Horizon Pharma plc
Form 10-Q
November 07, 2018

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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 September 30, 2018

OR

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

For the transition period from to

Commission File Number 001-35238

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 every Interactive Data File required to be submitted 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 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.

Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

Number of registrant's ordinary shares, nominal value \$0.0001, outstanding as of October 26, 2018: 167,625,915.

HORIZON PHARMA PLC

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share data)

	As of	As of December
	September 30,	
ASSETS	2018	2017
CURRENT ASSETS:		
Cash and cash equivalents	\$ 807,047	\$751,368
Restricted cash	6,399	6,529
Accounts receivable, net	391,117	405,214
Inventories, net	53,130	61,655
Prepaid expenses and other current assets	81,492	43,402
Total current assets	1,339,185	1,268,168
Property and equipment, net	16,592	20,405
Developed technology, net	2,204,633	2,443,949
Other intangible assets, net	4,835	5,441
Goodwill	426,441	426,441
Deferred tax assets, net	231	3,470
Other assets	27,469	36,081
Total assets	\$4,019,386	\$4,203,955
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Long-term debt—current portion	\$ <i>-</i>	\$10,625
Accounts payable	64,794	34,681
Accrued expenses	194,855	175,697
Accrued trade discounts and rebates	359,660	501,753
Accrued royalties—current portion	65,501	65,328
Deferred revenues—current portion	6,759	6,885
Total current liabilities	691,569	794,969
LONG-TERM LIABILITIES:		
Exchangeable notes, net	327,573	314,384
Long-term debt, net of current	1,563,239	1,576,646
Accrued royalties, net of current	295,122	291,185
Deferred revenues, net of current	_	9,713
Deferred tax liabilities, net	156,848	157,945
Other long-term liabilities	68,174	68,015
Total long-term liabilities	2,410,956	2,417,888
COMMITMENTS AND CONTINGENCIES		

SHAREHOLDERS' EQUITY:

Ordinary shares, \$0.0001 nominal value; 300,000,000 shares authorized;

167,907,117 and 164,785,083 shares issued at September 30, 2018 and December

31, 2017, respectively, and 167,522,751 and 164,400,717 shares outstanding at

September 30, 2018 and December 31, 2017, respectively	17	16
Treasury stock, 384,366 ordinary shares at September 30, 2018 and December 31, 2017	(4,585) (4,585)
Additional paid-in capital	2,337,565	2,248,979
Accumulated other comprehensive loss	(1,261) (983
Accumulated deficit	(1,414,875) (1,252,329)
Total shareholders' equity	916,861	991,098
Total liabilities and shareholders' equity	\$4,019,386	\$4,203,955

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

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

(In thousands, except share and per share data)

	Eartha Thus	a Montha Endad	Con the Nine	e Months Ended
		For the Three Months Ended		
	2018	September 30, 2018 2017		30, 2017
Net sales	\$325,311	\$271,646	2018 \$852,027	\$782,012
Cost of goods sold	99,011	125,517	315,185	394,783
Gross profit	226,300	146,129	536,842	387,229
OPERATING EXPENSES:	220,300	140,129	330,642	301,229
Research and development	21,169	17,928	63,079	194,090
Selling, general and administrative	161,585	153,952	517,858	487,670
Impairment of long-lived assets	1,603	133,932	39,455	22,270
Gain on sale of assets	(12,303	_	(12,303	22,270
	` '	171 000		704.020
Total operating expenses	172,054	171,880	608,089	704,030
Operating income (loss)	54,246	(25,751) (71,247) (316,801)
OTHER EXPENSE, NET:	(20, 427	(21.706	(01.021	(05.007
Interest expense, net	(30,437) (31,706) (91,921) (95,297)
Foreign exchange gain (loss)	35	275	(81) 167
Gain on divestiture	-	112	-	5,968
Loss on debt extinguishment	_	_	_	(533)
Other income, net	453	280	978	280
Total other expense, net	(29,949) (31,039) (91,024) (89,415)
Income (loss) before (benefit) expense for income				
taxes	24,297	(56,790) (162,271) (406,216)
(Benefit) expense for income taxes	(1,733) 7,181	1,863	(42,138)
Net income (loss)	\$26,030	\$(63,971) \$(164,134) \$(364,078)
Net income (loss) per ordinary share—basic	\$0.16	\$(0.39) \$(0.99) \$(2.24)
Weighted average ordinary shares outstanding—b	asic 167,047,10	04 163,447,208	8 166,018,60	03 162,810,551
Net income (loss) per ordinary share—diluted	\$0.15	\$(0.39) \$(0.99) \$(2.24)
Weighted average ordinary shares outstanding—d	iluted172,485,75	57 163,447,208	3 166,018,60	03 162,810,551
OTHER COMPREHENSIVE (LOSS) INCOME,				
NET OF TAX				
Foreign currency translation adjustments	\$(133) \$(209) \$(567) \$745
Pension remeasurements	_	_	289	_
Other comprehensive (loss) income	(133) (209) (278) 745
Comprehensive income (loss)	\$25,897	\$(64,180) \$(164,412) \$(363,333)

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 Nine Ended Septe 2018	
CASH FLOWS FROM OPERATING ACTIVITIES:	2010	2017
Net loss	\$(164,134)	\$(364,078)
Adjustments to reconcile net loss to net cash provided by operating activities:		1 (2 2) 2 2 2
Depreciation and amortization expense	206,696	213,155
Equity-settled share-based compensation	86,981	91,391
Royalty accretion	44,371	38,415
Royalty liability remeasurement	(2,151)	
Impairment of long-lived assets	39,455	22,270
Amortization of debt discount and deferred financing costs	16,879	15,863
Deferred income taxes	1,645	(62,989)
Gain on sale of assets	(12,303)	
Gain on divestiture		(2,635)
Acquired in-process research and development expense	_	148,769
Loss on debt extinguishment		533
Foreign exchange and other adjustments	243	(1,521)
Changes in operating assets and liabilities:		
Accounts receivable	14,060	(101,612)
Inventories	7,902	83,482
Prepaid expenses and other current assets	(35,526)	(4,435)
Accounts payable	30,119	(18,414)
Accrued trade discounts and rebates	(142,164)	139,461
Accrued expenses and accrued royalties	(6,299)	(42,842)
Deferred revenues	1,462	3,770
Other non-current assets and liabilities	(1,401)	(14,559)
Net cash provided by operating activities	85,835	141,080
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payment related to license agreement	(12,000)	
Proceeds from sale of assets	9,424	_
Proceeds from divestiture, net of cash divested	_	69,072
Payments for acquisitions, net of cash acquired	_	(168,818)
Purchases of property and equipment	(881)	(4,028)
Net cash used in investing activities	(3,457)	(103,774)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of term loans	(27,723)	(774,875)
Net proceeds from term loans	_	847,768
Proceeds from the issuance of ordinary shares in connection with warrant exercises	_	1,789
Proceeds from the issuance of ordinary shares through ESPP programs	4,711	3,856
Proceeds from the issuance of ordinary shares in connection with stock option exercises	9,753	1,762
Payment of employee withholding taxes relating to share-based awards	(12,882)	(5,640)
Repurchase of ordinary shares	_	(992)

Net cash (used in) provided by financing activities	(26,141)	73,668
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(688)	4,366
Net increase in cash, cash equivalents and restricted cash	55,549	115,340
Cash, cash equivalents and restricted cash, beginning of the period	757,897	516,150
Cash, cash equivalents and restricted cash, end of the period	\$813,446	\$631,490

HORIZON PHARMA PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(UNAUDITED)

(In thousands)

SUPPLEMENTAL CASH FLOW INFORMATION:

Cash paid for interest	\$67,118	\$74,378
Net cash paid for income taxes	40,409	2,054
Cash paid for debt extinguishment	—	145
SUPPLEMENTAL NON-CASH FLOW INFORMATION:		
Purchases of property and equipment included in accounts payable and accrued		
expenses	34	45

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 nine months ended September 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 nine months ended September 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 income (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 its 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

KRYSTEXXA® (pegloticase injection), for intravenous infusion

RAVICTI® (glycerol phenylbutyrate) oral liquid

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

QUINSAIRTM (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 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 this 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 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 this 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 \$16.5 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 nine months ended September 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 Nine Months Ended September 30, 2017			
		ASU No.	ASU No.	
		2016-18	2016-15	
	As filed	Reclassifica	ationReclassifica	tionAs
	As Illeu	(2)	(3)	adjusted
Net cash provided by operating activities	\$136,995	\$ —	\$ 4,085	\$141,080
Net cash used in investing activities	(103,209)) (565) —	(103,774)
Net cash provided by financing activities	77,753	_	(4,085) 73,668
Cash, cash equivalents and restricted cash, beginning of the				
period (1)	509,055	7,095	_	516,150
Cash, cash equivalents and restricted cash, end of the period (1)	624,960	6,530	_	631,490

- (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 \$6.5 million in the table above represent the Company's restricted cash balance at December 31, 2016 and September 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 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. For leases with a term of twelve months or less, the lessee is permitted to make an accounting policy election not to recognize lease assets and lease liabilities by class of underlying assets. ASU No. 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, effective for the Company beginning January 1, 2019. The Company does not expect the adoption will have a material impact on its consolidated statement of comprehensive income (loss). However, the new standard will require the Company to establish liabilities and corresponding right-of-use assets on its consolidated balance sheet for leases, primarily related to operating leases on rented office properties, that exist as of the January 1, 2019 adoption date. The guidance can be applied using either a modified retrospective approach at the beginning of the earliest period presented, or at the beginning of the period in which it is adopted. The Company will adopt this standard on January 1, 2019, using a modified retrospective approach at the adoption date through a cumulative-effect adjustment to retained earnings. The Company also expects to elect to not recognize lease assets and liabilities for leases with a term of twelve months or less.

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 that will be prescribed 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. The return 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 will be prescribed 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, sell-through sales data obtained from third-party information and estimated levels of inventory in the distribution channel 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 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 INCOME (LOSS) PER SHARE

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

	For the Three Months Ended		For the Nine Months Ende	
	September 30, 2018	2017	September 30, 2018	2017
	2016	2017	2016	2017
Basic net income (loss) per share calculation:				
Net income (loss)	\$26,030	\$(63,971)	\$(164,134)	\$(364,078)
Weighted average ordinary shares outstanding	167,047,104	163,447,208	166,018,603	162,810,551
Basic net income (loss) per share	\$0.16	\$(0.39)	\$(0.99)	\$(2.24)

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

	For the Three Months Ended		For the Nine N	Months Ended
	September 30,		September 30,	
	2018	2017	2018	2017
Diluted net income (loss) per share calculation:				
Net income (loss)	\$26,030	\$(63,971	\$(164,134	\$ (364,078)
Weighted average ordinary shares outstanding	172,485,757	163,447,208	166,018,603	162,810,551
Diluted net income (loss) per share	\$0.15	\$(0.39	\$(0.99) \$(2.24)

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of ordinary shares outstanding during the period. Diluted net income (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 income (loss) per share excluded 3.1 million and 10.6 million shares subject to equity awards for the three and nine months ended September 30, 2018, respectively, and 18.7 million and 18.2 million shares subject to equity awards and warrants for the three and nine months ended September 30, 2017, respectively, because their inclusion would have had an anti-dilutive effect on diluted net income (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 nine months ended September 30, 2018 and 2017.

NOTE 4 – ACQUISITIONS, DIVESTITURES AND OTHER ARRANGEMENTS

Acquisitions and divestitures

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 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 payment 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 income (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 ("Clinigen") for an upfront payment of €7.5 million (\$8.8 million when converted using a Euro-to-Dollar exchange rate at date of payment of 1.1683) and a potential additional contingent consideration payment of €3.0 million (\$3.5 million when converted using a Euro-to-Dollar exchange rate of 1.1673) (the "IMUKIN sale"). The Company continues to market interferon gamma-1b as ACTIMMUNE in the United States.

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 IMUKIN sale as a sale of assets, specifically a sale of intellectual property rights and a sale of inventory.

The gain on sale of assets recorded to the condensed consolidated statement of comprehensive income (loss) during the three and nine months ended September 30, 2018, was determined as follows (in thousands):

Cash proceeds including \$715 for inventory	\$9,477
Contingent consideration receivable	3,502
Less net assets sold:	
Inventory	(623)
Transaction costs	(53)
Gain on sale of assets	\$12,303

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 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 for teprotumumab. 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 separate agreements, the Company is also required to pay up to CHF103.0 million (\$104.9 million when converted using a CHF-to-Dollar exchange rate at September 30, 2018 of 1.0186) upon the attainment of various milestones related to approval, filing and net sales thresholds for teprotumumab. 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 a portion of annual worldwide net sales.

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 \$6.0 million in the condensed consolidated statement of comprehensive loss during the nine months ended September 30, 2017. Additionally, during the three months ended December 31, 2017, the Company recorded adjustments for working capital of \$0.3 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 and 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 September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30,	December 31,
	2018	2017
Raw materials	\$ 6,365	\$4,553
Work-in-process	28,428	27,589
Finished goods	18,337	29,513
Inventories, net	\$ 53,130	