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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2020  
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

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**Osmotica Pharmaceuticals plc**

(Exact name of registrant as specified in its charter)

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**Ireland**  
(State or other jurisdiction of  
incorporation or organization)

**Not Applicable**  
(I.R.S. Employer  
Identification No.)

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

Smaller reporting company

Emerging growth company

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

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

There were 62,585,832 ordinary shares (\$0.01 nominal value per share) outstanding as of November 09, 2020.

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## 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, including the impact of the COVID-19 pandemic on the sufficiency of our product supply, 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 sales of 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, 2020, we had total outstanding debt of approximately \$219.3 million (net of deferred financing costs), and we had unused commitments of \$50.0 million under our senior secured credit facilities. Our substantial debt could adversely affect our liquidity and our ability to raise additional capital to fund operations and could limit our ability to pursue our growth strategy or react to changes in the economy or our industry;
- we face intense competition from both brand and generic companies, which could significantly limit our growth and materially adversely affect our financial results;
- a business interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on could have a material adverse effect on our business;
- our profitability depends on our major customers, and if our relationships with them do not continue as expected, our business, prospects and results of operations could materially suffer;
- if we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell our products;

- our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business;
- our profitability depends on coverage and reimbursement by governmental authorities and other third-party payors and healthcare reform and other future legislation creates uncertainty and may lead to reductions in coverage or reimbursement levels;
- we are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations;
- our products or product candidates may cause adverse side effects that could delay or prevent their regulatory approval, or result in significant negative consequences following regulatory approval;
- manufacturing or quality control problems may damage our reputation, require costly remedial activities or otherwise negatively impact our business;
- our business may be adversely affected by the continuing coronavirus pandemic; and
- other factors that are described in the "Risk Factors" section of our Annual Report on Form 10-K that was filed on March 19, 2020 our Quarterly Reports on Form 10-Q that were filed on May 12, 2020 and August 11, 2020, and this Quarterly Report on Form 10-Q.

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**

(In thousands, except share and per share data)

	<u>September 30, 2020</u> <u>(Unaudited)</u>	<u>December 31, 2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 126,093	\$ 95,865
Trade accounts receivable, net	21,569	43,914
Inventories, net	21,703	21,305
Prepaid expenses and other current assets	6,805	11,546
Total current assets	<u>176,170</u>	<u>172,630</u>
Property, plant and equipment, net	28,664	30,238
Operating lease assets	3,233	4,983
Intangibles, net	117,904	153,986
Goodwill	100,855	100,855
Other non-current assets	420	563
Total assets	<u>\$ 427,246</u>	<u>\$ 463,255</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Trade accounts payable	\$ 7,909	\$ 8,495
Accrued liabilities	45,376	65,253
Current portion of obligation under finance leases	65	127
Current portion of lease liability	1,596	2,062
Total current liabilities	<u>54,946</u>	<u>75,937</u>
Long-term debt, net of non-current deferred financing costs	219,290	267,950
Long-term portion of obligation under finance leases	8	44
Long-term portion of lease liability	1,790	3,116
Deferred taxes	526	1,500
Total liabilities	<u>276,560</u>	<u>348,547</u>
Commitments and contingencies (See Note 11)		
Shareholders' equity:		
Ordinary shares (\$0.01 nominal value 400,000,000 shares authorized, 63,105,832 and 51,845,742 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively)	631	518
Preferred shares (\$0.01 nominal value 40,000,000 shares authorized, no shares issued and outstanding)	—	—
Euro deferred shares (€1.00 nominal value 25,000 shares authorized, no shares issued and outstanding)	—	—
Additional paid in capital	550,020	489,440
Accumulated deficit	(397,736)	(373,021)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	<u>150,686</u>	<u>114,708</u>
Total liabilities and shareholders' equity	<u>\$ 427,246</u>	<u>\$ 463,255</u>

See accompanying notes to unaudited condensed consolidated financial statements

**OSMOTICA PHARMACEUTICALS PLC****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(Unaudited)**

(In thousands, except share and per share data)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Net product sales	\$ 31,175	\$ 64,041	\$ 113,783	\$ 176,657
Royalty revenue	432	1,325	2,875	2,826
Licensing and contract revenue	25,564	95	26,694	637
Total revenues	57,171	65,461	143,352	180,120
Cost of goods sold (inclusive of amortization of intangibles)	16,717	27,312	57,301	89,160
Gross profit	40,454	38,149	86,051	90,960
Selling, general and administrative expenses	23,543	24,751	61,276	71,919
Research and development expenses	3,726	8,285	15,185	23,410
Impairment of intangibles	19,539	128,113	23,157	253,879
Total operating expenses	46,808	161,149	99,618	349,208
Operating loss	(6,354)	(123,000)	(13,567)	(258,248)
Interest expense and amortization of debt discount	3,564	4,504	11,368	13,555
Other non-operating gain	(153)	(177)	(241)	(719)
Total other non-operating expense	3,411	4,327	11,127	12,836
Loss before income taxes	(9,765)	(127,327)	(24,694)	(271,084)
Income tax benefit (expense)	1,132	14,623	(21)	26,824
Net and other comprehensive loss	\$ (8,633)	\$ (112,704)	\$ (24,715)	\$ (244,260)
Loss per share attributable to shareholders				
Basic and Diluted	\$ (0.14)	\$ (2.15)	\$ (0.41)	\$ (4.65)
Weighted average shares basic and diluted				
Basic and Diluted	62,785,866	52,476,540	59,979,834	52,504,518

See accompanying notes to unaudited condensed consolidated financial statements

OSMOTICA PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020 AND SEPTEMBER 30, 2019  
(Unaudited)

(In thousands, except share data)

	Ordinary shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount				
Balance at January 1, 2019	52,518,924	\$ 525	\$ 487,288	\$ (102,120)	\$ (1,846)	\$ 383,847
Net loss	—	—	—	(6,687)	—	(6,687)
Share compensation	—	—	1,169	—	—	1,169
Balance at March 31, 2019	52,518,924	\$ 525	\$ 488,457	\$ (108,807)	\$ (1,846)	\$ 378,329
Net loss	—	—	—	(124,869)	—	(124,869)
Change in foreign currency translation	—	—	—	—	—	—
Share compensation	—	—	1,327	—	—	1,327
Balance at June 30, 2019	52,518,924	\$ 525	\$ 489,784	\$ (233,676)	\$ (1,846)	\$ 254,787
Repurchase of ordinary shares	(355,571)	(4)	(1,335)	—	—	(1,338)
Net loss	—	—	—	(112,705)	—	(112,705)
Change in foreign currency translation	—	—	—	—	(383)	(383)
Share compensation	—	—	1,335	—	—	1,335
Balance at September 30, 2019	52,163,353	\$ 521	\$ 489,784	\$ (346,380)	\$ (2,229)	\$ 141,696
Balance at January 1, 2020	51,845,742	\$ 518	\$ 489,440	\$ (373,021)	\$ (2,229)	\$ 114,708
Net loss	—	—	—	(3,083)	—	(3,083)
Share compensation	181,966	2	1,107	—	—	1,109
Payments for taxes related to the net share settlement of equity awards	—	—	(616)	—	—	(616)
Proceeds from issuance of ordinary shares, net of offering costs	6,900,000	69	31,720	—	—	31,789
Repurchase of ordinary shares	(29,000)	—	(167)	—	—	(167)
Balance at March 31, 2020	58,898,708	\$ 589	\$ 521,484	\$ (376,104)	\$ (2,229)	\$ 143,740
Net loss	—	—	—	(12,999)	—	(12,999)
Share compensation	31,295	1	1,221	—	—	1,222
Payments for taxes related to the net share settlement of equity awards	—	—	(133)	—	—	(133)
Proceeds from issuance of ordinary shares, net of offering costs	—	—	—	—	—	—
Repurchase of ordinary shares	(169,257)	(2)	(917)	—	—	(919)
Balance at June 30, 2020	58,760,746	\$ 588	\$ 521,655	\$ (389,103)	\$ (2,229)	\$ 130,911
Net loss	—	—	—	(8,633)	—	(8,633)
Share compensation	22,554	—	1,508	—	—	1,508
Proceeds from issuance of ordinary shares, net of offering costs	5,000,000	50	30,599	—	—	30,649
Repurchase of ordinary shares	(677,468)	(7)	(3,742)	—	—	(3,749)
Balance at September 30, 2020	63,105,832	\$ 631	\$ 550,020	\$ (397,736)	\$ (2,229)	\$ 150,686

See accompanying notes to unaudited condensed consolidated financial statements

**OSMOTICA PHARMACEUTICALS PLC**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

(In thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (24,715)	\$ (244,260)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	16,589	50,605
Share compensation	3,836	3,831
Impairment of intangibles	23,157	253,879
Deferred income tax benefit	(974)	(28,493)
Loss on sale of fixed and leased assets	281	75
Bad debt provision	6	(160)
Amortization of deferred financing and loan origination fees	985	1,000
Write off of deferred financing fees in connection with prepayment	496	—
Change in operating assets and liabilities:		
Trade accounts receivable, net	22,339	22,722
Inventories, net	(398)	(2,857)
Prepaid expenses and other current assets	4,741	12,536
Trade accounts payable	(586)	(14,964)
Accrued and other current liabilities	(19,915)	(21,022)
Net cash provided by operating activities	<u>25,842</u>	<u>32,892</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from sale of fixed and leased assets	50	12
Payments on disposal of leased assets	(209)	(34)
Purchase of property, plant and equipment	(2,213)	(3,042)
Net cash used in investing activities	<u>(2,372)</u>	<u>(3,064)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments on finance lease obligations	(98)	(97)
Proceeds from public offering, net of issuance costs	62,440	—
Debt repayment	(50,000)	—
Repurchases of ordinary shares	(4,835)	(1,338)
Payments for taxes related to net share settlement of equity awards	(749)	—
Proceeds from insurance financing loan	—	1,314
Repayment of insurance financing loan	—	(2,691)
Net cash provided by (used in) financing activities	<u>6,758</u>	<u>(2,812)</u>
Net change in cash and cash equivalents	30,228	27,016
Effect on cash of changes in exchange rate	—	164
Cash and cash equivalents, beginning of period	95,865	70,834
Cash and cash equivalents, end of period	<u>\$ 126,093</u>	<u>\$ 98,014</u>
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	\$ 12,014	\$ 11,202
Cash paid for taxes	<u>\$ 1,435</u>	<u>\$ 545</u>

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

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

Immediately prior to the IPO and prior to the commencement of trading of Osmotica Pharmaceuticals plc's ordinary shares on the Nasdaq Global Select Market, Osmotica Holdings S.C.Sp. undertook a series of restructuring transactions that resulted in Osmotica Pharmaceuticals plc 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". Accordingly, all share and share amounts for all periods presented in the accompanying financial statements have been adjusted retroactively, where applicable, to reflect the Reorganization.

Until the Reorganization, Osmotica Pharmaceuticals plc did not conduct any operations (other than activities incidental to its formation, the Reorganization and the pursuit of an IPO). 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 information as of and for the three and nine months ended September 30, 2020 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 December 3, 2015 in connection with a business combination (the "Merger"), effective February 3, 2016, pursuant to a definitive agreement among Osmotica Holdings S.C.Sp., Vertical/Trigen Holdings, LLC ("Vertical/Trigen") and its members, and Osmotica Holdings Corp Limited and its shareholders, among others. 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.

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.

**OSMOTICA PHAMACEUTICALS PLC****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

**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 (“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, 2020, are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2020 or any period thereafter. The accompanying Condensed Consolidated Balance Sheet data as of December 31, 2019 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, 2019.

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

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive as of September 30, 2020 and 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Restricted stock units	2,785,197	1,438,642	2,785,197	1,237,614
Options to purchase ordinary shares	2,961,875	3,152,162	2,961,875	3,173,065

*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 receivable, accounts payable and debt approximate book value because of the short maturity of these financial instruments.

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

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

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

**OSMOTICA PHAMACEUTICALS PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

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.

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

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

**Note 3. Revenues**

The Company’s performance obligations are to provide its pharmaceutical products based upon purchase orders from distributors. The performance obligation is satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. The Company invoices its customers after the products have been delivered and invoice payments are generally due within 30 to 60 days of invoice date.

**OSMOTICA PHAMACEUTICALS PLC****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

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

Pharmaceutical Product	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Venlafaxine ER (VERT)	\$ 3,583	\$ 22,487	\$ 22,059	\$ 62,387
Methylphenidate ER	6,316	17,879	23,769	55,769
Divigel	7,801	6,416	23,032	18,833
Nitrofurantoin	2,242	1,990	9,205	1,990
Lorzone	214	3,750	4,280	12,082
OB Complete	1,629	2,589	5,266	7,195
Other	9,390	8,930	26,172	18,401
Net product sales	31,175	64,041	113,783	176,657
Royalty revenue	432	1,325	2,875	2,826
License and contract revenue	25,564	95	26,694	637
Total revenues	<u>\$ 57,171</u>	<u>\$ 65,461</u>	<u>\$ 143,352</u>	<u>\$ 180,120</u>

On July 28, 2020, the Company entered into a License Agreement with Santen Pharmaceutical Co. Ltd, granting Santen the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Under the agreement the Company received an upfront license milestone payment of \$25.0 million which was recognized as license and contract revenue in the quarter as all performance obligations were met. The Company is also entitled to royalty payments on net sales of RVL-1201 in Santen commercializations territories.

Development and regulatory milestone payments will be recognized when the Company is reasonably certain that they would not be reversed. Because the commercial milestone and royalty-based payments are associated with the transfer of a license, a performance obligation that was satisfied at or near the inception of the contract, the Company will recognize these payments when the sales triggering the payments are achieved. The Company intends to use estimates provided by Santen and will perform true-ups on a quarterly basis.

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of products to the customer under the terms of a contract, the Company records a contract liability. The Company classifies contract liabilities as deferred revenue. The Company had an immaterial amount of deferred revenue as of September 30, 2020. 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, 2020. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs*.

**Note 4. Accounts Receivable, Sales and Allowances**

The nature of the Company's business inherently involves, in the ordinary course, significant amounts and substantial volumes of transactions and estimates relating to allowances for product returns, chargebacks, rebates, allowance for

**OSMOTICA PHAMACEUTICALS PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

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

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

**OSMOTICA PHAMACEUTICALS PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

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

	September 30, 2020	December 31, 2019
Gross trade accounts receivable		
Trade accounts receivable	\$ 33,709	\$ 70,958
Royalty accounts receivable	1,098	702
Other receivable	1,914	2,186
Less reserves for:		
Chargebacks	(7,580)	(14,624)
Commercial rebates	(6,874)	(13,579)
Discounts and allowances	(698)	(1,591)
Allowance for credit losses	—	(138)
Total trade accounts receivable, net	<u>\$ 21,569</u>	<u>\$ 43,914</u>

The Company recorded the following adjustments to gross product sales (dollars in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Gross product sales	\$ 62,491	\$ 145,714	\$ 251,020	\$ 628,668
Less provisions for:				
Chargebacks	(19,352)	(52,195)	(96,664)	(290,230)
Government and managed care rebates	(4,301)	(6,792)	(14,048)	(16,854)
Commercial rebates	(5,227)	(25,818)	(17,736)	(130,621)
Product returns	(499)	7,204	(1,112)	2,027
Discounts and allowances	(1,373)	(3,045)	(5,520)	(12,839)
Advertising and promotions	(564)	(1,027)	(2,157)	(3,494)
Net product sales	<u>\$ 31,175</u>	<u>\$ 64,041</u>	<u>\$ 113,783</u>	<u>\$ 176,657</u>

The activity in the Company's allowance for customer deductions against trade accounts receivable was as follows (dollars in thousands):

	Chargebacks	Commercial Rebates	Discounts and Allowances	Credit Losses	Total
Balance at December 31, 2018	\$ 38,861	\$ 49,232	\$ 3,510	\$ 194	\$ 91,797
Provision	345,366	147,173	15,719	(190)	508,068
Charges processed	(369,603)	(182,826)	(17,638)	134	(569,933)
Balance at December 31, 2019	\$ 14,624	\$ 13,579	\$ 1,591	\$ 138	\$ 29,932
Provision	96,664	17,736	5,520	6	119,926
Charges processed	(103,708)	(24,441)	(6,413)	(144)	(134,706)
Balance at September 30, 2020	<u>\$ 7,580</u>	<u>\$ 6,874</u>	<u>\$ 698</u>	<u>\$ —</u>	<u>\$ 15,152</u>

**OSMOTICA PHAMACEUTICALS PLC****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

The activity in the Company's accrued liabilities for customer deductions by account was as follows (dollars in thousands):

	Product Returns	Government and Managed Care Rebates	Total
Balance at December 31, 2018	\$ 48,464	\$ 9,981	\$ 58,445
Provision	(3,932)	20,092	16,160
Charges processed	(11,075)	(25,206)	(36,281)
Balance at December 31, 2019	<u>\$ 33,457</u>	<u>\$ 4,867</u>	<u>\$ 38,324</u>
Provision	1,112	14,048	15,160
Charges processed	(11,967)	(15,040)	(27,007)
Balance at September 30, 2020	<u>\$ 22,602</u>	<u>\$ 3,875</u>	<u>\$ 26,477</u>

Provisions and utilizations of provisions activity in the current period which relate to the prior period revenues are not provided because to do so would be impracticable. The 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.

**Note 5. Inventories**

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

	September 30, 2020	December 31, 2019
Finished goods	\$ 16,526	\$ 15,319
Work in process	603	778
Raw materials and supplies	4,574	5,208
	<u>\$ 21,703</u>	<u>\$ 21,305</u>

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 (dollars in thousands):

	September 30, 2020	December 31, 2019
Balance at beginning of period	\$ 1,069	\$ 1,561
Provision	1,035	2,322
Charges processed	(207)	(2,814)
Balance at end of period	<u>\$ 1,897</u>	<u>\$ 1,069</u>

**OSMOTICA PHAMACEUTICALS PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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**Note 6. Goodwill and Other Intangible Assets**

The Company tests goodwill and indefinite-lived intangible assets for impairment annually as of October 1<sup>st</sup>, or more frequently whenever events or changes in circumstances indicate that the asset might be impaired. There were no events or circumstances requiring the Company to test for impairment of goodwill during the quarter. The carrying value of goodwill was \$100.9 million as of September 30, 2020 and December 31, 2019.

During the second and third quarters of 2020 circumstances and events pertaining to certain of our intangible assets related to generic competition and expectations of lower future cash flows prompted the Company to evaluate these assets for impairment. After evaluating these assets for recoverability, we further evaluated two intangible assets and determined that their fair value had decreased below their carrying value and thus fully impaired one asset and partially wrote down the carrying value of the asset. Accordingly, Developed Technology was impaired by \$3.6 million in the period ended June 30, 2020 and Product Rights was therefore impaired by \$19.5 million during the period ended September 30, 2020.

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 were not already fully amortized (dollars in thousands):

	<b>September 30, 2020</b>				<b>Weighted Average Remaining Amortization Period (Years)</b>
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Impairment</b>	<b>Net Carrying Amount</b>	
Distribution Rights	\$ 33,714	\$ (23,492)	\$ —	\$ 10,222	9.3
Product Rights	202,567	(162,150)	(19,539)	20,878	2.3
Tradenames	13,485	(3,565)	—	9,920	14.2
Developed Technology	52,466	(35,964)	(3,618)	12,884	10.9
IPR&D	64,000	—	—	64,000	Indefinite Lived
	<u>\$ 366,232</u>	<u>\$ (225,171)</u>	<u>\$ (23,157)</u>	<u>\$ 117,904</u>	

The gross carrying amounts and accumulated amortization in the table above is inclusive of \$15.0 million and have been fully impaired in the table above and inclusive as of September 30, 2020.

	<b>December 31, 2019</b>				<b>Weighted Average Remaining Amortization Period (Years)</b>
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Impairment</b>	<b>Net Carrying Amount</b>	
Distribution Rights	\$ 98,433	\$ (22,291)	\$ (64,719)	\$ 11,423	10.1
Product Rights	348,600	(152,348)	(146,033)	50,219	3.1
Tradenames	13,485	(3,035)	—	10,450	15.0
Developed Technology	125,461	(34,572)	(72,995)	17,894	10.9
IPR&D	64,000	—	—	64,000	Indefinite Lived
	<u>\$ 649,979</u>	<u>\$ (212,246)</u>	<u>\$ (283,747)</u>	<u>\$ 153,986</u>	

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

The gross carrying amounts and accumulated amortization in the table above is inclusive of \$10.4 million and have been fully impaired in the table above and inclusive as of December 31, 2019.

Changes in the net carrying amount of intangible assets were as follows (dollars in thousands):

	Distribution Rights	Product Rights	Tradenames	Developed Technology	IPR&D	Total
December 31, 2018	\$ 81,204	\$ 217,473	\$ 11,156	\$ 96,857	\$ 83,700	\$ 490,390
Amortization	(5,062)	(40,921)	(706)	(5,968)	—	(52,657)
Impairments	(64,719)	(146,033)	—	(72,995)	—	(283,747)
Reclassifications(A)	—	19,700	—	—	(19,700)	—
December 31, 2019	\$ 11,423	\$ 50,219	\$ 10,450	\$ 17,894	\$ 64,000	\$ 153,986
Amortization	(1,201)	(9,802)	(530)	(1,392)	—	(12,925)
Impairments	—	(19,539)	—	(3,618)	—	(23,157)
September 30, 2020	\$ 10,222	\$ 20,878	\$ 9,920	\$ 12,884	\$ 64,000	\$ 117,904

(A) IPR&D in the amount of \$19.7 million related to Osmolex ER was reclassified to Product Rights in the first quarter of 2019 when the product was launched. Osmolex ER was fully impaired during the second quarter of 2019.

As part of the Company's goodwill and intangible asset impairment assessments, 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 the 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 estimated cash flows for the Company's interim indefinite lived impairment test for the three months ended September 30, 2020 was 19.5%. 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.

Amortization expense of \$4.2 million and \$13.5 million for the three months ended September 30, 2020 and 2019, respectively, and \$12.9 million and \$47.2 million for the nine months ended September 30, 2020 and 2019, respectively was recorded as cost of goods sold. The amortization expense of acquired intangible assets for each of the following periods are expected to be as follows (dollars in thousands):

Years ending December 31	Amortization Expense
Remainder of 2020	\$ 3,120
2021	12,177
2022	7,609
2023	6,723
2024	4,774
Thereafter	19,501
Total	\$ 53,904

**OSMOTICA PHAMACEUTICALS PLC****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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**Note 7. Accrued Liabilities**

Accrued liabilities consist of the following (dollars in thousands):

	September 30, 2020	December 31, 2019
Accrued product returns	\$ 22,602	\$ 33,457
Accrued royalties	2,979	3,649
Accrued compensation	7,242	10,998
Accrued government and managed care rebates	3,875	4,867
Accrued research and development	975	3,028
Accrued expenses and other liabilities	7,332	8,477
Customer coupons	358	777
Deferred revenue	13	—
<b>Total</b>	<b>\$ 45,376</b>	<b>\$ 65,253</b>

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 (dollars in thousands):

	September 30, 2020	December 31, 2019
CIT Bank, N.A. Term Loan, net of deferred financing costs of \$2.1 million and \$3.4 million as of September 30, 2020 and December 31, 2019, respectively	\$ 219,290	\$ 267,950
Total debt	219,290	267,950
Less: current portion	—	—
Long-term debt	<u>\$ 219,290</u>	<u>\$ 267,950</u>

**Term Loan**

As of September 30, 2020, the interest rate was 4.75% for the Company's Term A Loan and 5.25% for the Term B Loan. As of December 31, 2019, the interest rate was 5.79% for the Term A Loan and 6.29% for the Term B Loan. The Company was in compliance with all covenants of the Term Loan Agreement as of September 30, 2020.

During the quarter ended September 30, 2020, the Company prepaid \$50.0 million in aggregate of the outstanding principal amount. The prepayments consisted of \$42.3 million of Term A Loan outstanding principal and \$7.7 million of Term B Loan outstanding principal. As required by the Third Amendment, the prepayments were made on a pro rata basis between the Term A Loan and the Term B Loan. The Company intends to continue to make interest payments accrued on the outstanding remaining balance through the date of maturity.

In accordance with ASC 470, when debt is prepaid within its contractual terms and the terms of the remaining debt are not modified, the prepayment should be treated as a partial extinguishment rather than a modification. This conclusion is reached without regard to consideration of the 10% cash flow test since no change to terms of the original debt

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instrument was modified in connection with the prepayment. The Third Amendment allows for partial prepayments without creating changes to the terms of Term Loan A or Term Loan B.

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

**Revolving Facility**

As of September 30, 2020 there were no amounts drawn under the \$50 million Revolving Facility with CIT Bank, N.A.

**Note 9. Concentrations and Credit Risk**

In the three and nine months ended September 30, 2020 and 2019, a significant portion of the Company's gross product sales reported were through three customers, and a significant portion of the Company's accounts receivable as of September 30, 2020 and December 31, 2019 were due from these customers as well. The following table sets forth the percentage of the Company's gross sales and accounts receivable attributable to these customers for the periods indicated:

	<b>Gross Product Sales</b>		<b>Gross Product Sales</b>	
	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Amerisource Bergen	35 %	18 %	32 %	9 %
Cardinal Health	21 %	36 %	21 %	52 %
McKesson	38 %	43 %	42 %	35 %
Combined Total	<u>94 %</u>	<u>97 %</u>	<u>95 %</u>	<u>96 %</u>

	<b>Gross Account Receivables</b>	
	<b>September 30, 2020</b>	<b>December 31, 2019</b>
	Amerisource Bergen	25 %
Cardinal Health	21 %	22 %
McKesson	47 %	51 %
Combined Total	<u>93 %</u>	<u>94 %</u>

**Purchasing**

For the three and nine months ended September 30, 2020, one supplier accounted for approximately 98% and 81%, respectively, of the Company's purchases of raw materials for products that are manufactured by the Company. For each of the three and nine months ended September 30, 2019, purchases of raw materials were not significant and one supplier accounted for approximately 81%, of the Company's purchases of raw materials for products that are manufactured by the Company for both periods.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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The Company purchases various Active Pharmaceutical Ingredient, (“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 that any of the purchase obligations represent levels above the normal course of business as of September 30, 2020.

**Note 10. Incentive Plans**

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

The Company recognized share-based compensation expense of \$1.3 million and \$1.3 million during the three months ended September 30, 2020 and 2019, respectively and \$3.7 million and \$3.8 million during the nine months ended September 30, 2020 and 2019, respectively, in each case inclusive of expense related to PSUs. As of September 30, 2020, the total remaining unrecognized compensation cost related to non-vested share-based compensation awards, including PSUs, amounted to \$13.9 million. During the three and nine months ended on September 30, 2020, the Company granted 35,500 and 1,767,426, respectively, of restricted stock units, inclusive of PSUs. During the three and nine months ended September 30, 2020, shares vested were 0 and 300,788, respectively. As of September 30, 2020 there were 2,785,197 restricted units, including performance stock units outstanding and the weighted-average remaining requisite service period of the non-vested stock options was 1.12 years and for non-vested restricted stock units, including performance stock units, was 3.13 years.

**Note 11. Commitments and Contingencies**

**Contingent Milestone Payments**

The Company has entered into strategic business agreements for the development and marketing of finished dosage form pharmaceutical products with various pharmaceutical development companies. Each strategic business agreement includes a future payment schedule for contingent milestone payments and in certain strategic business agreements, minimum royalty payments. The 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, various U.S. Food and Drug Administration and other regulatory approvals and the achievement of certain sales levels during a pre-defined period. The Company believes that aggregate amount of future milestone payments are currently immaterial to its financial statements.

**Supply Agreement Obligations**

The Company is engaged in various supply agreements with third parties which obligate the Company to purchase various API or finished products at contractual minimum levels. None of these agreements are individually or in the

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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aggregate material to the Company. Further, the Company does not believe that any of the purchase obligations represent levels above that of normal business demands as of September 30, 2020.

Legal Proceedings

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

On February 16, 2018, the Company received FDA approval for its amantadine extended release tablets under the trade name OSMOLEX ER. On that same date the Company filed in the Federal District Court for the District of Delaware a Complaint for Declaratory Judgment of Noninfringement of certain patents owned by Adamas Pharmaceuticals, Inc. (Osmotica Pharmaceutical US LLC and Vertical Pharmaceuticals, LLC vs. Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC). Adamas was served with the Complaint on February 21, 2018. Adamas filed an answer on April 13, 2018 denying the allegations in the Complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. The action is ongoing, but was stayed on May 23, 2019 at the parties' joint request.

On April 30, 2019, Osmotica Pharmaceuticals plc was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al.*, Superior Court of New Jersey, Somerset County No. SOM-L-000540-19. On May 10, 2019, a Complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al.*, Superior Court of New Jersey, Somerset County No. SOM-L-000617-19 was filed in the same court as the Shumacher action. The complaints name Osmotica Pharmaceuticals plc, certain of its directors and officers and the underwriters of its initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for the Company's initial public offering of ordinary shares. On July 22, 2019, Plaintiffs filed an Amended Complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. Defendants filed an Answer to the Amended Complaint on October 13, 2020, and the parties have exchanged discovery requests. The Company and Plaintiffs continue to discuss settlement options. The Company disputes the allegations in the complaint and intends to vigorously defend against the action. However, this litigation matter is still in an early stage and there is no assurance that the Company will be successful in its defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of the action, which could adversely affect the Company's results of operations and financial condition.

**Note 12. Income Taxes**

During the nine months ended September 30, 2020, the Company recognized an income tax expense of less than \$0.1 million on \$24.7 million of loss before income tax, compared to \$26.8 million of income tax benefit on \$271.1 million of loss before income tax during the comparable 2019 period.

Income taxes for the interim periods have been based on an estimated annual worldwide effective tax rate. Income tax (expense) benefit differs from the statutory income tax rate primarily due to the occurrence of orphan drug and research development credits, movement in a valuation allowance and the addition of state and foreign taxes.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

The Coronavirus Aid Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020 in the United States. The CARES Act and related notices include several significant provisions, including delaying certain payroll tax payments, mandatory transition tax payments under the Tax Cuts and Jobs Act, and estimated income tax payments that we expect to defer to future periods. We do not currently expect the CARES Act to have a material impact on our financial results, including on our annual estimated effective tax rate, or on our liquidity. We will continue to monitor and assess the impact the CARES Act and similar legislation in other countries may have on our business and financial results.

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.

Two of the Company's subsidiaries, Osmotica Pharmaceutical Corp. and Valkyrie Group Holding Inc., are under audit by the Internal Revenue Service for tax years 2016 and 2017. The Company received and has agreed with a proposed adjustment from the IRS and correspondingly recorded income tax expense of \$1.3 million, during the quarter ended September 30, 2020, inclusive of \$0.2 million interest.

*Valuation Allowance*

Net deferred tax assets arise due to the recognition of income and expense items for tax purposes, which differ from those used for financial statement purposes. ASC 740, Income Taxes, provides for the recognition of deferred tax assets if the realization of such assets is more likely than not. In assessing the need for a valuation allowance in the first quarter of year ending 2020, the Company considered all available objective and verifiable evidence both positive and negative, including historical levels of pre-tax income (loss) both on a consolidated basis and tax reporting entity basis, legislative developments, expectations and risks associated with estimates of future pre-tax income, and prudent and feasible tax planning strategies.

The Company assesses the realizability of the deferred tax assets at each balance sheet date based on actuals and forecasted operating results in order to determine the proper amount, if any, of a valuation allowance. As a result of this analysis, the Company determined that it is more likely than not that it will not realize the benefits of its net deferred tax assets and therefore has recorded a valuation allowance to reduce the carrying value of its net deferred tax assets. The Company continues to maintain 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.

**Note 13. Related Parties**

On August 22, 2018, the Company entered into a Master Service Agreement with United Biosource, LLC or ("UBC"), an Avista Capital Partners portfolio company, for prescription processing and patient access services. In November 2018, the Company and UBC entered into a Statement of Work for services valued at approximately \$2.4 million. The Company had accrued \$0.2 million of liabilities related to this agreement as of September 30, 2020 and had recognized \$0.2 million and \$0.8 million of related expense for the three and nine months ended September 30, 2020.

**OSMOTICA PHAMACEUTICALS PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(UNAUDITED)

**Note 14. Shareholders' Equity**

*Ordinary Share Repurchase Program*

In September 2019, the Company's Board of Directors authorized the repurchase of up to 5,251,892 ordinary shares pursuant to a share repurchase program. Purchases under the ordinary share repurchase program can be made on the open market or in privately negotiated transactions, with the size and timing of these purchases based on a number of factors, including the price and business and market conditions. The Company expects to retire ordinary shares acquired under the repurchase program. In the third quarter of 2020, the Company repurchased 677,468 ordinary shares for an aggregate of \$3.7 million.

*2019 Employee Share Purchase Plan*

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

The Company accounts for employee stock purchases made under its ESPP using the estimate grant date fair value of accounting in accordance with ASC 718, Stock Compensation. The purchase price discount and the look-back feature cause the ESPP to be compensatory and the Company to recognize compensation expense. The compensation cost is recognized on a straight-line basis over the requisite service period. The Company recognized less than \$0.1 million and \$0.1 million of compensation expense for the three and nine months ended September 30, 2020. The Company values ESPP shares using the Black-Scholes model.

As of September 30, 2020, there was less than \$0.1 million of unrecognized ordinary share compensation expense related to the ESPP, which is expected to be recognized over a weighted-average period of 0.50 years. On July 2, 2020, the Company issued 22,554 ordinary shares to the employees who participated in the ESPP during the offering period ended June 30, 2020.

*2020 Equity Offering*

On July 16, 2020 we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.4 million after deducting offering expenses.

## **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 Pharmaceuticals plc. 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. In the three and nine months ended September 30, 2020, we generated total revenues across our existing portfolio of promoted specialty ophthalmology, neurology and women’s health products, and other non-promoted products, many of which are complex formulations of generic drugs. In 2017, we received regulatory approval from the U.S. Food and Drug Administration, or the FDA, for M-72 (methylphenidate hydrochloride extended-release tablets, 72 mg) for the treatment of attention deficit hyperactivity disorder, or ADHD in patients aged 13 to 65, and, in 2018, we received regulatory approval from the FDA for Osmolex ER (amantadine extended-release tablets) for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions, which are involuntary muscle movements caused by certain medications, in adults. We launched M-72 in the second quarter of 2018 and completed the launch of Osmolex ER in January 2019. In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq™, (oxymetazoline hydrochloride ophthalmic solution, 0.1%), for the treatment of acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020.

We are focused on continuing the transition of our business to a specialty pharmaceutical company that develops and commercializes proprietary products. The primary drivers of our strategy are highlighted by the recent approval of Upneeq and the resubmission of our new drug application, or NDA, for arbaclofen extended release tablets. Some of our products use our proprietary osmotic-release drug delivery system, Osmodex, which we believe may offer advantages over alternative extended-release, or ER, technologies.

Our core competencies span drug development, manufacturing and commercialization. Our sales representatives are fully engaged in the launch and in-person promotion of Upneeq, while we continue to maintain some non-personal promotional efforts for certain other products in our portfolio, including Osmolex ER and M-72 in specialty neurology; and OB Complete, our family of prescription prenatal dietary supplements, and Divigel (estradiol gel, 0.1%) in women’s health. As of September 30, 2020, our commercial portfolio of promoted and non-promoted products consists of approximately 35 products. Certain of our key products, particularly those that incorporate our proprietary Osmodex drug delivery system, are or are expected to be manufactured in our Marietta, Georgia facility. Some of our products benefit from intellectual property protection, formulation and manufacturing complexities, data exclusivity, as well as U.S. Drug Enforcement Administration, or DEA, regulation and quotas for API.

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

On July 8, 2020, the FDA approved our NDA for Upneeq for the treatment of acquired blepharoptosis in adults. Upneeq was approved based on three Phase III clinical studies that supported Upneeq's efficacy and safety. Results from Upneeq's first Phase III clinical trial showed that the formulation met its primary efficacy endpoint and was well-tolerated. The 2:1 randomized, double-masked, placebo-controlled study comprised 140 patients with blepharoptosis in two treatment groups for 42 days. Patients treated with Upneeq received one drop in each eye each morning and patients treated with the placebo (vehicle) received one drop in each eye each morning. The primary efficacy endpoints were change from baseline in visual field using the Leicester Peripheral Field Test, or LPFT, on hour 6 on day 1 ( $p=0.0003$ ) and hour 2 on day 14 ( $p < 0.0001$ ). Patients who received Upneeq once-daily experienced a statistically significant improvement in visual field when compared to the placebo group. Upneeq was generally well tolerated by patients in this clinical trial when administered once daily over a 6-week period. There were no serious adverse events identified from treatment with Upneeq in this Phase III clinical trial. The second Phase III trial was a 6-week randomized, multicenter, double-masked, placebo-controlled study to evaluate the safety and efficacy of once-daily treatment of Upneeq compared with placebo for the treatment of acquired blepharoptosis. The primary endpoint was a measurement of the mean change from baseline of the number of points seen out of a total of 35 in the top four rows of the LPFT as measured in two time points: hour 6 on day 1 and hour two on day 14.

The secondary endpoint was a measurement of the distance between the center of the pupillary light reflex and the upper eyelid margin, or MRD-1. Topline results from the second Phase III trial showed that the trial met both the primary and secondary endpoints. The mean change from baseline on the LPFT on hour 6 on day 1 was 6.3 for Upneeq versus 2.1 for placebo ( $p < 0.0001$ ), and on hour two on day 14 was 7.7 for Upneeq versus 2.4 for placebo ( $p < 0.0001$ ). The results also showed a statistically significant improvement in MRD-1 at 5 and 15 minutes, and at 2 and 6 hours post dose on days 1 and 14. We also completed a Phase III 12-week randomized, multicenter, double-masked, placebo controlled safety study to evaluate the safety of Upneeq compared with placebo for the treatment of acquired blepharoptosis. Results of the safety study showed Upneeq was well tolerated when administered once daily over a 12-week period where the majority of adverse events were mild and did not require treatment. Results of the Upneeq pivotal efficacy studies were published in JAMA Ophthalmology on October 1, 2020.

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

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

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

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

In addition, we are developing our late-stage product candidate arbaclofen extended-release, or ER, tablets designed for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, or MS, for which we have completed Phase III clinical trials. In June 2020, we resubmitted our NDA for arbaclofen ER tablets for the alleviation of spasticity in MS to the FDA. Following recent completion of our 12-month open-label study assessing the long-term safety and tolerability of arbaclofen ER 80 mg per day, this resubmission also included the full results of our second Phase III efficacy study, Study OS440-3004. We believe that the safety and efficacy results from these studies, together with the entire data package from our clinical development program for arbaclofen ER, supports the clinical benefit of arbaclofen ER as a potential treatment for MS spasticity. On July 17, 2020 the Company received notice from the FDA

that it considered the resubmission a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020.

The co-primary endpoints of Study OS440-3004 were change from baseline in Total Numeric-transformed Ashworth Scale in the most affected limb, or TNmAS-MAL, scores and mean Clinical Global Impression of Change, or CGIC, scores on day 84. Results of OS440-3004 showed a statistically significant improvement from baseline to day 84 in TNmAS-MAL, scores in the arbaclofen ER tablet target dose of 40 mg per day (20 mg given twice a day) group compared to the placebo group. Subjects dosed with 80 mg per day (40 mg given twice a day) also derived clinical benefit. Though the mean CGIC, score for arbaclofen ER was not significantly better than placebo, subjects treated with arbaclofen ER tablets did not show a mean worsening of CGIC scores after treatment.

The long-term open-label Study OS440-3005 dosed subjects for up to one year on arbaclofen ER. The majority of subjects enrolled completed the study on the arbaclofen 80 mg per day dose. Subjects dosed with arbaclofen ER up to 80 mg daily showed an overall improvement from baseline scores in the TNmAS measure up to one year.

On November 10, 2020, the Company and its board of directors announced that it is undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include asset disposals, re-financings, commercialization or collaboration agreements. The review will also include the initiation of a process for the sale of the Company, which will commence shortly.

### **Business Update Regarding COVID-19**

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

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

We and our third-party contract manufacturing partners have been able to operate our manufacturing facilities at or near normal levels. While we currently do not anticipate significant interruptions in our manufacturing supply chain, the COVID-19 pandemic and related mitigation efforts may have a negative impact in the future on our third party suppliers' and contract manufacturing partners' ability to manufacture our products or to have our products reach all markets.

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

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

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included herein and in our annual report on Form 10-K.

## **Financial Operations Overview**

### *Segment Information*

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

## **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 Upneeq, M-72, Divigel and the OB Complete family of prescription prenatal dietary supplements, methylphenidate ER, VERT and nitrofurantoin and other non-promoted products. We ship product to a customer pursuant to a purchase order, which in certain cases is pursuant to a master agreement with that customer, and we invoice the customer upon shipment. For these sales we recognize revenue when control has transferred to the customer, which is typically on delivery to the customer. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which includes estimated chargebacks, commercial rebates, discounts and allowances at the time revenues are recognized.

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

*Licensing 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 the purpose of sub-distribution. Licensing revenue is recognized when the performance obligation identified in the arrangement is completed. Variable considerations, such as returns on product sales, government program rebates, price adjustments and prompt pay discounts associated with licensing revenue, are generally the responsibility of our commercial partners.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses consist primarily of personnel expenses, including salaries and benefits for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expenses also include corporate facility costs, including rent, utilities, legal fees related to corporate matters, share based compensation 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 and, incremental director and officer liability insurance costs, as well as costs related to compliance with the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act.

### *Research and Development*

Costs for research and development are charged as incurred and include employee-related expenses (including salaries and benefits, share based compensation, travel and expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations and service providers that assist in conducting clinical and

preclinical studies), costs associated with preclinical activities and development activities and costs associated with regulatory operations.

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

## Results of Operations

### Comparison of Three Months Ended September 30, 2020 and 2019

#### Financial Operations Overview

The following table presents revenues and expenses for the three months ended September 30, 2020 and 2019 (dollars in thousands):

	<b>Three Months Ended September 30,</b>		<b>% Change</b>
	<b>2020</b>	<b>2019</b>	
Net product sales	\$ 31,175	\$ 64,041	(51)%
Royalty revenue	432	1,325	(67)%
Licensing and contract revenue	25,564	95	26,809 %
Total revenues	57,171	65,461	(13)%
Cost of goods sold (inclusive of amortization of intangibles)	16,717	27,312	(39)%
Gross profit	40,454	38,149	6 %
Gross profit percentage	71 %	58 %	
Selling, general and administrative expenses	23,543	24,751	(5)%
Research and development expenses	3,726	8,285	(55)%
Impairment of intangibles	19,539	128,113	(85)%
Total operating expenses	46,808	161,149	(71)%
Interest expense and amortization of debt discount	3,564	4,504	(21)%
Other non-operating gain	(153)	(177)	(14)%
Total other non-operating expense	3,411	4,327	(21)%
Loss before income taxes	(9,765)	(127,327)	(92)%
Income tax benefit	1,132	14,623	(92)%
Net loss	<u>\$ (8,633)</u>	<u>\$ (112,704)</u>	<u>(92)%</u>

#### Revenue

The following table presents total revenues for the three months ended September 30, 2020 and 2019 (dollars in thousands):

	<b>Three Months Ended September 30,</b>		<b>% Change</b>
	<b>2020</b>	<b>2019</b>	
Venlafaxine ER (VERT)	\$ 3,583	\$ 22,487	(84)%
Methylphenidate ER	6,316	17,879	(65)%
Divigel	7,801	6,416	22 %
Nitrofurantoin	2,242	1,990	13 %
Lorzone	214	3,750	(94)%
OB Complete	1,629	2,589	(37)%
Other	9,390	8,930	5 %
Net product sales	31,175	64,041	(51)%
Royalty revenue	432	1,325	(67)%
Licensing and contract revenue	25,564	95	26,809 %
Total revenues	<u>\$ 57,171</u>	<u>\$ 65,461</u>	<u>(13)%</u>

*Total Revenues* - Total revenues decreased by \$8.3 million to \$57.2 million for the three months ended September 30, 2020, as compared to \$65.5 million for the three months ended September 30, 2019 primarily due to a decrease in net product sales, partially offset by higher licensing and contract revenue.

*Net Product Sales* - Net product sales decreased by \$32.8 million to \$31.2 million for the three months ended September 30, 2020, as compared to \$64.0 million for the three months ended September 30, 2019. Approximately \$15.3 million of this decrease is attributable to lower realized net prices, and \$17.5 million was due to lower volumes of products sold. Net sales of methylphenidate ER (including M-72) decreased 65% during the quarter due to price erosion from generic competitors resulting in significantly lower net selling prices and volumes. Net sales of VERT decreased 84% reflecting additional generic competition resulting in lower volumes and net realized selling prices. We expect that additional competition for both methylphenidate ER and VERT from current competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of these products during the remainder of 2020 and in future years. VERT sales were favorably impacted by \$1.6 million in the aggregate related to product returns during the three months ended September 30, 2020 based on actual experience. There can be no assurance that actual product returns experience and other adjustments will continue to favorably impact net sales in 2020 and in future periods.

Product sales of Lorzone decreased by \$3.6 million to \$0.2 million for the three months ended September 30, 2020 compared to \$3.8 million for the three months ended September 30, 2019, reflecting lower sales volumes due to the launches of generic competitors in late 2019 and 2020 and the transition of sales to the Company's authorized generic product during the quarter. Sales of Divigel increased approximately 22% driven primarily by the launch of a new dosage strength together with targeted promotional activities and strong patient access. Product sales of nitrofurantoin increased by \$0.2 million to \$2.2 million for the three months ended September 30, 2020 compared to \$2.0 million for the three months ended September 30, 2019 primarily due to higher volumes of products sold. Product sales of OB Complete decreased by \$1.0 million to \$1.6 million, for the three months ended September 30, 2020 compared to \$2.6 million for the three months ended September 30, 2019 due to lower sales volumes and realized net pricing. Other sales increased \$0.5 million largely due to growth of other non-promoted products.

*Royalty Revenue* - Royalty revenue decreased by \$0.8 million for the three months ended September 30, 2020, relative to the three months ended September 30, 2019 reflecting lower sales of licensed products by our license partner.

*Licensing and Contract Revenue* - Licensing and contract revenue increased \$25.5 million during the three months ended September 30, 2020 primarily reflecting license agreement with Santen Pharmaceutical Co. Ltd, granting the exclusive development, registration, and commercialization rights to RVL-1201 outside of the United States of America. Under the agreement, the Company received an upfront milestone payment of \$25.0 million that was not subject to additional performance obligations.

*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, 2020 and 2019 (dollars in thousands):

	<b>Three Months Ended</b>		<b>% Change</b>
	<b>September 30,</b>		
	<b>2020</b>	<b>2019</b>	
Amortization of intangible assets	\$ 4,201	\$ 13,451	(69)%
Depreciation expense	650	625	4 %
Royalty expense	2,035	2,399	(15)%
Other cost of goods sold	9,831	10,837	(9)%
<b>Total cost of goods sold</b>	<b>\$ 16,717</b>	<b>\$ 27,312</b>	<b>(39)%</b>

Total cost of goods sold decreased \$10.6 million in the three months ended September 30, 2020 to \$16.7 million as compared to \$27.3 million for the three months ended September 30, 2019. The decrease was primarily driven by a decrease in amortization of intangible assets largely due to lower amortization of VERT and methylphenidate ER, lower royalty expenses and lower production costs, partially offset by higher samples and regulatory fees.

Gross profit percentage increased to 71% for the three months ended September 30, 2020 compared to 58% in the same period in 2019. Excluding amortization and depreciation, our gross profit percentage decreased to 79% as compared to 80% for each of the three months ended September 30, 2020 and 2019, respectively.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased \$1.3 million during the three months ended September 30, 2020 to \$23.5 million as compared to \$24.8 million in the three months ended September 30, 2019. The decrease in our selling, general and administrative expenses reflects salesforce reductions in the first quarter of 2020, offset by higher costs related to the launch of Upneeq and costs associated with the Santen license transaction.

*Research and Development*

Research and development expenses decreased by \$4.6 million in the three months ended September 30, 2020 to \$3.7 million as compared to \$8.3 million in the three months ended September 30, 2019. The decrease primarily reflects the completion of clinical studies related to arbaclofen ER and the NDA filing fees for Upneeq which were incurred in the third quarter of 2019.

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

	<b>Three Months Ended September 30,</b>		<b>% Change</b>
	<b>2020</b>	<b>2019</b>	
Arbaclofen ER	\$ 372	\$ 1,181	(69)%
RVL-1201	315	3,190	(90)%
Other	3,039	3,914	(22)%
Total	<u>\$ 3,726</u>	<u>\$ 8,285</u>	<u>(55)%</u>

*Impairment of Intangibles Assets*

Impairment of intangible assets of \$19.5 million during the three months ended September 30, 2020 related to the write-down to fair value of methylphenidate ER as a result of lower revenue due to generic competition. The following table details the impairment charges for such period (in thousands):

<b>Asset/Asset Group</b>	<b>Three Months Ended September 30, 2020</b>	
	<b>Impairment Charge</b>	<b>Reason For Impairment</b>
<i>Product Rights</i>		
Methylphenidate ER	<u>\$ 19,539</u>	Lower anticipated revenue due to generic competition.
<b>Total Impairment Charges for three months ended September 30, 2020</b>	<u><u>\$ 19,539</u></u>	

*Interest Expense and Amortization of Debt Discount*

Interest expense and amortization of debt discount decreased by \$0.9 million in the three months ended September 30, 2020 to \$3.6 million as compared to \$4.5 million in the three months ended September 30, 2019. The decrease reflects lower interest rates and prepayment of debt during the quarter, partially offset by a write-off of deferred financing fees.

*Income Tax Benefit (Expense)*

During the three months ended September 30, 2020, the Company recognized income tax benefit of \$1.1 million on \$9.8 million of loss before income tax, compared to \$14.6 million of income tax benefit on \$127.3 million of loss before income tax during the comparable 2019 period.

Income taxes for the interim periods have been based on an estimated annualized worldwide effective tax rate. Income tax (expense) benefit differs from the statutory income tax rate primarily due to the occurrence of orphan drug and research development credits, movement in a valuation allowance and the addition to state and foreign taxes.

The income tax expense was based on the applicable federal, state and foreign 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.

**Comparison of Nine Months Ended September 30, 2020 and 2019**

*Financial Operations Overview*

The following table presents revenues and expenses for the nine months ended September 30, 2020 and 2019 (dollars in thousands):

	<b>Nine Months Ended September 30,</b>		<b>% Change</b>
	<b>2020</b>	<b>2019</b>	
Net product sales	\$ 113,783	\$ 176,657	(36)%
Royalty revenue	2,875	2,826	2 %
Licensing and contract revenue	26,694	637	4,091 %
Total revenues	<u>143,352</u>	<u>180,120</u>	<u>(20)%</u>
Cost of goods sold (inclusive of amortization of intangibles)	<u>57,301</u>	<u>89,160</u>	<u>(36)%</u>
Gross profit	86,051	90,960	(5)%
Gross profit percentage	60 %	51 %	
Selling, general and administrative expenses	61,276	71,919	(15)%
Research and development expenses	15,185	23,410	(35)%
Impairment of intangibles	23,157	253,879	(91)%
Total operating expenses	<u>99,618</u>	<u>349,208</u>	<u>(71)%</u>
Interest expense and amortization of debt discount	11,368	13,555	(16)%
Other non-operating gain	(241)	(719)	(66)%
Total other non-operating expense	<u>11,127</u>	<u>12,836</u>	<u>(13)%</u>
Loss before income taxes	(24,694)	(271,084)	(91)%
Income tax benefit (expense)	(21)	26,824	(100)%
Net loss	<u>\$ (24,715)</u>	<u>\$ (244,260)</u>	<u>(90)%</u>

*Revenue*

The following table presents total revenues for the nine months ended September 30, 2020 and 2019 (dollars in thousands):

	<b>Nine Months Ended September 30,</b>		<b>% Change</b>
	<b>2020</b>	<b>2019</b>	
Venlafaxine ER (VERT)	\$ 22,059	\$ 62,387	(65)%
Methylphenidate ER	23,769	55,769	(57)%
Divigel	23,032	18,833	22 %
Nitrofurantoin	9,205	1,990	363 %
Lorzone	4,280	12,082	(65)%
OB Complete	5,266	7,195	(27)%
Other	<u>26,172</u>	<u>18,401</u>	<u>42 %</u>
Net product sales	113,783	176,657	(36)%
Royalty revenue	2,875	2,826	2 %
Licensing and contract revenue	26,694	637	4,091 %
Total revenues	<u>\$ 143,352</u>	<u>\$ 180,120</u>	<u>(20)%</u>

*Total Revenues* - Total revenues decreased by \$36.7 million to \$143.4 million for the nine months ended September 30, 2020, as compared to \$180.1 million for the nine months ended September 30, 2019 primarily due to a decrease in net product sales, partially offset by higher licensing and contract revenue.

*Net Product Sales* - Net product sales decreased by \$62.9 million to \$113.8 million for the nine months ended September 30, 2020, as compared to \$176.7 million for the nine months ended September 30, 2019. Approximately \$39.1 million of this decrease was attributable to lower realized net prices, and \$23.8 million was due to lower volumes of products sold. Net sales of methylphenidate ER (including M-72) decreased 57% for the nine months ended September 30, 2020 due to price erosion from additional competitors entering the market, resulting in significantly lower net selling prices.

Net sales of VERT decreased 65% during the nine months ended September 30, 2020 due to additional generic competition resulting in lower volumes and net realized selling prices. VERT sales were favorably impacted by \$9.4 million, in the aggregate related to product returns and other adjustments during the nine months ended September 30, 2020 based on actual experience. There can be no assurance that actual product returns experience or other adjustments will continue to favorably impact net sales in 2020 and in future periods. We expect that the additional competition for both methylphenidate ER and VERT from these competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of these products during the remainder of 2020 and in future years.

Product sales of Lorzone decreased 65% for the nine months ended September 30, 2020 reflecting lower sales volumes due to the launch of generic competitors in late 2019 and 2020, and transition of sales to the Company's authorized generic product during the current year period. We expect that additional competition for Lorzone from current competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of Lorzone during the remainder of 2020 and in future years. Sales of Divigel increased approximately 22% driven primarily by the launch of a new dosage strength in 2020 together with targeted promotional activities and strong patient access. Product sales of OB Complete decreased 27% due to lower volume of products sold, partially offset by higher net realized pricing. Product sales of Nitrofurantoin increased 363% reflecting higher sales volumes and higher net realized pricing. Nitrofurantoin was launched in the third quarter of 2019. Other sales increased \$7.8 million, or 42%, during the period largely due to higher sales of a non-promoted product.

*Royalty Revenue* - Royalty revenue remained flat for the nine months ended September 30, 2020, relative to the nine months ended September 30, 2019.

*Licensing and Contract Revenue* - Licensing and contract revenue increased \$26.1 million for the nine months ended September 30, 2020 primarily reflecting license agreement with Santen Pharmaceutical Co. Ltd, granting the exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as EMEA countries. Under the agreement, the Company received an upfront milestone payment of \$25.0 million.

*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, 2020 and 2019 (dollars in thousands):

	<b>Nine Months Ended</b>		<b>% Change</b>
	<b>September 30,</b>		
	<b>2020</b>	<b>2019</b>	
Amortization of intangible assets	\$ 12,926	\$ 47,187	(73)%
Depreciation expense	1,959	1,868	5 %
Royalty expense	7,830	6,682	17 %
Other cost of goods sold	34,586	33,423	3 %
<b>Total cost of goods sold</b>	<b>\$ 57,301</b>	<b>\$ 89,160</b>	<b>(36)%</b>

Cost of goods sold decreased \$31.9 million in the nine months ended September 30, 2020 to \$57.3 million as compared to \$89.2 million for the nine months ended September 30, 2019. The decrease was primarily driven by a decrease in amortization of intangible assets largely due to lower amortization of VERT and methylphenidate ER, partially offset by higher royalty expenses due to the launch of nitrofurantoin which occurred during the second half of 2019, sample expenses reflecting the launch of Upneeq in 2020 and higher unit production costs.

Gross profit percentage increased to 60% for the nine months ended September 30, 2020 compared to 51% in the same period in 2019. Excluding amortization and depreciation, our gross profit percentage decreased to 70% for the nine months ended September 30, 2020 as compared with 78% for the nine months ended September 30, 2019, largely driven by higher royalty expenses, sample expenses and higher unit production costs.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased \$10.6 million during the nine months ended September 30, 2020 to \$61.3 million as compared to \$71.9 million in the nine months ended September 30, 2019. The decrease in our selling, general and administrative expenses reflects salesforce reductions in the third quarter of 2019 and the first quarter of 2020, combined with lower spending on marketing, partially offset by higher general and administrative expenses largely due to costs associated with the Santen license transaction during the period.

*Research and Development*

Research and development expenses decreased by \$8.2 million in the nine months ended September 30, 2020 to \$15.2 million as compared to \$23.4 million in the nine months ended September 30, 2019. The decrease largely reflects the completion of Phase III clinical trials of both arbaclofen ER and RVL-1201 during the first and second quarters of 2019, respectively, and NDA filing fees for RVL-1201 incurred in the third quarter of 2019.

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

	<u>Nine Months Ended September 30,</u>		<u>% Change</u>
	<u>2020</u>	<u>2019</u>	
Arbaclofen ER	2,720	6,331	(57)%
RVL-1201	2,629	5,771	(54)%
Other	9,836	11,308	(13)%
Total	<u>\$ 15,185</u>	<u>\$ 23,410</u>	<u>(35)%</u>

*Impairment of Intangibles Assets*

Impairment of intangible assets of \$23.3 million during the nine months ended September 30, 2020 related to the write-down to fair value of methylphenidate as a result of lower revenue due to generic competition and oxybutynin due to lower expected future cash flows. The following table details the impairment charges for such period (in thousands):

<u>Asset/Asset Group</u>	<u>Nine Months Ended September 30, 2020</u>	
	<u>Impairment Charge</u>	<u>Reason For Impairment</u>
<i>Product Rights</i>		
Methylphenidate ER	<u>\$ 19,539</u>	Lower anticipated revenue due to generic competition.
<i>Developed Technology</i>		
Oxybutynin	<u>\$ 3,618</u>	Lower expected future cash flows.
Total Impairment Charges for nine months ended September 30, 2020	<u>\$ 23,157</u>	

*Interest Expense and Amortization of Debt Discount*

Interest expense and amortization of debt discount decreased by \$2.2 million in the nine months ended September 30, 2020 to \$11.4 million as compared to \$13.6 million in the nine months ended September 30, 2019. The decrease reflects lower interest rates and prepayment of debt.

*Other Non-operating (Income) Expenses, net*

Other non-operating expense was \$0.2 million and \$0.7 million for the nine months ended September 30, 2020 and 2019, respectively.

*Income Tax Expense*

During the nine months ended September 30, 2020, the Company recognized income tax expense of less than \$0.1 million on \$24.7 million of loss before income tax, compared to \$26.8 million of income tax benefit on \$271.1 million of income before income tax during the comparable 2019 period.

Income taxes for the interim periods have been based on an estimated annualized worldwide effective tax rate.

The income tax expense was based on the applicable federal, state and foreign 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.

**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, interest or principal payments on our debt, as well as strategic business and product acquisitions. During the third quarter of 2020 we prepaid \$50 million of term loans.

As of September 30, 2020, we had cash and cash equivalents of \$126.1 million and borrowing availability under the Revolver of \$50.0 million. We also had \$221.4 million aggregate principal amount borrowed under our term loans.

As of September 30, 2020, the interest rate was 4.75% and 5.25% for our Term A Loan and Term B Loan, respectively. As of September 30, 2019, the interest rate was 5.79% and 6.29% for our Term A Loan and Term B Loan, respectively.

At September 30, 2020, there were no outstanding borrowings or outstanding letters of credit under the Revolver.

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

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

Our non-promoted products, including methylphenidate ER and VERT compete in generic markets for which competition has eroded, and will continue to erode, profitability over time. During 2019 several companies launched competing versions of methylphenidate ER. Additionally, there were three approvals and one launch of competing dosage strengths of VERT during 2019. During the nine month period ended on September 30, 2020, there were two launches of generic VERT, and as of September 30, 2020 there were three approved AB rated generic forms of Lorzone. As a result, we have experienced, and anticipate that we will continue to experience, price erosion negatively affecting profitability of both methylphenidate ER, VERT and Lorzone in 2020 and future years.

We believe that our existing cash balances, cash we expect to generate from operations from our existing product portfolio, 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, drug development and commercialization costs, 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. We expect our near term levels of cash flow to be negatively affected by price competition on methylphenidate ER, VERT and Lorzone, and increased expenses associated with new product launches. As a result, we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations. This could, among other things, force us to raise additional funds or force us to reduce our expenses through cost cutting measures either of which could have a material adverse effect on our business. During the third quarter of 2019 and first quarter of 2020, the Company realigned and reduced its operating infrastructure to prepare for the launch of Upneeq. During 2019 and continuing through the second quarter of 2020, the company implemented additional cost savings measures to reduce expenses. Additionally, the Company is exploring options to raise additional capital by, for example, out-licensing or partnering rights to arbaclofen ER, divesting non-strategic assets, strategic business development, and/or conducting one or more public or private debt or equity financings, which could be dilutive to our shareholders. Such actions may not be on favorable terms and the proceeds from such actions may not be sufficient to meet our obligations.

To continue to grow our business over the longer term, we plan to commit resources to internal product development, which may include clinical trials of product candidates, and expansion of our commercial, manufacturing and other operations. In addition, 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 facilities could be required for certain financings.

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

### Cash Flows

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

	Nine Months Ended September 30,		Change
	2020	2019	
Net cash provided by operating activities	\$ 25,842	\$ 32,892	\$ (7,050)
Net cash used in investing activities	(2,372)	(3,064)	692
Net cash provided by (used in) financing activities	6,758	(2,812)	9,570
Effect on cash of changes in exchange rate	—	164	(164)
Net increase in cash and cash equivalents	<u>\$ 30,228</u>	<u>\$ 27,180</u>	<u>\$ 3,048</u>

#### *Net cash provided by operating activities*

Cash flows from operating activities are primarily driven by earnings from operations (excluding the impact of non-cash items), the timing of cash receipts and disbursements related to accounts receivable and accounts payable and the timing of inventory transactions and changes in other working capital amounts. Net cash provided by operating activities was \$25.8 million for the nine months ended September 30, 2020, and net cash provided by operating activities was \$32.9 million for the nine months ended September 30, 2019.

The decrease in cash provided by operating activities for the nine months ended September 30, 2020, was primarily as a result of lower net income after considering non-cash adjustments, partially offset by higher cash provided from operating assets and liabilities, particularly prepaid expenses and accounts payable as compared to the nine months ended September 30, 2019.

#### *Net cash used in investing activities*

Our uses of cash in investing activities during the nine months ended September 30, 2020 and 2019 reflected purchases of property, plant and equipment of \$2.2 million and \$3.0 million, respectively.

#### *Net cash provided by (used in) financing activities*

Net cash provided by financing activities of \$6.8 million during the nine months ended September 30, 2020 largely reflecting net proceeds raised from equity offerings in January and July, 2020, offset by prepayments of term loans in the third quarter of 2020, and share repurchases.

Net cash used in financing activities of \$2.8 million during the nine months ended September 30, 2019 primarily related to payments to an insurance premium financing loan and share repurchases.

### Contractual Obligations

During the three months ended September 30, 2020 the Company prepaid \$50.0 million of term loans. There have been no other material changes outside the ordinary course of our business in our contractual obligations during the nine months ended September 30, 2020 from those as of December 31, 2019 as set forth in our filed Annual Report on Form 10-K. The Company believes the aggregate amount of potential future milestone payments are currently immaterial to our financial statements.

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

In order to understand our 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***

*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 credit losses. 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 (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied).

*Licensing 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 selling, general and administrative expenses. 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 credit losses 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, 2020. 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, 2020.

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, 2020 (in thousands):

	Chargebacks	Commercial Rebates	Government and Managed Care Rebates	Product Returns	Discounts and Allowances	Total
Balance at December 31, 2018	\$ 38,861	\$ 49,232	\$ 9,981	\$ 48,464	\$ 3,510	\$ 150,048
Provision	345,366	147,173	20,092	(3,932)	15,719	524,418
Charges processed	(369,603)	(182,826)	(25,206)	(11,075)	(17,638)	(606,348)
Balance at December 31, 2019	\$ 14,624	\$ 13,579	\$ 4,867	\$ 33,457	\$ 1,591	\$ 68,118
Provision	96,664	17,736	14,048	1,112	5,520	135,080
Charges processed	(103,708)	(24,441)	(15,040)	(11,967)	(6,413)	(161,569)
Balance September 30, 2020	\$ 7,580	\$ 6,874	\$ 3,875	\$ 22,602	\$ 698	\$ 41,629

Total items deducted from gross product sales were \$135.1 million (excluding \$2.2 million in provisions for advertising and promotion), or 53.8% as a percentage of gross product sales during the nine months ended September 30, 2020. As gross product sales have declined due to recent decreases in selling prices, sales deductions as a percentage of gross product sales are correspondingly less.

*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, and 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 \$96.7 million, or 38.5% as a percentage of gross product sales for the nine months ended September 30, 2020. 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, and 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 \$17.7 million, or 7.1% as a percentage of gross product sales for the nine months ended September 30, 2020. 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 and managed care rebates were \$14.0 million, or 5.6% as a percentage of gross product sales for the nine months ended September 30, 2020.

*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 three 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 a benefit of \$1.1 million, or 0.4% as a percentage of gross product sales for the nine months ended September 30, 2020.

*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 \$2.2 million, or 0.9% as a percentage of gross product sales for the nine months ended September 30, 2020. Advertising and promotions as a percentage of gross product sales did not change materially during the periods presented.

*Discounts and allowances* were \$5.5 million, or 2.2% as a percentage of gross product sales for the nine months ended September 30, 2020. 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, 2020, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is \$82.6 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.

#### *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.

During the nine months ended September 30, 2020 we assessed goodwill for indications of impairment and based on this assessment of indications performed, we determined that no additional evaluation was necessary and we did not recognize an impairment charge. A sustained decline in our market capitalization, even if due to macroeconomic or industry-wide factors, could put pressure on the carrying value of our goodwill and cause the Company to conduct additional impairment tests. A determination that all or a portion of our goodwill is impaired, although a non-cash charge to operations, could have a material adverse effect on our business, consolidated financial condition and results of operations.

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. Beginning in 2018, we have been assessing for indications of impairment of IPR&D assets quarterly. Based on results of the assessment of impairment indications performed, we determined that no additional evaluation was required and we did not recognize impairment charges to IPR&D as of September 30, 2020.

## *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 September 30, 2020, the Company had a federal net operating loss carryover of \$2.2 million and net operating loss carryovers in certain foreign tax jurisdictions of approximately \$13.6 million which will begin to expire in 2022. At September 30, 2020, the Company had total tax credit carryovers of approximately \$4.1 million, primarily consisting of Federal Orphan Drug Tax Credit carryovers. These credit carryovers are expected to be fully realized prior to their expiration, beginning in 2036.

We make an evaluation at the end of each reporting period as to whether or not some or all of the undistributed earnings of our subsidiaries are indefinitely reinvested. While we have concluded in the past that some of such undistributed

earnings are indefinitely reinvested, facts and circumstances may change in the future. Changes in facts and circumstances may include a change in the estimated capital needs of our subsidiaries, or a change in our corporate liquidity requirements. Such changes could result in our management determining that some or all of such undistributed earnings are no longer indefinitely reinvested. In that event, we would be required to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely reinvested outside the relevant tax jurisdiction.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020 in the United States. The CARES Act and related notices include several significant provisions, including delaying certain payroll tax payments, mandatory transition tax payments under the TCJ Act, and estimated income tax payments that we expect to defer to future periods. We do not currently expect the CARES Act to have a material impact on our financial results, including on our annual estimated effective tax rate, or on our liquidity. We will continue to monitor and assess the impact the CARES Act and similar legislation in other countries may have on our business and financial results.

Two of the Company's subsidiaries, Osmotica Pharmaceutical Corp. and Valkyrie Group Holding Inc., are under audit by the Internal Revenue Service for tax years 2016 and 2017. The Company received and has agreed with a proposed adjustment from the IRS and correspondingly recorded income tax expense of \$1.3 million, this period, inclusive of \$0.2 million interest.

#### *Share-based Compensation*

Prior to the consummation of our initial public offering, or IPO our employees were eligible to receive awards from the Osmotica Holdings S.C.Sp. 2016 Equity Incentive Plan. Prior to the completion of our IPO, the board of directors approved a new equity-based incentive compensation plan, which took effect prior to the completion of our initial public offering. Therefore, employees are now eligible to receive awards under our 2018 Equity Incentive Plan.

Our share-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, the volatility of equity comparables, the expected term of the options, the risk-free interest rate, expected dividends and other objective and subjective variables.

#### *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, 2020, our liabilities denominated in foreign currencies were not material.

We are exposed to fluctuations in interest rates on our senior secured credit facilities. An increase in interest rates could have a material impact on our cash flow. As of September 30, 2020, a 100 basis point increase in assumed interest rates for our variable interest credit facilities would have an annual impact of approximately \$2.3 million on interest expense.

As of September 30, 2020, we had cash and cash equivalents of \$126.1 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

Inflation generally affects us by increasing our cost of labor, API 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, 2020.

#### **Item 4. Controls and Procedures**

Our principal executive officer and our principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

#### **Changes in internal control over financial reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2020 that have materially affected, or are 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. The action is ongoing, but was stayed on May 23, 2019 at the parties’ joint request. 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.

On April 30, 2019, Osmotica Pharmaceuticals plc was served with a complaint in an action entitled *Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19*. On May 10, 2019, a Complaint entitled *Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19* was filed in the same court as the Shumacher action. The complaints name Osmotica Pharmaceuticals plc, certain of its directors and officers and the underwriters of its initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for the Company's initial public offering of ordinary shares. On July 22, 2019, Plaintiffs filed an Amended Complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. Defendants filed an Answer to the Amended Complaint on October 13, 2020, and the parties have exchanged discovery requests. The Company disputes the allegations in the complaints and intends to vigorously defend against the action. However, this litigation matter is still in an early stage and there is no assurance that we will be successful in our defense or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of the action, which could adversely affect the Company's results of operations and financial condition. At this time there is no loss that is probable or reasonably estimatable.

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 Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2020 and June 30, 2020.

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

## (c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table contains information regarding purchases of our ordinary shares made during the quarter ended September 30, 2020 by or on behalf of Osmotica Pharmaceuticals plc or any “affiliated purchaser,” as defined by Rule 10b-18(a)(3) of the Securities Exchange Act of 1934:

Period	Issuer Purchases of Equity Securities			
	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs(1)
07/1/20 - 07/31/20	-	-	-	4,380,453
08/1/20 - 08/31/20	220,000	5.98	220,000	4,160,453
09/1/20 - 09/30/20	417,468	5.31	417,468	3,742,985
Total	637,468	\$ 5.54	637,468	

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

**Item 6. Exhibits.**

- EXHIBIT 10.1 - [License Agreement, dated as of July 28, 2020, by and between RVL Pharmaceuticals, Inc. and Santen Pharmaceutical Co. Ltd. \(incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed July 31, 2020, Commission File No. 001-38709\)](#)
- 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 10, 2020

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

Dated: November 10, 2020

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

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 10, 2020

/s/ Brian Markison

\_\_\_\_\_  
Name: Brian Markison

Title: Chief Executive Officer and Chairman  
of the Board of Directors  
(Principal Executive Officer)

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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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 10, 2020

/s/ Andrew Einhorn

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

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**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, 2020 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 10, 2020

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

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**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, 2020 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 10, 2020

/s/ Andrew Einhorn

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Andrew Einhorn  
Chief Financial Officer  
(Principal Financial Officer)

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