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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, 2021  
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 83,280,591 ordinary shares (\$0.01 nominal value per share) outstanding as of November 12, 2021.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans, and 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," "should," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives and financial needs. Examples of forward-looking statements include, among others, statements we make regarding: our intentions, beliefs or current expectations concerning, among other things, future operations; future financial performance, trends and events, particularly relating to sales of our product and the development, approval and introduction of new products; U.S. Food and Drug Administration, or the FDA, and other regulatory applications, approvals and actions; the continuation of historical trends; our ability to manage costs and service our debt; 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:

- Due to our dependence on Upneeq, our business would be materially adversely affected if this product does not perform as well as expected;
- our ability to continue our operations requires that we raise additional capital and our operations could be curtailed if we are unable to obtain additional funding as or when needed;
- Upneeq may fail to achieve market acceptance by clinicians and patients, or others in the medical community, and the market opportunity for Upneeq may be smaller than we estimate;
- failures of or delays in clinical trials could result in increased costs to us and could prevent 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;
- 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 may face competition, including from other drug manufacturers and compounding pharmacies, which could significantly limit our growth and materially adversely affect our financial results;
- a business interruption at our pharmacy or at facilities operated by third parties that we rely on, could have a material adverse effect on our business;
- if we are unable to develop or maintain our sales capabilities, we may not be able to effectively market or sell Upneeq or any other products we may develop;

- 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;
- 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 product or product candidates may cause undesirable side effects or have other adverse properties that could delay or prevent their regulatory approval or limit the scope of any approved package insert or market acceptance, or result in significant negative consequences following marketing approval;
- manufacturing or quality control problems may damage our reputation, require costly remedial activities or otherwise negatively impact our business;
- we may in the future become subject to rules applicable to PFICs;
- our business may be adversely affected by the continuing coronavirus pandemic; and
- other factors that are described in the "Risk Factors" section of this Quarterly Report on Form 10-Q and our Current Report on Form 8-K filed on September 8, 2021.

The forward-looking statements included in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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, 2021</u>	<u>December 31, 2020</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,352	\$ 114,053
Accounts receivable, net	4,190	3,149
Inventories, net	824	1,831
Prepaid expenses and other current assets	10,019	12,592
Assets held for sale	—	41,529
Total current assets	23,385	173,154
Property, plant and equipment, net	851	2,391
Operating lease assets	1,651	1,953
Intangibles, net	27,210	35,090
Goodwill	55,847	55,847
Other non-current assets	603	373
Assets held for sale	—	102,141
Total assets	<u>\$ 109,547</u>	<u>\$ 370,949</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Trade accounts payable	\$ 4,449	\$ 3,128
Accrued liabilities	18,521	16,951
Current portion of debt, net of deferred financing costs	29,925	—
Current portion of obligation under finance leases	6	20
Current portion of lease liability	1,029	1,199
Income taxes payable - current portion	—	2
Liabilities held for sale	—	34,484
Total current liabilities	53,930	55,784
Long-term debt, net of non-current deferred financing costs	—	219,525
Long-term portion of lease liability	701	871
Income taxes payable - long term portion	1	—
Deferred taxes	165	345
Liabilities held for sale	—	568
Total liabilities	54,797	277,093
Commitments and contingencies (See Note 12)		
Shareholders' equity:		
Ordinary shares (\$0.01 nominal value 400,000,000 shares authorized, 63,127,288 and 62,545,832 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively)	631	625
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	554,156	548,070
Accumulated deficit	(497,808)	(452,610)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	54,750	93,856
Total liabilities and shareholders' equity	<u>\$ 109,547</u>	<u>\$ 370,949</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>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Net product sales	\$ 2,196	\$ 586	\$ 4,451	\$ 998
Royalty revenue	—	165	190	629
Licensing revenue	—	25,000	10,000	25,000
Total revenues	2,196	25,751	14,641	26,627
Cost of goods sold	1,147	1,185	2,535	1,794
Gross profit	1,049	24,566	12,106	24,833
Selling, general and administrative expenses	24,841	21,360	63,769	54,028
Research and development expenses	1,376	1,779	5,789	9,264
Impairment of intangibles	—	—	7,880	—
Total operating expenses	26,217	23,139	77,438	63,292
Operating income (loss)	(25,168)	1,427	(65,332)	(38,459)
Gain on sales of product rights, net	—	—	5,636	—
Operating income (loss)	(25,168)	1,427	(59,696)	(38,459)
Interest expense and amortization of debt discount	735	1,071	1,750	3,560
Other non-operating (gain) loss	120	(51)	1,312	246
Total other non-operating expense	855	1,020	3,062	3,806
Income (loss) before income taxes	(26,023)	407	(62,758)	(42,265)
Income tax expense (benefit)	324	(1,308)	415	(5,042)
Income (loss) from continuing operations	(26,347)	1,715	(63,173)	(37,223)
Gain on sales of discontinued operations	4,373	—	4,373	—
Income (loss) from discontinued operations before income tax expense	3,983	(10,171)	14,219	17,571
Income tax expense (benefit) - discontinued operations	(132)	177	617	5,063
Income (loss) from discontinued operations, net of tax	8,488	(10,348)	17,975	12,508
Net and other comprehensive loss	\$ (17,859)	\$ (8,633)	\$ (45,198)	\$ (24,715)
(Loss) income per share attributable to shareholders:				
Basic and Diluted, loss from continuing operations	\$ (0.42)	\$ 0.03	\$ (1.01)	\$ (0.62)
Basic and Diluted, income from discontinued operations	0.13	(0.16)	0.29	0.21
Basic and Diluted loss per share	\$ (0.28)	\$ (0.14)	\$ (0.72)	\$ (0.41)
Weighted average shares basic and diluted:				
Basic	62,945,898	62,785,866	62,798,123	59,979,834
Diluted	62,945,898	63,285,258	62,798,123	59,979,834

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, 2021 AND SEPTEMBER 30, 2020  
(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, 2020	51,845,742	\$ 518	\$ 489,440	\$ (373,021)	\$ (2,229)	\$ 114,708
Repurchase of ordinary shares	(29,000)	—	(167)	—	—	(167)
Share compensation	181,966	2	1,107	—	—	1,109
Net loss	—	—	—	(3,083)	—	(3,083)
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
Balance at March 31, 2020	58,898,708	589	521,484	(376,104)	(2,229)	143,740
Repurchase of ordinary shares	(169,257)	(2)	(917)	—	—	(919)
Share compensation	31,295	1	1,221	—	—	1,222
Net loss	—	—	—	(12,999)	—	(12,999)
Payments for taxes related to the net share settlement of equity awards	—	—	(133)	—	—	(133)
Balance at June 30, 2020	58,760,746	588	521,655	(389,103)	(2,229)	130,911
Repurchase of ordinary shares	(677,468)	(7)	(3,742)	—	—	(3,749)
Share compensation	22,554	—	1,508	—	—	1,508
Net loss	—	—	—	(8,633)	—	(8,633)
Proceeds from issuance of ordinary shares, net of offering costs	5,000,000	50	30,599	—	—	30,649
Balance at September 30, 2020	63,105,832	\$ 631	\$ 550,020	\$ (397,736)	\$ (2,229)	\$ 150,686
Balance at January 1, 2021	62,545,832	\$ 625	\$ 548,070	\$ (452,610)	\$ (2,229)	\$ 93,856
Share compensation	173,299	2	1,309	—	—	1,311
Net loss	—	—	—	(9,612)	—	(9,612)
Payments for taxes related to the net share settlement of equity awards	—	—	(358)	—	—	(358)
Balance at March 31, 2021	62,719,131	627	549,021	(462,222)	(2,229)	85,197
Share compensation	128,931	1	1,232	—	—	1,233
Net loss	—	—	—	(17,727)	—	(17,727)
Payments for taxes related to the net share settlement of equity awards	—	—	(249)	—	—	(249)
Balance at June 30, 2021	62,848,062	628	550,004	(479,949)	(2,229)	68,454
Share compensation	133,064	2	4,277	—	—	4,279
Net loss	—	—	—	(17,859)	—	(17,859)
Payments for taxes related to the net share settlement of equity awards	—	—	(160)	—	—	(160)
Proceeds from issuance of ordinary shares, net of offering costs	146,162	1	35	—	—	36
Balance at September 30, 2021	63,127,288	\$ 631	\$ 554,156	\$ (497,808)	\$ (2,229)	\$ 54,750

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>2021</b>	<b>2020</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss from continuing operations	\$ (63,173)	\$ (37,223)
Net income from discontinued operations	17,975	12,508
Net loss	(45,198)	(24,715)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	8,068	16,589
Share compensation	6,592	3,836
Impairment of intangibles	7,880	23,157
Deferred income tax benefit	(180)	(974)
Gain on sale of product rights, net	(5,636)	—
Gain on sale of discontinued operations	(4,373)	—
Loss on sale of fixed and leased assets	1,229	281
Bad debt provision	—	6
Amortization of deferred financing and loan origination fees	746	985
Write off of deferred financing and loan origination fees in connection with prepayment	1,387	496
Change in operating assets and liabilities:		
Accounts receivable, net	4,643	22,339
Inventories, net	2,256	(398)
Prepaid expenses and other current assets	(3,316)	4,741
Other non-current assets	(603)	—
Trade accounts payable	515	(586)
Accrued and other current liabilities	(4,347)	(19,915)
Net cash provided by (used in) operating activities	(30,337)	25,842
<b>Cash Flows from Investing Activities:</b>		
Proceeds from sale of fixed and leased assets	40	50
Payments on disposal of leased assets	—	(209)
Proceeds from product rights disposal	7,300	—
Proceeds from discontinued operations	110,845	—
Purchase of property, plant and equipment	(1,657)	(2,213)
Net cash provided by (used in) investing activities	116,528	(2,372)
<b>Cash flows from Financing Activities:</b>		
Payments on finance lease obligations	(35)	(98)
Proceeds from public offering, net of issuance costs	36	62,440
Proceeds from purchases of stock under ESPP	234	—
Debt repayment	(191,360)	(50,000)
Repurchases of ordinary shares	—	(4,835)
Payments for taxes related to net share settlement of equity awards	(767)	(749)
Net cash provided by (used in) financing activities	(191,892)	6,758
Net change in cash and cash equivalents	(105,701)	30,228
Cash and cash equivalents, beginning of period	114,053	95,865
Cash and cash equivalents, end of period	\$ 8,352	\$ 126,093
<b>Supplemental disclosure of cash and non-cash transactions:</b>		
Cash paid for interest	\$ 7,166	\$ 12,014
Cash paid for taxes	\$ 2,060	\$ 1,439

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

On August 27, 2021, the Company closed the divestiture of its portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility, (the “Legacy Business”) to certain affiliates of Alora Pharmaceuticals, or Alora, for \$111 million in cash upon closing, subject to certain adjustments, and up to \$60 million in contingent milestone payments. Pursuant to the agreement the Company post-closing retained the rights to Upneeq and to arbaclofen extended release tablets which is under development for the treatment of spasticity in multiple sclerosis. With the divestiture of the Legacy Business the primary focus of the Company will be on the commercialization and development of specialty pharmaceuticals in the ocular and medical aesthetics therapeutic areas.

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

Unless otherwise indicated or required by the context, references throughout to “Osmotica,” or the “Company”, refer to our continuing operations following the sale or the Legacy Business to Alora. A description of our business prior to the consummation of the transaction is included in Item 1. “Business”, in Part I of the Annual Report on Form 10-K for the year ended December 31, 2020 that was previously filed with the Securities and Exchange Commission (“SEC”) on March 30, 2021.

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

*Going Concern Evaluation*

As of September 30, 2021, the Company’s cash and cash equivalents totaled \$8.4 million. For the fiscal year ended December 31, 2020 and the three and nine months ended September 30, 2021 the Company incurred net losses of \$79.6 million, \$17.9 million and \$45.2 million, respectively. On August 27, 2021, the Company announced the closing of the divestiture of the Company’s portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility, or the Legacy Business, to certain affiliates of Alora Pharmaceuticals for \$111 million in cash upon closing, subject to certain post-closing adjustments, and up to \$60 million in contingent milestone payments, or the Transaction. Pursuant to the Transaction the Company retained the rights to Upneeq and to arbaclofen extended release tablets, which is under development for the treatment of spasticity in multiple sclerosis. Proceeds from the divestiture of the Legacy business, together with cash on hand were used to repay \$186.1 million of debt. As of September 30, 2021, the Company had interest bearing debt of \$29.9 million, net of deferred financing fees, with a maturity date of November 21, 2021.

On October 12, 2021 the Company issued \$55.0 million of senior secured notes to a lender, a portion of the proceeds of which, together with the proceeds from the underwritten offering described below, were used to repay \$30.7 million of outstanding term loans, accrued interest and related fees and expenses. Also on October 12, 2021 the Company issued 14,000,000 ordinary shares and warrants to purchase 16,100,000 shares in an underwritten offering, raising net proceeds

**OSMOTICA PHAMACEUTICALS PLC**

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

(UNAUDITED)

of approximately \$32.5 million. The remaining net proceeds from the issuance of the senior notes and ordinary shares is being used for general corporate purposes.

The divestiture of the Legacy Business resulted in the loss of substantially all the Company's revenue generating assets and the Company's business plan is focused on the launch of its commercial product, Upneeq, which diminished the Company's cash flows in at least the near term, in particular cash inflows from product sales. The Company will require additional capital to fund its operating needs, including the commercialization of Upneeq and other activities. Accordingly, the Company expects to incur significant expenditures and increasing operating losses in the future. As a result, the Company's current sources of liquidity will not be sufficient to meet its obligations for the 12 months following the date the unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q are issued. These conditions give rise to substantial doubt as to our ability to operate as a going concern. Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

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

- raise funds through additional sales of our ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings.
- raise capital through additional debt facilities, including convertible debt.
- partner or sell a portion or all rights to any of our assets to potentially secure additional non-dilutive funds.

There can be no assurance the Company will receive cash proceeds from any of these potential resources or, to the extent cash proceeds are received, such proceeds would be sufficient to support the Company's current operating plan for at least the next 12 months from the date the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q are issued. The sale of additional equity or convertible debt securities may result in additional dilution to the Company's stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of the Company's ordinary shares and could contain covenants that would restrict the Company's operations. Additional funds may not be available when needed, on terms that are acceptable to the Company, or at all.

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

*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 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

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

(UNAUDITED)

nine months ended September 30, 2021, are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2021 or any period thereafter. The accompanying Condensed Consolidated Balance Sheet data as of December 31, 2020 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, 2020.

The Company accounted for the sale of the Legacy Business in accordance with Accounting Standards Codification, ASC, 205 Discontinued Operations and Accounting Standards Update, ASU, No. 2014-08, Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity. The Company followed the held-for-sale criteria as defined in ASC 360 and ASC 205. ASC 205 requires that a component of an entity that has been disposed of or is classified as held for sale and has operations and cash flows that can be clearly distinguished from the rest of the entity be reported as assets held for sale and discontinued operations. In the period a component of an entity has been disposed of or classified as held for sale, the results of operations for the periods presented are reclassified into separate line items, net of tax, in the unaudited condensed consolidated statements of operations. Assets and liabilities are also reclassified into separate line items on the related condensed consolidated balance sheets for the periods presented. The statements of cash flows for the periods presented are also reclassified to reflect the results of discontinued operations as separate line items. ASU 2014-08 requires that only a disposal of a component of an entity, or a group of components of an entity, that represents a strategic shift that has, or will have, a major effect on the reporting entity's operations and financial results be reported in the financial statements as discontinued operations. ASU 2014-08 also provides guidance on the financial statement presentations and disclosures of discontinued operations.

Due to the sale of the Legacy Business during the third quarter of 2021, in accordance with ASC 205, Discontinued Operations, the Company has classified the results of the Legacy Business as discontinued operations in our unaudited condensed consolidated statements of operations and cash flows for all periods presented. All assets and liabilities associated with our Legacy Business were therefore classified as assets and liabilities of discontinued operations in our condensed consolidated balance sheets as of December 31, 2020. All amounts included in the notes to the unaudited condensed consolidated financial statements relate to continuing operations unless otherwise noted. For additional information, see Note 3, Discontinued Operations.

*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 time and performance-based 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, 2021 and 2020:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Performance and restricted stock units	1,456,910	2,092,419	1,456,910	2,591,811
Options to purchase ordinary shares	2,650,946	2,772,805	2,650,946	2,772,805
Shares to be purchased through employee stock purchase plan	79,919	—	79,919	—

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

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

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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.

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

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

**Note 3. Discontinued Operations**

On August 27, 2021, we closed the divestiture of the Company’s Legacy Business, to certain affiliates of Alora Pharmaceuticals for \$111 million in cash upon closing, subject to certain post-closing adjustments, and up to \$60 million in contingent milestone payments.

We have determined the divestiture of the Legacy Business represents a strategic shift that will have a major effect on our business and therefore met the criteria for classification as discontinued operations at September 30, 2021. Accordingly, the Legacy Business is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. The related assets and liabilities of the Legacy Business are classified as assets and liabilities of discontinued operations in the condensed consolidated balance sheets as of December 31, 2020 and the results of operations from the Legacy Business as discontinued operations in the condensed consolidated statements of operations. Applicable amounts in prior years have been recast to conform to this discontinued operations presentation. We recognized a gain on the sale of the Legacy Business upon closing.

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

(UNAUDITED)

The following table presents the results of the discontinued operations for the three- and nine -month periods ended September 30, 2021 and 2020:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Total revenues	\$ 15,551	\$ 31,421	\$ 61,785	\$ 116,726
Cost of goods sold (exclusive of depreciation and amortization shown separately below)	4,973	10,938	23,435	41,583
Selling, general and administrative expense	740	2,185	4,209	7,247
Depreciation and amortization	—	4,592	6,583	13,925
Impairment of intangibles	—	19,539	—	23,157
Research and development expenses	3,189	1,947	5,882	5,921
Income (loss) from operations	6,649	(7,780)	21,676	24,893
Interest expense	1,495	2,493	6,399	7,808
Other income (loss), net	1,171	(102)	1,058	(486)
Income (loss) from discontinued operations before costs of disposal and provision for income taxes	3,983	(10,171)	14,219	17,571
Income tax expense (benefit)	(132)	177	617	5,063
Income (loss) from discontinued operations before gain on disposal	4,115	(10,348)	13,602	12,508
Gain on sales of discontinued operations	4,373	—	4,373	—
Income (loss) from discontinued operations, net of tax	\$ 8,488	\$ (10,348)	\$ 17,975	\$ 12,508

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

	Nine months ended September 30,	
	2021	2020
Cash flows from operating activities:		
Depreciation and amortization	\$ 6,583	\$ 13,925
Share compensation	619	260
Impairment of intangibles	—	23,157
Cash flows from investing activities:		
Purchase of property, plant and equipment	\$ (1,335)	\$ (1,707)

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

(UNAUDITED)

The following table summarizes the carrying amounts of major classes of assets and liabilities of discontinued operations as of December 31, 2020.

	<b>December 31, 2020</b>
Cash and cash equivalents	\$ —
Accounts receivable, net	23,263
Inventories	16,103
Prepaid expenses and other current assets	2,163
Total current assets of discontinued operations	<u>41,529</u>
Property, plant and equipment, net	25,663
Operating lease right-of-use assets	803
Goodwill	45,008
Intangible assets, net	30,667
Total non-current assets of discontinued operations	<u>102,141</u>
Total assets of discontinued operations	<u>\$ 143,670</u>
Accounts payable	\$ 3,640
Accrued liabilities	30,566
Current portion of operating lease liabilities	278
Total current liabilities of discontinued operations	<u>34,484</u>
Operating lease liabilities, net of current portion	568
Total non-current liabilities of discontinued operations	568
Total liabilities of discontinued operations	<u>35,052</u>
Net assets of discontinued operations	<u>\$ 108,618</u>

The following table presents the gain on the sale for the quarter ended September 30, 2021:

	<b>September 30, 2021</b>
Cash proceeds	\$ 111,848
Less: transaction costs	(6,335)
Less: net assets transferred	(101,140)
Gain on sale, pre-tax	<u>\$ 4,373</u>

**Note 4. Revenues**

The Company's performance obligations are to provide its pharmaceutical products based upon purchase orders from customers. The performance obligation is satisfied at a point in time, typically upon delivery, when the customer obtains control of the pharmaceutical product. The Company collects payments in advance from its customers.

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

(UNAUDITED)

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

Pharmaceutical Products	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Upneeq	\$ 2,196	\$ 52	\$ 4,451	\$ 52
Osmolex	—	534	—	946
Net product sales	2,196	586	4,451	998
Royalty revenue	—	165	190	629
Licensing revenue	—	25,000	10,000	25,000
Total revenues	\$ 2,196	\$ 25,751	\$ 14,641	\$ 26,627

On July 28, 2020, the Company entered into a License Agreement with Santen Pharmaceutical Co. Ltd, granting Santen exclusive development, registration, and commercialization rights to RVL-1201 in Japan, China, and other Asian countries as well as Europe, the Middle East and Africa (“EMEA”) countries. Under the agreement the Company is entitled to certain development and regulatory milestone payments. The Company is also entitled to royalty payments on net sales of RVL-1201 in Santen commercialization territories. During the three and nine months ended September 30, 2021, the Company received \$0.0 million and \$10.0 million, respectively, which were recognized as license revenue in the periods as all performance obligations were met.

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of products to the customer under the terms of a contract, the Company records a contract liability. The Company classifies contract liabilities as deferred revenue. The Company had deferred revenue of \$0.2 million for the nine months ended September 30, 2021.

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, 2021. The Company has no costs to obtain or fulfill contracts meeting the capitalization criteria under ASC Topic 340, *Other Assets and Deferred Costs*.

**Note 5. Accounts Receivable**

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

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

	September 30, 2021	December 31, 2020
Gross accounts receivable:		
Accounts receivable	\$ —	\$ 196
Royalty accounts receivable	—	55
Other receivable	4,190	2,903
Less reserves for:		
Commercial rebates	—	(4)
Discounts and allowances	—	(1)
Total accounts receivable, net	\$ 4,190	\$ 3,149

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Gross product sales	\$ 2,355	\$ 647	\$ 4,611	\$ 1,497
Less provisions for:				
Chargebacks	(1)	—	(2)	—
Government and managed care rebates	—	(57)	—	(96)
Commercial rebates	—	2	—	(50)
Product returns	—	(3)	—	(67)
Discounts and allowances	(158)	(1)	(158)	(12)
Advertising and promotions	—	(2)	—	(274)
Net product sales	<u>\$ 2,196</u>	<u>\$ 586</u>	<u>\$ 4,451</u>	<u>\$ 998</u>

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

	<u>Commercial Rebates</u>	<u>Discounts and Allowances</u>	<u>Total</u>
Balance at January 1, 2020	\$ 7	\$ 2	\$ 9
Provision	56	14	70
Charges processed	(59)	(15)	(74)
Balance at December 31, 2020	\$ 4	\$ 1	\$ 5
Provision	—	158	158
Charges processed	(4)	(159)	(163)
Balance at September 30, 2021	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

**Note 6. Inventories**

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Finished goods	\$ 824	\$ 1,593
Work in process	—	90
Raw materials and supplies	—	148
	<u>\$ 824</u>	<u>\$ 1,831</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. There was no allowance for excess, obsolete, and net realizable value inventory in the nine months ended September 30, 2021 or year ended December 31, 2020.

**Note 7. 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. The Company evaluated goodwill as of September 30, 2021 in conjunction with the sale of Legacy Business and determined that there

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

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were no indications that the fair value of goodwill was less than its carrying value. The following table sets forth the carrying value of goodwill as of September 30, 2021 and December 31, 2020.

	<b>Goodwill</b>
January 1, 2020	\$ 55,847
Impairments	—
December 31, 2020	55,847
Impairments	—
September 30, 2021	\$ 55,847

Impairments of indefinite-lived In-Process R&D assets for the nine months ended September 30, 2021 and year ended December 31, 2020, were \$7.9 million and \$28.9 million, respectively, related to arbaclofen ER due to delay in anticipated commercialization of the product candidate, if approved.

As part of the Company's intangible asset impairment assessment, the Company estimates the fair value of the intangible asset using an income approach that utilizes a discounted cash flow model, or, where appropriate, a market approach. The discounted cash flow models are dependent upon our estimates of future cash flows and other factors. These estimates of future cash flows involve assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amounts, allocation and timing of cash flows and the probability of achieving the estimated cash flows and (ii) future economic conditions. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. Indefinite-lived intangible assets classified as in-process research and development, or IPRD, are subject to adjustments reducing their anticipated revenues and costs by a probability of success, or POS, factor based upon empirical research of probabilities a new drug candidate would be approved based on the candidate's stage of clinical development. The POS factor applied to the IPRD asset on the impairment assessment for the nine months ended September 30, 2021 and for the year ended December 31, 2020 was 69.6% and the discount rate was 12.5%. The Company believes the discount rates and other inputs and assumptions are consistent with those that a market participant would use.

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, 2021</b>				
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Impairment</b>	<b>Net Carrying Amount</b>	<b>Weighted Average Remaining Amortization Period (Years)</b>
IPR&D	\$ 35,090	\$ —	\$ (7,880)	\$ 27,210	Indefinite Lived
	<u>\$ 35,090</u>	<u>\$ —</u>	<u>\$ (7,880)</u>	<u>\$ 27,210</u>	

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

(UNAUDITED)

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

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

	Intangible Assets		Total	
January 1, 2020	\$	64,000	\$	64,000
Amortization		—		—
Impairments		(28,910)		(28,910)
December 31, 2020		<u>35,090</u>		<u>35,090</u>
Amortization		—		—
Impairments		(7,880)		(7,880)
September 30, 2021	\$	<u>27,210</u>	\$	<u>27,210</u>

There was no amortization expense for the nine months ended September 30, 2021 or 2020.

**Note 8. Accrued Liabilities**

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

	September 30, 2021	December 31, 2020
Accrued chargeback	\$ —	\$ 1,376
Accrued product returns	—	88
Accrued royalties	144	29
Accrued compensation	6,570	6,232
Accrued government and managed care rebates	—	46
Accrued research and development	312	721
Accrued expenses and other liabilities	11,289	8,455
Customer coupons	—	4
Deferred revenue	206	—
Total	<u>\$ 18,521</u>	<u>\$ 16,951</u>

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

(UNAUDITED)

**Note 9. Financing Arrangements**

The composition of the Company's debt and financing obligations were as follows (dollars in thousands):

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
CIT Bank, N.A. Term Loan, net of deferred financing costs of \$0.1 million and \$1.8 million as of September 30, 2021 and December 31, 2020, respectively	\$ 29,925	\$ 219,525
Total debt	29,925	219,525
Less: current portion	(29,925)	—
Long-term debt	<u>\$ —</u>	<u>\$ 219,525</u>

**Term Loan**

As of September 30, 2021, 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, 2020, the interest rate was 4.75% for the Term A Loan and 5.25% for the Term B Loan. The Company was in compliance with all covenants of the Term Loan Agreement as of September 30, 2021.

**Revolving Facility**

In connection with the Fifth Amendment to the credit agreement with CIT Bank, N.A. which became effective on August 27, 2021 the Company terminated its revolving credit facility. Additionally, the Company prepaid \$186.1 million in aggregate of the outstanding principal amount of its term loans. The prepayments consisted of \$157.4 million of Term A Loan outstanding principal and \$28.7 million of Term B Loan outstanding principal. The prepayments were made on a pro-rata basis between the Term A Loan and the Term B Loan.

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. During the second quarter, pursuant to the terms of Fourth Amendment to the Credit Agreement, the Company exercised its right to cure a shortfall in the financial covenants which resulted in the mandatory prepayment of \$5.3 million of term loans.

As a result of the partial extinguishment, the Company has elected, as an accounting policy in accordance with ASC 470-50-40-2, to write off a proportionate amount of the unamortized fees at the time that the financing was partially settled in accordance with the terms of the Third Amendment. The unamortized debt issuance costs are allocated between the remaining original loan balance and the portion of the loan paid down on a pro-rata basis. During the three and nine months ended September 30, 2021, the Company wrote off \$1.4 million and \$1.4 million of debt issuance costs, respectively, relating to the prepayments and recorded the expense in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss.

On October 12, 2021 the Company issued \$55 million of senior secured notes and completed an equity follow-on offering of 14,000,000 ordinary shares and warrants to purchase 16,100,000 shares. A portion of the proceeds from these transactions was used to fully repay term loans outstanding under the credit agreement as of September 30, 2021, see Note 17, Subsequent Events.

**Note 10. Concentrations and Credit Risk**

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

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

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*Purchasing*

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

**Note 11. Incentive Plans**

The Company recognized share-based compensation expense of \$5.9 million and \$3.3 million during the nine months ended September 30, 2021 and 2020, respectively. In connection with the divestiture of the Company's Legacy Business, we accelerated the vesting of certain options, restricted stock units and performance stock units under our incentive plans during the quarter. As of September 30, 2021, the total remaining unrecognized compensation cost related to non-vested share-based compensation awards, amounted to \$5.4 million. During the nine months ended on September 30, 2021 and 2020, there were 150,188 and 1,644,778, respectively, grants of restricted stock units. During the nine months ended September 30, 2021 and 2020, shares vested were 451,061 and 280,381, respectively. As of September 30, 2021, there were 1,456,910 restricted units, including performance stock units outstanding and the weighted-average remaining requisite service period of the non-vested stock options was 1.05 years and for non-vested restricted stock units was 2.32 years.

**Note 12. Commitments and Contingencies**

*Contingent Milestone Payments*

Upon closing of the Legacy Business divestiture, the only strategic business agreements remaining with the Company are those related to the acquisition of Upneeq and its related intellectual property. The amount of future contingent milestone payments under the intellectual property license agreement, based on certain levels of US and ex-US sales of Upneeq, was \$1.3 million in the aggregate as of September 30, 2021, in addition to royalties paid to the licensor on net sales of Upneeq. The Company is also obligated to pay earn out payments pursuant to the acquisition of RevvitaLid, Inc., the original owner of Upneeq, as a percentage of US and ex-US sales of Upneeq. The Company believes the earn-out payments are currently immaterial to its financial statements.

*Supply Agreement Obligations*

The only supply agreement remaining with the Company after the divestiture of the Legacy Business is that related to the supply of Upneeq, which contains no minimum purchase obligations.

*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,

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

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2018 denying the allegations in the Complaint and reserving the ability to raise counterclaims as the litigation progresses. On September 20, 2018, Adamas filed an amended answer to the Company's Complaint for Declaratory Judgment of Noninfringement, with counterclaims alleging infringement of certain patents included in the Company's Complaint and requesting that the court grant Adamas damages, injunctive relief and attorneys' fees. On December 2, 2020, we entered into an agreement to settle the litigation with Adamas. Under the terms of the agreement, both parties agreed to drop their respective claims relating to the patent litigation, and Adamas agreed to acquire the global rights to Osmolex ER from the Company for \$7.5 million. The sale of the global rights to Osmolex ER closed in January 2021 at which time the related gain was recorded. The sale of the global rights to Osmolex ER closed in January 2021 and a gain of \$5.6 million was recorded in the condensed consolidated statements of operations and comprehensive loss under gain on sale of product rights, net.

Additionally, in connection with the settlement and the sale of the global rights to Osmolex ER, the parties entered into a supply agreement pursuant to which the Company agreed to supply Adamas with amantadine extended release tablets for a six-year term, subject to possible two-year extensions and customary closing conditions at market rates. The supply agreement transferred to Alora as part of the divestiture of the Legacy Business.

On April 30, 2019, the Company was served with a complaint in an action entitled Leo Shumacher, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000540-19. On May 10, 2019, a Complaint entitled Jeffrey Tello, et al., v. Osmotica Pharmaceuticals plc, et al., Superior Court of New Jersey, Somerset County No. SOM-L-000617-19 was filed in the same court as the Shumacher action. The complaints named the Company, certain of the Company's directors and officers and the underwriters of the Company's initial public offering as defendants in putative class actions alleging violations of Sections 11 and 15 of the Securities Act of 1933 related to the disclosures contained in the registration statement and prospectus used for the Company's initial public offering of ordinary shares. On July 22, 2019, the plaintiffs filed an amended complaint consolidating the two actions, reiterating the previously pled allegations and adding an additional individual defendant. The parties participated in a mediation and reached an agreement in principle to settle the litigation on December 15, 2020. The parties subsequently negotiated a settlement agreement setting forth the terms of the settlement. On May 18, 2021, plaintiffs filed an unopposed motion for preliminary approval of the settlement and notice to the proposed settlement class, which motion was granted by the court on June 11, 2021. The settlement, which was finally approved by the Court on November 10, 2021, calls for a payment by the Company of \$5.25 million (a portion of which was covered by applicable insurance) and which fully resolves all claims asserted in the litigation against all defendants named in the litigation, including the Company. No party admitted any wrongdoing as part of the settlement, which was reached to avoid the further cost and distraction of litigation.

On April 19, 2021, Vertical Pharmaceuticals, LLC ("Vertical") was served with a complaint in an action entitled United States ex rel. Lupinetti, et al. v. Exeltis USA, Inc., et al., Northern District of Illinois, No. 1:19-cv-00825. The complaint named Vertical and four other pharmaceutical manufacturers as defendants in a suit alleging violations of the federal False Claims Act and state corollary statutory schemes related to the labelling, marketing, and reimbursement of several prenatal vitamins. The United States government declined to intervene in the action and the plaintiff has chosen to proceed with the litigation as a qui tam relator on behalf of the federal government and 29 individual states seeking monetary damages, statutory civil penalties, and costs and fees. We have retained outside counsel to defend us against the claims. On June 18, 2021, we and the other defendants in the action filed a Joint Motion to Dismiss, and on August 2, 2021, Plaintiff filed an Opposition to the Joint Motion to Dismiss. 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. There was not a loss that is probable or reasonably estimatable as of September 30, 2021.

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**Note 13. Income Taxes**

During the nine months ended September 30, 2021, the Company recognized an income tax expense on continuing operations of \$0.4 million on \$62.8 million of loss before income tax, compared to \$5.0 million of income tax benefit on \$42.3 million of loss before income tax during the comparable 2020 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.

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.

*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 nine months ended September 30, 2021, 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 14. Related Parties**

There were no related party transactions during the three months ended September 30, 2021 and had recognized no related expenses for the nine months ended September 30, 2021.

**Note 15. 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

**OSMOTICA PHAMACEUTICALS PLC**

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

(UNAUDITED)

factors, including the price and business and market conditions. The Company expects to retire ordinary shares acquired under the repurchase program. In the nine months ended September 30, 2021, the Company did not repurchase ordinary shares.

*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 of compensation expense for the nine months ended September 30, 2021. The Company values ESPP shares using the Black-Scholes model.

As of September 30, 2021, 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, 2021, the Company issued 37,111 ordinary shares to the employees who participated in the ESPP during the offering period ended September 30, 2021.

*2020 Equity Offering*

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.

On July 16, 2020 we completed a follow-on equity offering and allotted 5.0 million ordinary shares. The aggregate proceeds from the follow-on offering were approximately \$30.6 million after deducting offering expenses.

**Note 16. Restructuring Expenses**

In April 2021, the Company curtailed operations and implemented workforce reductions in its research and development subsidiary in Buenos Aires, Argentina. These restructuring activities were associated with the Company's plans to reduce expenses and better align business activities with the Company's corporate strategy. As a result, the Company recognized \$4.5 million of restructuring expenses in operating expenses which were incurred in the nine month period ending on September 30, 2021. The restructuring expenses consisted of \$3.2 million one-time employee related termination benefits, and \$1.3 million of asset disposal costs related to leasehold improvements at the Buenos Aires location.

**OSMOTICA PHAMACEUTICALS PLC**

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

(UNAUDITED)

Of the \$4.5 million of restructuring expenses, \$2.0 million were recognized in Selling, General and Administrative expenses, \$1.2 million were recognized in Research and Development expenses, and \$1.3 million of asset disposal costs were recognized in non-operating expenses.

**Note 17. Subsequent Events**

On October 1, 2021, the Company entered into a Note Purchase Agreement (the "Note Purchase Agreement") with, among others, Athyrium Opportunities IV Acquisition LP, as administrative agent, and certain purchasers party thereto from time to time (the "Purchaser"). The Note Purchase Agreement provides for the issuance of senior secured notes (the "Notes") to Purchaser in an aggregate principal amount of up to \$100 million in three separate tranches. The first tranche of Notes was issued in an aggregate principal amount equal to \$55,000,000 on October 12, 2021. At any time after October 12, 2021 but prior to the first anniversary thereof, upon the satisfaction of certain conditions, including a minimum net product sales target for Upneeq over a specified period of time, the Company may request the issuance of second tranche Notes in an aggregate principal amount of up to \$20,000,000. At any time after October 12, 2021 but prior to the second anniversary thereof, the Company may request the issuance of third tranche Notes in an aggregate principal amount of up to \$25,000,000, which shall be funded in the sole discretion of the Purchasers.

The Notes are guaranteed on a senior secured basis by certain of the Company's subsidiaries. The Notes and guarantees are secured by substantially all of the assets of the Company and its U.S. subsidiaries, including a security interest in substantially all of the tangible and intangible assets of the Issuer and each guarantor, including intellectual property rights and personal property consisting of inventory, related accounts, cash and deposit accounts. The Notes bear interest at a rate of 9.0% plus adjusted three-month LIBOR, with a LIBOR floor of 1.50% and LIBOR cap of 3.00%, payable in cash quarterly arrear, and will mature five (5) years following the date of issuance of the first tranche of Notes.

The Notes may be voluntarily prepaid upon the satisfaction of certain conditions and with each such prepayment being accompanied by, as applicable, (1) a make-whole premium, (2) an exit fee of 2.0% of the principal amount of the Notes prepaid, (3) certain other fees, indemnities and expenses and (4) all accrued interest on the principal amount of the Notes being so prepaid. The exit fee described in (2) above is payable on the principal amount of all Notes prepaid or repaid, including upon the repayment of the Notes upon maturity.

Subject to certain exceptions and qualifications, the Note Purchase Agreement contains covenants that, among other things, limit the Issuer's ability and the ability of its restricted subsidiaries, including the guarantors, to:

- incur additional indebtedness or issue certain disqualified capital stock;
- create liens;
- transfer or sell assets;
- make certain investments, loans, advances and acquisitions;
- engage in consolidations, amalgamations or mergers, or sell, transfer or otherwise dispose of all or substantially all of their assets; and
- enter into certain transactions with affiliates.

The Note Purchase Agreement also provides for events of default which, if any of them occurs and is continuing, would require or permit (x) the principal of, premium, if any, exit fee and accrued interest on the Notes to become or to be declared due and payable and (y) the termination of the commitments (if any) of each purchaser to purchase Notes.

As a condition to the effectiveness of the Note Purchase Agreement, on October 1, 2021, the Company entered into a share subscription agreement with the Purchaser for the issuance and sale of 6,148,832 ordinary shares for a price of \$0.01 per share. The Company issued the shares to the Purchaser on October 12, 2021.

**OSMOTICA PHAMACEUTICALS PLC**

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

**(UNAUDITED)**

On October 12, 2021, a portion of the proceeds of the first tranche notes, together with the proceeds from the underwritten offering described below, were used to repay in full the \$29.9 million, net of deferred financing fees, outstanding under the Credit Agreement dated as of February 3, 2016 (as amended) between the Company, CIT Bank, N.A., and the other parties thereto (the "Credit Agreement") together with \$0.7 million in fees and accrued interest. The remainder of the proceeds from the first tranche notes and the issuance of ordinary shares will be used for working capital and general corporate purposes, including the launch of Upneeq.

Further, on October 12, 2021 the Company completed a follow-on offering and issued and allotted 14,000,000 ordinary shares of the Company and warrants to purchase up to 14,000,000 ordinary shares, at a public offering price of \$2.50 per share and accompanying warrant. In addition, the Company granted the underwriter a 30-day option to purchase up to an additional 2,100,000 ordinary shares and/or warrants to purchase additional 2,100,000 ordinary shares at the public offering price, less the underwriting discounts and commissions. On October 11, 2021 the underwriter exercised its option to purchase additional warrants to purchase up to 2,100,000 ordinary shares. The warrants have an exercise price of \$3.10 per share, were immediately exercisable and will expire 3.5 years from the date of issuance. The aggregate net proceeds from the follow-on offering were approximately \$32.5 million after deducting underwriting commissions and 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 “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements.” Our actual results may differ materially from those contained in or implied by any forward-looking statements. 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 specialty pharmaceutical company focused on the commercialization and development of products that target markets with underserved patient populations. In July 2020, we received regulatory approval from the FDA for RVL-1201, or Upneeq, (oxymetazoline hydrochloride ophthalmic solution, 0.1%), for the treatment of acquired blepharoptosis, or droopy eyelid, in adults. We launched Upneeq in September 2020 to a limited number of eye care professionals and expanded our commercialization efforts in 2021 among ophthalmology, optometry and oculoplastic specialties. We believe Upneeq is the first non-surgical treatment option approved by the FDA for acquired blepharoptosis.

On August 27, 2021, we announced the closing of the divestiture of the Company’s portfolio of branded and non-promoted products and its Marietta, Georgia manufacturing facility, (the “Legacy Business”), to certain affiliates of Alora Pharmaceuticals (“Alora”) for \$111 million in cash upon closing, subject to certain post-closing adjustments, and up to \$60 million in contingent milestone payments, (the “Transaction”). Pursuant to the Transaction we retained the rights to Upneeq and to arbaclofen extended release tablets, which is under development for the treatment of spasticity in multiple sclerosis. As a result, our business is now primarily focused on the commercialization and development of specialty pharmaceuticals in the ocular and medical aesthetics therapeutic areas.

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

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

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. On July 17, 2020 we received notice from the FDA that it considered the resubmission a complete response to the July 9, 2016 action letter and set a goal date for a FDA decision on the NDA of December 29, 2020. On December 28, 2020 we received a complete response letter, or CRL indicating the FDA could not approve the NDA in its then current form. The CRL stated that we did not provide adequate justification (including in our most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, one of the co-primary endpoints. On January 23, 2021, we submitted a Type A meeting request to the FDA to discuss the CRL’s recommendations and obtain advice on a path forward for the NDA.

The meeting took place on March 4, 2021, during which we explored selective review of the currently available data and options for a path forward for FDA approval, including conducting another clinical study. On August 2, 2021, we submitted a Special Protocol Assessment, or SPA, to the FDA proposing an additional clinical study for arbaclofen ER. FDA responded in a letter dated October 15, 2021, indicating that they are unable to issue an agreement on the submitted protocol. We are reviewing the FDA's comments and may request a Type A meeting with the Division to discuss the protocol. We intend to revise the protocol and statistical analysis plan and resubmit the SPA agreement request.

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

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

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

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

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

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

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in our Current Report on Form 8-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 product 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*

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

*Net product sales*—Our revenues consist of sales of Upneeq sold through the pharmacy operations of RVL. RVL ships Upneeq to our customers pursuant to prescriptions which in certain cases are fulfilled by a third party pharmacy partner. All sales are made pursuant to credit cards for which we are paid prior to shipment. We recognize revenue when control has transferred to the customer, which is typically on delivery to the customer. Accordingly a portion of revenue is deferred until we have evidence the product was delivered to the customer. The amount of revenue we recognize is equal to the selling price, adjusted for any variable consideration, which largely consists of disputed chargebacks, at the time revenues are recognized.

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

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

### *Selling, General and Administrative Expenses*

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

### *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.

*Discontinued Operations*

Due to the sale of the Legacy Business during the third quarter of 2021, the Company has classified the results of the Legacy Business as discontinued operations, and all assets and liabilities associated with our Legacy Business were classified as assets and liabilities of discontinued operations for all periods presented.

**Results of Operations****Comparison of Three Months Ended September 30, 2021 and 2020***Financial Operations Overview*

The following table presents revenues and expenses for the three months ended September 30, 2021 and 2020 (dollars in thousands):

	<b>Three Months Ended September 30,</b>		<b>% change</b>
	<b>2021</b>	<b>2020</b>	
Net product sales	\$ 2,196	\$ 586	275 %
Royalty revenue	—	165	(100)%
Licensing revenue	—	25,000	(100)%
Total revenues	2,196	25,751	(91)%
Cost of goods sold	1,147	1,185	(3)%
Gross profit	1,049	24,566	(96)%
Gross profit percentage	48 %	95 %	
Selling, general and administrative expenses	24,841	21,360	16 %
Research and development expenses	1,376	1,779	(23)%
Total operating expenses	26,217	23,139	13 %
Operating income (loss)	(25,168)	1,427	(1,864)%
Interest expense and amortization of debt discount	735	1,071	(31)%
Other non-operating (gain) loss	120	(51)	(335)%
Total other non-operating expense	855	1,020	(16)%
Income (loss) before income taxes	(26,023)	407	(6,494)%
Income tax expense (benefit)	324	(1,308)	(125)%
Income (loss) from continuing operations	(26,347)	1,715	(1,636)%
Gain on sales of discontinued operations	4,373	—	NM
Income (loss) from discontinued operations before income tax expense	3,983	(10,171)	(139)%
Income tax expense (benefit) - discontinued operations	(132)	177	(175)%
Income (loss) from discontinued operations, net of tax	8,488	(10,348)	(182)%
Net and other comprehensive loss	\$ (17,859)	\$ (8,633)	107 %

NM-Not Meaningful

*Revenue*

The following table presents total revenues for the three months ended September 30, 2021 and 2020 (dollars in thousands):

<b>Pharmaceutical Products</b>	<b>Three Months Ended September 30,</b>		
	<b>2021</b>	<b>2020</b>	<b>% change</b>
Upneeq	\$ 2,196	\$ 52	4,123 %
Osmolex	—	534	(100)%
Net product sales	2,196	586	275 %
Royalty revenue	—	165	(100)%
Licensing revenue	—	25,000	(100)%
Total revenues	<u>\$ 2,196</u>	<u>\$ 25,751</u>	<u>(91)%</u>

*Total Revenues* - Total revenues decreased by \$23.6 million to \$2.2 million for the three months ended September 30, 2021, as compared to \$25.8 million for the three months ended September 30, 2020 primarily due to a decrease in license revenue from the Santen license recognized during the prior year period.

*Net Product Sales* - Net product sales increased by \$1.6 million to \$2.2 million for the three months ended September 30, 2021, as compared to \$0.6 million for the three months ended September 30, 2020. The increase in product sales of Upneeq was primarily attributable to an increase in volume of sales as the product was commercially launched in September, 2020. The decrease in product sales of Osmolex reflects the divestiture of the product in January, 2021.

*Royalty Revenue* - Royalty revenue decreased by \$0.2 million for the three months ended September 30, 2021, relative to the three months ended September 30, 2020, as the underlying product licenses expired during the second quarter of 2021.

*Licensing Revenue* - Licensing revenue decreased \$25.0 million during the three months ended September 30, 2021 as there were no milestone payments under the Santen license agreement recognized during the quarter as compared to the prior year period.

*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, 2021 and 2020 (dollars in thousands):

	<b>Three Months Ended September 30,</b>		
	<b>2021</b>	<b>2020</b>	<b>% change</b>
Depreciation expense	\$ 13	\$ 2	550 %
Royalty expense	144	11	1,209 %
Other costs of goods sold	990	1,172	(16)%
Total costs of goods sold	<u>\$ 1,147</u>	<u>\$ 1,185</u>	<u>(3)%</u>

Total cost of goods sold decreased \$0.1 million in the three months ended September 30, 2021 to \$1.1 million as compared to \$1.2 million for the three months ended September 30, 2020. The decrease was primarily driven by the absence of product costs for Osmolex which was divested in January, 2021 and higher product costs for Upneeq reflecting a full quarter of product sales as compared to the prior year period as the product was launched in September, 2020.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased \$3.4 million during the three months ended September 30, 2021 to \$24.8 million as compared to \$21.4 million in the three months ended September 30, 2020. The increase in our selling, general and administrative expenses reflects higher selling expenses associated with the expanded sales force and higher marketing expenses due to the Upneeq launch during 2021 as compared to the prior year period.

Selling, general and administrative expenses include share compensation expenses of \$3.2 million and \$1.1 million for the three months ended September 30, 2021 and 2020, respectively. The increase in share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy business during the quarter.

### *Research and Development*

Research and development expenses decreased by \$0.4 million in the three months ended September 30, 2021 to \$1.4 million as compared to \$1.8 million in the three months ended September 30, 2020. The decrease primarily reflects lower spending on arbaclofen ER and lower headcount costs, partially offset by higher spending on a new formulation of Upneeq.

Research and development expenses include share compensation \$0.4 million and \$0.1 million for the three months ended September 30, 2021 and 2020, respectively. The increase of share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy business during the quarter.

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>2021</b>	<b>2020</b>	
Arbaclofen ER	\$ 57	\$ 372	(85)%
RVL-1201	427	315	36 %
Other	892	1,092	(18)%
Total	<u>\$ 1,376</u>	<u>\$ 1,779</u>	<u>(23)%</u>

### *Impairment of Intangible Assets*

There was no impairment of intangible assets during the three months ended September 30, 2021.

### *Interest Expense and Amortization of Debt Discount*

Interest expense and amortization of debt discount decreased by \$0.4 million in the three months ended September 30, 2021 to \$0.7 million as compared to \$1.1 million in the three months ended September 30, 2020. The decrease due to lower levels of debt reflecting prepayments made during 2020 and 2021.

### *Income Tax Benefit (Expense)*

During the three months ended September 30, 2021, we recognized income tax expense on continued operations of \$0.3 million on \$26.0 million of loss before income tax, compared to \$1.3 million of income tax benefit on \$0.4 million of income before income tax during the comparable 2020 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.

*Discontinued Operations*

For the three months ended September 30, 2021 the Company recognized income from discontinued operations, net of tax, of \$8.5 million. For the three months ended September 30, 2020 the Company recognized income from discontinued operations, net of tax of \$10.4 million.

**Comparison of Nine Months Ended September 30, 2021 and 2020**

*Financial Operations Overview*

The following table presents revenues and expenses for the nine months ended September 30, 2021 and 2020 (dollars in thousands):

	<b>Nine Months Ended September 30,</b>		<b>% change</b>
	<b>2021</b>	<b>2020</b>	
Net product sales	\$ 4,451	\$ 998	346 %
Royalty revenue	190	629	(70)%
Licensing revenue	10,000	25,000	(60)%
Total revenues	14,641	26,627	(45)%
Cost of goods sold	2,535	1,794	41 %
Gross profit	12,106	24,833	(51)%
Gross profit percentage	83 %	93 %	
Selling, general and administrative expenses	63,769	54,028	18 %
Research and development expenses	5,789	9,264	(38)%
Impairment of intangibles	7,880	—	NM %
Total operating expenses	77,438	63,292	22 %
Gain on sales of product rights, net	5,636	—	NM %
Operating loss	(59,696)	(38,459)	55 %
Interest expense and amortization of debt discount	1,750	3,560	(51)%
Other non-operating (gain) loss	1,312	246	433 %
Total other non-operating expense	3,062	3,806	(20)%
Loss before income taxes	(62,758)	(42,265)	48 %
Income tax expense (benefit)	415	(5,042)	(108)%
Loss from continuing operations	(63,173)	(37,223)	70 %
Gain on sales of discontinued operations	4,373	—	NM %
Income from discontinued operations before income tax expense	14,219	17,571	(19)%
Income tax expense - discontinued operations	617	5,063	(88)%
Income from discontinued operations, net of tax	17,975	12,508	44 %
Net and other comprehensive loss	\$ (45,198)	\$ (24,715)	83 %

NM-Not Meaningful

*Revenue*

The following table presents total revenues for the nine months ended September 30, 2021 and 2020 (dollars in thousands):

<b>Pharmaceutical Products</b>	<b>Nine Months Ended September 30,</b>		
	<b>2021</b>	<b>2020</b>	<b>% change</b>
Upneeq	\$ 4,451	\$ 52	8,460 %
Osmolex	—	946	(100)%
Net product sales	4,451	998	346 %
Royalty revenue	190	629	(70)%
Licensing revenue	10,000	25,000	(60)%
Total revenues	<u>\$ 14,641</u>	<u>\$ 26,627</u>	<u>(45)%</u>

*Total Revenues* - Total revenues decreased by \$12.0 million to \$14.6 million for the nine months ended September 30, 2021, as compared to \$26.6 million for the nine months ended September 30, 2020 primarily due to a decrease in licensing revenue.

*Net Product Sales* - Net product sales increased by \$3.5 million to \$4.5 million for the nine months ended September 30, 2021, as compared to \$1.0 million for the nine months ended September 30, 2020. Product sales of Upneeq increased \$4.4 million due to a \$4.2 million increase in unit volume and a \$0.2 million increase in realized price. Upneeq was commercially launched in September, 2020. The decrease in product sales of Osmolex reflects the divestiture of the product in January, 2021.

*Royalty Revenue* - Royalty revenue decreased by \$0.4 million for the nine months ended September 30, 2021, relative to the nine months ended September 30, 2020 due to the expiration of the underlying product licenses during the second quarter of 2021.

*Licensing Revenue* - Licensing revenue decreased \$15.0 million during the nine months ended September 30, 2021 reflecting lower milestone payments under the Santen license agreement recognized during 2021 as compared to the prior year period.

*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, 2021 and 2020 (dollars in thousands):

	<b>Nine Months Ended September 30,</b>		
	<b>2021</b>	<b>2020</b>	<b>% change</b>
Depreciation expense	\$ 42	\$ 2	2,000 %
Royalty expense	287	35	720 %
Other costs of goods sold	2,206	1,757	26 %
Total costs of goods sold	<u>\$ 2,535</u>	<u>\$ 1,794</u>	<u>41 %</u>

Total cost of goods sold increased \$0.7 million in the nine months ended September 30, 2021 to \$2.5 million as compared to \$1.8 million for the nine months ended September 30, 2020. The increase was primarily driven by higher volumes of Upneeq sold during 2021 and higher royalty expense, partially offset by a decrease in the costs of goods associated with Osmolex which was divested in January, 2021.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased \$9.8 million during the nine months ended September 30, 2021 to \$63.8 million as compared to \$54.0 million in the nine months ended September 30, 2020. The increase in our selling, general and administrative expenses primarily reflects higher selling expenses associated with a salesforce expansion and higher marketing expenses associated with the launch of Upneeq during 2021 as compared to the prior year period.

Selling, general and administrative expenses include share compensation expenses of \$5.0 million and \$2.9 million for the nine months ended September 30, 2021 and 2020, respectively. The increase in share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy business during the quarter.

*Research and Development*

Research and development expenses decreased by \$3.5 million in the nine months ended September 30, 2021 to \$5.8 million as compared to \$9.3 million in the nine months ended September 30, 2020. The decrease primarily reflects lower headcount, lower spending on arbaclofen ER, Upneeq and other R&D projects, partially offset by severance costs related to the cessation of operations in the Company's Argentine subsidiary during the second quarter.

Research and development expenses include share compensation \$0.7 million and \$0.4 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of share compensation expense reflects the acceleration of vesting of equity awards triggered by the divestiture of the Legacy business during the quarter.

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

	<b>Nine Months Ended September 30,</b>		<b>% change</b>
	<b>2021</b>	<b>2020</b>	
Arbaclofen ER	\$ 662	\$ 2,720	(76)%
RVL-1201	1,015	2,629	(61)%
Other	4,112	3,915	5 %
Total	<u>\$ 5,789</u>	<u>\$ 9,264</u>	<u>(38)%</u>

*Impairment of Intangible Assets*

Impairment of intangible assets of \$7.9 million during the three months ended September 30, 2021 related to the write-down to fair value of arbaclofen ER due to delay in anticipated commercialization of the product candidate, if approved. The following table details the impairment charges for such period (in thousands):

<b>Asset/Asset Group</b>	<b>Nine Months Ended September 30, 2021</b>	
	<b>Impairment Charge</b>	<b>Reason For Impairment</b>
<i>In-Process R&amp;D</i>		
Arbaclofen ER	\$ 7,880	Delay in anticipated commercialization of the product candidate, if approved.
Total Impairment Charges for nine months ended September 30, 2021	<u>\$ 7,880</u>	

#### *Interest Expense and Amortization of Debt Discount*

Interest expense and amortization of debt discount decreased by \$1.8 million in the nine months ended September 30, 2021 to \$1.8 million as compared to \$3.6 million in the nine months ended September 30, 2020. The decrease reflects lower interest rates and prepayment of debt during 2020 and 2021.

#### *Other non-operating (gain) loss*

Other non-operating loss of \$1.3 million for the nine month period ended on September 30, 2021 increased \$1.1 million from other non-operating gain of \$0.2 million for the nine months ended September 30, 2020. The loss resulted primarily from asset disposal costs related to leasehold improvements associated with the curtailment of operations in Argentina during the second quarter of 2021.

#### *Income Tax Benefit (Expense)*

During the nine months ended September 30, 2021, we recognized income tax expense on continuing operations of \$0.4 million on \$62.8 million of loss before income tax, compared to \$5.0 million of income tax benefit on \$42.3 million of loss before income tax during the comparable 2020 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.

#### *Discontinued Operations*

For the nine months ended September 30, 2021 the Company recognized loss from discontinued operations, net of tax, of \$18.0 million. For the nine months ended September 30, 2020 the Company recognized income from discontinued operations, net of tax of \$12.5 million.

#### **Liquidity and Capital Resources**

Our principal sources of liquidity are cash and cash equivalents on hand. We had cash and cash equivalents of \$8.4 million as of September 30, 2021. Our primary uses of cash are to fund operating expenses, product development costs, capital expenditures, and debt service payments.

As of September 30, 2021, the interest rate was 4.75% and 5.25% for our Term A Loan and Term B Loan, respectively. As of September 30, 2020, the interest rate was 4.75% and 5.25% for our Term A Loan and Term B Loan, respectively.

On September 8, 2021, we entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., or Cantor under which the Company may offer and sell its ordinary shares having aggregate sales proceeds of up to \$75.0 million from time to time through Cantor as its sales agent by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including, without limitation, sales made directly on the Nasdaq Global Select Market or any other existing trading market for the Company's ordinary shares. As of September 30, 2021 we had sold 146,162 of our ordinary shares for aggregate proceeds of \$0.5 million and net proceeds to us of \$0.04 million, after deducting commissions payable by us.

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 underwriting discounts and commissions and offering expenses. Proceeds from the offering were used for working capital and general corporate purposes.

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

#### *Going Concern*

As of September 30, 2021, the Company's cash and cash equivalents totaled \$8.4 million. For the fiscal year ended December 31, 2020 and the three and nine months ended September 30, 2021 the Company incurred net losses of \$79.6 million, \$17.9 million and \$45.2 million, respectively. On August 27, 2021, we announced the closing of the Transaction. Pursuant to the Transaction we retained the rights to Upneeq and to arbaclofen extended release tablets, which is under development for the treatment of spasticity in multiple sclerosis. Proceeds from the divestiture of the Legacy business, together with cash on hand were used to repay \$186.1 million of debt. As of September 30, 2021, the Company had interest bearing debt of \$29.9 million, net of deferred financing fees, with a maturity date of November 21, 2021.

On October 12, 2021 the Company issued \$55.0 million of senior secured notes to a lender, a portion of the proceeds of which, together with the proceeds from the underwritten offering described below, were used to repay \$30.7 million of outstanding term loans, accrued interest and related fees and expenses. Also on October 12, 2021 the Company issued 14,000,000 ordinary shares and warrants to purchase 16,100,000 shares in an underwritten offering, raising net proceeds of approximately \$32.5 million. The remaining net proceeds from the issuance of the senior notes and ordinary shares is being used for general corporate purposes.

The divestiture of the Legacy Business resulted in the loss of substantially all the Company's revenue generating assets and the Company's business plan is focused on the launch of its Upneeq, which will diminish the Company's cash flows in at least the near term, in particular cash inflows from product sales. The Company will require additional capital to fund its operating needs, including the commercialization of Upneeq and other activities. Accordingly, the Company expects to incur significant expenditures and increasing operating losses in the future. As a result, the Company's current sources of liquidity will not be sufficient to meet its obligations for the 12 months following the date the unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q are issued. These conditions give rise to substantial doubt as to our ability to operate as a going concern. Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets.

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

- raise funds through additional sales of our ordinary shares, through equity sales agreements with broker/dealers or other public or private equity financings.
- raise capital through additional debt facilities, including convertible debt.
- partner or sell a portion or all rights to any of our assets to potentially secure additional non-dilutive funds.

There can be no assurance that we will receive cash proceeds from any of these potential resources or, to the extent cash proceeds are received, such proceeds would be sufficient to support our current operating plan for at least the next 12 months from the date the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q are issued. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our

ordinary shares and could contain covenants that would restrict our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all.

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

### **Cash Flows**

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

	Nine Months Ended September 30,		Change
	2021	2020	
Net cash provided by (used in) operating activities	\$ (30,337)	\$ 25,842	\$ (56,179)
Net cash provided by (used in) investing activities	116,528	(2,372)	118,900
Net cash provided by (used in) financing activities	(191,892)	6,758	(198,650)
Net increase (decrease) in cash and cash equivalents	<u>\$ (105,701)</u>	<u>\$ 30,228</u>	<u>\$ (135,929)</u>

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

Cash flows from operating activities are primarily driven by earnings from operations (excluding the impact of non-cash items), the timing of cash receipts and disbursements related to accounts receivable and accounts payable and the timing of inventory transactions and changes in other working capital amounts. Net cash used in operating activities was \$30.3 million for the nine months ended September 30, 2021, and net cash provided by operating activities was \$25.8 million for the nine months ended September 30, 2020.

The additional cash used in operating activities for the nine months ended September 30, 2021, was primarily as a result of lower net income after considering non-cash adjustments and by cash used in working capital assets and liabilities as compared to the nine months ended September 30, 2020.

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

Net cash provided by investing activities was \$116.5 million during the nine months ended September 30, 2021 as compared to cash used in investing activities of \$2.4 million during the nine months ended September 30, 2020. The change reflected proceeds of \$7.3 million from the sale of Osmolex product rights in January 2021, and proceeds from the sale of the Legacy Business in August, 2021 together with lower purchases of property, plant and equipment during the nine months ended September 30, 2021.

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

Net cash used in financing activities was \$191.9 million as compared to net cash provided by financing activities of \$6.8 million during the nine months ended September 30, 2021 and 2020, respectively. The change largely reflects the higher prepayment of term loans during the second and third quarters of 2021 as compared to the prior year period and the net proceeds raised from equity offerings in January, 2020.

### **Contractual Obligations**

There have been no material changes outside the ordinary course of our business in our contractual obligations during the nine months ended September 30, 2021 from those as of December 31, 2020 as set forth in our filing on Form 8-K on

September 8, 2021. We believe 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 determine the transaction price based on fixed consideration. In determining the transaction price, a significant financing component does not exist since the customer pays for the product in advance of the transfer of the product.

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

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

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

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

#### *Valuation of long-lived assets*

As of September 30, 2021, our combined long-lived assets balance, including property, plant and equipment and finite-lived intangible assets, is \$0.9 million.

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

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

Recoverability of an asset that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to the asset. In the event the carrying amount of the asset exceeds its undiscounted future cash flows and the carrying amount is not considered recoverable, impairment may exist. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations.

#### *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, 2021 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 us 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 will be placed into service and subject to amortization as an intangible asset. 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 the fair value of our IPR&D asset was in excess of its carrying value and, accordingly, no impairment charge was recognized in the three month period ending September 30, 2021.

#### *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, 2021, the Company had federal and state net operating loss carryover of \$29.1 million and net operating loss carryovers in certain foreign tax jurisdictions of approximately \$3.7 million which will begin to expire in 2022. At September 30, 2021, we had total tax credit carryovers of approximately \$6.7 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 2035.

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

### *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.

### **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, 2021, our liabilities denominated in foreign currencies were not material.

As of September 30, 2021, we had cash and cash equivalents of \$8.4 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, 2021.

### **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, 2021. 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, 2021, 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, 2021 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.**

The information under the caption “Legal Proceedings” set forth in Note 12 in the accompanying notes to the consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

### **Item 1A. Risk Factors.**

In addition to the risk factors in our Current Report on form 8-K filed with the SEC on September 8, 2021, we are also subject to the risk factors below, which should be considered carefully in evaluating our risk profile. The following risk factors should be read in conjunction with the risk factors described in our Current Report on form 8-K filed with the SEC on September 8, 2021. Except as set forth below, there have been no material changes from the risk factors described in our Current Report on form 8-K filed with the SEC on September 8, 2021

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

Following the divestiture of the Legacy Business we lost substantially all of our revenue generating assets, and our business plan is now focused on the launch of Upneeq, which does not generate sufficient cash flows to fund the Company’s operating needs. We will require additional capital to fund our operating needs, including the commercialization of Upneeq, interest on our secured notes and other activities. Accordingly, we expect to incur significant expenditures and operating losses in the future. These conditions give rise to substantial doubt as to our ability to operate as a going concern as our current sources of liquidity will not be sufficient to meet our obligations through the next 12 months. In addition, we are subject to certain minimum liquidity levels under our Note Purchase Agreement with Athyrium which may further restrict our operations and require us to obtain additional funding sooner. Our ability to continue as a going concern will require us to obtain additional funding, generate positive cash flow from operations and/or enter into strategic alliances or sell assets. We may seek to raise additional capital through sales of our common stock, including through equity sales agreements with broker/dealers or other public or private equity financings, through new debt facilities, including convertible debt or through a sale of a portion or all rights to any of our assets. We cannot provide assurance that we will receive cash proceeds from any of these potential sources or to the extent cash proceeds are received, that such proceeds would be sufficient to support our current operating plan or allow to continue as a going concern. Additional funds may not be available when we need them on terms that are acceptable to us or at all and the terms of any such financings may impose operating restrictions on us that limit or restrict our ability to operate our business, which could adversely affect our ability to pursue the commercialization of Upneeq and other activities on our intended timeline or at all.

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

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties. Such

attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. As a global pharmaceutical company, our systems are subject to frequent attacks. For example, we were recently subject to an attack involving the Conti ransomware strain. We were able to restore our systems, but we are still investigating the data that may have been accessed by the attacker. Due to the nature of some of the attacks and potential attacks on our systems, there is a risk that such attacks may remain undetected for a period of time. Service interruptions could also result from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

**Item 6. Exhibits.**

- EXHIBIT 10.1 - [Note Purchase Agreement dated October 1, 2021, between Osmotica Pharmaceutical Corp., Osmotica Pharmaceuticals plc, Osmotica Holdings US LLC, Athyrium Opportunities IV Acquisition LP and the Purchasers from time to time party thereto \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2021, Commission File No.001-38709\)](#)
- EXHIBIT 10.2 [Share Subscription Agreement dated October 1, 2021, between Osmotica Pharmaceuticals plc and Athyrium Opportunities IV Acquisition LP \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 6, 2021, Commission File No.001-38709\)](#).
- 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 - Inline XBRL Instance Document.
- EXHIBIT 101.SCH - Inline XBRL Taxonomy Extension Schema Document.
- EXHIBIT 101.CAL - Inline XBRL Taxonomy Extension Calculation Linkbase Document.
- EXHIBIT 101.DEF - Inline XBRL Taxonomy Extension Definition Linkbase Document.
- EXHIBIT 101.LAB - Inline XBRL Taxonomy Extension Label Linkbase Document.
- EXHIBIT 101.PRE - Inline XBRL Taxonomy Extension Presentation Linkbase Document.
- EXHIBIT 104\* Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.\*)

\* Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the U.S. Securities and Exchange Commission upon request.

**SIGNATURES**

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

**Osmotica Pharmaceuticals plc**

Dated: November 15, 2021

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

Dated: November 15, 2021

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 15, 2021

/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 15, 2021

/s/ Andrew Einhorn

\_\_\_\_\_  
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, 2021 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 15, 2021

/s/ Brian Markison  
\_\_\_\_\_  
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, 2021 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 15, 2021

/s/ Andrew Einhorn

\_\_\_\_\_  
Andrew Einhorn  
Chief Financial Officer  
(Principal Financial Officer)

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