$ (42.31)
Weighted average units basic and diluted				
Basic and Diluted	1,000,515	1,000,515	1,000,515	1,000,515

See accompanying notes to unaudited condensed consolidated financial statements

OSMOTICA PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN PARTNERS' CAPITAL
FOR THE NINE MONTHS ENDED SEPTEMBER 30,2018

	Partners' capital	Accumulated other comprehensive loss	Total
Balance at December 31, 2017	$ 419,903,400	$ (633,146)	$ 419,270,254
Cumulative effect of change in accounting standard (See Note 2)	1,047,477	—	1,047,477
Net loss	(3,574,093)	—	(3,574,093)
Change in foreign currency translation	—	(1,238,527)	(1,238,527)
Partners' distributions	(2,026)	—	(2,026)
Balance at September 30, 2018 (Unaudited)	$ 417,374,758	$ (1,871,673)	$ 415,503,085

See accompanying notes to unaudited condensed consolidated financial statements

OSMOTICA PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,574,093)	$ (42,332,512)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	61,323,279	24,938,692
Loss on sale of fixed assets	12,892	—
Impairment of intangible assets	6,173,000	72,447,638
Deferred income tax benefit	(12,239,448)	(32,786,195)
Bad debt provision	(1,293,005)	(1,052,368)
Change in fair value of contingent consideration	—	182,396
Payment for contingent consideration	—	(1,991,288)
Amortization of deferred financing and loan origination fees	1,260,709	1,645,681
Non-cash interest expense	—	3,960,706
Change in operating assets and liabilities:		
Trade accounts receivable, net	(33,820,526)	18,808,736
Inventories, net	(8,647,027)	(132,901)
Prepaid expenses and other current assets	6,441,774	3,877,946
Other non-current assets	(1,800)	—
Trade accounts payable	(9,063,242)	(21,848,780)
Accrued and other current liabilities	601,713	10,289,036
Net cash provided by operating activities	7,174,226	36,006,787
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	10,000	—
Purchase of property, plant and equipment	(2,998,039)	(7,126,104)
Net cash used in investing activities	(2,988,039)	(7,126,104)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Distributions to Partners	(2,026)	(2,544,746)
Contributions from Partners	—	128,000
Payments on capital lease obligations	(81,822)	(107,821)
Proceeds from insurance financing loan	974,699	—
Repayment of insurance financing loan	(484,270)	—
Debt repayment	(6,140,066)	(5,251,908)
Payment for contingent consideration	—	(8,508,712)
Net cash used in financing activities	(5,733,485)	(16,285,187)
Net change in cash and cash equivalents	(1,547,298)	12,595,496
Effect on cash of changes in exchange rate	(993,332)	524,281
Cash and cash equivalents, beginning of period	34,743,152	19,558,570
Cash and cash equivalents, end of period	$ 32,202,522	$ 32,678,347
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 14,510,054	$ 15,929,055
Income taxes paid	$ 711,696	$ 10,161,472
Purchase of fixed assets by entering into capital lease	$ 260,113	$ —

See accompanying notes to unaudited condensed consolidated financial statements

OSMOTICA PHAMACEUTICALS PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 $58.4 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 being 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".

Until the Reorganization, 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 unaudited condensed 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.

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

Basis of Presentation—The accompanying unaudited condensed consolidated financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("GAAP") and under the rules and regulations of the United States Securities and Exchange Commission

OSMOTICA PHAMACEUTICALS PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(UNAUDITED)

("SEC") for interim reporting. In management's opinion, the interim financial data presented includes all adjustments (consisting solely of normal recurring items) necessary for fair presentation. All intercompany accounts and transactions have been eliminated. Certain information required by GAAP has been condensed or omitted in accordance with rules and regulations of the SEC. Operating results for the three and nine months ended September 30, 2018, are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2018 or any period thereafter. The accompanying Condensed Consolidated Balance Sheet data as of December 31, 2017 was derived from the audited consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2017. Except for the revenue recognition accounting policy that was updated as a result of adopting Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification ("ASC") Topic 606), the Company's significant accounting policies have not changed substantially from those previously described in the consolidated financial statements for the year ended December 31, 2017 that are included in the Company's Registration Statement on Form S-1, as amended.

Principles of Consolidation—The accompanying condensed consolidated financial statements include the accounts of Osmotica Holdings S.C.Sp. 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 GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Product Sales—Revenue is recognized at the point in time when the Company's performance obligations with its 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. In the event that the Company 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. 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, commercial rebates, discounts and allowances and doubtful accounts. 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

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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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(UNAUDITED)

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.

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

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive at September 30, 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Unit options to purchase units	70,400	71,400	70,400	71,400

Fair Value of Financial Instruments—The Company's financial instruments include cash and cash equivalents, accounts receivable, accounts payable and short and long-term debt. The fair values of cash and cash equivalents, accounts

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receivable and accounts payable approximate book value because of the short maturity of these financial instruments. The estimated fair value of the borrowing under the term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2 of the fair value hierarchy).

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.

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 condensed 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 Financial Accounting Standards Board ("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 condensed 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 condensed consolidated financial statements resulting from the adoption of this guidance.

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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 condensed 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 restrospective basis with a cumulative-effect adjustment recorded to retained earnings as of the beginning of the period of adoption. The Company was required to adopt this standard on January 1, 2018. Subsequent to the issuance of the June 2018 condensed consolidated financial statements, 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 condensed consolidated financial statements.

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. 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 condensed consolidated financial statements. The Company is currently evaluating the impact of the new accounting standard and intends to adopt effective January 1, 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

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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.

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. This standard is effective upon issuance. The Company is currently evaluating the impact of the new accounting standard.

Note 3. Revenues

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Pharmaceutical Product	**2018**	**2017**	**2018**	**2017**
Venlafaxine ER	$ 15,893,616	$ 23,647,777	$ 50,377,620	$ 85,291,721
Methylphenidate ER	33,247,942	16,539,747	100,573,444	16,539,747
Lorzone	4,324,952	5,176,568	12,536,874	16,109,309
Divigel	5,129,394	4,470,532	15,062,262	13,170,503
OB Complete	2,457,036	2,203,263	7,557,733	7,608,954
Other	4,390,878	2,640,310	10,155,733	24,183,203
Net product sales	65,443,818	54,678,197	196,263,666	162,903,437
Royalty revenue	903,260	(1,085,212)	1,655,541	5,121,751
License and contract revenue	(2,233)	148,198	85,392	1,391,566
Total revenues	$ 66,344,845	$ 53,741,183	$ 198,004,599	$ 169,416,754

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 September 30, 2018. 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 September 30, 2018. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs.*

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Note 4. Accounts Receivable, Sales and Allowances

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

Accounts receivable result primarily from sales of pharmaceutical products, amounts due under revenue sharing, license and royalty arrangements, which inherently involves, in the ordinary course of business, estimates relating to allowances for product returns, chargebacks, rebates, 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 Condensed Consolidated Statements of Operations and Comprehensive Loss.

Trade accounts receivable, net consists of the following:

	September 30, 2018	December 31, 2017
Gross trade accounts receivable		
Trade accounts receivable	$ 128,869,712	$ 110,592,198
Royalty accounts receivable	2,125,758	4,002,272
Other receivable	—	184,808
Less reserves for:		
Chargebacks	(30,612,518)	(32,342,377)
Commercial rebates	(23,877,097)	(39,233,419)
Discounts and allowances	(3,274,171)	(3,484,587)
Doubtful accounts	(513,413)	(2,080,938)
Total trade accounts receivable, net	$ 72,718,271	$ 37,637,957

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The Company recorded the following adjustments to gross product sales:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Gross product sales	$ 225,747,442	$ 172,712,184	$ 688,398,828	$ 437,006,141
Less provisions for:				
Chargebacks	(87,655,437)	(51,622,571)	(261,081,159)	(140,521,777)
Government rebates	(5,231,672)	(10,687,540)	(15,574,538)	(22,113,361)
Commercial rebates	(59,217,332)	(42,214,629)	(182,605,338)	(78,918,807)
Product returns	(2,418,150)	(8,653,792)	(13,979,253)	(18,467,177)
Discounts and allowances	(4,545,341)	(3,904,313)	(14,987,285)	(10,543,788)
Advertising and promotions	(1,235,692)	(951,142)	(3,907,589)	(3,537,794)
Net product sales	$ 65,443,818	$ 54,678,197	$ 196,263,666	$ 162,903,437

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 December 31, 2017	$ 32,342,377	$ 39,233,419	$ 3,484,587	$ 2,080,938	$ 77,141,321
Provision	261,081,159	182,605,338	14,987,285	(1,293,005)	457,380,777
Charges processed	(262,811,018)	(197,961,660)	(15,197,701)	(274,520)	(476,244,899)
Balance at September 30, 2018	$ 30,612,518	$ 23,877,097	$ 3,274,171	$ 513,413	$ 58,277,199

The activity in the Company's accrued liabilities for customer deductions by account is as follows:

	Product Returns	Government Rebates	Total
Balance at December 31, 2017	$ 43,299,324	$ 14,151,714	$ 57,451,038
Provision	13,979,253	15,574,538	29,553,791
Charges processed	(12,647,618)	(18,386,934)	(31,034,552)
Balance at September 30, 2018	$ 44,630,959	$ 11,339,318	$ 55,970,277

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 current systems and processes of the Company do not capture the chargeback and rebate settlements by the period in which the original sales transaction was recorded. The Company uses a combination of factors and applications to estimate the dollar amount of reserves for chargebacks and rebates at each month end. Variable consideration is included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. The Company regularly monitors the reserves based on an analysis of the Company's product sales and most recent claims, wholesaler inventory, current pricing, and anticipated future pricing changes. If amounts are different from the estimate due to changes from estimated rates, accrual rate adjustments are considered prospectively when determining provisions in accordance with authoritative GAAP.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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Note 5. Inventories

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

	September 30, 2018	December 31, 2017
Finished goods	$ 14,338,521	$ 10,467,243
Work in process	4,177,779	789,413
Raw materials and supplies	7,077,597	5,690,214
	$ 25,593,897	$ 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, obsolete, and net realizable value inventory account was as follows:

	Allowance for excess and obsolete inventory
Balance at December 31, 2017	$ 3,066,620
Provision	2,451,938
Charges processed	(2,676,877)
Balance at September 30, 2018	$ 2,841,681

Note 6. 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. There were no events or changes in circumstances since October 1, 2017 for the Company to test for impairment of goodwill. The carrying value of goodwill was $152,815,716 as of September 30, 2018 and December 31, 2017.

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

	September 30, 2018					
	Gross Carrying Amount	Accumulated Amortization	Reclassifications	Impairment	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Distribution Rights	$ 98,433,377	$ (15,412,236)	$ —	$ —	$ 83,021,141	12.2
Product Rights	326,530,149	(94,307,926)	—	—	232,222,223	4.3
Tradenames	13,485,000	(2,152,805)	—	—	11,332,195	16.2
Developed Technology	138,133,333	(28,597,118)	—	(6,173,000)	103,363,215	12.4
IPR&D	91,300,000	—	—	—	91,300,000	Indefinite Lived
	$ 667,881,859	$ (140,470,085)	$ —	$ (6,173,000)	$ 521,238,774	

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	December 31, 2017					
	Gross Carrying Amount	Accumulated Amortization	Reclassifications (restated)	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 the net carrying amount of intangible assets were as follows:

	Distribution Rights	Product Rights	Tradenames	Developed Technology	IPR&D	Total
December 31, 2017	$ 88,543,095	$ 276,628,055	$ 11,861,632	$ 117,055,928	$ 91,300,000	$ 585,388,710
Amortization	(5,521,954)	(44,405,832)	(529,437)	(7,519,713)	—	(57,976,936)
Impairments	—	—	—	(6,173,000)	—	(6,173,000)
September 30, 2018	$ 83,021,141	$ 232,222,223	$ 11,332,195	$ 103,363,215	$ 91,300,000	$ 521,238,774

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 Company's 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, 2017 annual goodwill and indefinite-lived intangible assets impairment test ranged from 9.0% to 8.5%, 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. Any impairment charges resulting from annual or interim goodwill and intangible asset impairment assessments are recorded to Impairment of intangible assets in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

The Company recorded impairment charges in intangibles in the amount of $6,173,000 and $30,747,638 for the three months ended September 30, 2018 and 2017, respectively, and $6,173,000 and $72,447,638 for the nine months ended September 30, 2018 and 2017, respectively. The impairment of $6,173,000 relates to the write down to fair value of our Nifedipine intangible asset for which we receive a royalty based on gross profit generated by our license partner.

Amortization expense of $19,302,133 and $8,811,122 for the three months ended September 30, 2018 and 2017, respectively, and $57,776,936 and $22,623,659 for the nine months ended September 30, 2018 and 2017, respectively

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was recorded as cost of goods sold. The amortization expense of acquired intangible assets for each of the following five years and thereafter are expected to be as follows:

Years ending December 31	Amortization Expense
Remainder of 2018	$ 18,974,028
2019	69,711,697
2020	68,324,749
2021	66,160,668
2022	43,919,941
Thereafter	162,847,691
	$ 429,938,774

Note 7. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2018	December 31, 2017
Accrued product returns	$ 44,630,959	$ 43,299,324
Accrued royalties	7,661,494	12,325,232
Accrued compensation	6,659,670	6,342,731
Accrued government rebates	11,339,318	14,151,714
Accrued expenses and other liabilities	10,400,382	5,153,356
Customer coupons	884,951	425,911
Deferred revenue	—	228,122
	$ 81,576,774	$ 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 8. Financing Arrangements

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

	September 30, 2018	December 31, 2017
CIT Bank, N.A. Term Loan, net of deferred financing costs of $5,775,696 and $6,894,816 as of September 30, 2018 and December 31, 2017, respectively	$ 315,584,239	$ 320,605,185
Note payable — insurance financing	490,429	—
	316,074,668	320,605,185
Less: current portion	(6,065,749)	(6,655,604)
Long-term debt	$ 310,008,919	$ 313,949,581

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Term Loan

As of September 30, 2018, the interest rate was 5.99% for the Company's Term A Loan and 6.49% for the Term B Loan. As of December 31, 2017, the interest rate was 5.25% for the Term A Loan and 5.75% for the Term B Loan. The Company was in compliance with all covenants of the Term Loan Agreement as of September 30, 2018.

Note 9. Concentrations and Credit Risk

In the three and nine months ended September 30, 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 September 30, 2018 and December 31, 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			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amerisource Bergen	6 %	8 %	7 %	29 %
Cardinal Health	55 %	51 %	54 %	29 %
McKesson	35 %	34 %	34 %	31 %
Combined Total	96 %	93 %	95 %	89 %

	Gross Account Receivables	
	September 30, 2018	December 31, 2017
Amerisource Bergen	4 %	7 %
Cardinal	56 %	57 %
McKesson	36 %	29 %
Combined Total	96 %	93 %

Purchasing

For the three and nine months ended September 30, 2018, one supplier accounted for more than 54% and 77%, respectively, of the Company's purchases of raw materials for products that are manufactured by the Company. For the three and nine months ended September 30, 2017, three suppliers accounted for approximately 99% and 88%, respectively, of the Company's purchases of raw materials for products that are manufactured by the Company.

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.

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Note 10. Incentive Plans

Share-based Compensation — Osmotica Holdings S.C.Sp. 2016 Equity Incentive Plan

Option Awards

The table below summarizes the Time and Performance Award activities for the nine months ended September 30, 2018:

	Number of Units			Weighted Average Exercise Price	Weighted Average Contractual Term
	Time	Performance	Total		
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 September 30, 2018	35,200	35,200	70,400	$ —	7.6 years
Vested Options at September 30, 2018	16,323	—	16,323	$ 640	

Note 11. Commitments and Contingencies

Operating Leases

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 $165,691 and $145,348 for the three months ended September 30, 2018 and 2017, respectively, and $493,825 and $436,917 for the nine months ended September 30, 2018 and 2017, respectively. Total rent expense charged to research and development was $44,862 and $65,420 for the three months ended September 30, 2018 and 2017, respectively, and $191,430 and $209,472 for the nine months ended September 30, 2018 and 2017, respectively. The rent expense charged to cost of goods sold was $81,141 and $92,584 for the three months ended September 30, 2018 and 2017, respectively, and $264,957 and

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$279,489 for the nine months ended September 30, 2018 and 2017, respectively. The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the leases as follows:

Years ending December 31	Operating Leases
Remainder of 2018	$ 272,682
2019	1,327,606
2020	1,364,334
2021	1,099,551
2022	870,344
Thereafter	490,514
	$ 5,425,031

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 required under the capital lease together with its present value of the net minimum lease payments of $259,596 for the remainder of the year ended December 31, 2018 through December 31, 2021.

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.

The following table lists the Company’s enforceable and legally binding royalty obligations as of September 30, 2018:

	Royalty Obligations
Less than 1 year	$ 1,375,000
1 to 3 years	3,281,250
3 to 5 years	2,000,000
More than 5 years	2,333,333
	$ 8,989,583

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 or 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

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The following table lists the Company's enforceable and legally binding purchase obligations as of September 30, 2018:

	Purchase Obligations
Less than 1 year	$ 4,000,000
1 to 3 years	8,000,000
3 to 5 years	4,000,000
	$ 16,000,000

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.

In February 2017, a former employee of the Company filed with the Equal Employment Opportunity Commission ("EEOC") a Charge of Discrimination based on disability and sexual orientation. While the Charge of Discrimination was pending at the EEOC, the employee declared bankruptcy. In November 2017, the EEOC issued a determination of no probable cause following the filing of the Company's position statement without further investigation. This started a period of 90 days during which the former employee could bring a law suit in Federal Court to pursue the claim. On February 16, 2018, the Chapter 7 Trustee for the employee filed a lawsuit in the Federal District Court for the Northern District of Georgia alleging gender and disability discrimination and retaliation, seeking reinstatement of the employee, back pay and unspecified damages (*Chapter 7 Trustee vs. Osmotica Pharmaceutical US LLC*). On June 22, 2018, the Company and counsel for the Chapter 7 Trustee agreed to settle the matter for an immaterial amount subject to approval of the Bankruptcy Court.

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 and an answer on April 13, 2018 denying the allegations in the Complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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On April 30, 2018, Vertical Pharmaceuticals, LLC was served with a Complaint in an action entitled *State of Arkansas, ex rel, Scott Ellington, et al., v. Purdue Pharma, L.P., et al Crittenden County Circuit Court, No. CV-2018-268.* The State of Arkansas brought suit against numerous manufacturers and distributors of opioid products alleging that defendants were negligent and created a public nuisance by shipping opioid products into Arkansas without proper controls and alleging violations of the Arkansas Uniform Narcotic Drug Act, Arkansas Controlled Substances Act, and the Arkansas Drug Dealer Liability Act. On July 17, 2018, the Court entered an Order dismissing Vertical from the lawsuit without prejudice.

Note 12. Income Taxes

During the nine months ended September 30, 2018, the Company recognized an income tax benefit of $2.0 million on $5.6 million of loss before income tax, compared to $16.8 million of income tax benefit on $59.1 million of loss before income tax during the comparable 2017 period.

The income tax (expense) benefit for the nine months ending September 30, 2018 and for the same period in 2017 reflect significant differences in the usual relationship of income tax expense (benefit) to the income (loss) 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 nine months ended September 30, 2018 and for the same period in 2017 respectively; a disproportionate change in the income tax rate for the nine months ended September 30, 2018 as a result of credits from research and development when compared to the income (loss) before income taxes; and the fact that in both periods in question there are ordinary losses in certain foreign tax jurisdictions that the Company operates in 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 quarter ended September 30, 2018 there were favorable discrete items of $1.5 million included in the income tax provision related to the 2017 return to provision adjustment to the Orphan Drug and Research and Development credits.

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 September 30, 2018, and September 30, 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.

The Company provides reserves for potential payments of income tax to various tax authorities or does not recognize income tax benefits related to uncertain tax positions and other issues. Tax benefits for uncertain tax positions are based on a determination of whether a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized, assuming that the matter in question will be decided based on its technical merits. The Company’s policy is to record interest and penalties in the provision for income taxes.

The Company sells its products in various jurisdictions and is subject to federal, foreign, state and local taxes. While the Company believes that it has properly paid or accrued for all such taxes based on its interpretation of applicable law, tax laws are complex, and interpretations differ. As a result, on February 26, 2018, the Company filed requests to enter into Voluntary Disclosure Agreements with the States of New Jersey and Georgia related to prior and current period sales and use taxes. The ultimate liability of the Company in respect to such taxes cannot be estimated with any certainty at this time. As of this report, the outcome of these requests is not expected to be material to the Company.

For the nine months ended September 30, 2018, the Company has 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

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No. 118, or SAB 118. The Company will continue to analyze the impact of the U.S. Tax Cuts and Jobs Act under SAB 118 and will record adjustments to provisional amounts as such analyses are refined.

Note 13. Related Parties

As of September 30, 2018, and December 31, 2017, respectively the Company had a $135,000 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 three months ended September 30, 2018 and 2017, the Company incurred rent expense under this lease of $51,271 and $74,765. For the nine months ended September 30, 2018 and 2017, the Company incurred rent expense under this lease of $202,642 and $239,395.

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.

Note 14. Subsequent Events

As described in Note 1, the Company completed the Reorganization on October 17, 2018 and the IPO on October 22, 2018.

Upon the IPO, an amendment to the Osmotica Pharmaceuticals S.C.Sp. 2016 Equity Incentive Plan went into effect, resulting in the conversion of Time Awards and Performance Awards into options to purchase ordinary shares of Osmotica Pharmaceuticals plc on the same basis as common units of Osmotica Pharmaceuticals S.C.Sp. with corresponding adjustments to the exercise price of the options. In connection with the conversion, the Time Awards will continue to vest according to the original schedule of equal annual installments on each of the first four anniversaries of the time vesting dates and the Performance Awards will be converted into options that vest solely based on the passage of time, with the Performance Awards vesting in equal annual installments on each of the first four anniversaries of the IPO.

In addition, upon the IPO the Osmotica Pharmaceuticals plc 2018 Incentive Plan went into effect and the Company’s board reserved 4,100,000 ordinary shares for issuance under the plan.

Item 2. 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 "Cautionary Note Regarding Forward-Looking Statements." Our actual results may differ materially from those contained in or implied by any forward-looking statements. This discussion and analysis is based upon the historical financial statements of Osmotica Holdings S.C.Sp. Prior to the Reorganization (as defined in Note 14, Subsequent Events to our condensed consolidated financial statements included in this report), Osmotica Pharmaceuticals plc had no material assets and conducted no operations other than activities incidental to its formation, the Reorganization and our initial public offering. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31.

Overview

We are a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. We 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. We recently received regulatory approval from the U.S. Food and Drug Administration, or 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 are preparing to launch Osmolex ER in the second half of 2018. In addition, we have a late-stage development pipeline highlighted by two new drug application, or NDA, candidates in Phase III clinical trials: Ontinua ER (arbaclofen extended-release tablets) for muscle spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid. Many of our products use our proprietary osmotic-release drug delivery system, Osmodex, which we believe offers advantages over alternative extended-release, or ER, technologies.

Our core competencies span drug development, manufacturing and commercialization. Our specialized neurology and women's health sales teams support the ongoing commercialization of our existing promoted product portfolio as well as the launch of new products. As of September 30, 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 most recently launched M-72 in the second quarter of 2018, and we expect to launch Osmolex ER, which was approved by the FDA on February 16, 2018, in the second half of 2018. We also sell a portfolio consisting of approximately 35 non-promoted products, which has generated strong cash flow. The cash flow from these non-promoted products has contributed to our robust investments in research and development and business development activities. Many of our existing products benefit from several potential barriers to entry, including intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as U.S. Drug Enforcement Administration, or DEA, regulation and quotas for active pharmaceutical ingredients, or API. Certain of our key products, particularly those that incorporate our proprietary Osmodex drug delivery system, are or are expected to be manufactured in our Marietta, Georgia facility.

We are focused on progressing our pipeline, which is highlighted by two Phase III candidates under clinical development — Ontinua ER and RVL-1201. We developed Ontinua ER using our proprietary Osmodex drug delivery system and believe this formulation will provide an efficacious and safe treatment for muscle spasticity in multiple sclerosis patients. Ontinua ER has been designated by the FDA as an Orphan Drug in this indication. We are also exploring opportunities for Ontinua ER in additional indications, such as opioid and alcohol use disorders. 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 expects to undertake the future development and 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, Basis of Presentation and *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included elsewhere in this report.

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 venlafaxine ER or VERT and methylphenidate ER. 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 title and risk of loss has passed to the customer, which is typically upon delivery to the customer and when estimated provisions for revenue reserves are reasonably determinable. The amount of revenue we recognize is equal to the selling price, adjusted for our estimates of a number of significant sales deductions.

Royalty revenue—Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. Our commercial partners are obligated to report their net product sales and the resulting royalty payments.

Licensing and contract revenue—We recognize revenue from a contractual arrangement when product is shipped to our commercial partners. Licensing revenue is recognized in the period in which the product subject to the arrangement is sold or services are rendered. Sales deductions, 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 and we do not record any payments. Licensing and contract revenues are shown net of costs in situations where it has been determined that we are an agent in the relationship.

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 Three Months Ended September 30, 2018 and 2017

Financial Operations Overview

The following table presents revenues and expenses for the three months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,		
	2018	2017	% Change
Net product sales	$ 65,444	$ 54,678	20 %
Royalty revenue	903	(1,085)	(183)%
Licensing and contract revenue	(2)	148	(101)%
Total Revenue	66,345	53,741	23 %
Cost of goods sold (inclusive of amortization of intangibles)	32,012	21,464	49 %
Gross profit	34,333	32,277	6 %
Gross profit percentage	*52 %*	*60 %*	
Selling, general and administrative expenses	17,450	13,259	32 %
Research and development expenses	13,310	6,492	105 %
Impairment of intangible assets	6,173	30,748	(80)%
Total operating expenses	36,933	50,499	(27)%
Interest expense and amortization of debt discount	5,311	7,301	(27)%
Other non-operating income, net	(434)	(1,203)	(64)%
Total other non-operating expenses, net	4,877	6,098	(20)%
Loss before income taxes	(7,477)	(24,320)	(69)%
Income tax benefit	2,489	12,047	(79)%
Net loss	$ (4,988)	$ (12,273)	(59)%

Revenue

The following table presents total revenues for the three months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,		
	2018	2017	% Change
Venlafaxine ER	$ 15,894	$ 23,648	(33)%
Methylphenidate ER	33,248	16,540	101 %
Lorzone	4,325	5,177	(16)%
Divigel	5,129	4,471	15 %
OB Complete	2,457	2,203	12 %
Other	4,391	2,639	66 %
Net product sales	65,444	54,678	20 %
Royalty revenue	903	(1,085)	(183)%
Licensing and contract revenue	(2)	148	(101)%
Total revenues	$ 66,345	$ 53,741	23 %

Total Revenues. Total revenues increased by $12.6 million to $66.3 million for the three months ended September 30, 2018, as compared to $53.7 million for the three months ended September 30, 2017.

Net Product Sales. Net product sales increased by $10.8 million to $65.4 million for the three months ended September 30, 2018, as compared to $54.7 million for the three months ended September 30, 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. Product sales from VERT decreased by 33% for the three months ended September 30, 2018, reflecting a greater proportion of sales from our lower priced authorized generic product during the period. Currently, two other companies sell competing dosage strengths of VERT.

Product sales from Lorzone declined 16% for the three months ended September 30, 2018, reflecting the shift of promotional efforts to M-72 which was launched earlier in 2018 while product sales from Divigel increased by 15%, reflecting targeted promotional activities and strong patient access. Product sales from the OB Complete family of prescription prenatal dietary supplements increased by 12% during the three months ended September 30, 2018 compared to the prior year period following the discontinuation of our OB Gold pre-natal vitamin line in the first half of 2017, which led to a temporary decline in sales for the OB Complete family of products. Sales from other non-promoted products sales increased by 66%.

Royalty Revenue. Royalty revenue increased by $2.0 million for the three months ended September 30, 2018. Royalty revenue for the three months ended September 30, 2017 was negatively affected by actual expenses that were in excess of a previously accrued estimate for which an adjustment was made during the period.

Licensing and Contract Revenue. Licensing and contract revenue decreased by $0.2 million in 2018 primarily due to lower sales of Tramadol to our license partner, together with a true-up adjustment on another product.

Cost of Goods Sold and Gross Profit Percentage

The following table presents a breakdown of total cost of goods sold for the three months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,		
	2018	2017	% Change
Amortization of intangible assets	$ 19,302	$ 8,811	119 %
Depreciaton expense	674	544	24 %
Royalty expense	2,043	3,196	(36)%
Other cost of goods sold	9,993	8,913	12 %
Total cost of goods sold	$ 32,012	$ 21,464	49 %

Cost of goods sold increased $10.5 million in the three months ended September 30, 2018 to $32.0 million as compared to $21.5 million in the three months ended September 30, 2017. The increase was primarily driven by a $10.5 million increase in amortization of intangible assets, largely attributable to the transfer of methylphenidate ER to definite-lived intangible assets following its approval and launch in the third quarter of 2017. Royalty expense decreased by $1.2 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 $1.0 million increase in other cost of goods sold was mostly due to a change in product mix.

Gross profit percentage decreased to 52% for the three months ended September 30, 2018 as compared with 60% for the three months ended September 30, 2017, primarily due to the increase in amortization expense for methylphenidate ER. Excluding amortization and depreciation, our gross profit percentage increased to 82% for the three months ended September 30, 2018 as compared with 78% for the three months ended September 30, 2017, primarily due to a greater proportion of methylphenidate ER sales, and the 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 $4.2 million in the three months ended September 30, 2018 to $17.5 million as compared to $13.3 million in the three months ended September 30, 2017. Selling, general and administrative expenses increased primarily due to an expansion of our field force in early 2018, expenses associated with the launch of M-72 and pre-launch activities for Osmolex ER and expenses related to our initial public offering.

Research and Development

Research and development expenses increased by $6.8 million in the three months ended September 30, 2018 to $13.3 million as compared to $6.5 million in the three months ended September 30, 2017. The increase was largely attributable to clinical trial costs of Ontinua ER and RVL-1201, each of which are in Phase III clinical trials, together with additional headcount.

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

	Three Months Ended September 30, 2018	2017	% Change
Osmolex ER	$ 948	$ 366	159 %
Ontinua ER	4,472	551	712 %
RVL 1201	3,023	—	NM %
Other	4,867	5,575	(13)%
Total	$ 13,310	$ 6,492	105 %

NM - Not meaningful

Impairment of Intangible Assets

Impairment of intangible assets of $6.2 million during the three months ended September 30, 2018 relates to the write down to fair value of our Nifedipine intangible asset for which we receive a royalty based on gross profit generated by our license partner. During the three months ended September 30, 2018, increased competition affected the selling price of the product and certain other issues were the principal reasons for the impairment of the asset. During the three months ended September 30, 2017 we took impairment charges related to certain of our Product Rights, Developed Technology and In-Process R&D intangible assets. The following table details the impairment charges for such period (in thousands):

	Three Months Ended September 30, 2017	
Asset/Asset Group	Impairment Charge	Reason For Impairment
Product Rights		
Hydromorphone ER	$ 6,567	Sales underperforming expectations due to competition
Other Product Rights	489	Discontinued products/lower sales expectations
	7,056	
Developed Technology		
Oxybutinin License Royalty	8,767	Revenue underperforming expectations due to new generic market entrant
In-Process R&D		
Osmolex ER	8,900	Delay in approval date and product launch
Other Generic Products in Development	6,025	Delay in finalizing formulation development
	14,925	
Total Impairment Charges for three months ended September 30, 2017	$ 30,748	

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by $2.0 million in the three months ended September 30, 2018 to $5.3 million as compared to $7.3 million in the three months ended September 30, 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, net

Other non-operating income was $0.4 million and $1.2 million for the three months ended September 30, 2018 and 2017, respectively.

Income Tax Expense

During the three months ended September 30, 2018, we recognized income tax benefit of $2.5 million on $7.5 million of loss before income tax, compared to $12.0 million of income tax benefit on $24.3 million of loss before income tax during the comparable 2017 period.

The income tax expense was based on the applicable federal and state tax rates for those periods. For periods with income before provision for income taxes, favorable tax items result in a decrease in the effective tax rate, while unfavorable tax items result in an increase in the effective tax rate. For periods with a loss before benefit from income taxes, favorable tax items result in an increase in the effective tax rate, while unfavorable tax items result in a decrease in the effective tax rate.

The income tax expense (benefit) for the three months ending September 30, 2018 and for the same period in 2017 reflect significant differences in the usual relationship of income tax expense (benefit) to the income (loss) 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 three months ended September 30, 2018 compared to the same period in 2017; a disproportionate change in the income tax rate for the three months ended September 30, 2018 as a result of credits from research and development when compared to the income (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 three months ended September 30, 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.

Comparison of Nine Months Ended September 30, 2018 and 2017

Financial Operations Overview

The following table presents revenues and expenses for the nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Nine Months Ended September 30,		
	2018	2017	% Change
Net product sales	$ 196,264	$ 162,903	20 %
Royalty revenue	1,656	5,122	(68)%
Licensing and contract revenue	85	1,392	(94)%
Total Revenue	198,005	169,417	17 %
Cost of goods sold (inclusive of amortization of intangibles)	99,150	77,364	28 %
Gross profit	98,855	92,053	7 %
Gross profit percentage	*50 %*	*54 %*	
Selling, general and administrative expenses	51,289	41,300	24 %
Research and development expenses	32,451	18,187	78 %
Impairment of intangible assets	6,173	72,448	(91)%
Total operating expenses	89,913	131,935	(32)%
Interest expense and amortization of debt discount	15,396	21,721	(29)%
Other non-operating income, net	(881)	(2,485)	(65)%
Total other non-operating expenses, net	14,515	19,236	(25)%
Loss before income taxes	(5,573)	(59,118)	(91)%
Income tax benefit	1,999	16,786	(88)%
Net loss	$ (3,574)	$ (42,332)	(92)%

Revenue

The following table presents total revenues for the nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Nine Months Ended September 30,		
	2018	2017	% Change
Venlafaxine ER	$ 50,378	$ 85,292	(41)%
Methylphenidate ER	100,573	16,540	508 %
Lorzone	12,537	16,109	(22)%
Divigel	15,062	13,171	14 %
OB Complete	7,558	7,609	(1)%
Other	10,156	24,182	(58)%
Net product sales	196,264	162,903	20 %
Royalty revenue	1,656	5,122	(68)%
Licensing and contract revenue	85	1,392	(94)%
Total revenues	$ 198,005	$ 169,417	17 %

Total Revenues. Total revenues increased by $28.6 million to $198.0 million for the nine months ended September 30, 2018, as compared to $169.4 million for the nine months ended September 30, 2017.

Net Product Sales. Net product sales increased by $33.4 million to $196.3 million for the nine months ended September 30, 2018, as compared to $162.9 million for the nine months ended September 30, 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. Product sales from VERT decreased by 41% for the nine months ended September 30, 2018, reflecting a greater proportion of sales from our lower priced authorized generic product, which accounted for

substantially all VERT unit volume during the period. Currently, two other companies sell competing dosage strengths of VERT.

Product sales from Lorzone declined 22% for the nine months ended September 30, 2018, reflecting the shift of promotional efforts to M-72 which was launched earlier in the second quarter of 2018, partially offset by price increases instituted in early 2018. Product sales from Divigel increased by 14%, driven primarily by targeted promotional activities and strong patient access. Product sales from the OB Complete family of prescription prenatal dietary supplements decreased by 1% as sales levels stabilized following the discontinuation of our OB Complete Gold prenatal vitamin line during 2017. Other non-promoted product sales decreased by 58%, primarily 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.

Royalty Revenue. Royalty revenue decreased by $3.5 million for the nine months ended September 30, 2018 compared to the prior year period, primarily due to lower product sales.

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 nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Nine Months Ended September 30,		
	2018	2017	% Change
Amortization of intangible assets	$ 57,777	$ 22,624	155 %
Depreciaton expense	1,952	1,279	53 %
Royalty expense	9,079	21,610	(58)%
Other cost of goods sold	30,342	31,851	(5)%
Total cost of goods sold	$ 99,150	$ 77,364	28 %

Cost of goods sold increased $21.8 million in the nine months ended September 30, 2018 to $99.2 million as compared to $77.4 million in the nine months ended September 30, 2017. The increase was primarily driven by a $35.2 million increase in amortization of intangible assets, largely attributable to the transfer of methylphenidate ER to definite-lived intangible assets, following its approval and launch in the third quarter of 2017. The increase in depreciation expense is largely attributable to an expansion project for our manufacturing facility in Marietta, Georgia which was completed during the second quarter of 2017, after which we began recognizing depreciation expense on the project. Royalty expense decreased by $12.5 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 $1.5 million decrease in other cost of goods sold is mostly due to change in product mix.

Gross profit percentage decreased to 50% for the nine months ended September 30, 2018 as compared with 54% for the nine months ended September 30, 2017, primarily due to the increase in amortization expense for methylphenidate ER. Excluding amortization and depreciation, our gross profit percentage increased to 80% for the nine months ended September 30, 2018 as compared with 68% for the nine months ended September 30, 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 $10.0 million in the nine months ended September 30, 2018 to $51.3 million as compared to $41.3 million in the nine months ended September 30, 2017. The increase in our selling, general and administrative expenses reflects costs we incurred related to our initial public offering, severance expenses due to restructuring of our sales force, expenses related to the launch of M-72 and Osmolex ER and additions of headcount, including our sales force.

Research and Development

Research and development expenses increased by $14.3 million in the nine months ended September 30, 2018 to $32.5 million as compared to $18.2 million in the nine months ended September 30, 2017. The increase was largely attributable to clinical trial costs of Ontinua ER and RVL-1201, each of which are in Phase III clinical trials, together with additional headcount.

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

	Nine Months Ended September 30,		
	2018	2017	% Change
Osmolex ER	$ 1,577	$ 3,084	(49)%
Ontinua ER	11,847	2,978	298 %
RVL 1201	4,944	—	NM %
Other	14,083	12,125	16 %
Total	$ 32,451	$ 18,187	78 %

NM – Not meaningful

Impairment of Intangible Assets

Impairment of intangible assets of $6.2 million during the nine months ended September 30, 2018 relates the write down to fair value of our Nifedipine intangible asset for which we receive a royalty based on gross profit generated by our license partner. During the nine months ended September 30, 2018, increased competition affected the selling price of the product and certain other issues were the principal reasons for impairment of the assets. During the nine months ended September 30, 2017 we took impairment charges related to certain of our Product Rights, Developed Technology

and In-Process R&D intangible assets. The following table details the impairment charges for such period (in thousands):

	Nine Months Ended September 30, 2017	
Asset/Asset Group	**Impairment Charge**	**Reason For Impairment**
Product Rights		
Hydromorphone ER	$ 6,567	Sales underperforming expectations due to competition
Other Product Rights	489	Discontinued products/lower sales expectations
	7,056	
Developed Technology		
Oxybutinin License Royalty	8,767	Revenue underperforming expectations due to new generic market entrant
In-Process R&D		
Osmolex ER	8,900	Delay in approval date and product launch
Ontinua ER	23,100	Delay in commencement of Phase III Trial
Generic Product “A”	18,600	Delay in finalizing formulation development
Other Generic Products in Development	6,025	Discontinued products/lower sales expectations post launch
	56,625	
Total Impairment Charges for nine months ended September 30, 2017	$ 72,448	

Interest Expense and Amortization of Debt Discount

Interest expense and amortization of debt discount decreased by $6.3 million in the nine months ended September 30, 2018 to $15.4 million as compared to $21.7 million in the nine months ended September 30, 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, net

Other non-operating income was $0.9 million and $2.5 million for the nine months ended September 30, 2018 and 2017, respectively.

Income Tax Expense

During the nine months ended September 30, 2018, we recognized income tax benefit of $2.0 million on $5.6 million of loss before income tax, compared to $16.8 million of income tax benefit on $59.1 million of loss before income tax during the comparable 2017 period.

The income tax expense was based on the applicable federal and state tax rates for those periods. For periods with income before provision for income taxes, favorable tax items result in a decrease in the effective tax rate, while unfavorable tax items result in an increase in the effective tax rate. For periods with a loss before benefit from income taxes, favorable tax items result in an increase in the effective tax rate, while unfavorable tax items result in a decrease in the effective tax rate.

The income tax expense (benefit) for the nine months ending September 30, 2018 and for the same period in 2017 reflect significant differences in the usual relationship of income tax expense (benefit) to the income (loss) 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 nine months ended September 30, 2018 compared to the same period in 2017; a disproportionate change in the income tax rate for the nine months ended September 30, 2018 as a result of credits from research and development when compared to the income (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 nine months ended September 30, 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 September 30, 2018, we had cash and cash equivalents of $32.2 million and borrowing availability under the Revolver of $50.0 million. We also had $321.4 million aggregate principal amount borrowed under our term loans and $0.5 million under our note payable for insurance financing. During the nine months ended September 30, 2018 we generated $7.2 million of cash from operations, and during the nine months ended September 30, 2017, we generated cash flows from operations of $36.0 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.

As of September 30, 2018, the interest rate was 5.99% and 6.49% 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 September 30, 2018, there were no outstanding borrowings or outstanding letters of credit under the Revolver. Availability under the Revolver as of September 30, 2018, was $50.0 million.

On October 22, 2018, we completed our initial public offering (the “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 $58.4 million after deducting underwriting discounts and commissions and estimated offering expenses.

During the nine months ended September 30, 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 may erode profitability over time. 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 of 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):

	Nine Months Ended September 30,		
	2018	2017	Change
Net cash provided by operating activities	$ 7,174	36,007	$ (28,833)
Net cash used in investing activities	(2,988)	(7,126)	4,138
Net cash used in financing activities	(5,733)	(16,285)	10,552
Effect on cash of changes in exchange rate	(993)	524	(1,517)
Net (decrease) increase in cash and cash equivalents	$ (2,540)	$ 13,120	$ (15,660)

Net cash provided by (used in) 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 payable and the timing of inventory transactions and changes in other working capital amounts. Net cash provided by operating activities was $7.2 million and $36.0 million for the nine months ended September 30, 2018 and 2017, respectively. Non-cash items were $55.2 million and $67.3 million for the nine months ended September 30, 2018 and 2017, respectively, and include depreciation and amortization expense, impairment of intangible assets, change in estimated allowance for bad debt, change in fair value of contingent consideration and deferred income tax benefit.

The decrease in cash provided by operating activities in the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, was significantly impacted by changes in working capital, primarily as a result of greater level of accounts receivable and inventories, increased spending on research and development and higher selling, general and administrative expenses, offset by higher earnings from operations.

Net cash outflow related to working capital was $44.5 million for the nine months ended September 30, 2018 as compared with the net cash inflow of $11 million for the nine months ended September 30, 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 level of prepaid assets during the period.

During the nine months ended September 30, 2018, accounts receivable were a $33.8 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 $8.6 million primarily due to increased methylphenidate ER inventories to meet customer demand. Prepaid expenses and other current assets were a $6.4 million source of funds while accounts payable, represented a $9.1 million use of funds.

Net cash used in investing activities

Our uses of cash in investing activities during the nine months ended September 30, 2018 and 2017 reflected purchases of property, plant and equipment and were $3.0 million and $7.1 million, respectively. Expenditures in the first nine months of 2017 reflected the completion of the expansion of a construction project for our Marietta, Georgia manufacturing facility, and the purchase of other property, plant and equipment.

Net cash used in financing activities

Net cash used in financing activities of $5.7 million during the nine months ended September 30, 2018 primarily related to the $6.1 million repayment of term loans, partially offset by $0.5 million net proceeds from insurance financing loans.

Net cash used in financing activities of $16.3 million during the nine months ended September 30, 2017 primarily related to debt repayments, 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

There have been no material changes outside the ordinary course of our business in our contractual obligations during the nine months ended September 30, 2018 from those as of December 31, 2017 as set forth in our filed Registration Statement on Form S-1, as amended.

Critical Accounting Estimates

The significant accounting policies and bases of presentation are described in Note 2, Basis of Presentation and *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included elsewhere in this report.

Summary of Significant Accounting Policies. The preparation of our condensed 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 condensed 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 entity 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 partially 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, 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, 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 September 30, 2018. 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 each respective product at September 30, 2018.

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 nine months ended September 30, 2018 (in thousands):

	Chargebacks	Commercial Rebates	Government Rebates	Product Returns	Discounts and Allowances	Total
Balance at December 31, 2017	$ 32,343	$ 39,234	$ 14,152	$ 43,300	$ 3,485	$ 132,514
Provision	261,081	182,605	15,574	13,979	14,987	488,226
Charges processed	(262,811)	(197,962)	(18,387)	(12,648)	(15,198)	(507,006)
Balance September 30, 2018	$ 30,613	$ 23,877	$ 11,339	$ 44,631	$ 3,274	$ 113,734

Total items deducted from gross product sales were $488.2 million (excluding $3.9 million in provisions for advertising and promotion), or 70.9% as a percentage of gross product sales during the nine months ended September 30, 2018.

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 $261.1 million, or 37.9% as a percentage of gross product sales for the nine months ended September 30, 2018. 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 $182.6 million, or 26.5% as a percentage of gross product sales for the nine months ended September 30, 2018. 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 $15.6 million, or 2.3% as a percentage of gross product sales for the nine months ended September 30, 2018.

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 nine 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 $14.0 million, or 2.0% as a percentage of gross product sales for the nine months ended September 30, 2018.

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 were $3.9 million, or 0.6% as a percentage of gross product sales for the nine months ended September 30, 2018. Advertising and promotions as a percentage of gross product sales did not change materially in during the periods presented.

Discounts and allowances were $15.0 million, or 2.2% as a percentage of gross product sales for the nine months ended September 30, 2018. Discounts and allowances as a percentage of gross product sales did not change materially during the periods presented.

Valuation of long-lived assets

As of September 30, 2018, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is $461.2 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.

We recorded impairment charges of $6.2 million regarding definite-lived intangible assets for the nine months ended September 30, 2018.

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. 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 five-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.

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

If the fair value of the IPR&D is less than its carrying amount, an impairment loss is recognized for the difference. Based on results of the impairment assessment performed, we did not recognize impairment charges to IPR&D as of September 30, 2017. Beginning in 2018, we have been evaluating the impairment of IPR&D assets quarterly. Based on the results of this evaluation we did not recognized impairment charges as of September 30, 2018.

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 provision (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 and/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, 2017, we had a U.S. federal net operating loss of $4.4 million. This loss is subject to limitation under IRC Section 382 related to the 2017 change in ownership of RevitaLid. The net operating loss is expected to be utilized in full prior to its expiration, and therefore, no valuation allowance has been recorded against it. We also had

losses in certain foreign and state tax jurisdictions of $90.2 million and $1.0 million, respectively. As the losses in the foreign jurisdictions have been deemed more-likely-than-not to expire unused, a full valuation allowance has been recorded against these net operating losses. The net operating losses will begin to expire in 2022. At December 31, 2017, we had total tax credit carryovers of $9.1 million. These credit carryovers are expected to be fully realized prior to their expiration, beginning in 2036. The estimates discussed above have not changed significantly during the nine months ended September 30, 2018.

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 nine months ended September 30, 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 will continue to analyze the impact of the U.S. Tax Cuts and Jobs Act under SAB 118 and will record adjustments to provisional amounts as such analyses are refined.

Share-based Compensation

Prior to the consummation of our initial public offering, our employees were eligible to receive awards from the 2016 Plan (as defined in Note 10, Incentive Plans to our consolidated financial statements included elsewhere in this report).

Prior to the completion of our initial public offering, the compensation committee of the board of directors made recommendations to the board of directors regarding an equity-based incentive compensation plan that took effect prior to the completion of our initial public offering. Therefore, employees are eligible to receive awards from the new 2018 Plan.

Our stock-based compensation cost will be measured at the grant date based on the fair value of the award and will be recognized as expense over the requisite service period, which will generally represent the vesting period. We will use the Black Scholes valuation model for estimating the fair value on the date of grant of stock options. The fair value of stock option awards will be affected by our valuation assumptions, including the estimated fair value of our ordinary shares, the volatility of equity comparables, the expected term of the options, the risk-free interest rate, expected dividends and other objective and subjective variables. For valuations after the consummation of our initial public offering, our board of directors (or its compensation committee) will generally determine 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.

Recently Issued Accounting Standards

For a discussion of recent accounting pronouncements, please see Note 2, Basis of Presentation and *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included elsewhere in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

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

foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of September 30, 2018, our liabilities denominated in foreign currencies were not material.

We are exposed to fluctuations in interest rates on our senior secured credit facilities. An increase in interest rates could have a material impact on our cash flow. As of September 30, 2018, a 100 basis point increase in assumed interest rates for our variable interest credit facilities would have an annual impact of approximately $3.2 million on interest expense.

As of September 30, 2018, we had cash and cash equivalents of $32.2 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

Inflation generally affects us by increasing our cost of labor, API and clinical trials. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2018.

Item 4. Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on that evaluation, as of September 30, 2018, our principal executive/financial officer concluded that our disclosure controls and procedures were not effective. We intend to implement remedial measures designed to address the ineffectiveness of our disclosure controls and procedures as described more fully below.

Changes in Internal Control over Financial Reporting

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

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

- hiring additional personnel and engaging external consultants who possess the requisite skills in certain technical areas important to our financial reporting;
- assessing the required training needs to provide for the continued development of our finance personnel;

- performing a comprehensive review of current procedures to ensure compliance with our accounting policies and GAAP;
- improving the process of reviewing the consolidation, supporting schedules and related reconciliations in our financial reporting;
- enhancing existing and developing additional monitoring controls to provide reasonable assurance that we maintain sufficient oversight of the performance of internal control over financial reporting responsibilities;
- reassessing our existing framework used to identify and implement corrective actions on a timely, prioritized basis with defined accountability; and
- designing and implementing enhanced controls over the preparation, analysis and review of significant accounts that operate at the appropriate level of precision to prevent or detect a material misstatement of such balances at period end.

While we have implemented plans to remediate the material weakness, we cannot assure you that we will be successful in remediating the material weakness in a timely manner, or at all, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

Other than as described above, there was no change in our internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

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

On February 16, 2018, upon receipt of approval for Osmolex ER from the FDA, we filed suit against Adamas in the U.S. District Court for the District of Delaware seeking a declaratory judgment that Osmolex ER does not infringe, directly or indirectly, any valid and enforceable claim of any of the 11 patents enumerated in our complaint. On September 20, 2018, Adamas filed an amended answer with counterclaims alleging infringement of certain patents included in our complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. Adamas commercializes a different amantadine product, an extended-release capsule marketed and sold as Gocovri ™. We intend to vigorously defend our rights to commercialize Osmolex ER free and clear of any of these patents. However, this litigation is at a very early stage. If we do not prevail in this litigation, we could be exposed to injunctive relief, or damages, either of which could materially and adversely affect our business, financial condition and results of operations.

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

Item 1A. Risk Factors.

There have been no material changes from the risk factors described in our Registration Statement on Form S-1, as amended.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Initial Public Offering of Ordinary Shares

On October 17, 2018, our Registration Statement on Form S-1, as amended (File No. 333-227357), relating to our IPO, was declared effective by the SEC. The offering commenced on October 17, 2018 and, on October 22, 2018, we closed the issuance and allotment of the 7,647,500 ordinary shares at a price of $7.00 per ordinary share. The number of shares issued in the IPO reflected the exercise in full of the underwriters' option to purchase 997,500 additional ordinary shares. Jefferies, Barclays, RBC Capital Markets and Wells Fargo Securities acted as joint lead book-running managers for the offering.

We raised a total of $53.5 million in gross proceeds in the IPO, or approximately $45.3 million in net proceeds, after deducting underwriting discounts of $3.7 million, net of reimbursement and estimated expenses of approximately $4.5 million. On October 31, 2018, the net proceeds from the IPO were used to repay $42.3 million of our Term A Loan and $7.7 million of our Term B Loan, together with accrued and unpaid interest.

Item 6. Exhibits.

EXHIBIT 31.1	-	Principal Executive Officer Certification Pursuant to Securities Exchange Act Rules 13a—14 and 15d—14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
EXHIBIT 31.2	-	Principal Financial Officer Certification Pursuant to Securities Exchange Act Rules 13a—14 and 15d—14 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
EXHIBIT 32.1	-	Principal Executive Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
EXHIBIT 32.2	-	Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
EXHIBIT 101.INS	-	XBRL Instance Document.
EXHIBIT 101.SCH	-	XBRL Taxonomy Extension Schema Document.
EXHIBIT 101.CAL	-	XBRL Taxonomy Extension Calculation Linkbase Document.
EXHIBIT 101.DEF	-	XBRL Taxonomy Extension Definition Linkbase Document.
EXHIBIT 101.LAB	-	XBRL Taxonomy Extension Label Linkbase Document.
EXHIBIT 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 thereunto duly authorized.

Osmotica Pharmaceuticals plc

Dated: November 8, 2018

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

Dated: November 8, 2018

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Markison, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Osmotica Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

/s/ Brian Markison
Name: Brian Markison
Title: Chief Executive Officer and Chairman
of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Einhorn, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Osmotica Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

/s/ Andrew Einhorn
Name: Andrew Einhorn
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Osmotica Pharmaceuticals plc (the "Company") on Form 10-Q for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Markison, Chief Executive Officer and Chairman of the Board of Directors of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2018

/s/ Brian Markison
Brian Markison
Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Osmotica Pharmaceuticals plc (the “Company”) on Form 10-Q for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Einhorn, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2018

/s/ Andrew Einhorn
Andrew Einhorn
Chief Financial Officer
(Principal Financial Officer)