Horizon Pharma plc
Form 10-Q
August 08, 2018

T	IN	T	ľ	ויו	E.	$\Box$	(	7	Г.	٨	П	ויו	ES	1
ι	יונ	N	u		Γ,	IJ		•	1	4		ш	-	١,

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from to

Commission File Number 001-35238

#### HORIZON PHARMA PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland Not Applicable (State or other jurisdiction (I.R.S. Employer

of incorporation or organization) Identification No.)

Connaught House, 1st Floor

1 Burlington Road, Dublin 4, D04 C5Y6, Ireland Not Applicable

(Address of principal executive offices) (Zip Code)

011 353 1 772 2100

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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

(Do not check if a smaller reporting company) 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

Number of registrant's ordinary shares, nominal value \$0.0001, outstanding as of July 27, 2018: 166,629,738.

# HORIZON PHARMA PLC

# INDEX

		Page
		No.
PART I.	<u>. FINANCIAL INFORMATION</u>	
Item 1.	<u>Financial Statements</u>	1
	Condensed Consolidated Balance Sheets as of June 30, 2018 and as of December 31, 2017 (Unaudited)	1
	Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended	
	<u>June 30, 2018 and 2017 (Unaudited)</u>	2
	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and 2017	
	(Unaudited)	3
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	34
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	51
Item 4.	Controls and Procedures	51
PART I	I. OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	52
Item 1A	Risk Factors	52
Item 6.	<u>Exhibits</u>	96
	<u>Signatures</u>	98

# PART I. FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS

# HORIZON PHARMA PLC

# CONDENSED CONSOLIDATED BALANCE SHEETS

# (UNAUDITED)

(In thousands, except share data)

	As of June 30, 2018	As of December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$710,211	\$751,368
Restricted cash	6,394	6,529
Accounts receivable, net	403,671	405,214
Inventories, net	50,105	61,655
Prepaid expenses and other current assets	64,231	43,402
Total current assets	1,234,612	1,268,168
Property and equipment, net	18,070	20,405
Developed technology, net	2,272,154	2,443,949
Other intangible assets, net	5,039	5,441
Goodwill	426,441	426,441
Deferred tax assets, net	4,185	3,470
Other assets	29,224	36,081
Total assets	\$3,989,725	\$4,203,955
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Long-term debt—current portion	<b>\$</b> —	\$10,625
Accounts payable	31,110	34,681
Accrued expenses	173,619	175,697
Accrued trade discounts and rebates	449,683	501,753
Accrued royalties—current portion	65,604	65,328
Deferred revenues—current portion	5,629	6,885
Total current liabilities	725,645	794,969
LONG-TERM LIABILITIES:		
Exchangeable notes, net	323,105	314,384
Long-term debt, net of current	1,562,013	1,576,646
Accrued royalties, net of current	293,626	291,185
Deferred revenues, net of current	<del></del>	9,713
Deferred tax liabilities, net	157,404	157,945
Other long-term liabilities	67,782	68,015
Total long-term liabilities	2,403,930	2,417,888
COMMITMENTS AND CONTINGENCIES		

## SHAREHOLDERS' EQUITY:

Ordinary shares, \$0.0001 nominal value; 300,000,000 shares authorized; 166,974,870 and 164,785,083 shares issued at June 30, 2018 and December 31, 2017, respectively, and 166,590,504 and 164,400,717 shares outstanding at June 30, 2018 and December 31, 2017, respectively 17 16 Treasury stock, 384,366 ordinary shares at June 30, 2018 and December 31, 2017 (4,585 ) (4,585 Additional paid-in capital 2,306,754 2,248,979 Accumulated other comprehensive loss (1,128)) (983 Accumulated deficit (1,440,908) (1,252,329)Total shareholders' equity 991,098 860,150 Total liabilities and shareholders' equity \$3,989,725 \$4,203,955

The accompanying notes are an integral part of these condensed consolidated financial statements.

# HORIZON PHARMA PLC

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share data)

	For the Three Months Ended		For the Six Months Ended		
	June 30,		June 30,		
	2018	2017	2018	2017	
Net sales	\$302,835	\$289,507	\$526,716	\$510,366	
Cost of goods sold	100,082	130,150	216,174	269,266	
Gross profit	202,753	159,357	310,542	241,100	
OPERATING EXPENSES:					
Research and development	24,265	163,101	41,910	176,162	
Selling, general and administrative	176,674	159,653	356,273	333,718	
Impairment of long-lived assets	_	22,270	37,853	22,270	
Total operating expenses	200,939	345,024	436,036	532,150	
Operating income (loss)	1,814	(185,667	) (125,494	) (291,050 )	
OTHER EXPENSE, NET:					
Interest expense, net	(31,030	) (31,608	) (61,484	) (63,591 )	
Foreign exchange (loss) gain	(5	) 151	(115	) (108 )	
Gain on divestiture	<u> </u>	5,856	<u>—</u>	5,856	
Loss on debt extinguishment	<del></del>	<del>_</del>	<del></del>	(533)	
Other income (expense), net	347	(35	) 525	_	
Total other expense, net	(30,688	) (25,636	) (61,074	) (58,376 )	
Loss before expense (benefit) for income taxes	(28,874	) (211,303	) (186,568	) (349,426 )	
Expense (benefit) for income taxes	3,962	(1,767	) 3,596	(49,320 )	
Net loss	\$(32,836	) \$(209,536	) \$(190,164	) \$(300,106 )	
Net loss per ordinary share—basic and diluted	\$(0.20	) \$(1.29	) \$(1.15	) \$(1.85)	
Weighted average ordinary shares outstanding—bas	ic				
and					
diluted	165,536,8	26 162,931,930	164,921,72	2 162,486,946	
OTHER COMPREHENSIVE (LOSS) INCOME,					
NET OF TAX					
Foreign currency translation adjustments	(897	) 626	(434	) 954	
Pension remeasurements	289	_	289		
Other comprehensive (loss) income	(608	) 626	(145	) 954	
Comprehensive loss	\$(33,444	) \$(208,910	) \$(190,309	) \$(299,152 )	

The accompanying notes are an integral part of these condensed consolidated financial statements.

# HORIZON PHARMA PLC

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	For the Six Months Ended June 30, 2018 2017	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(190,164)	\$(300,106)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	137,447	143,014
Equity-settled share-based compensation	58,554	57,960
Royalty accretion	29,475	25,694
Royalty liability remeasurement	(2,151)	(2,944)
Impairment of long-lived assets	37,853	22,270
Amortization of debt discount and deferred financing costs	11,185	10,629
Deferred income taxes	(1,753)	(79,486)
Acquired in-process research and development expense	_	148,609
Gain on divestiture	_	(2,635)
Loss on debt extinguishment	_	533
Foreign exchange and other adjustments	459	613
Changes in operating assets and liabilities:		
Accounts receivable	1,742	(97,267)
Inventories	11,549	67,736
Prepaid expenses and other current assets	(21,738)	2,434
Accounts payable	(3,592)	29,823
Accrued trade discounts and rebates	(52,138)	116,950
Accrued expenses and accrued royalties	(14,099)	(86,235)
Deferred revenues	333	384
Other non-current assets and liabilities	(1,988)	14,755
Net cash provided by operating activities	974	72,731
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payment related to license agreement	(12,000)	_
Payments for acquisitions, net of cash acquired	_	(167,850)
Proceeds from divestiture, net of cash divested	_	69,072
Purchases of property and equipment	(762)	(2,627)
Net cash used in investing activities	(12,762)	(101,405)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of term loans	(27,722)	(774,875)
Net proceeds from term loans	_	847,768
Proceeds from the issuance of ordinary shares in connection with warrant exercises	_	11
Proceeds from the issuance of ordinary shares through ESPP programs	4,734	3,856
Proceeds from the issuance of ordinary shares in connection with stock option exercises	3,672	1,297
Payment of employee withholding taxes related to share-based awards	(9,185)	(5,202)
Repurchase of ordinary shares		(992)
Net cash (used in) provided by financing activities	(28,501)	71,863
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(1,003)	2,196

Net (decrease) increase in cash, cash equivalents and restricted cash	(41,292	) 45,385
Cash, cash equivalents and restricted cash, beginning of the period	757,897	516,150
Cash, cash equivalents and restricted cash, end of the period	\$716,605	\$561,535

# SUPPLEMENTAL CASH FLOW INFORMATION:

Cash paid for interest	\$55,516	\$58,396
Net cash paid for income taxes	27,332	1,519
Cash paid for debt extinguishment	_	145
SUPPLEMENTAL NON-CASH FLOW INFORMATION:		
Purchases of property and equipment included in accounts payable and accrued		
expenses	107	939
Purchases of acquired in-process research and development included in accounts		
payable and accrued expenses	_	859

The accompanying notes are an integral part of these condensed consolidated financial statements.

#### HORIZON PHARMA PLC

#### NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### NOTE 1 – BASIS OF PRESENTATION AND BUSINESS OVERVIEW

#### **Basis of Presentation**

The unaudited condensed consolidated financial statements presented herein have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The December 31, 2017 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by GAAP.

Unless otherwise indicated or the context otherwise requires, references to the "Company", "we", "us" and "our" refer to Horizon Pharma plc and its consolidated subsidiaries. The unaudited condensed consolidated financial statements presented herein include the accounts of the Company and its wholly owned subsidiaries. All intra-company transactions and balances have been eliminated.

The impairment recorded during the three and six months ended June 30, 2017, of \$22.3 million of the asset recognized in connection with the acquisition of certain rights to interferon gamma-1b, as further described in Note 4, was previously included within "selling, general and administrative" expenses. For prior-period comparisons, the Company now includes this amount in the "impairment of long-lived assets" line item in its condensed consolidated statement of comprehensive loss.

#### **Business Overview**

The Company is a biopharmaceutical company focused on researching, developing and commercializing innovative medicines that address unmet treatment needs for rare and rheumatic diseases. By expanding our pipeline of medicines in development and exploring all potential uses for currently marketed medicines, the Company strives to make a powerful difference for patients, their caregivers and physicians. The Company has two reportable segments, referred to as the "orphan and rheumatology segment" and the "primary care segment". The Company markets eleven medicines in the areas of orphan diseases, rheumatology and primary care.

The Company's marketed medicines are:

#### Orphan and Rheumatology

RAVICTI® (glycerol phenylbutyrate) oral liquid

KRYSTEXXA® (pegloticase injection), for intravenous infusion

PROCYSBI® (cysteamine bitartrate) delayed-release capsules, for oral use

ACTIMMUNE® (interferon gamma-1b) injection, for subcutaneous use

RAYOS® (prednisone) delayed-release tablets; marketed as LODOTRA® outside the United States

BUPHENYL® (sodium phenylbutyrate) Tablets and Powder; marketed as AMMONAPS® in certain European countries and Japan

QUINSAIR<sup>TM</sup> (levofloxacin) solution for inhalation

**Primary Care** 

PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID 2%"), for topical use

DUEXIS® (ibuprofen/famotidine) tablets, for oral use

VIMOVO® (naproxen/esomeprazole magnesium) delayed-release tablets, for oral use

MIGERGOT® (ergotamine tartrate & caffeine suppositories), for rectal use

#### NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Recent Accounting Pronouncements

From time to time, the Company adopts new accounting pronouncements issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies.

Effective January 1, 2018, the Company adopted Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("ASU No. 2014-09"). The new standard aims to achieve a consistent application of revenue recognition within the United States, resulting in a single revenue model to be applied by reporting companies under GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is required to be applied retrospectively to each prior reporting period presented or modified retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The Company elected to utilize the modified retrospective method. The performance obligations identified by the Company under Accounting Standards Codification ("ASC") Topic 606, Revenue From Contracts With Customers, are similar to the unit of account and performance obligation determination under ASC Topic 605, Revenue Recognition. The implementation of this guidance did not have a material impact on the Company's condensed consolidated financial statements as the timing of revenue recognition for its primary revenue stream, product sales, did not significantly change. Certain of the Company's contracts for sales outside the United States include variable consideration that the Company was precluded from recognizing because the amounts were contingent. The Company concluded that the new standard required a cumulative-effect adjustment of certain deferred revenues under these contracts that were originally expected to be recognized in the future. Upon adoption on January 1, 2018, the Company reclassified \$11.3 million of deferred revenue directly to retained earnings. Following this reclassification, no amounts remained in deferred revenue relating to these contracts. In addition, as a result of the adoption of ASU No. 2014-09, the Company now presents all allowances for medicine returns in accrued expenses on the condensed consolidated balance sheet. This resulted in a reclassification of \$37.9 million of allowances for medicine returns from "accounts receivable, net" to "accrued expenses" in the consolidated balance sheet at December 31, 2017, and a reclassification of \$11.9 million between the "accounts receivable" and "accrued expenses and accrued royalties" line items within the changes in operating assets and liabilities section of the condensed consolidated statement of cash flow for the six months ended June 30, 2017.

Effective January 1, 2018, the Company adopted ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory ("ASU No. 2016-16"). ASU No. 2016-16 was issued to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Previously, GAAP prohibited the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset has been sold to an outside party which has resulted in diversity in practice and increased complexity within financial reporting. ASU No. 2016-16 requires an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs and does not require new disclosures. Upon adoption, the Company applied the modified retrospective basis through a cumulative-effect adjustment to retained earnings and the Company reclassified \$9.3 million of unrecognized deferred charges directly to retained earnings.

Effective January 1, 2018, the Company adopted ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU No. 2017-09"). The amendment amends the scope of modification accounting for share-based payment arrangements, provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC Topic 718, Compensation- Stock Compensation. Upon adoption, the Company applied the prospective method and will account for future modifications, if any, under this guidance. The adoption of ASU No. 2017-09 did not have a material impact on the Company's condensed consolidated financial statements.

Effective January 1, 2018, the Company adopted ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU No. 2016-18"). ASU No. 2016-18 addresses diversity in practice related to the classification and presentation of changes in restricted cash on the statement of cash flows. ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the

beginning-of-period and end-of-period total amounts shown on the statement of cash flows.

Effective January 1, 2018, the Company adopted ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU No. 2016-15"). ASU No. 2016-15 provides guidance on the following eight specific cash flow classification issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle.

The following table summarizes the adjustments made to conform prior period classifications as a result of the adoption of ASU No. 2016-18 and ASU No. 2016-15 (in thousands):

For the Six Months Ended June 30, 2017			
	ASU No.	ASU No.	
	2016-18	2016-15	
A o filed	Reclassific	ationReclassifica	tionAs
As filed	(2)	(3)	adjusted
\$68,646	\$ —	\$ 4,085	\$72,731
(101,576	) 171	_	(101,405)
75,948	_	(4,085	) 71,863
509,055	7,095		516,150
554,269	7,266	_	561,535
	As filed \$68,646 (101,576 75,948 509,055	ASU No. 2016-18 Reclassifica (2) \$68,646 \$ — (101,576) 171 75,948 — 509,055 7,095	ASU No. 2016-15 2016-18 2016-15 ReclassificationReclassificat (2) (3) \$68,646 \$ — \$ 4,085 (101,576) 171 — 75,948 — (4,085) 509,055 7,095 —

- (1) Cash, cash equivalents and restricted cash, beginning of the period and end of the period presented in the "As filed" column in the table above excludes restricted cash.
- (2)\$7.1 million and \$7.3 million in the table above represent the Company's restricted cash balance at December 31, 2016 and June 30, 2017, respectively.
- (3) Upon adoption of ASU No. 2016-15, the Company reclassified prepayment penalties and debt extinguishment costs of \$3.8 million and \$0.3 million, respectively, from operating activities to financing activities. Effective January 1, 2018, the Company adopted ASU No. 2017-04, Intangibles Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU No. 2017-04"), to eliminate the second step of the goodwill impairment test. ASU No. 2017-04 requires an entity to measure a goodwill impairment loss as the amount by which the carrying value of a reporting unit exceeds its fair value. Additionally, an entity should include the income tax effects from any tax deductible goodwill on the carrying value of the reporting unit when measuring a goodwill impairment loss, if applicable. The Company will apply ASU No. 2017-04 in future goodwill impairment testing. The adoption of ASU No. 2017-04 did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU No. 2016-02"). Under ASU No. 2016-02, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU No. 2016-02 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU No. 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early adoption permitted. The Company is currently in the process of evaluating the impact of adoption of ASU No. 2016-02 on its condensed consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU No. 2018-07"). ASU No. 2018-07 largely aligns the accounting for share-based payment awards issued to employees and non-employees. The Company is required to apply ASU No. 2018-07 to fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The Company expects to adopt ASU No. 2018-07 on January 1, 2019, and it does not expect the adoption of ASU No. 2018-07 to have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-08, Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made ("ASU No. 2018-08"). The new guidance applies to all entities that receive or make contributions, including business entities. The Company is required to apply ASU No. 2018-08 to contributions received during annual periods beginning after June 15, 2018, including interim periods within those annual periods. The Company is required to apply ASU No. 2018-08 to contributions provided during annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. The Company will adopt the standard on January 1, 2019, using prospective application to any new agreements entered into after the effective date. The Company does not expect the adoption of ASU No. 2018-08 to have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission ("SEC") did not, or are not expected to, have a material impact on the Company's condensed consolidated financial statements and related disclosures.

#### Significant Accounting Policies

As described above, effective January 1, 2018, the Company adopted ASU No. 2014-09. The Company modified its critical accounting policies related to revenue recognition following the adoption of ASU No. 2014-09, and the Company's updated policies are described below.

### Revenue Recognition

In the United States, the Company sells its medicines primarily to wholesale distributors and specialty pharmacy providers. In other countries, the Company sells its medicines primarily to wholesale distributors and other third-party distribution partners. These customers subsequently resell the Company's medicines to health care providers and patients. In addition, the Company enters into arrangements with health care providers and payers that provide for government-mandated or privately-negotiated discounts and allowances related to the Company's medicines. Revenue is recognized when performance obligations under the terms of a contract with a customer are satisfied. The majority of the Company's contracts have a single performance obligation to transfer medicines. Accordingly, revenues from medicine sales are recognized when the customer obtains control of the Company's medicines, which occurs at a point in time, typically upon delivery to the customer. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring medicines and is generally based upon a list or fixed price less allowances for medicine returns, rebates and discounts. The Company sells its medicines to wholesale pharmaceutical distributors and pharmacies under agreements with payment terms typically less than 90 days. The Company's process for estimating reserves established for these variable consideration components does not differ materially from the Company's historical practices.

#### Medicine Sales Discounts and Allowances

The nature of the Company's contracts gives rise to variable consideration because of allowances for medicine returns, rebates and discounts. Allowances for medicine returns, rebates and discounts are recorded at the time of sale to wholesale pharmaceutical distributors and pharmacies. The Company applies significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company will be required to make adjustments to these allowances in the future. The Company's adjustments to gross sales are discussed further below.

#### Commercial Rebates

The Company participates in certain commercial rebate programs. Under these rebate programs, the Company pays a rebate to the commercial entity or third-party administrator of the program. The Company calculates accrued commercial rebate estimates using the expected value method. The Company accrues estimated rebates based on contract prices, estimated percentages of medicine sold to qualified patients and estimated levels of inventory in the distribution channel and records the rebate as a reduction of revenue. Accrued commercial rebates are included in "accrued trade discounts and rebates" on the condensed consolidated balance sheet.

#### Distribution Service Fees

The Company includes distribution service fees paid to its wholesalers for distribution and inventory management services as a reduction to revenue. The Company calculates accrued distribution service fee estimates using the most likely amount method. The Company accrues estimated distribution fees based on contractually determined amounts, typically as a percentage of revenue. Accrued distribution service fees are included in "accrued trade discounts and rebates" on the condensed consolidated balance sheet.

## Patient Access Programs

The Company offers discount card and other programs such as its HorizonCares program to patients under which the patient receives a discount on his or her prescription. In certain circumstances when a patient's prescription is rejected by a managed care vendor, the Company will pay for the full cost of the prescription. The Company reimburses pharmacies for this discount through third-party vendors. The Company reduces gross sales by the amount of actual co-pay and other patient assistance in the period based on the invoices received. The Company also records an accrual to reduce gross sales for estimated co-pay and other patient assistance on units sold to distributors that have not yet been prescribed/dispensed to a patient. The Company calculates accrued co-pay and other patient assistance fee estimates using the expected value method. The estimate is based on contract prices, estimated percentages of medicine that will be prescribed to qualified patients, average assistance paid based on reporting from the third-party vendors and estimated levels of inventory in the distribution channel. Accrued co-pay and other patient assistance fees are included in "accrued trade discounts and rebates" on the condensed consolidated balance sheet. Patient assistance programs include both co-pay assistance and fully bought down prescriptions.

#### Sales Returns

Consistent with industry practice, the Company maintains a return policy that allows customers to return medicines within a specified period prior to and subsequent to the medicine expiration date. Generally, medicines may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the medicine expiration date or the time that the medicine is dispensed to the patient. The majority of medicine returns result from medicine dating, which falls within the range set by the Company's policy, and are settled through the issuance of a credit to the customer. The Company calculates sales returns using the expected value method. The estimate of the provision for returns is based upon the Company's historical experience with actual returns. This period is known to the Company based on the shelf life of medicines at the time of shipment. The Company records sales returns in "accrued expenses" and as a reduction of revenue.

### **Prompt Pay Discounts**

As an incentive for prompt payment, the Company offers a 2% cash discount to customers. The Company calculates accrued prompt pay discounts using the most likely amount method. The Company expects that all customers will comply with the contractual terms to earn the discount. The Company records the discount as an allowance against "accounts receivable, net" and a reduction of revenue.

#### Government Rebates

The Company participates in certain federal government rebate programs such as Medicare Coverage Gap and Medicaid. The Company calculates accrued government rebate estimates using the expected value method. The Company accrues estimated rebates based on percentages of medicine sold to qualified patients, estimated rebate percentages and estimated levels of inventory in the distribution channel that are expected to be sold to qualified patients and records the rebates as a reduction of revenue. Accrued government rebates are included in "accrued trade discounts and rebates" on the condensed consolidated balance sheet.

### **Government Chargebacks**

The Company provides discounts to federal government qualified entities with whom the Company has contracted. These federal entities purchase medicines from the wholesale pharmaceutical distributors at a discounted price, and the wholesale pharmaceutical distributors then charge back to the Company the difference between the current retail price and the contracted price that the federal entities paid for the medicines. The Company calculates accrued government chargeback estimates using the expected value method. The Company accrues estimated chargebacks based on contract prices and sell-through sales data obtained from third-party information and records the chargeback as a reduction of revenue. Accrued government chargebacks are included in "accrued trade discounts and rebates" on the condensed consolidated balance sheet.

#### **Bad Debt Expense**

The Company's medicines are sold to wholesale pharmaceutical distributors and pharmacies. The Company monitors its accounts receivable balances to determine the impact, if any, of such factors as changes in customer concentration, credit risk and the realizability of its accounts receivable, and records a bad debt reserve when applicable.

#### Segment Reporting

Effective as of the second quarter of 2018, management realigned the Company's reportable segments to reflect changes in the manner in which the chief operating decision maker ("CODM") assesses financial information for decision-making purposes. See Note 13 for further details. The Company's accounting policy for segment reporting is described below.

The Company determined that it operates in two reportable segments, an orphan and rheumatology segment and a primary care segment. The Company's reportable segments are reported in a manner consistent with the internal reporting provided to the CODM. The Company's CODM has been identified as its chief executive officer. The Company has no transactions between reportable segments.

#### NOTE 3 – NET LOSS PER SHARE

The following table presents basic and diluted net loss per share for the three and six months ended June 30, 2018 and 2017 (in thousands, except share and per share data):

	For the Three Months Ended June 30,		For the Six M June 30,	onths Ended
	2018	2017	2018	2017
Basic and diluted net loss per share calculation:				
Net loss	\$(32,836	) \$(209,536	\$(190,164)	) \$(300,106 )
Weighted average ordinary shares outstanding	165,536,826	162,931,930	164,921,722	162,486,946
Basic and diluted net loss per share	\$(0.20	) \$(1.29	\$(1.15)	) \$(1.85)

Basic net loss per share is computed by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue ordinary shares were exercised, converted into ordinary shares, or resulted in the issuance of ordinary shares that would have shared in the Company's earnings.

The computation of diluted net loss per share excluded 11.0 million and 11.6 million shares subject to equity awards for the three and six months ended June 30, 2018, respectively, and 21.5 million and 18.0 million shares subject to equity awards and warrants for the three and six months ended June 30, 2017, respectively, because their inclusion would have had an anti-dilutive effect on diluted net loss per share.

The potentially dilutive impact of the March 2015 private placement of \$400.0 million aggregate principal amount of 2.50% Exchangeable Senior Notes due 2022 (the "Exchangeable Senior Notes") by Horizon Pharma Investment Limited ("Horizon Investment"), a wholly owned subsidiary of the Company, is determined using a method similar to the treasury stock method. Under this method, no numerator or denominator adjustments arise from the principal and interest components of the Exchangeable Senior Notes because the Company has the intent and ability to settle the Exchangeable Senior Notes' principal and interest in cash. Instead, the Company is required to increase the diluted net (loss) income per share denominator by the variable number of shares that would be issued upon conversion if it settled the conversion spread obligation with shares. For diluted net (loss) income per share purposes, the conversion spread obligation is calculated based on whether the average market price of the Company's ordinary shares over the reporting period is in excess of the exchange price of the Exchangeable Senior Notes. There was no calculated spread added to the denominator for the three and six months ended June 30, 2018 and 2017.

EMENTS
5

Acquisitions

Acquisition of River Vision

On May 8, 2017, the Company acquired 100% of the equity interests in River Vision Development Corp. ("River Vision") for upfront cash payments totaling approximately \$150.3 million, including cash acquired of \$6.3 million, with additional potential future milestone and royalty payments contingent on the satisfaction of certain regulatory milestones and sales thresholds. Pursuant to ASC 805 (as amended by ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business ("ASU No. 2017-01")), the Company accounted for the River Vision acquisition as the purchase of an in-process research and development asset and, pursuant to ASC Topic 730, Research and Development, recorded the purchase price as research and development expense during the year ended December 31, 2017. Further, the Company recognized approximately \$13.1 million of federal net operating losses, \$2.8 million of state net operating losses and \$5.8 million of federal tax credits. The acquired tax attributes were set up as deferred tax assets for which a comparable amount was recorded as a deferred credit in long-term liabilities. The deferred tax assets were further netted with the net deferred tax liabilities of the U.S. group.

Under the agreement for the acquisition of River Vision, the Company is required to pay up to \$325.0 million upon the attainment of various milestones related to U.S. Food and Drug Administration ("FDA") approval and net sales thresholds. The agreement also includes a royalty payment of three percent of the portion of annual worldwide net sales exceeding \$300.0 million (if any). Under a separate agreement, the Company is also required to pay up to CHF103.0 million (\$104.0 million when converted using a CHF-to-Dollar exchange rate at June 30, 2018 of 1.0095) upon the attainment of various milestones related to approval, filing and net sales thresholds. During the year ended December 31, 2017, CHF2.0 million (\$2.0 million when converted using a CHF-to-Dollar exchange rate at the date of payment of 1.0169) was paid in relation to these milestones. The separate agreement also includes a royalty payment of between nine percent and twelve percent of the portion of annual worldwide net sales.

Acquisition and Subsequent Sale of Additional Rights to Interferon Gamma-1b

On June 30, 2017, the Company completed its acquisition of certain rights to interferon gamma-1b from Boehringer Ingelheim International GmbH ("Boehringer Ingelheim International") in all territories outside of the United States, Canada and Japan, as the Company previously held marketing rights to interferon gamma-1b in these territories, and in connection therewith, paid Boehringer Ingelheim International €19.5 million (\$22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406). Boehringer Ingelheim International commercialized interferon gamma-1b as IMUKIN in an estimated thirty countries, primarily in Europe and the Middle East. Upon closing, during the year ended December 31, 2017, the Company accounted for the €19.5 million payment (\$22.3 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1406) as the acquisition of an asset which was immediately impaired as projections for future net sales of IMUKIN in these territories did not exceed the related costs, and included the payment in the "impairment of long-lived assets" line item in its condensed consolidated statement of comprehensive loss. On July 24, 2018, the Company sold its rights to interferon gamma-1b in all territories outside the United States, Canada and Japan to Clinigen Group plc for an upfront payment and a potential additional contingent consideration payment. The Company continues to market interferon gamma-1b as ACTIMMUNE in the United States.

#### Divestiture of PROCYSBI and QUINSAIR rights in the EMEA Regions

On June 23, 2017, the Company completed the sale of its European subsidiary that owned the marketing rights to PROCYSBI and QUINSAIR in Europe, the Middle East and Africa ("EMEA") regions (the "Chiesi divestiture") to Chiesi Farmaceutici S.p.A. ("Chiesi") for an upfront payment of \$72.5 million, which reflects \$3.1 million of cash divested, with additional potential milestone payments based on sales thresholds.

Pursuant to ASU No. 2017-01, the Company accounted for the Chiesi divestiture as a sale of a business. The Company determined that the sale of the business and its assets in connection with the Chiesi divestiture did not constitute a strategic shift and that it did not and will not have a major effect on its operations and financial results. Accordingly, the operations associated with the Chiesi divestiture are not reported as discontinued operations.

The gain on divestiture recorded during the year ended December 31, 2017, was determined as follows (in thousands):

Cash proceeds	\$72,462
Add reimbursement of royalties	27,101
Less net assets sold:	
Developed technology	(47,261)
Goodwill	(16,285)
Other	(24,482)
Transaction and other costs	(5,268)
Gain on divestiture	\$6,267

The Company recorded a gain on divestiture of \$5.9 million in the condensed consolidated statement of comprehensive loss during the three and six months ended June 30, 2017. Additionally, during the second half of 2017 the Company recorded adjustments for working capital of \$0.4 million and the total gain on divestiture recorded

amounted to \$6.3 million.

Under the terms of its agreement with Chiesi, the Company will continue to pay third parties for the royalties on sales of PROCYSBI and QUINSAIR in the EMEA regions, and Chiesi will reimburse the Company for those royalties. At the date of divestiture, the Company recorded an asset of \$27.1 million to "other assets", which represented the estimated amounts that are expected to be reimbursed from Chiesi for the PROCYSBI and QUINSAIR royalties. These estimated royalties are accrued in "accrued expenses" and "other long-term liabilities".

Transaction and other costs primarily relate to professional and license fees attributable to the divestiture.

#### Other Arrangements

#### Licensing agreement

On December 12, 2017, the Company entered into an agreement to license HZN-003 (formerly MEDI4945), a potential next-generation biologic for uncontrolled gout, from MedImmune LLC ("MedImmune"), the global biologics research and development arm of the AstraZeneca Group. HZN-003 is a pre-clinical, genetically engineered uricase derivative with optimized uricase and optimized PEGylation technology that has the potential to improve the response rate to the biologic as well as the potential for subcutaneous dosing. Under the terms of the agreement, the Company agreed to pay MedImmune an upfront cash payment of \$12.0 million with additional potential future milestone payments of up to \$153.5 million contingent on the satisfaction of certain development and sales thresholds. The \$12.0 million upfront payment was accounted for as the acquisition of an asset and was recorded as "research and development" expenses in the condensed consolidated statement of comprehensive loss during the year ended December 31, 2017 and included in "accrued expenses" as of December 31, 2017. The upfront payment was subsequently paid in January 2018.

#### NOTE 5 – INVENTORIES

Inventories are stated at the lower of cost or market value. Inventories consist of raw materials, work-in-process and finished goods. The Company has entered into manufacturing and supply agreements for the manufacture of finished goods or the purchase of raw materials and production supplies. The Company's inventories include the direct purchase cost of materials and supplies and manufacturing overhead costs.

The components of inventories as of June 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	June 30,	December 31,
	2018	2017
Raw materials	\$6,205	\$ 4,553
Work-in-process	25,200	27,589
Finished goods	18,700	29,513
Inventories, net	\$50,105	\$61,655

Finished goods at December 31, 2017 included \$17.0 million of stepped-up KRYSTEXXA inventory. During the six months ended June 30, 2018, the Company recorded the remaining \$17.0 million of KRYSTEXXA inventory step-up expense to cost of goods sold. During the three and six months ended June 30, 2017, the Company recorded \$19.3 million and \$33.7 million, respectively, of KRYSTEXXA and MIGERGOT inventory step-up expense and \$14.5 million and \$40.8 million, respectively, of PROCYSBI and QUINSAIR inventory step-up expense to cost of goods sold.

KRYSTEXXA inventory step-up was fully expensed by March 31, 2018. As a result, the costs of goods sold related to KRYSTEXXA have decreased significantly beginning with the second quarter of 2018 to levels consistent with the historical costs of goods sold before the Company's acquisition of Crealta Holdings LLC.

Because inventory step-up expense is acquisition-related, will not continue indefinitely and has a significant effect on the Company's gross profit, gross margin percentage and net (loss) income for all affected periods, the Company discloses balance sheet and income statement amounts related to inventory step-up within the notes to the condensed consolidated financial statements.

## NOTE 6 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets as of June 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	June 30,	December 31,
	2018	2017
Deferred charge for taxes on intra-company profit	\$10,297	\$ 535
Prepaid income taxes	9,806	8
Rabbi trust assets	8,292	6,490
Medicine samples inventory	7,777	11,415
Other prepaid expenses and other current assets	28,059	24,954
Prepaid expenses and other current assets	\$64,231	\$ 43,402

## NOTE 7 – PROPERTY AND EQUIPMENT

Property and equipment as of June 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	June 30,	December 31,
	2018	2017
Software	\$14,855	\$14,956
Leasehold improvements	9,859	9,415
Machinery and equipment	4,800	4,819
Computer equipment	2,226	2,235
Other	2,331	2,508
	34,071	33,933
Less accumulated depreciation	(16,220)	(13,672)
Construction in process	219	144
Property and equipment, net	\$18,070	\$20,405

Depreciation expense was \$1.6 million and \$1.8 million for the three months ended June 30, 2018 and 2017, respectively, and was \$3.1 million and \$3.6 million for the six months ended June 30, 2018 and 2017, respectively.

#### NOTE 8 – GOODWILL AND INTANGIBLE ASSETS

#### Goodwill

The gross carrying amount of goodwill as of June 30, 2018 and December 31, 2017 was \$426.4 million.

As discussed in Note 13, during the second quarter of 2018, management realigned the Company's reportable segments to reflect changes in the manner in which the CODM assesses financial information for decision-making purposes. This resulted in a change in the Company's operating segments and reporting units. The Company allocated goodwill to its new reporting units using a relative fair value approach. In addition, the Company completed an assessment of any potential goodwill impairment for all reporting units immediately prior to the allocation and determined that no impairment existed. The table below presents goodwill for the Company's reportable segments as of June 30, 2018 (in thousands):

	Orphan and	Primary	
	Rheumatology	Care	Total
Goodwill	\$ 371,883	\$54,558	\$426,441

During the year ended December 31, 2017, in connection with the Chiesi divestiture, the Company recorded a reduction to goodwill of \$16.3 million. See Note 4 for further details.

As of June 30, 2018, there were no accumulated goodwill impairment losses.

#### **Intangible Assets**

As of June 30, 2018, the Company's finite-lived intangible assets consisted of developed technology related to ACTIMMUNE, BUPHENYL/AMMONAPS, KRYSTEXXA, LODOTRA, MIGERGOT, PENNSAID 2%, PROCYSBI, RAVICTI, RAYOS and VIMOVO, as well as customer relationships for ACTIMMUNE.

During the three and six months ended June 30, 2017, in connection with the Chiesi divestiture, the Company recorded a reduction in the net book value of developed technology related to PROCYSBI of \$47.3 million. See Note 4 for further details.

The Company tests its intangible assets for impairment when events or circumstances may indicate that the carrying value of these assets exceeds their fair value. During the six months ended June 30, 2018, the Company recorded an impairment of \$37.9 million to fully write off the book value of developed technology related to PROCYSBI in Canada and Latin America due primarily to lower anticipated future net sales based on a Patented Medicine Prices Review Board review. The fair value of developed technology was determined using an income approach.

Intangible assets as of June 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	June 30, 20	18			December 3	31, 2017	
			Accumulated	d Net Book		Accumulated	d Net Book
	Cost Basis	Impairmen	t Amortizatioi	n Value	Cost Basis	Amortization	n Value
Developed technology	\$3,115,695	\$ (37,853	)\$ (805,688	)\$2,272,154	\$3,115,695	\$ (671,746	)\$2,443,949
Customer relationships	8,100		(3,061	) 5,039	8,100	(2,659	) 5,441
Total intangible assets	\$3 123 795	\$ (37.853	)\$ (808 749	)\$2 277 193	\$3 123 795	\$ (674.405	)\$2.449.390

Amortization expense for the three months ended June 30, 2018 and 2017 was \$67.0 million and \$69.8 million, respectively, and was \$134.3 million and \$139.5 million for the six months ended June 2018 and 2017, respectively. As of June 30, 2018, estimated future amortization expense was as follows (in thousands):

2018 (July to December)	\$135,449
2019	256,658
2020	255,962
2021	248,456
2022	243,872
Thereafter	1,136,796
Total	\$2,277,193

#### NOTE 9 - OTHER ASSETS

Included in other assets at June 30, 2018 and December 31, 2017, was \$23.9 million and \$24.6 million, respectively, which represents the long-term portion of the estimated amounts that are expected to be reimbursed from Chiesi for PROCYSBI and QUINSAIR royalties.

### NOTE 10 - ACCRUED EXPENSES

Accrued expenses as of June 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	June 30,	December 31,
	2018	2017
Payroll-related expenses	\$52,806	\$56,338

Edgar Filing: Horizon Pharma plc - Form 10-Q

Allowances for returns	42,214	37,863
Consulting and professional services	35,848	27,542
Accrued interest	13,785	14,127
Accrued upfront payment related to license agreement	_	12,000
Accrued other	28,966	27,827
Accrued expenses	\$173,619	\$175,697

Accrued other as of June 30, 2018 and December 31, 2017 included \$3.7 million and \$2.1 million, respectively, related to a loss on inventory purchase commitments.

## NOTE 11 – ACCRUED TRADE DISCOUNTS AND REBATES

Accrued trade discounts and rebates as of June 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Accrued wholesaler fees and commercial rebates	\$167,443	\$190,215
Accrued co-pay and other patient assistance	179,213	230,533
Accrued government rebates and chargebacks	103,027	81,005
Accrued trade discounts and rebates	\$449,683	\$501,753
Invoiced wholesaler fees and commercial rebates, co-pay		
and other patient assistance, and government rebates and		
chargebacks in accounts payable	7,296	15,042
Total customer-related accruals and allowances	\$456,979	\$516,795

The following table summarizes changes in the Company's customer-related accruals and allowances from December 31, 2017 to June 30, 2018 (in thousands):

	Wholesaler Fees and Commercial Rebates	Co-Pay and Other Patient Assistance	Government Rebates and Chargebacks	Total
Balance at December 31, 2017	\$ 190,485	\$ 232,325	\$ 93,985	\$516,795
Current provisions relating to sales during the six				
months ended June 30, 2018	301,257	1,027,240	187,469	1,515,966
Adjustments relating to prior-year sales	(667)	(374)	(12,529	) (13,570 )
Payments relating to sales during the six months				
ended June 30, 2018	(133,639)	(848,027)	(82,732	) (1,064,398)
Payments relating to prior-year sales	(189,661)	(231,951)	(76,202	) (497,814 )
Balance at June 30, 2018	\$ 167,775	\$ 179,213	\$ 109,991	\$456,979

## NOTE 12 - ACCRUED ROYALTIES

During the six months ended June 30, 2018, changes to the liability for royalties for medicines acquired through business combinations consisted of the following (in thousands):

Balance as of December 31, 2017	356,513
Remeasurement of royalty liabilities	(2,151)
Royalty payments	(24,527)
Accretion expense	29,375
Other royalty expense	20
Balance as of June 30, 2018	359,230
Accrued royalties - current portion as of June 30, 2018	65,604
Accrued royalties, net of current as of June 30, 2018	\$293,626

#### NOTE 13 – SEGMENT AND OTHER INFORMATION

Effective as of the second quarter of 2018, management realigned the Company's reportable segments to reflect changes in the manner in which the CODM assesses financial information for decision-making purposes. All prior year amounts have been reclassified to conform to the Company's current reporting structure.

The Company has two reportable segments, the orphan and rheumatology segment and the primary care segment, and the Company reports net sales and segment operating income for each segment.

The orphan and rheumatology segment includes the marketed medicines ACTIMMUNE, BUPHENYL/AMMONAPS, KRYSTEXXA, PROCYSBI, QUINSAIR, RAVICTI and RAYOS/LODOTRA. The primary care segment consists of four marketed medicines, including DUEXIS, MIGERGOT, PENNSAID 2% and VIMOVO.

Management structured the business into two segments to improve operating and resource allocation decisions to align with the Company's long-term strategic goal of transforming into a leading rare disease medicine company.

The Company's CODM evaluates the financial performance of the Company's segments based upon segment operating income. Segment operating income is defined as loss before expense (benefit) for income taxes adjusted for the items set forth in the reconciliation below. Items below income from operations are not reported by segment, since they are excluded from the measure of segment profitability reviewed by the Company's CODM. Additionally, certain expenses are not allocated to a segment. The Company does not report balance sheet information by segment as no balance sheet by segment is reviewed by the Company's CODM. The accounting policy for the Company's segments is described in Note 2.

The following table reflects net sales by medicine for the Company's reportable segments for the three and six months ended June 30, 2018 and 2017 (in thousands):

Three	Months	Ended	Siv N	Monthe	Ended
Tillee I	wionuis	Ellueu	OIX I	vionuis	CHUCU

	June 30,	June 30,		
	2018	2017	2018	2017
KRYSTEXXA	\$58,608	\$38,301	\$105,326	\$69,915
RAVICTI	56,958	47,239	106,051	91,114
PROCYSBI	38,433	36,679	73,367	70,959
ACTIMMUNE	27,382	28,819	52,240	55,021
RAYOS	13,452	11,643	24,142	21,901

Edgar Filing: Horizon Pharma plc - Form 10-Q

BUPHENYL	5,244	6,231	10,986	12,555
LODOTRA	1,535	1,804	1,650	2,672
QUINSAIR	97	1,407	218	3,200
Orphan and Rheumatology segment net sales	\$201,709	\$172,123	\$373,980	\$327,337
PENNSAID 2%	47,610	51,221	74,413	92,831
DUEXIS	30,728	43,603	46,405	61,332
VIMOVO	21,856	21,130	30,235	26,012
MIGERGOT	932	1,430	1,683	2,854
Primary Care segment net sales	\$101,126	\$117,384	\$152,736	\$183,029
Total net sales	\$302,835	\$289,507	\$526,716	\$510,366

The table below provides reconciliations of the Company's segment operating income to the Company's total loss before expense (benefit) for income taxes for the three and six months ended June 30, 2018 and 2017 (in thousands):

	Ended June 30,		For the Six Ended June 2018	
Segment operating income:				
Orphan and Rheumatology	\$70,609	\$64,662	\$113,713	\$114,386
Primary Care	45,883	62,423	36,311	65,042
Reconciling items:				
Amortization, accretion and step-up:				
Intangible amortization expense	(66,989)			
Accretion of royalty liabilities	(14,797)	(12,735)		(25,694)
Inventory step-up expense	(53)	(33,895)		
Interest expense, net	(31,030)	(31,608)	(61,484)	(63,591)
Share-based compensation	(30,721)	(27,768)	(58,554)	(56,237)
Restructuring and realignment costs	(7,039)	(5,193)	(10,381)	(5,193)
Litigation settlements	(4,250)		(4,250)	
Depreciation	(1,551)	(1,755)	(3,104)	(3,561)
Acquisition/divestiture-related costs	(1,775)	(153,385)	(5,686)	(163,424)
Drug substance harmonization costs	(475)	(745)	(1,279)	(5,044)
Charges relating to discontinuation of Friedreich's ataxia program	(272)	3,103	(1,222)	3,103
Fees related to term loan refinancings	(15)	45	(42)	(4,098)
Foreign exchange (loss) gain	(5)	151	(115)	(108)
Impairment of long-lived assets	_	(22,270)	(37,853)	(22,270)
Remeasurement of royalties for medicines acquired through business				
combinations			2,151	2,944
Gain on divestiture	_	5,856	_	5,856
Upfront and milestone payments related to license agreements			(90)	
Loss on debt extinguishment		_	<del></del>	(533)
Other income (expense), net	347	(35)	525	
Royalties for medicines acquired through business combinations	13,259	11,622	25,780	22,939
Loss before expense (benefit) for income taxes	\$(28,874)	\$(211,303)	\$(186,568)	\$(349,426)

The following tables present the amount and percentage of gross sales to customers that represented more than 10% of the Company's gross sales included in its two reportable segments, and all other customers as a group for the three and six months ended June 30, 2018 and 2017 (in thousands, except percentages):

	For the Three Months Ended June 30,					
	2018			2017		
	Amount	% of Gr	oss	Amount	% of Gross	
		Sales			Sales	
Customer A	\$292,914	26	%	\$337,770	32	%
Customer B	277,705	25	%	321,639	30	%
Customer C	126,881	11	%	144,241	13	%

Edgar Filing: Horizon Pharma plc - Form 10-Q

Other Customers	430,296	38	%	268,034	25	%
Gross Sales	\$1,127,796	100	%	\$1,071,684	100	%

For the Six Months Ended June 3	0,
---------------------------------	----

	1 of the Six Months Ended valle 30,						
	2018			2017			
	Amount	% of Gross		Amount	% of Gross		
		Sales			Sales		
Customer A	\$569,725	27	%	\$588,859	29	%	
Customer B	495,562	24	%	627,191	31	%	
Customer C	239,047	12	%	283,465	14	%	
Other Customers	777,901	37	%	500,742	26	%	
Gross Sales	\$2 082 235	100	0/0	\$2,000,257	100	0/0	

Geographic revenues are determined based on the country in which the Company's customers are located. The following tables present a summary of net sales attributed to geographic sources for the three and six months ended June 30, 2018 and 2017 (in thousands, except percentages):

	Three Months Ended June 30, 2018		Three Months Ended June 30, 2017		
	Amount	% of Total Net Sales	Amount	% of Total Net Sales	
United States	\$ 295,939	98%	\$ 279,012	96%	
Rest of world	6,896	2%	10,495	4%	
Net sales	\$ 302,835		\$ 289,507		
	Six Months Ended Ju-	ne 30, 2018	Six Months Ended Ju	ne 30, 2017	
	Amount	% of Total Net Sales	Amount	% of Total Net Sales	
United States	\$ 515,310	98%	\$ 489,897	96%	
Rest of world	11,406	2%	20,469	4%	
Net sales	\$ 526,716		\$ 510,366		

#### NOTE 14 – FAIR VALUE MEASUREMENTS

The following tables and paragraphs set forth the Company's financial instruments that are measured at fair value on a recurring basis within the fair value hierarchy. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The following describes three levels of inputs that may be used to measure fair value:

Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its money market funds. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities.

As of June 30, 2018, the Company's restricted cash included bank time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. Level 2 inputs, obtained from various third-party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data.

Other current assets and other long-term liabilities recorded at fair value on a recurring basis are composed of investments held in a rabbi trust and the related deferred liability for deferred compensation arrangements. Quoted

prices for this investment, primarily in mutual funds, are available in active markets. Thus, the Company's investments related to deferred compensation arrangements and the related long-term liability are classified as Level 1 measurements in the fair value hierarchy.

The Company transfers its financial assets and liabilities between the fair value hierarchies at the end of each reporting period. There were no transfers between the different levels of the fair value hierarchy during the six months ended June 30, 2018 or 2017.

Assets and liabilities measured at fair value on a recurring basis

The following tables set forth the Company's financial assets and liabilities at fair value on a recurring basis as of June 30, 2018 and December 31, 2017 (in thousands):

	June 30, 2018				
		Level	Level		
	Level 1	2	3	Total	
Assets:					
Bank time deposits	\$	\$3,000	\$ —	\$3,000	
Money market funds	662,657	_	_	662,657	
Other current assets	8,156			8,156	
Total assets at fair value	\$670,813	\$3,000	\$ —	\$673,813	
Liabilities:					
Other long-term liabilities	(8,156)	_	_	(8,156)	
Total liabilities at fair value	\$(8,156)	<b>\$</b> —	\$ —	\$(8,156)	

	December	31, 2017		
		Level	Level	
	Level 1	2	3	Total
Assets:				
Bank time deposits	<b>\$</b> —	\$3,000	\$ —	\$3,000
Money market funds	687,000			687,000
Other current assets	6,490			6,490
Total assets at fair value	\$693,490	\$3,000	\$ —	\$696,490
Liabilities:				
Other long-term liabilities	(6,490)	_		(6,490 )
Total liabilities at fair value	\$(6.490)	\$	\$ —	\$(6.490)

## NOTE 15 – DEBT AGREEMENTS

The Company's outstanding debt balances as of June 30, 2018 and December 31, 2017, consisted of the following (in thousands):

	June 30,	December 31,	
	2018	2017	
2017 Term Loan Facility	\$818,026	\$ 845,750	
2023 Senior Notes	475,000	475,000	
2024 Senior Notes	300,000	300,000	
Exchangeable Senior Notes	400,000	400,000	
Total face value	1,993,026	2,020,750	
Debt discount	(97,737)	(108,054	)

Deferred financing fees	(10,171)	(11,041	)
Total long-term debt	1,885,118	1,901,655	
Less: long-term debt—current portion	_	(10,625	)
Long-term debt, net of current portion	\$1,885,118	\$ 1,891,030	

#### 2017 Term Loan Facilities

On October 23, 2017, Horizon Pharma, Inc. ("HPI") and Horizon Pharma USA, Inc. ("HPUSA" and, together with HPI, in such capacity, the "Borrowers"), wholly owned subsidiaries of the Company, borrowed approximately \$845.8 million aggregate principal amount of loans (the "October 2017 Refinancing Loans") pursuant to an amendment (the "October 2017 Refinancing Amendment") to the credit agreement, dated as of May 7, 2015, by and among the Borrowers, the Company and certain of its subsidiaries as guarantors, the lenders party thereto from time to time and Citibank, N.A., as administrative agent and collateral agent, as amended by Amendment No. 1, dated as of October 25, 2016, and Amendment No. 2, dated March 29, 2017 (the "March 2017 Credit Agreement") (the "2017 Term Loan Facility"). As used herein, all references to the "Credit Agreement" are references to the March 2017 Credit Agreement, as amended by the October 2017 Refinancing Amendment.

The October 2017 Refinancing Loans were incurred as a separate new class of term loans under the Credit Agreement with substantially the same terms as the previously outstanding senior secured term loans incurred on March 29, 2017 under the March 2017 Credit Agreement (the "October 2017 Refinanced Loans") to effectuate a repricing of the October 2017 Refinanced Loans. The Borrowers used the proceeds of the October 2017 Refinancing Loans to repay the October 2017 Refinanced Loans, which totaled approximately \$845.8 million. The October 2017 Refinancing Loans bear interest, at the Borrowers' option, at a rate equal

to either the London Inter-Bank Offer Rate ("LIBOR"), plus an applicable margin of 3.25% per year (subject to a LIBOR floor of 1.00%), or the adjusted base rate plus 2.25%. The adjusted base rate is defined as the greater of (a) LIBOR (using one-month interest period) plus 1.00%, (b) prime rate, (c) fed funds plus 0.5%, and (d) 2.00%. The Credit Agreement provides for (i) the October 2017 Refinancing Loans, (ii) one or more uncommitted additional incremental loan facilities subject to the satisfaction of certain financial and other conditions, and (iii) one or more uncommitted refinancing loan facilities with respect to loans thereunder. The Credit Agreement allows for the Company and certain of its subsidiaries to become borrowers under incremental or refinancing facilities.

The obligations under the Credit Agreement (including obligations in respect of the October 2017 Refinancing Loans) and any swap obligations and cash management obligations owing to a lender (or an affiliate of a lender) thereunder are guaranteed by the Company and each of the Company's existing and subsequently acquired or formed direct and indirect subsidiaries (other than certain immaterial subsidiaries, subsidiaries whose guarantee would result in material adverse tax consequences and subsidiaries whose guarantee is prohibited by applicable law). The obligations under the Credit Agreement (including obligations in respect of the October 2017 Refinancing Loans) and any such swap and cash management obligations are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected security interest in (i) all tangible and intangible assets of the Borrowers and the guarantors, except for certain customary excluded assets, and (ii) all of the capital stock owned by the Borrowers and guarantors thereunder (limited, in the case of the stock of certain non-U.S. subsidiaries of the Borrowers, to 65% of the capital stock of such subsidiaries). The Borrowers and the guarantors under the Credit Agreement are individually and collectively referred to herein as a "Loan Party" and the "Loan Parties," as applicable.

The Company elected to exercise its reinvestment rights under the mandatory prepayment provisions of the March 2017 Credit Agreement with respect to the net proceeds from the Chiesi divestiture. To the extent the Company had not applied such net proceeds to permitted acquisitions (including the acquisition of rights to products and products lines) and/or the acquisition of capital assets within 365 days of the receipt thereof (or committed to so apply and then applied within 180 days after the end of such 365-day period), the Company was required to make a mandatory prepayment under the March 2017 Credit Agreement in an amount equal to the unapplied net proceeds. On June 21, 2018, the Company repaid \$23.5 million under the mandatory prepayment provisions of the March 2017 Credit Agreement.

Borrowers under the Credit Agreement are permitted to make voluntary prepayments of the loans under the Credit Agreement at any time without payment of a premium. The Borrowers are required to make mandatory prepayments of loans under the Credit Agreement (without payment of a premium) with (a) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (b) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions), (c) net cash proceeds from issuances of debt (other than certain permitted debt), and (d) 50% of the Company's excess cash flow (subject to decrease to 25% or 0% if the Company's first lien leverage ratio is less than 2.25:1 or 1.75:1, respectively). The October 2017 Refinancing Loans are amortized in equal quarterly installments that began on December 31, 2017, in an aggregate annual amount equal to 1.00% of the original principal amount of the October 2017 Refinanced Loans (i.e. \$850.0 million), with any remaining balance payable on March 29, 2024, the final maturity date of the October 2017 Refinancing Loans. Following the mandatory prepayment on June 21, 2018, as described above, the Company is not required to pay any further quarterly installments until June 30, 2020.

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions.

Events of default under the Credit Agreement include: (i) the failure by any Borrower to timely make payments due under the Credit Agreement; (ii) material misrepresentations or misstatements in any representation or warranty by any Loan Party when made; (iii) failure by any Loan Party to comply with the covenants under the Credit Agreement and other related agreements; (iv) certain defaults under a specified amount of other indebtedness of the Company or

its subsidiaries; (v) insolvency or bankruptcy-related events with respect to the Company or any of its material subsidiaries; (vi) certain undischarged judgments against the Company or any of its restricted subsidiaries; (vii) certain ERISA-related events reasonably expected to have a material adverse effect on the Company and its restricted subsidiaries taken as a whole; (viii) certain security interests or liens under the loan documents ceasing to be, or being asserted by the Company or its restricted subsidiaries not to be, in full force and effect; (ix) any loan document or material provision thereof ceasing to be, or any challenge or assertion by any Loan Party that such loan document or material provision is not, in full force and effect; and (x) the occurrence of a change of control. If one or more events of default occurs and continues beyond any applicable cure period, the administrative agent may, with the consent of the lenders holding a majority of the loans and commitments under the facilities, or will, at the request of such lenders, terminate the commitments of the lenders to make further loans and declare all of the obligations of the Loan Parties under the March 2017 Credit Agreement to be immediately due and payable.

The interest on the Company's 2017 Term Loan Facility is variable and as of June 30, 2018, the interest rate on the 2017 Term Loan Facility was 5.375% and the effective interest rate was 5.80%.

As of June 30, 2018, the fair value of the amounts outstanding under the 2017 Term Loan Facility was approximately \$816.0 million, categorized as a Level 2 instrument, as defined in Note 14.

#### 2023 Senior Notes

On April 29, 2015, Horizon Pharma Financing Inc. ("Horizon Financing"), a wholly owned subsidiary of the Company, completed a private placement of \$475.0 million aggregate principal amount of 6.625% Senior Notes due 2023 (the "2023 Senior Notes") to certain investment banks acting as initial purchasers who subsequently resold the 2023 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"), and in offshore transactions to non-U.S. persons in reliance on Regulation S under the Securities Act. The net proceeds from the offering of the 2023 Senior Notes were approximately \$462.3 million, after deducting the initial purchasers' discount and offering expenses payable by Horizon Financing.

In connection with the closing of the acquisition of Hyperion Therapeutics, Inc. ("Hyperion") on May 7, 2015, Horizon Financing merged with and into HPI and, as a result, the 2023 Senior Notes became HPI's general unsecured senior obligations. The obligations under the 2023 Senior Notes are fully and unconditionally guaranteed on a senior unsecured basis by the Company and all of the Company's direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

The 2023 Senior Notes accrue interest at an annual rate of 6.625% payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2015. The 2023 Senior Notes will mature on May 1, 2023, unless earlier repurchased or redeemed.

Some or all of the 2023 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. In addition, the 2023 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2023 Senior Notes, HPI or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If the Company undergoes a change of control, HPI will be required to make an offer to purchase all of the 2023 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If the Company or certain of its subsidiaries engages in certain asset sales, HPI will be required under certain circumstances to make an offer to purchase the 2023 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

The indenture governing the 2023 Senior Notes contains covenants that limit the ability of the Company and its restricted subsidiaries to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, merge, consolidate with or merge or sell all or substantially all of their assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to the Company. Certain of the covenants will be suspended during any period in which the notes receive investment grade ratings. The indenture governing the 2023 Senior Notes also includes customary events of default.

As of June 30, 2018, the interest rate on the 2023 Senior Notes was 6.625% and the effective interest rate was 6.68%.

As of June 30, 2018, the fair value of the 2023 Senior Notes was approximately \$478.6 million, categorized as a Level 2 instrument, as defined in Note 14.

#### 2024 Senior Notes

On October 25, 2016, HPI and HPUSA (together, in such capacity, the "2024 Issuers"), completed a private placement of \$300.0 million aggregate principal amount of 8.750% Senior Notes due 2024 (the "2024 Senior Notes") to certain

investment banks acting as initial purchasers who subsequently resold the 2024 Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act. The net proceeds from the offering of the 2024 Senior Notes were approximately \$291.9 million, after deducting the initial purchasers' discount and offering expenses payable by the 2024 Issuers.

The obligations under the 2024 Senior Notes are the 2024 Issuers' general unsecured senior obligations and are fully and unconditionally guaranteed on a senior unsecured basis by the Company and all of the Company's direct and indirect subsidiaries that are guarantors from time to time under the Credit Agreement.

The Company used the net proceeds from the offering of the 2024 Senior Notes as well as \$375.0 million principal amount of senior secured term loans under the Company's term loan facility to fund a portion of the acquisition of Raptor Pharmaceutical Corp. ("Raptor"), repay Raptor's outstanding debt, and pay any prepayment premiums, fees and expenses in connection with the foregoing.

The 2024 Senior Notes accrue interest at an annual rate of 8.750% payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2017. The 2024 Senior Notes will mature on November 1, 2024, unless earlier repurchased or redeemed.

Except as described below, the 2024 Senior Notes may not be redeemed before November 1, 2019. Thereafter, some or all of the 2024 Senior Notes may be redeemed at any time at specified redemption prices, plus accrued and unpaid interest to the redemption date. At any time prior to November 1, 2019, some or all of the 2024 Senior Notes may be redeemed at a price equal to 100% of the aggregate principal amount thereof, plus a make-whole premium and accrued and unpaid interest to the redemption date. Also prior to November 1, 2019, up to 35% of the aggregate principal amount of the 2024 Senior Notes may be redeemed at a redemption price of 108.75% of the aggregate principal amount thereof, plus accrued and unpaid interest, with the net proceeds of certain equity offerings. In addition, the 2024 Senior Notes may be redeemed in whole but not in part at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest and additional amounts, if any, to, but excluding, the redemption date, if on the next date on which any amount would be payable in respect of the 2024 Senior Notes, the 2024 Issuers or any guarantor is or would be required to pay additional amounts as a result of certain tax-related events.

If the Company undergoes a change of control, the 2024 Issuers will be required to make an offer to purchase all of the 2024 Senior Notes at a price in cash equal to 101% of the aggregate principal amount thereof plus accrued and unpaid interest to, but not including, the repurchase date. If the Company or certain of its subsidiaries engages in certain asset sales, the 2024 Issuers will be required under certain circumstances to make an offer to purchase the 2024 Senior Notes at 100% of the principal amount thereof, plus accrued and unpaid interest to the repurchase date.

The indenture governing the 2024 Senior Notes contains covenants that limit the ability of the Company and its restricted subsidiaries to, among other things, pay dividends or distributions, repurchase equity, prepay junior debt and make certain investments, incur additional debt and issue certain preferred stock, incur liens on assets, engage in certain asset sales, merge, consolidate with or merge or sell all or substantially all of their assets, enter into transactions with affiliates, designate subsidiaries as unrestricted subsidiaries, and allow to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to the Company. Certain of the covenants will be suspended during any period in which the notes receive investment grade ratings. The indenture also includes customary events of default.

As of June 30, 2018, the interest rate on the 2024 Senior Notes was 8.750% and the effective interest rate was 9.20%.

As of June 30, 2018, the fair value of the 2024 Senior Notes was approximately \$321.8 million, categorized as a Level 2 instrument, as defined in Note 14.

## **Exchangeable Senior Notes**

On March 13, 2015, Horizon Investment completed a private placement of \$400.0 million aggregate principal amount of Exchangeable Senior Notes to certain investment banks acting as initial purchasers who subsequently resold the Exchangeable Senior Notes to qualified institutional buyers as defined in Rule 144A under the Securities Act. The net proceeds from the offering of the Exchangeable Senior Notes were approximately \$387.2 million, after deducting the initial purchasers' discount and offering expenses payable by Horizon Investment.

The Exchangeable Senior Notes are fully and unconditionally guaranteed, on a senior unsecured basis, by the Company (the "Guarantee"). The Exchangeable Senior Notes and the Guarantee are Horizon Investment's and the Company's senior unsecured obligations. The Exchangeable Senior Notes accrue interest at an annual rate of 2.50% payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2015. The Exchangeable Senior Notes will mature on March 15, 2022, unless earlier exchanged, repurchased or redeemed. The initial exchange rate is 34.8979 ordinary shares of the Company per \$1,000 principal amount of the Exchangeable Senior Notes (equivalent to an initial exchange price of approximately \$28.66 per ordinary share). The exchange rate

will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or upon a tax redemption, Horizon Investment will increase the exchange rate for a holder who elects to exchange its Exchangeable Senior Notes in connection with such a corporate event or a tax redemption in certain circumstances.

Other than as described below, the Exchangeable Senior Notes may not be redeemed by the Company.

## **Issuer Redemptions:**

Optional Redemption for Changes in the Tax Laws of a Relevant Taxing Jurisdiction: Horizon Investment may redeem the Exchangeable Senior Notes at its option, prior to March 15, 2022, in whole but not in part, in connection with certain tax-related events.

Provisional Redemption on or After March 20, 2019: On or after March 20, 2019, Horizon Investment may redeem for cash all or a portion of the Exchangeable Senior Notes if the last reported sale price of ordinary shares of the Company has been at least 130% of the exchange price then in effect for at least twenty trading days whether or not consecutive) during any thirty consecutive trading day period ending on, and including, the trading day immediately preceding the date on which Horizon Investment provide written notice of redemption. The redemption price will be equal to 100% of the principal amount of the Exchangeable Senior Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date; provided that if the redemption date occurs after a regular record date and on or prior to the corresponding interest payment date, Horizon Investment will pay the full amount of accrued and unpaid interest due on such interest payment date to the record holder of the Exchangeable Senior Notes on the regular record date corresponding to such interest payment date, and the redemption price payable to the holder who presents an Exchangeable Senior Note for redemption will be equal to 100% of the principal amount of such Exchangeable Senior Note.

## Holder Exchange Rights:

Holders may exchange all or any portion of their Exchangeable Senior Notes at their option at any time prior to the close of business on the business day immediately preceding December 15, 2021 only upon satisfaction of one or more of the following conditions:

- 1. Exchange upon Satisfaction of Sale Price Condition During any calendar quarter commencing after the calendar quarter ended June 30, 2015 (and only during such calendar quarter), if the last reported sale price of ordinary shares of the Company for at least twenty trading days (whether or not consecutive) during the period of thirty consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable exchange price on each applicable trading day.
- 2. Exchange upon Satisfaction of Trading Price Condition During the five business day period after any ten consecutive trading day period in which the trading price per \$1,000 principal amount of Exchangeable Senior Notes for each trading day of such period was less than 98% of the product of the last reported sale price of ordinary shares of the Company and the applicable exchange rate on such trading day.
- 3. Exchange upon Notice of Redemption Prior to the close of business on the business day immediately preceding December 15, 2021, if Horizon Investment provides a notice of redemption, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date.

As of June 30, 2018, none of the above conditions had been satisfied and no exchange of Exchangeable Senior Notes had been triggered.

On or after December 15, 2021, a holder may exchange all or any portion of its Exchangeable Senior Notes at any time prior to the close of business on the second scheduled trading day immediately preceding the maturity date regardless of the foregoing conditions.

Upon exchange, Horizon Investment will settle exchanges of the Exchangeable Senior Notes by paying or causing to be delivered, as the case may be, cash, ordinary shares or a combination of cash and ordinary shares, at its election.

The Company recorded the Exchangeable Senior Notes under the guidance in ASC Topic 470-20, Debt with Conversion and Other Options, and separated them into a liability component and equity component. The carrying amount of the liability component of \$268.9 million was determined by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component of \$119.1 million represented by the embedded conversion option was determined by deducting the fair value of the liability component of \$268.9 million from the initial proceeds of \$387.2 million ascribed to the convertible debt instrument as a whole. The initial debt discount of \$131.1 million is being charged to interest expense over the life of the Exchangeable Senior Notes using the effective interest rate method.

As of June 30, 2018, the interest rate on the Exchangeable Senior Notes was 2.50% and the effective interest rate was 8.88%.

As of June 30, 2018, the fair value of the Exchangeable Senior Notes was approximately \$381.0 million, categorized as a Level 2 instrument, as defined in Note 14.

## NOTE 16 – OTHER LONG-TERM LIABILITIES

Included in other long-term liabilities at June 30, 2018 and December 31, 2017, is \$25.7 million and \$26.4 million, respectively, representing the fair value of the long-term portion of the contingent liability for royalties potentially payable on sales by Chiesi under agreements related to PROCYSBI and QUINSAIR.

Other long-term liabilities at June 30, 2018 and December 31, 2017, included \$6.0 million and \$7.8 million, respectively, related to a loss on inventory purchase commitments.

#### NOTE 17 – COMMITMENTS AND CONTINGENCIES

#### **Purchase Commitments**

Patheon Pharmaceuticals Inc. ("Patheon") is obligated to manufacture PROCYSBI for the Company through December 31, 2021. The Company must provide Patheon with rolling, non-binding forecasts of PROCYSBI, with a portion of the forecast being a firm written order. Cambrex Profarmaco Milano ("Cambrex") is obligated to manufacture PROCYSBI active pharmaceutical ingredient ("API") for the Company through November 30, 2020. The Company must provide Cambrex with rolling, non-binding forecasts, with a portion of the forecast being the minimum floor of the firm order that must be placed. At June 30, 2018, the Company had a binding purchase commitment with Patheon for PROCYSBI of \$2.3 million, to be delivered through December 2018, and with Cambrex for PROCYSBI API of \$3.3 million, to be delivered through December 2020.

Under an agreement with Boehringer Ingelheim Biopharmaceuticals GmbH ("Boehringer Ingelheim Biopharmaceuticals"), they are required to manufacture and supply ACTIMMUNE and IMUKIN to the Company. The Company is required to purchase minimum quantities of finished medicine during the term of the agreement, which term extends to at least June 30, 2024. As of June 30, 2018, the minimum binding purchase commitment to Boehringer Ingelheim Biopharmaceuticals was \$22.9 million (converted using a Dollar-to-Euro exchange rate of 1.1683) through July 2024. As of June 30, 2018, the Company also committed to incur an additional \$2.7 million for the harmonization of the drug substance manufacturing process with Boehringer Ingelheim Biopharmaceuticals.

Under the Company's agreement with Bio-Technology General (Israel) Ltd ("BTG Israel"), the Company has agreed to purchase certain minimum annual order quantities and is obligated to purchase at least eighty percent of its annual world-wide bulk product requirements for KRYSTEXXA from BTG Israel. The term of the agreement runs until December 31, 2030, and will automatically renew for successive three year periods unless earlier terminated by either party upon three years' prior written notice. The agreement may be terminated earlier by either party in the event of a force majeure, liquidation, dissolution, bankruptcy or insolvency of the other party, uncured material breach by the other party or after January 1, 2024, upon three years' prior written notice. Under the agreement, if the manufacture of the bulk product is moved out of Israel, the Company may be required to obtain the approval of the Israeli Office of the Chief Scientist ("OCS") because certain KRYSTEXXA intellectual property was initially developed with a grant funded by the OCS. The Company issues eighteen-month forecasts of the volume of KRYSTEXXA that the Company expects to order. The first six months of the forecast are considered binding firm orders. At June 30, 2018, the Company had a binding purchase commitment with BTG Israel for KRYSTEXXA of \$48.0 million, to be delivered through December 31, 2026.

Jagotec AG ("Jagotec") or its affiliates are required to manufacture and supply RAYOS/LODOTRA exclusively to the Company in bulk. The earliest the agreement can expire is December 31, 2023, and the minimum purchase commitment is in force until December 2023. At June 30, 2018, the minimum purchase commitment based on tablet

pricing in effect under the agreement was \$6.1 million through December 2023. Additionally, purchase orders relating to the manufacture of RAYOS/LODOTRA of \$0.5 million were outstanding at June 30, 2018.

Nuvo Pharmaceuticals Inc. (formerly known as Nuvo Research Inc.) ("Nuvo") is obligated to manufacture and supply PENNSAID 2% to the Company. The term of the supply agreement is through December 31, 2029, but the agreement may be terminated earlier by either party for any uncured material breach by the other party of its obligations under the supply agreement or upon the bankruptcy or similar proceeding of the other party. At least ninety days prior to the first day of each calendar month during the term of the supply agreement, the Company submits a binding written purchase order to Nuvo for PENNSAID 2% in minimum batch quantities. At June 30, 2018, the Company had a binding purchase commitment with Nuvo for PENNSAID 2% of \$3.4 million, to be delivered through September 2018.

Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") is obligated to manufacture and supply DUEXIS to the Company in final, packaged form, and the Company is obligated to purchase DUEXIS exclusively from Sanofi-Aventis U.S. for the commercial requirements of DUEXIS in North America, South America and certain countries and territories in Europe, including the European Union ("EU") member states and Scandinavia. The agreement term extends until May 2021, and automatically renews for successive two-year terms unless terminated by either party upon two years' prior written notice. At June 30, 2018, the Company had a binding purchase commitment to Sanofi-Aventis U.S. for DUEXIS of \$6.8 million, to be delivered through November 2018.

Excluding the above, additional purchase orders and other commitments relating to the manufacture of RAVICTI, BUPHENYL, QUINSAIR, VIMOVO and MIGERGOT of \$10.9 million were outstanding at June 30, 2018. Additionally, at June 30, 2018, the Company had a binding commitment related to process validation activities for teprotumumab of \$2.0 million, binding batch purchase commitments for teprotumumab of \$5.6 million and a binding reserve payment related to the manufacture of teprotumumab of \$2.1 million.

See Note 4 for details of other agreements entered into by the Company.

## Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows. In addition, the Company from time to time has billing disputes with vendors in which amounts invoiced are not in accordance with the terms of their contracts.

In November 2015, the Company received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents and information related to its patient access programs and other aspects of its marketing and commercialization activities. The Company is unable to predict how long this investigation will continue or its outcome, but it anticipates that it may continue to incur significant costs in connection with the investigation, regardless of the outcome. The Company may also become subject to similar investigations by other governmental agencies. The investigation by the U.S. Attorney's Office and any additional investigations of the Company's patient access programs and sales and marketing activities may result in damages, fines, penalties or other administrative sanctions against the Company.

#### Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. In connection with the federal securities class action litigation (described in Note 18 below), the Company received notice from the Underwriter Defendants (as defined below) of their intention to seek indemnification and received and paid several invoices from the Underwriter Defendants. On November 14, 2016, all defendants moved to dismiss the plaintiffs' amended complaint. Plaintiffs filed their opposition to the motion to dismiss on December 21, 2016. On January 18, 2018, the District Court dismissed all Plaintiffs' claims against all Defendants, and denied the Plaintiffs any further opportunity to amend their complaint. On February 16, 2018, plaintiffs filed a notice of appeal of the District Court's ruling to the Second Circuit Court of Appeals. On June 8, 2018, Plaintiffs voluntarily dismissed the appeal with Defendants' consent. The Company may record charges in the future as a result of these indemnification obligations.

In accordance with its memorandum and articles of association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. Additionally, the Company has entered into, and intends to continue to enter into, separate indemnification agreements with its directors and executive officers. These agreements, among other things, require the Company to indemnify its directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of the Company's directors or executive officers, or any of the Company's subsidiaries or any other company or enterprise to which the person provides services at the Company's request. In connection with the federal securities class action litigation (described in Note 18 below), the Company has paid legal fees and costs on behalf of itself and the current and former officers and directors of the Company who are named as defendants in that litigation. The Company also has a director and officer insurance policy that enables it to recover a portion of any amounts paid for current and future potential claims. All of the Company's officers and directors have also entered into separate indemnification agreements with HPI.

#### **NOTE 18 - LEGAL PROCEEDINGS**

#### **RAVICTI**

On March 17, 2014, Hyperion received notice from Par Pharmaceutical, Inc. ("Par Pharmaceutical") that it had filed an Abbreviated New Drug Application (an "ANDA") with the FDA seeking approval for a generic version of the Company's medicine RAVICTI. The ANDA contained a Paragraph IV Patent Certification alleging that two of the patents covering RAVICTI are invalid and/or will not be infringed by Par Pharmaceutical's manufacture, use or sale of the medicine for which the ANDA was submitted. Hyperion filed suit in the United States District Court for the Eastern District of Texas, Marshall Division, against Par Pharmaceutical on April 23, 2014 (the "Par Texas action"), seeking an injunction to prevent the approval of Par Pharmaceutical's ANDA and/or to prevent Par Pharmaceutical from selling a generic version of RAVICTI. The Company has taken over and is responsible for this patent litigation.

Additional patents covering RAVICTI have been issued since April 2014, and after receiving Paragraph IV Certification notices from Par Pharmaceutical with respect to those patents, the Company filed suit in the United States District Court for the District of New Jersey against Par Pharmaceutical on June 30, 2016 (the "Par New Jersey action"), seeking an injunction to prevent the approval of Par Pharmaceutical's ANDA and/or to prevent Par Pharmaceutical from selling a generic version of RAVICTI. The lawsuit alleges that Par Pharmaceutical has infringed the Company's patents covering RAVICTI by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the FDA's Orange Book (the "Orange Book"). The Par New Jersey action has been stayed pending the Patent Trial and Appeals Board (the "PTAB") issuing a final written decision on the inter parte review (the "IPR") relating to one of the patents that is the subject of the lawsuit.

On April 29, 2015, Par Pharmaceutical filed Petitions for IPR of two of the Company's patents covering RAVICTI. In September 2016 and November 2016, the PTAB issued two final written decisions, finding all of the claims in one of the patents to be unpatentable and all of the claims in the other patent to be patentable. The Company did not appeal the PTAB's final written decision with respect to the patent found to be unpatentable. On December 29, 2016, Par Pharmaceutical filed a notice of appeal with the Federal Circuit to appeal the final written decision of the PTAB concerning the patent held to be patentable.

On July 13, 2017, Par Pharmaceutical filed Petitions for IPR of three of the Company's patents covering RAVICTI. The IPR requests were granted on January 30, 2018.

On September 4, 2015, the Company received notice from Lupin Limited of Lupin Limited's Paragraph IV Patent Certification against two of the Company's patents covering RAVICTI, advising that Lupin Limited had filed an ANDA with the FDA for a generic version of RAVICTI. On November 6, 2015, the Company also received notice of Lupin Limited's Paragraph IV Patent Certification against another of the Company's patents covering RAVICTI. On October 19, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin Limited and Lupin Pharmaceuticals Inc. (collectively, "Lupin"), seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed three of the Company's patents covering RAVICTI by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the Orange Book. The commencement of the patent infringement lawsuit stays, or bars, FDA approval of Lupin's ANDA for 30 months or until an earlier District Court decision that the subject patents are not infringed or are invalid. After receiving additional Paragraph IV Certification notices from Lupin, the Company filed an additional suit in the United States District Court for the District of New Jersey against Lupin on

July 21, 2016, seeking an injunction to prevent the approval of Lupin's ANDA and/or to prevent Lupin from selling a generic version of RAVICTI. The lawsuit alleges that Lupin has infringed two of the Company's patents covering RAVICTI by filing an ANDA seeking approval from the FDA to market generic versions of RAVICTI prior to the expiration of the patents. The subject patents are listed in the Orange Book. The Lupin New Jersey actions have been stayed pending the resolution of the PTAB's IPR relating to one of the patents that is the subject of one of the actions.

On April 1, 2016, Lupin filed a Petition for IPR of one of the Company's patents covering RAVICTI. On September 26, 2017, the PTAB issued its final written decision, finding that the challenged claims of the patent are unpatentable. The Company filed a Notice of Appeal on November 22, 2017. On March 27, 2017, Lupin filed two Petitions to request an IPR of an additional two of the Company's patents covering RAVICTI. On September 28, 2017, the PTAB issued its orders granting Lupin's petitions to institute an IPR of the patents.

On August 8, 2017, the Company filed suit against Lupin and Par Pharmaceutical, alleging infringement of one of the Company's newly issued patents covering RAVICTI, in the United States District Court for New Jersey. On January 12, 2018, Lupin filed a Petition for IPR of the newly issued patent. The Company's Preliminary Patent Owner Response is due by May 23, 2018.

On June 27, 2018, the Company and Lupin entered into a Settlement and License Agreement ("Settlement Agreement") under which they agreed to file stipulations of dismissal with the District Court regarding the district court litigation and a joint request for termination in the IPRs. Lupin further agreed to withdraw from the appeal pending before the Federal Circuit Court of Appeals. The Settlement Agreement also provides for a full settlement and release by each party of all claims that relate to Lupin's generic version of RAVICTI or the litigation, the IPRs or the appeal. Under the Settlement Agreement, the license entry date is July 1, 2026; however, Lupin may be able to enter the market earlier in certain circumstances.

## PENNSAID 2%

On November 13, 2014, the Company received a Paragraph IV Patent Certification from Watson Laboratories, Inc., now known as Actavis Laboratories UT, Inc. ("Actavis UT"), advising that Actavis UT had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On December 23, 2014, June 30, 2015, August 11, 2015 and September 17, 2015, the Company filed four separate suits against Actavis UT and Actavis plc (collectively "Actavis"), in the United States District Court for the District of New Jersey, with each of the suits seeking an injunction to prevent approval of the ANDA. The lawsuits alleged that Actavis has infringed nine of the Company's patents covering PENNSAID 2% by filing an ANDA seeking approval from the FDA to market a generic version of PENNSAID 2% prior to the expiration of certain of the Company's patents listed in the Orange Book. These four suits were consolidated into a single suit. On October 27, 2015 and on February 5, 2016, the Company filed two additional suits against Actavis, in the United States District Court for the District of New Jersey, for patent infringement of three additional Company patents covering PENNSAID 2%.

On August 17, 2016, the District Court issued a Markman opinion holding certain of the asserted claims of seven of the Company's patents covering PENNSAID 2% invalid as indefinite. On March 16, 2017, the Court granted Actavis' motion for summary judgment of non-infringement of the asserted claims of three of the Company's patents covering PENNSAID 2%. In view of the Markman and summary judgment decisions, a bench trial was held on March 21-30, 2017, regarding a claim of one of the Company's patents covering PENNSAID 2%. On May 14, 2017, the Court issued its opinion upholding the validity of claim of the patent, which Actavis had previously admitted its proposed generic diclofenac sodium topical solution product would infringe. Actavis filed its Notice of Appeal on June 16, 2017. The Company also filed its Notice of Appeal of the District Court's rulings on certain claims of eleven of the Company's patents covering PENNSAID 2%. The Company's opening brief was filed on August 14, 2017. Actavis's opening brief, challenging the District Court's judgment on U.S. Patent 9,066,913, was filed on October 10, 2017, and the Company's brief defending the judgment was filed on November 20, 2017. The parties are awaiting the decision of the Federal Circuit Court of Appeals.

On August 18, 2016, the Company filed suit in the United States District Court for the District of New Jersey against Actavis for patent infringement of four of the Company's newly issued patents covering PENNSAID 2%. All four of such patents are listed in the Orange Book. This litigation is currently stayed by agreement of the parties.

The Company received from Actavis a Paragraph IV Patent Certification notice, dated September 27, 2016, against an additional newly issued patent covering PENNSAID 2%, advising that Actavis had filed an ANDA with the FDA for a generic version of PENNSAID 2%. The subject patent is listed in the Orange Book.

On March 18, 2015, the Company received a Paragraph IV Patent Certification against seven of the Company's patents covering PENNSAID 2% from Lupin, advising that Lupin had filed an ANDA with the FDA for a generic version of PENNSAID 2%. On April 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin, seeking an injunction to prevent the approval of the ANDA. The lawsuit alleges that Lupin has infringed six of the Company's patents covering PENNSAID 2% by filing an ANDA seeking approval from the FDA to market generic versions of PENNSAID 2% prior to the expiration of certain of the Company's patents listed in the Orange Book.

On June 30, 2015, the Company filed suit in the United States District Court for the District of New Jersey against Lupin for patent infringement of a newly issued patent covering PENNSAID 2%. On August 11, 2015, the Company filed an amended complaint in the United States District Court for the District of New Jersey against Lupin that added another newly issued patent covering PENNSAID 2% to the litigation. On September 17, 2015, the Company again filed an additional suit in the United States District Court for the District of New Jersey against Lupin for infringement of another newly issued patent covering PENNSAID 2%.

On October 27, 2015, February 5, 2016 and August 18, 2016, the Company filed three separate suits in the United States District Court for the District of New Jersey against Lupin for patent infringement of seven of the Company's patents covering PENNSAID 2%. All seven patents are listed in the Orange Book. On May 30, 2018, the Company finalized settlement of the cases against Lupin and the cases are now dismissed. Under the Settlement Agreement with Lupin, the license entry date is October 17, 2027; however, Lupin may be able to enter the market earlier in certain circumstances.

Between April 2016 and April 2017, the Company received from Apotex Inc. four notices of Paragraph IV Patent Certification against eighteen of the Company's patents covering PENNSAID 2%. All of the subject patents are listed in the Orange Book.

#### **DUEXIS**

On May 29, 2018, the Company received notice from Alkem Laboratories, Inc. ("Alkem") that it had filed an ANDA with the FDA seeking approval for a generic version of DUEXIS. The ANDA contained a Paragraph IV Patent Certification alleging that the patents covering DUEXIS are invalid and/or will not be infringed by Alkem's manufacture, use or sale of the medicine for which the ANDA was submitted. The Company filed suit in the United States District Court of Delaware against Alkem on July 9, 2018, seeking an injunction to prevent the approval of Alkem's ANDA and/or to prevent Alkem from selling a generic version of DUEXIS.

#### **VIMOVO**

Currently, patent litigation is pending in the United States District Court for the District of New Jersey and the Court of Appeals for the Federal Circuit against three generic companies intending to market VIMOVO prior to the expiration of certain of the Company's patents listed in the Orange Book. They are collectively known as the VIMOVO cases, and involve the following sets of defendants: (i) Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "Dr. Reddy's"); (ii) Lupin; and (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Mylan"). Patent litigation in the United States District Court for the District of New Jersey against a fourth generic company, Teva Pharmaceuticals Industries Limited (formerly known as Actavis Laboratories FL, Inc., which itself was formerly known as Watson Laboratories, Inc. – Florida) and Actavis Pharma, Inc. (collectively, "Actavis Pharma"), was dismissed on January 10, 2017 after the court granted Actavis' motion to compel enforcement of a settlement agreement. On February 3, 2017, the Company appealed this dismissal decision to the Court of Appeals for the Federal Circuit. The Company understands that Dr. Reddy's has entered into a settlement with AstraZeneca with respect to patent rights directed to Nexium® (esomeprazole) for the commercialization of VIMOVO. The settlement agreement, however, has no effect on the Aralez Pharmaceuticals Inc. ("Aralez") VIMOVO patents, which are still the subject of patent litigations. As part of the Company's acquisition of the U.S. rights to VIMOVO, the Company has taken over and is responsible for the patent litigation that includes the Aralez patents licensed to the Company under the amended and restated collaboration and license agreement for the United States with Aralez.

The VIMOVO cases were filed on April 21, 2011, July 25, 2011, October 28, 2011, January 4, 2013, May 10, 2013, June 28, 2013, October 23, 2013, May 13, 2015 and November 24, 2015 and collectively include allegations of infringement of certain of the Company's patents covering VIMOVO. On January 25, 2016, the Company filed a new case against Actavis Pharma including allegations of infringement of additional Company patents covering VIMOVO. This case was subsequently consolidated with the Actavis Pharma case involving others of the Company's patents covering VIMOVO.

The District Court consolidated all of the cases pending against Dr. Reddy's, Lupin, Mylan and Actavis Pharma into two separate cases for purposes of discovery. The District Court entered final judgment for one of the consolidated cases on July 21, 2017, and both sides have appealed the District Court's judgment to the Court of Appeals for the Federal Circuit. A trial date for the other consolidated cases has not yet been set.

On August 24, 2017, Mylan filed a Petition for IPR of one of the Company's patents covering VIMOVO. The Company filed its Preliminary Patent Owner Response on December 12, 2017. On March 8, 2018, the PTAB instituted Mylan's Petition for IPR. On March 22, 2018, the Company filed a Request for Rehearing of the decision to institute IPR, which was denied by the PTAB on May 25, 2018. On April 6, 2018, Dr. Reddy's filed a Petition for IPR of the same patent challenged by Mylan and a motion for joinder with Mylan's IPR. The Company filed an opposition to Dr. Reddy's motion for joinder on May 9, 2018. The parties are awaiting the PTAB's decision regarding Dr. Reddy's Petition.

On December 4, 2017, Mylan filed a Petition for IPR of another of the Company's patents covering VIMOVO. The PTAB instituted an IPR proceeding on Mylan's Petition on June 14, 2018.

#### Other

Beginning on March 8, 2016, two federal securities class action lawsuits (captioned Schaffer v. Horizon Pharma plc, et al., Case No. 16-cv-01763-JMF and Banie v. Horizon Pharma plc, et al., Case No. 16-cv-01789-JMF) were filed in the United States District Court for the Southern District of New York against the Company and certain of the Company's current and former officers (the "Officer Defendants"). On March 24, 2016, the court consolidated the two actions under Schaffer v. Horizon Pharma plc, et al. On June 3, 2016, the court appointed Locals 302 and 612 of the International Union of Operating Engineers-Employers Construction Industry Retirement Trust and the Carpenters Pension Trust Fund for Northern California as lead plaintiffs and Labaton Sucharow LLP as lead counsel. On July 25, 2016, lead plaintiffs and additional named plaintiff Automotive Industries Pension Trust Fund filed their consolidated complaint, which they subsequently amended on October 7, 2016, including additional current and former officers, the Company's Board of Directors (the "Director Defendants"), and underwriters involved with the Company's April 2015 public offering (the "Underwriter Defendants") as defendants. The plaintiffs alleged that certain of the Company and the Officer Defendants violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by making false and/or misleading statements about, among other things; (a) the Company's financial performance, (b) the Company's business prospects and drug-pricing practices, (c) the Company's sales and promotional practices, and (d) the Company's design, implementation, performance, and risks associated with the Company's Prescriptions-Made-Easy program. The plaintiffs alleged that certain of the Company, the Director Defendants and the Underwriter Defendants violated sections 11, 12(a)(2) and 15 of the Securities Act in connection with the Company's April 2015 public offering. The plaintiffs sought, among other things, an award of damages allegedly sustained by plaintiffs and the putative class, including a reasonable allowance for costs and attorneys' fees. On November 14, 2016, all defendants moved to dismiss the plaintiffs' amended complaint. Plaintiffs' filed their opposition to the motion to dismiss on December 21, 2016. On January 18, 2018, the District Court dismissed all plaintiffs' claims against all defendants, and denied the plaintiffs any further opportunity to amend their complaint. On February 16, 2018, plaintiffs filed a notice of appeal of the District Court's ruling to the Second Circuit Court of Appeals. On June 8, 2018, the plaintiffs voluntarily dismissed their appeal, ending the lawsuit.

#### NOTE 19 – SHARE-BASED AND LONG-TERM INCENTIVE PLANS

The Company's equity incentive plans at June 30, 2018, include its 2005 Stock Plan, 2011 Equity Incentive Plan, 2014 Employee Stock Purchase Plan ("2014 ESPP"), 2014 Equity Incentive Plan ("2014 EIP") and 2014 Non-Employee Equity Plan. As of June 30, 2018, an aggregate of 2,490,908 ordinary shares were authorized and available for future issuance under the 2014 ESPP, an aggregate of 6,784,635 ordinary shares were authorized and available for future grants under the 2014 EIP and an aggregate of 116,163 ordinary shares were authorized and available for future grants under the 2014 Non-Employee Equity Plan. On February 21, 2018, the Compensation Committee of the Company's Board of Directors approved, subject to shareholder approval, an amendment to the 2014 EIP, increasing the number of ordinary shares that may be issued under the 2014 EIP by 10,800,000 ordinary shares. On May 3, 2018, the shareholders of the Company approved such amendment to the 2014 EIP.

## **Stock Options**

The following table summarizes stock option activity during the six months ended June 30, 2018:

Edgar Filing: Horizon Pharma plc - Form 10-Q

Weighted

Average

Contractual

		Weighted	Term	Aggregate
		Average	Remaining	Intrinsic Value
	Options	Exercise Price	(in years)	(in thousands)
Outstanding as of December 31, 2017	14,275,316	\$ 18.04	6.97	\$ 25,005
Granted	403,973	14.41		
Exercised	(529,495)	6.93		
Forfeited	(442,390)	18.34		
Expired	(206,061)	19.80		
Outstanding as of June 30, 2018	13,501,343	18.33	6.53	29,880
Exercisable as of June 30, 2018	10 225 857	17 93	6.08	27 861

Stock options typically have a contractual term of ten years from grant date.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The determination of the fair value of each stock option is affected by the Company's share price on the date of grant, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected share price volatility over the expected life of the awards and actual and projected stock option exercise behavior. The weighted average fair value per share of stock option awards granted during the six months ended June 30, 2018 and 2017, and assumptions used to value stock options, were as follows:

	For the S Months I 2018		d June 30, 2017	
Dividend yield	_		_	
Risk-free interest rate	2.3%-2.8	3%	1.9%-2.0	%
Weighted average expected volatility	49.5	%	49.1	%
Expected life (in years)	5.6		6.0	
Weighted average grant-date fair value per share of options granted	\$ 6.93		\$ 8.24	

## Dividend yields

The Company has never paid dividends and does not anticipate paying any dividends in the near future. Additionally, the Credit Agreement (described in Note 15 above), as well as the indentures governing the 2024 Senior Notes and the 2023 Senior Notes (each as described in Note 15 above), contain covenants that restrict the Company from issuing dividends.

#### Risk-Free Interest Rate

The Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate as of the date of grant.

## Volatility

The Company used an average historical share price volatility of comparable companies to be representative of future share price volatility, as the Company did not have sufficient trading history for its ordinary shares.

#### **Expected Term**

Given the Company's limited historical exercise behavior, the expected term of options granted was determined using the "simplified" method since the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. Under this approach, the expected term is presumed to be the average of the vesting term and the contractual life of the option.

### **Forfeitures**

As share-based compensation expense recognized in the condensed consolidated statements of comprehensive loss is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures based on actual forfeiture experience, analysis of employee turnover and other factors. The Company adopted ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, on January 1, 2017 and elected to retain a forfeiture rate after adoption.

## **Restricted Stock Units**

The following table summarizes restricted stock unit activity for the six months ended June 30, 2018:

Weighted Average

Grant-Date Fair

	Number of Units	Va	alue Per Unit
Outstanding as of December 31, 2017	5,283,850	\$	14.77
Granted	4,392,136		15.49
Vested	(1,743,109	)	14.51
Forfeited	(346,998	)	15.18
Outstanding as of June 30, 2018	7,585,879	\$	15.23

The grant-date fair value of restricted stock units is the closing price of the Company's ordinary shares on the date of grant.

#### Performance Stock Unit Awards

The following table summarizes performance stock unit awards ("PSUs") activity for the six months ended June 30, 2018:

		Weighted			Recorded
		Average			Weighted
		Grant-Date	Average		Average
	Number	Fair Value	Illiquidity	y	Fair Value
	of Units	Per Unit	Discount		Per Unit
Outstanding as of December 31, 2017	7,854,880				
Granted	1,413,257	\$ 16.08	2.6	%	\$ 15.66
Forfeited	(19,314)	16.64	0.0	%	16.64
Expired (1)	(7,854,880)	14.82	14.9	%	12.60
Outstanding as of June 30, 2018	1,393,943				

(1) During the six months ended June 30, 2018, the final tranches of the Company's PSUs outstanding at December 31, 2017 expired due to failure to meet the Company's minimum total compounded annual shareholder rate of return ("TSR") requirement.

On January 5, 2018, the Company awarded PSUs to key executive participants ("2018 PSUs"). Vesting of the 2018 PSUs was contingent upon receiving shareholder approval of amendments to our 2014 Equity Incentive Plan, which were approved on May 3, 2018. The 2018 PSUs utilize two performance metrics, a short-term component tied to business performance and a long-term component tied to relative compounded annual TSR, as follows:

\$0% of the 2018 PSUs that may vest (such portion of the PSU award, the "Relative TSR PSUs") are determined by reference to the level of the Company's relative TSR over the three-year period ending December 31, 2020, as measured against the TSR of each company included in the Nasdaq Biotechnology Index (NBI) during such three-year period. Generally, in order to earn any portion of the Relative TSR PSUs, the participant must also remain in continuous service with the Company through the earlier of January 1, 2021 or the date immediately prior to a change in control. If a change in control occurs prior to December 31, 2020, the level of the Company's relative TSR will be measured through the date of the change in control.

70% of the 2018 PSUs that may vest (such portion of the PSU award, the "Net Sales PSUs"), are determined by reference to the Company's net sales for its business units during 2018 (being the orphan business unit, rheumatology business unit and primary care business unit), weighted with the orphan business unit and rheumatology business unit comprising the majority of the target sales (with respect to the total PSU award). If, and to the extent earned, the Net Sales PSUs portion will vest in three equal annual installments on each anniversary of January 5, 2018, subject to the participant's continued service with the Company through the applicable vesting dates. If a divestiture of any of the Company's business units occurs before December 31, 2018, other than in connection with a change in control, the portion of the Net Sales PSUs that may vest based upon net sales of the applicable business unit will be calculated based on the greater of: (i) 100% achievement of net sales target for the applicable business unit or (ii) the portion of

the Net Sales PSUs that would have been earned if the divestiture had not occurred as determined by the compensation committee of the Company's board of directors. If a change in control occurs before December 31, 2018, the portion of the Net Sales PSUs that may vest will be calculated based on the greater of: (i) 100% achievement of net sales target for the applicable business unit or (ii) the portion of the Net Sales PSUs that would have been earned if the divestiture had not occurred, as determined by the compensation committee of the Company's board of directors.

All PSUs outstanding at June 30, 2018, may vest in a range of between 0% and 200%, based on the performance metrics described above. The Company accounts for the 2018 PSUs as equity-settled awards in accordance with ASC 718. Because the value of the Relative TSR PSUs are dependent upon the attainment of a level of TSR, it requires the impact of the market condition to be considered when estimating the fair value of the Relative TSR PSUs. As a result, the Monte Carlo model is applied and the most significant valuation assumptions used during the six months ended June 30, 2018, include:

Valuation date stock price	\$13.87	7
Expected volatility	71.3	%
Risk free rate	2.6	%

The value of the Net Sales PSUs is calculated at the end of each quarter based on the expected payout percentage based on estimated full period performance against targets, and the Company adjusts the expense quarterly.

## **Share-Based Compensation Expense**

The following table summarizes share-based compensation expense included in the Company's condensed consolidated statements of operations for the six months ended June 30, 2018 and 2017 (in thousands):

	For the Six Months Ended June 30		
	2018 2017		
Share-based compensation expense			
Cost of goods sold	\$ 1,893	\$ 1,001	
Research and development	4,649	4,362	
Selling, general and administrative	52,012	50,874	
Total share-based compensation expense	\$ 58,554	\$ 56,237	

During the six months ended June 30, 2018 and 2017, the Company recognized \$0.8 million of tax benefit and \$0.2 million of tax detriment, respectively, related to share-based compensation resulting from the current share prices in effect at the time of the exercise of stock options and vesting of restricted stock units. In addition, during the six months ended June 30, 2018, \$20.4 million of deferred tax assets related to previously recognized share-based compensation expense related to PSUs was charged to income tax expense. As of June 30, 2018, the Company estimates that pre-tax unrecognized compensation expense of \$156.0 million for all unvested share-based awards, including stock options, restricted stock units and PSUs, will be recognized through the first quarter of 2022. The Company expects to satisfy the exercise of stock options and future distribution of shares for restricted stock units and PSUs by issuing new ordinary shares which have been reserved under the 2014 EIP.

#### Cash Incentive Program

On January 5, 2018, the Committee approved a performance cash incentive program for the Company's executive leadership team, including its executive officers (the "Cash Incentive Program"). Participants receiving awards under the Cash Incentive Program will be eligible to earn a cash bonus based upon target award levels set forth below and based upon achievement of specified Company goals. The maximum payout under the Cash Incentive Program is approximately \$15.0 million. Of the total cash bonus award that may be earned under the Cash Incentive Program, 70% will be determined by reference to achieving an aggressive percentage increase in KRYSTEXXA vial sales during 2018 as compared to KRYSTEXXA vial sales during 2017 and 30% will be determined by reference to the achievement of patient enrollment levels in the teprotumumab phase 3 clinical trial by December 31, 2018.

If and to the extent earned based upon application of the performance criteria, such determined portion of the cash bonus award will vest and become payable in three equal annual installments on each anniversary of January 5, 2018, subject to the participant's continued services with the Company through the applicable vesting dates, the date of any earlier change in control, or a termination due to death or disability.

The Company accounted for the Cash Incentive Program as a deferred compensation plan under ASC 710 and will recognize the anticipated payout expense using straight-line recognition through the end of the 36-month vesting period. During the three and six months ended June 30, 2018, the Company recorded an expense of \$1.3 million and \$2.5 million, respectively, to the condensed consolidated statement of comprehensive loss related to the Cash Incentive Program.

#### NOTE 20 – INCOME TAXES

The Company accounts for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by valuation allowances when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are recorded at the currently enacted rates which will be in effect at the time when the temporary differences are expected to reverse in the country where the underlying assets and liabilities are located. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the period in which the change is enacted.

The following table presents the expense (benefit) for income taxes for the three and six months ended June 30, 2018 and 2017 (in thousands):

	For the Three Months Endedor the Six Months Ended				
	June 30,		June 30,		
	2018	2017	2018	2017	
Loss before expense (benefit) for income taxes	\$ (28,874)	\$ (211,303	) \$(186,568)	\$(349,426)	
Expense (benefit) for income taxes	3,962	(1,767	) 3,596	(49,320)	
Net loss	\$ (32,836)	\$ (209,536	) \$(190,164)	\$(300,106)	

During the three and six months ended June 30, 2018, the Company recorded an expense for income taxes of \$4.0 million and \$3.6 million, respectively. During the three and six months ended June 30, 2017, the Company recorded a benefit for income taxes of \$1.8 million and \$49.3 million, respectively. The expense for income taxes during the three months ended June 30, 2018 resulted primarily from a write-off of deferred tax assets related to previously recognized share-based compensation expense for PSUs that expired unvested during June 2018 and a revaluation of the Company's U.S. net deferred tax liability as a result of state legislation changes passed during the three months ended June 30, 2018.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the date of enactment for companies to complete the accounting under ASC 740, Income Taxes. In accordance with SAB 118, the Company reflected the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 was complete. To the extent that the Company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, the Company recorded a provisional estimate in the consolidated financial statements as of December 31, 2017. The Company recognized a net income tax benefit of \$74.9 million for the year ended December 31, 2017, associated with the items it could reasonably estimate. This benefit reflected the revaluation of its U.S. net deferred tax liability based on the U.S. federal tax rate of 21 percent, partially offset by the write-off of the deferred tax asset related to its U.S. interest expense carryforwards. On April 2, 2018, the U.S. Treasury Department and the U.S. Internal Revenue Service issued Notice 2018-28 ("the notice") which provides guidance for computing the business interest expense limitation under the Tax Act and clarifies the treatment of interest disallowed and carried forward under Section 163(i) of the Internal Revenue Code, as amended ("Section 163(j)"), prior to enactment of the Tax Act. In accordance with the measurement period provisions under SAB 118 and the guidance in the notice the Company reinstated the deferred tax asset related to its U.S. interest expense carryforwards under Section 163(j) based on the new U.S. federal tax rate of 21 percent. The impact of the deferred tax asset reinstatement in accordance with SAB 118 was a \$35.9 million increase to the Company's benefit for income taxes and a corresponding decrease to the U.S. group net deferred tax liability position. The impact of this reinstatement has been recognized as a discrete tax adjustment during the six months ended June 30, 2018 and resulted in a 19.2% increase in the Company's effective tax rate during the period. The Company is still analyzing the Tax Act and refining its calculations and the results of this analysis could potentially impact the provisional amounts recorded during the three months ended December 31, 2017 and during the six months ended June 30, 2018, and would be reflected in the 2018 income tax provision.

# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the related notes that appear elsewhere in this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties which are subject to safe harbors under the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements include, but are not limited to, statements concerning our strategy and other aspects of our future operations, future financial position, future revenues, projected costs, expectations regarding demand and acceptance for our medicines, growth opportunities and trends in the market in which we operate, prospects and plans and objectives of management. The words "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "will", "would" and similar expressions are intended to identify forward-look statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this report and in our other filings with the Securities and Exchange Commission, or SEC. We do not assume any obligation to update any forward-looking statements.

Unless otherwise indicated or the context otherwise requires, references to "we", "us" and "our" refer to Horizon Pharma plc and its consolidated subsidiaries.

#### **OUR BUSINESS**

We are a biopharmaceutical company focused on researching, developing and commercializing innovative medicines that address unmet treatment needs for rare and rheumatic diseases. By expanding our pipeline of medicines in development and exploring all potential uses for currently marketed medicines, we strive to make a powerful difference for patients, their caregivers and physicians.

Effective as of the second quarter of 2018, management realigned our reportable segments to reflect changes in the manner in which our chief operating decision maker, or CODM, assesses financial information for decision-making purposes. All prior year amounts have been reclassified to conform to our current reporting structure.

We have two reportable segments, (i) the orphan and rheumatology segment, our strategic growth business, and (ii) the primary care segment, and we report net sales and segment operating income for each segment.

Our marketed medicines are:

## Orphan and Rheumatology

RAVICTI® (glycerol phenylbutyrate) oral liquid

KRYSTEXXA® (pegloticase injection), for intravenous infusion

PROCYSBI® (cysteamine bitartrate) delayed-release capsules, for oral use

ACTIMMUNE® (interferon gamma-1b) injection, for subcutaneous use

RAYOS® (prednisone) delayed-release tablets; marketed as LODOTRA® outside the United States

BUPHENYL® (sodium phenylbutyrate) Tablets and Powder; marketed as AMMONAPS® in certain European countries and Japan

QUINSAIR<sup>TM</sup> (levofloxacin) solution for inhalation

**Primary Care** 

PENNSAID® (diclofenac sodium topical solution) 2% w/w, or PENNSAID 2%, for topical use

DUEXIS® (ibuprofen/famotidine) tablets, for oral use

VIMOVO® (naproxen/esomeprazole magnesium) delayed-release tablets, for oral use

MIGERGOT® (ergotamine tartrate & caffeine suppositories), for rectal use

Acquisitions and Divestitures

Since January 1, 2017, we completed the following acquisitions and divestitures:

On June 30, 2017, we completed our acquisition of certain rights to interferon gamma-1b from Boehringer Ingelheim International GmbH, or Boehringer Ingelheim International, in all territories outside of the United States, Canada and Japan. On July 24, 2018, we sold the rights to interferon gamma-1b in all territories outside the United States, Canada and Japan to Clinigen Group plc., or Clinigen, for an upfront payment and a potential additional contingent consideration payment.

On June 23, 2017, we sold our European subsidiary that owned the marketing rights to PROCYSBI® (cysteamine bitartrate) delayed-release capsules and QUINSAIR<sup>TM</sup> (levofloxacin inhalation solution) in Europe, the Middle East and Africa, or EMEA, regions, or the Chiesi divestiture, to Chiesi Farmaceutici S.p.A., or Chiesi.

On May 8, 2017, we completed our acquisition of River Vision Development Corp., or River Vision, which added the late development-stage rare disease biologic medicine candidate teprotumumab to our research and development pipeline.

Strategy

Our strategy is to continue the transformation of Horizon Pharma plc into a balanced, diversified, sustainable-growth biopharmaceutical company predominantly focused on rare disease medicines. We are executing on our strategy by accelerating the growth of our rare disease medicine portfolio through differentiated commercial strategies, business development efforts and the expansion of our pipeline with post-marketing and development-stage programs. We are strongly committed to helping ensure patient access to their medicines and support services, and by investing in the further development of medicines for patients with rare or underserved diseases.

## Orphan and Rheumatology

Our rare disease medicines, RAVICTI, PROCYSBI, ACTIMMUNE, BUPHENYL and QUINSAIR, are our marketed orphan medicines. Our strategy for RAVICTI is to drive growth through increased awareness and diagnosis of urea cycle disorders, and to drive conversion from older-generation nitrogen scavengers, such as generic forms of sodium phenylbutyrate, to RAVICTI, based on the medicine's differentiated benefits. With respect to PROCYSBI, our strategy is to drive conversion of patients from older-generation immediate-release capsules of cysteamine bitartrate to PROCYSBI, increase the uptake of diagnosed but untreated patients and identify previously undiagnosed patients who are suitable for treatment. Our strategy with respect to ACTIMMUNE includes driving growth by increasing awareness and diagnosis of chronic granulomatous disease and increasing the length and persistence of treatment.

With our May 2017 acquisition of River Vision, we added the late-stage rare disease biologic medicine candidate teprotumumab to our pipeline. Teprotumumab, which successfully completed a Phase 2 clinical trial and is currently enrolling patients in a Phase 3 confirmatory trial, targets the treatment of moderate-to-severe thyroid eye disease, a debilitating autoimmune condition that presents in patients with Graves' disease. Our strategy for teprotumumab is to support its continued clinical development and pursue regulatory approval. The River Vision acquisition further demonstrates our commitment to rare disease medicines and expands and diversifies our rare disease medicine pipeline to support sustainable longer-term growth. Our Phase 3 clinical trial evaluating teprotumumab for the treatment of moderate-to-severe active thyroid eye disease was initiated during the fourth quarter of 2017 and we anticipate that data from the trial will be available during the second quarter of 2019.

The rare disease medicine KRYSTEXXA is our primary marketed rheumatology medicine. We are focused on optimizing and maximizing the peak sales potential of KRYSTEXXA by expanding our commercialization efforts, as well as investing in education, patient and physician outreach, and investigation programs that demonstrate KRYSTEXXA as an effective treatment of chronic refractory gout, or uncontrolled gout, which is refractory (unresponsive) to conventional therapies. We believe that KRYSTEXXA represents a significant opportunity and potential growth driver within our orphan and rheumatology segment. We also market the rheumatology medicine RAYOS/LODOTRA.

#### **Primary Care**

Our strategy with respect to our primary care medicines, which include PENNSAID 2%, DUEXIS, VIMOVO and MIGERGOT, is to educate physicians about these clinically differentiated medicines and the benefits they offer. Patients are able to fill prescriptions for these medicines through pharmacies participating in our HorizonCares

patient access program, as well as other pharmacies. In addition, we have evolved our commercial strategy to enter into business arrangements with pharmacy benefit managers, or PBMs, and other payers to secure formulary status and reimbursement of our primary care medicines. The business arrangements with the PBMs generally require us to pay administrative fees and rebates to the PBMs and other payers for qualifying prescriptions.

We market all of our medicines in the United States through our field sales force, which numbered approximately 425 representatives as of June 30, 2018.

## **RESULTS OF OPERATIONS**

Comparison of Three Months Ended June 30, 2018 and 2017

## Consolidated Results

The table below should be referenced in connection with a review of the following discussion of our results of operations for the three months ended June 30, 2018, compared to the three months ended June 30, 2017.

	For the Three Months Ended				
	June 30, 2018	2017	Changa		
	(in thousar	2017	Change		
Net sales	\$302,835	\$289,507	\$13,328		
Cost of goods sold	100,082	•	(30,068)		
Gross profit	202,753		43,396		
Operating expenses:					
Research and development	24,265	163,101	(138,836)		
Selling, general and administrative	176,674	159,653	17,021		
Impairment of long-lived assets	_	22,270	(22,270)		
Total operating expenses	200,939	345,024	(144,085)		
Operating income (loss)	1,814	(185,667)	187,481		
Other expense, net:					
Interest expense, net	(31,030)	(31,608)	578		
Foreign exchange (loss) gain	(5)	151	(156)		
Gain on divestiture	<del></del>	5,856	(5,856)		
Other income (expense), net	347	(35)	382		
Total other expense, net	(30,688)	(25,636)	(5,052)		
Loss before expense (benefit) for income taxes	(28,874)	(211,303)	182,429		
Expense (benefit) for income taxes	3,962	(1,767)	5,729		
Net loss	\$(32,836)	\$(209,536)	\$176,700		

Net sales. Net sales increased \$13.3 million, or 4.6%, to \$302.8 million during the three months ended June 30, 2018, from \$289.5 million during the three months ended June 30, 2017.

The following table reflects net sales by medicine for the three months ended June 30, 2018 and 2017 (in thousands, except percentages):

Three	M	onthe	End	ed
THICE	IVI	CHILLIS	a i biidi	CU

	June 30,		Change	Change	
	2018	2017	\$	%	
KRYSTEXXA	\$58,608	\$38.301	\$20.307	53	%

Edgar Filing: Horizon Pharma plc - Form 10-Q

56,958	47,239	9,719	21	%
38,433	36,679	1,754	5	%
27,382	28,819	(1,437)	(5	)%
13,452	11,643	1,809	16	%
5,244	6,231	(987)	(16	)%
1,535	1,804	(269)	(15	)%
97	1,407	(1,310)	(93	)%
\$201,709	\$172,123	\$29,586	17	%
\$47,610	\$51,221	\$(3,611)	(7	)%
30,728	43,603	(12,875)	(30	)%
21,856	21,130	726	3	%
932	1,430	(498)	(35	)%
\$101,126	\$117,384	\$(16,258)	(14	)%
\$302,835	\$289,507	\$13,328	5	%
	38,433 27,382 13,452 5,244 1,535 97 \$201,709 \$47,610 30,728 21,856 932 \$101,126	38,433 36,679 27,382 28,819 13,452 11,643 5,244 6,231 1,535 1,804 97 1,407 \$201,709 \$172,123 \$47,610 \$51,221 30,728 43,603 21,856 21,130 932 1,430 \$101,126 \$117,384	38,433 36,679 1,754 27,382 28,819 (1,437) 13,452 11,643 1,809 5,244 6,231 (987) 1,535 1,804 (269) 97 1,407 (1,310) \$201,709 \$172,123 \$29,586 \$47,610 \$51,221 \$(3,611) 30,728 43,603 (12,875) 21,856 21,130 726 932 1,430 (498) \$101,126 \$117,384 \$(16,258)	38,433       36,679       1,754       5         27,382       28,819       (1,437)       (5         13,452       11,643       1,809       16         5,244       6,231       (987)       (16         1,535       1,804       (269)       (15         97       1,407       (1,310)       (93         \$201,709       \$172,123       \$29,586       17         \$47,610       \$51,221       \$(3,611)       (7         30,728       43,603       (12,875)       (30         21,856       21,130       726       3         932       1,430       (498)       (35         \$101,126       \$117,384       \$(16,258)       (14

The increase in net sales during the three months ended June 30, 2018, was primarily due to higher net sales in our orphan and rheumatology segment, partially offset by lower net sales in our primary care segment.

## Orphan and Rheumatology

KRYSTEXXA. Net sales increased \$20.3 million, or 53%, to \$58.6 million during the three months ended June 30, 2018, from \$38.3 million during the three months ended June 30, 2017. Net sales increased by approximately \$22.4 million resulting from volume growth, partially offset by a decrease of approximately \$2.1 million due to lower net pricing.

RAVICTI. Net sales increased \$9.7 million, or 21%, to \$56.9 million during the three months ended June 30, 2018, from \$47.2 million during the three months ended June 30, 2017. Net sales in the United States increased by approximately \$8.6 million, which was composed of an increase of \$7.9 million due to higher net pricing and approximately \$0.7 million resulting from volume growth. Net sales outside the United States increased by approximately \$1.1 million primarily due to higher sales volume.

PROCYSBI. Net sales increased \$1.7 million, or 5%, to \$38.4 million during the three months ended June 30, 2018, from \$36.7 million during the three months ended June 30, 2017. Net sales in the United States increased by approximately \$4.8 million, which was composed of an increase of \$4.7 million due to higher net pricing and approximately \$0.1 million resulting from volume growth. Net sales outside the United States decreased by approximately \$3.1 million primarily as a result of the Chiesi divestiture in June 2017.

ACTIMMUNE. Net sales decreased \$1.4 million, or 5%, to \$27.4 million during the three months ended June 30, 2018, from \$28.8 million during the three months ended June 30, 2017. Net sales decreased by approximately \$2.8 million resulting from lower volume, partially offset by an increase of approximately \$1.4 million due to higher net pricing.

RAYOS. Net sales increased \$1.8 million, or 16%, to \$13.4 million during the three months ended June 30, 2018, from \$11.6 million during the three months ended June 30, 2017. Net sales increased by approximately \$3.6 million resulting from volume growth, partially offset by a decrease of approximately \$1.8 million due to lower net pricing.

BUPHENYL. Net sales decreased \$1.0 million, or 16%, to \$5.2 million during the three months ended June 30, 2018, from \$6.2 million during the three months ended June 30, 2017. Net sales decreased by approximately \$2.1 million resulting from lower volume, partially offset by an increase of \$1.1 million due to higher net pricing.

LODOTRA. Net sales decreased \$0.3 million, or 15%, to \$1.5 million during the three months ended June 30, 2018, from \$1.8 million during the three months ended June 30, 2017. The decrease was the result of decreased medicine shipments to our European distribution partner, Mundipharma International Corporation Limited, or Mundipharma. LODOTRA shipments to Mundipharma are not linear or directly tied to Mundipharma's in-market sales and can therefore fluctuate significantly from quarter to quarter.

QUINSAIR. Net sales decreased \$1.3 million, or 93%, to \$0.1 million during the three months ended June 30, 2018, from \$1.4 million during the three months ended June 30, 2017, primarily as a result of lower volume following the Chiesi divestiture in June 2017.

#### **Primary Care**

PENNSAID 2%. Net sales decreased \$3.6 million, or 7%, to \$47.6 million during the three months ended June 30, 2018, from \$51.2 million during the three months ended June 30, 2017. Net sales decreased by approximately \$5.3 million resulting from lower volume, partially offset by an increase of approximately \$1.7 million due to higher net pricing.

DUEXIS. Net sales decreased \$12.9 million, or 30%, to \$30.7 million during the three months ended June 30, 2018, from \$43.6 million during the three months ended June 30, 2017. Net sales decreased by approximately \$12.4 million

due to lower net pricing and approximately \$0.5 million resulting from lower volume.

VIMOVO. Net sales increased \$0.7 million, or 3%, to \$21.8 million during the three months ended June 30, 2018, from \$21.1 million during the three months ended June 30, 2017. Net sales increased by approximately \$5.5 million due to higher net pricing, partially offset by a decrease of approximately \$4.8 million resulting from lower volume.

MIGERGOT. Net sales decreased \$0.5 million, or 35%, to \$0.9 million during the three months ended June 30, 2018, from \$1.4 million during the three months ended June 30, 2017. Net sales decreased by approximately \$0.3 million resulting from lower volume and approximately \$0.2 million due to lower net pricing.

The table below reconciles our gross to net sales for the three months ended June 30, 2018 and 2017 (in millions, except percentages):

	Three Months Ended			Three Months Ended				
	June 30, 2	201	8		June 30, 2	201	7	
	Amount		% of Gross	Sales	Amount		% of Gross	Sales
Gross sales	\$ 1,127.8		100.0	%	\$ 1,071.7		100.0	%
Adjustments to gross sales:								
Prompt pay discounts	(20.1	)	(1.8	)%	(21.3	)	(2.0	)%
Medicine returns	(8.8)	)	(0.8	)%	(15.0)	)	(1.4	)%
Co-pay and other patient assistance	(540.0	)	(47.9	)%	(497.0	)	(46.4	)%
Wholesaler fees and commercial rebates	(164.2	)	(14.5	)%	(168.3	)	(15.7	)%
Government rebates and chargebacks	(91.9	)	(8.1	)%	(80.6	)	(7.5	)%
Total adjustments	(825.0	)	(73.1	)%	(782.2	)	(73.0	)%
Net sales	\$ 302.8		26.9	%	\$ 289.5		27.0	%

Cost of Goods Sold. Cost of goods sold decreased \$30.1 million to \$100.1 million during the three months ended June 30, 2018, from \$130.2 million during the three months ended June 30, 2017. As a percentage of net sales, cost of goods sold was 33.1% during the three months ended June 30, 2018, compared to 45.0% during the three months ended June 30, 2017. The decrease in cost of goods sold was primarily attributable to a \$33.8 million decrease in inventory step-up expense.

Because inventory step-up expense is acquisition-related, will not continue indefinitely and has a significant effect on our gross profit, gross margin percentage and net income (loss) for all affected periods, we disclose balance sheet and income statement amounts related to inventory step-up within the notes to the condensed consolidated financial statements. The decrease in inventory step-up expense of \$33.8 million recorded to cost of goods sold during the three months ended June 30, 2018, compared to the prior year period was due to KRYSTEXXA, MIGERGOT and PROCYSBI inventory step-up being fully expensed by March 31, 2018, resulting in no material inventory step-up expense being recorded during the three months ended June 30, 2018, compared to KRYSTEXXA and MIGERGOT inventory step-up expense of \$19.3 million and PROCYSBI and QUINSAIR inventory step-up expense of \$14.5 million recorded during the three months ended June 30, 2017.

Research and Development Expenses. Research and development expenses decreased \$138.8 million to \$24.3 million during the three months ended June 30, 2018, from \$163.1 million during the three months ended June 30, 2017. The decrease was primarily attributable to \$147.7 million related to the acquisition of River Vision during the three months ended June 30, 2017. Pursuant to ASC 805 (as amended by ASU No. 2017-01), we accounted for the River Vision acquisition as the purchase of an in-process research and development, or IPR&D, asset and, pursuant to ASC 730, recorded the purchase as a research and development expense during the three months ended June 30, 2017. Excluding the costs attributable to the acquisition of River Vision, research and development expenses increased by \$8.9 million during the three months ended June 30, 2018, compared to the three months ended June 30, 2017, primarily due to the costs associated with the development of teprotumumab.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$17.0 million to \$176.7 million during the three months ended June 30, 2018, from \$159.7 million during the three months ended June 30, 2017. The increase was primarily attributable to an \$11.4 million increase in employee costs, primarily as a result of the expansion of our KRYSTEXXA sales force during the second half of 2017 and \$4.3 million recorded during the three months ended June 30, 2018 related to litigation settlements.

Impairment of Long-Lived Assets. Impairment of long-lived assets of \$22.3 million during the three months ended June 30, 2017, represents the impairment of a non-current asset recorded following payment to Boehringer Ingelheim International for the acquisition of certain rights to interferon gamma-1b. This was previously included within "selling,

general and administrative" expenses. On July 24, 2018, we sold the rights to interferon gamma-1b in all territories outside the United States, Canada and Japan to Clinigen for an upfront payment and a potential additional contingent consideration payment.

Gain on divestiture. During the three months ended June 30, 2017, we completed the Chiesi divestiture for an upfront payment of \$72.2 million, including \$3.1 million of cash divested, with additional potential milestone payments based on sales thresholds and we recorded a gain of \$5.9 million on the divestiture.

Expense (benefit) for Income Taxes. During the three months ended June 30, 2018, we recorded an expense for income taxes of \$4.0 million compared to a benefit for income taxes of \$1.8 million during the three months ended June 30, 2017. The increased expense for income taxes during the three months ended June 30, 2018, resulted primarily from a write-off of deferred tax assets related to previously recognized share-based compensation expense for performance stock units, or PSUs, that expired unvested during June 2018 and a revaluation of our U.S. net deferred tax liability as a result of state legislation changes passed during the three months ended June 30, 2018.

In relation to our outstanding PSUs at December 31, 2017, as our share price was lower than \$33.86 for the twenty trading days ending June 22, 2018, approximately \$10.2 million of deferred tax assets at December 31, 2017, related to previously recognized share-based compensation expense was charged to income tax expense during the three months ended June 30, 2018.

Information by Segment

#### Orphan and Rheumatology

The following table reflects our orphan and rheumatology net sales and segment operating income for the three months ended June 30, 2018 and 2017 (in thousands, except percentages).

	For the Th Months Er 30,				
	2018	2017	Change	% Change	;
Net sales	\$201,709	\$172,123	\$29,586	17	%
Segment operating income	70,609	64,662	5,947	9	%

The increase in orphan and rheumatology net sales during the three months ended June 30, 2018 is described in the Consolidated Results section above.

Segment operating income. Orphan and rheumatology segment operating income increased \$5.9 million to \$70.6 million during the three months ended June 30, 2018, from \$64.7 million during the three months ended June 30, 2017. The increase was primarily attributable to an increase in net sales of \$29.6 million as described above, partially offset by an increase in selling, general and administrative expenses of \$13.8 million primarily as a result of the expansion of our KRYSTEXXA sales force during the second half of 2017, and an increase in research and development expenses of \$7.5 million primarily due to the costs associated with the development of teprotumumab.

## **Primary Care**

The following table reflects our primary care net sales and segment operating income for the three months ended June 30, 2018 and 2017 (in thousands, except percentages).

	For the Three					
	Months Ended June					
	30,			01		
	2018	2017	Change	% Change		
Net sales	\$101,126	\$117,384	\$(16,258)	(14	%)	
Segment operating income	45,883	62,423	(16,540)	(26	%)	

The decrease in primary care net sales during the three months ended June 30, 2018 is described in the Consolidated Results section above.

Segment operating income. Primary care segment operating income decreased \$16.5 million to \$45.9 million during the three months ended June 30, 2018, from \$62.4 million during the three months ended June 30, 2017. The decrease was primarily attributable to a decrease in net sales of \$16.3 million as described above.

The table below provides reconciliations of our segment operating income to our total loss before expense (benefit) for income taxes for the three months ended June 30, 2018 and 2017 (in thousands):